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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from to

Commission file number: **001-37799**

Tactile Systems Technology, Inc.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**3701 Wayzata Blvd, Suite 300** **Minneapolis, Minnesota 55416** (Address and zip code of principal executive offices)	**41-1801204** (I.R.S. Employer Identification No.)

(612) 355-5100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.001 Per Share	TCMD	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None
(Title of class)

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on $7.30, the closing price of the shares of common stock on June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter) as reported by The Nasdaq Stock Market LLC on such date, was $146,541,485. The number of shares of registrant's Common Stock outstanding as of February 17, 2023 was 20,250,951.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Stockholders, scheduled to be held on May 8, 2023 are incorporated by reference into Part III of this Report.

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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This Annual Report on Form 10-K contains forward-looking statements regarding us, our business prospects and our results of operations that are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those that may be anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described in Part I, Item 1A. “Risk Factors” and elsewhere in this report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the Securities and Exchange Commission, or the SEC, that advise interested parties of the risks and factors that may affect our business.

All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition, are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this Annual Report on Form 10-K. These risks, uncertainties and other factors include, but are not limited to:

- the impacts of inflation, rising interest rates or a recession;
- the adequacy of our liquidity to pursue our business objectives;
- our ability to obtain reimbursement from third-party payers for our products;
- adverse economic conditions or intense competition;
- price increases for supplies and components;
- wage and component price inflation;
- loss of a key supplier;
- entry of new competitors and products;
- compliance with and changes in federal, state and local government regulation;
- loss or retirement of key executives, including prior to identifying a successor;
- technological obsolescence of our products;
- technical problems with our research and products;
- our ability to expand our business through strategic acquisitions;
- our ability to integrate acquisitions and related businesses;
- the impacts of the COVID-19 pandemic on our business, financial condition and results of operations, and our inability to mitigate such impacts;
- the effects of current and future U.S. and foreign trade policy and tariff actions; and

- the inability to carry out research, development and commercialization plans.

You should read the matters described in Part I, Item 1A. "Risk Factors" and the other cautionary statements made in this Annual Report on Form 10-K. We cannot assure you that the forward-looking statements in this report will prove to be accurate and therefore you are encouraged not to place undue reliance on forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. You are urged to carefully review and consider the various disclosures made by us in this report and in other filings with the SEC that advise of the risks and factors that may affect our business. Other than as required by law, we expressly disclaim any intent or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

RISK FACTORS SUMMARY

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 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.

PART I

Item 1. Business.

Overview

Tactile 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 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, we generated revenue of $246.8 million and had a net loss of $17.9 million. Our revenue increased 19% during the year ended December 31, 2022, compared to the year ended December 31, 2021.

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 and Entre 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 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

2013. The Entre 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 system. Sales and rentals of our lymphedema products generated $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, 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 $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 invest in our commercial infrastructure, consisting of our direct sales force, DME sales team, patient training resources, 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, we employed a field staff of 287, which consisted of 250 field sales representatives and 24 field managers for our lymphedema products, as well as a team of 13 supporting our airway clearance products. This compares to a field staff of 262 as of December 31, 2021, which consisted of approximately 233 field sales representatives and 19 field managers for our lymphedema products, as well as a team of 10 supporting our airway clearance products.

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 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 and Entre 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 275 million lives in the United States. In 2022 we served over 65,000 patients with our compression therapy devices and cumulatively have served over 395,000 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 clinics 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

Lymphedema

The 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 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, 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 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, 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. 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 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 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 system provides improved quality of life and clinical outcomes and delivers significant cost savings to payers and patients.

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 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 Opportunity

Bronchiectasis 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.

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.

Our Strategy

Our goal is to become a leader in the at-home treatment of 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 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.

Our Products

We market Flexitouch and Entre systems as at-home therapies for the treatment of lymphedema and chronic venous insufficiency. We market AfloVest 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 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 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 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 Entre 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.

Kylee

In 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 device. Once a patient starts using the device, they can use Kylee to record their treatments and symptoms, and capture photos of their condition for sharing with their healthcare team. Flexitouch Plus controllers include Bluetooth technology, which is now viewable using Kylee.

AffloVest

We 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).

Impact 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 pneumatic 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 ulcers 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 Neck

An 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 Evidence

The 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.

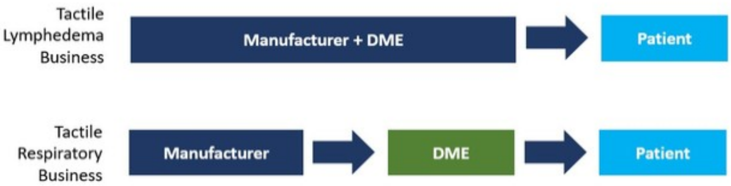
In 2020, a chart review study of 30 patients compared the need for antibiotic therapy due to exacerbation, based on the number of prescriptions, emergency room visits and hospitalizations in the period approximately six months before each patient started AffloVest HFCWO therapy compared to the period 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.

The AffloVest has a history of clinical evidence, and Tactile Medical is committed to supporting additional studies to further support the benefits of this differentiated HFCWO technology.

Sales and Marketing

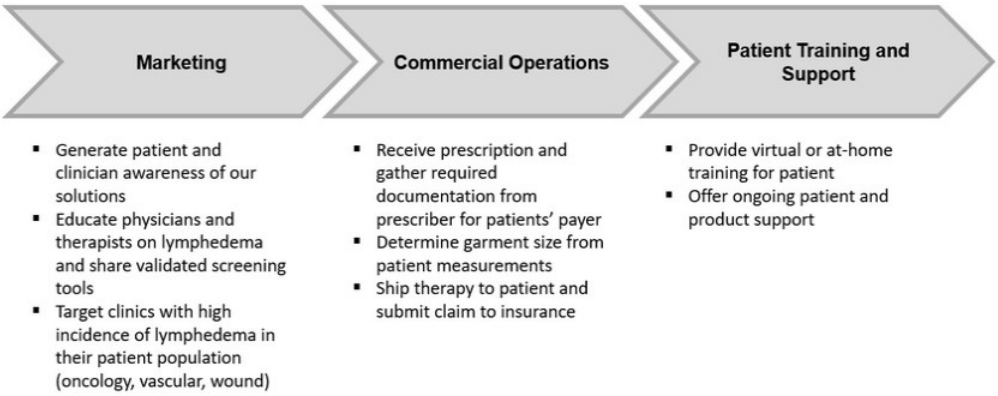
Unlike many of our competitors, we utilize a direct-to-patient and -provider model to market our lymphedema products directly to patients and clinics, providing high-quality customer service and capturing both the manufacturer and distributor margins. The direct channel allows us to focus on two of our 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 candidates who are regularly on other respiratory therapies (such as oxygen, nebulizers, non-invasive ventilators, etc.) and who might benefit from the use of our AffloVest. The below chart reflects these models:



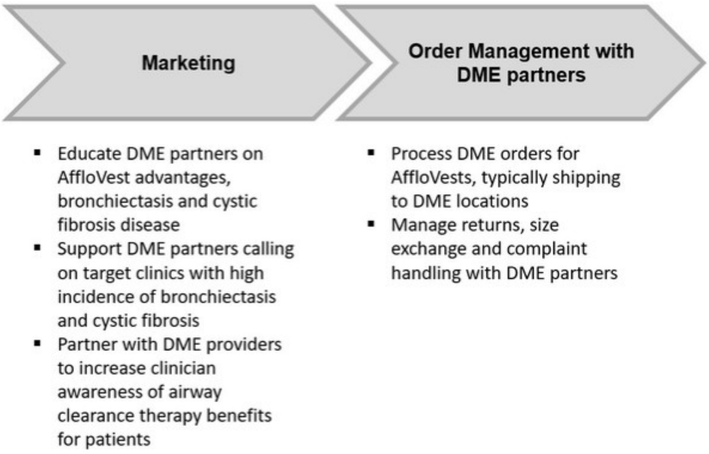
Our direct-to-patient and -provider lymphedema business is composed of a direct sales force, patient training and support, reimbursement capabilities and medical expertise to educate, expand awareness, coordinate referrals and obtain payment for our products.

The chart below describes our U.S. direct-to-patient and -provider model for 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 market to, and educate, DME providers and clinicians about the AffloVest advantages. As of December 31, 2022, 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 chart below describes our DME model.



As of December 31, 2022, we employed a 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.

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 Process

Private insurers and other payers represented approximately 57% and 68% of our revenue in 2022 and 2021, respectively, while Medicare represented approximately 19% and 17% of our revenue in 2022 and 2021, respectively, Veterans Administration hospitals represented approximately 10% and 13% of our revenue in 2022 and 2021, respectively, and DME distributors represented approximately 14% and 2% of our revenue in 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, and appeals when necessary. The reimbursement operations function is organized into “regional payer lanes” so that each case is handled throughout the process by experts in specific payer requirements.

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 rate of greater than 80% for the last six years, and a greater than 90% Medicare claims submitted approval rate for the last six 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 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 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 other ICD-10 diagnosis codes.

Research and Clinical Operations

We 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 $7.1 million and $5.7 million for the years ended December 31, 2022 and 2021, respectively.

Manufacturing and Quality Assurance

Our 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.

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 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. In 2021, we also received our Medical Device Single Audit Program ("MDSAP") certification. 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 and Entre 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.

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 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, 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 applicable to a device are premarket notification, also called 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 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 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 require a new clearance or approval. Thus, modifications to our existing devices will be evaluated to ensure ongoing compliance to the FDA requirements.

Further, 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.

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 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 any of the following sanctions: Warning 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 of our subcontractors. 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.

FTC 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 of products or services to attain and maintain accreditation in order to participate in federally funded healthcare programs. To attain and maintain accreditation, 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. 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 offered to our clinicians in connection with the sales 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 that 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 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 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. In addition, amendments to the Federal False Claims Act 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 and other insurers directly for each sale 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 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.

The 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 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 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 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";

- 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.

Foreign 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 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 Medicare Administrative Contractors responsible for processing durable medical equipment claims, sets forth additional coverage criteria that impacts Medicare coverage for our products. Our Medicare business was 19% of revenue in 2022 compared to 17% in 2021.

Because Medicare criteria is extensive, we have a team dedicated to educating prescribers 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. 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 to educate them accordingly. While this approach has had positive impact, we do not know if or when additional payers may adopt 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 sets of patents, including patents relating to our Flexitouch system and other wearable compression-related technologies. As of December 31, 2022, we owned about 188 issued patents globally, of which 62 were issued U.S. patents. As of December 31, 2022, we owned about 30 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 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, the Flexitouch logo design, Entre, AffloVest, and AffloVest Pro 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 trademark is registered in Australia and Japan, and the AffloVest trademark is registered in Australia, the European Union, New Zealand and the United Kingdom.

Seasonality

Our 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, we had 982 employees. We have 566 employees who are based throughout the United States, as well as 416 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.

Talent and Retention: In 2022, we continued to focus on recruitment, hiring, and retention to ensure high quality talent and a strong fit for specific roles and the Company. Our recruitment efforts are expanding through strong recruiting and hiring processes, as well as utilization and enhancements of our recruiting platform we implemented in 2021. The company intranet facilitates employee inclusion, provides resources, and advances transparent communication efforts. We have also implemented an internal platform for 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 employee engagement survey that we rolled out in December 2022.

Available Information

We 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.

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 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, Entre 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 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 revenue is primarily generated from our lymphedema products and we are therefore highly dependent on these products.

Our lymphedema products accounted for 86% and 98% of our revenue for the years ended December 31, 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;

- 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 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;

- 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 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.

During most of 2020, 2021 and the first quarter of 2022, our direct sales force for our lymphedema product line experienced increased turnover and difficulty in recruiting qualified replacements. Although we saw some level of recovery in 2022 after the first quarter, we cannot assure you that this recovery will continue or that we will be able to recruit and retain quality candidates for our direct sales force. For our respiratory therapy products, we rely on DME providers for all aspects of sales, reimbursement, training and support. 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 on our ability to hire, train, retain and motivate skilled sales personnel with significant technical knowledge of lymphedema and chronic venous insufficiency, and our ability to maintain and expand relationships with our current, and enter into relationships with new, distributors of our airway clearance products. 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.

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 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 particularly during most of 2020 and 2021, and during the first quarter of 2022. 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 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.

Further, the extent to which the COVID-19 pandemic, including any resurgence or variant strains of the virus, 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, the remedial actions, any vaccine mandates and stimulus measures adopted by governmental authorities, and to what extent normal economic and operating conditions can resume. 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, economic, social and governmental impacts of the 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 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 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.

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, Hill-Rom, Philips Medical and Electromed. Other competitors include Airos Medical, Inc. and NormaTec Industries. Many of the companies developing or marketing competing products enjoy several competitive advantages, including:

- significantly greater name recognition;
- 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, patent 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;

- 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 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.

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 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 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. 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.

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 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.

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 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.

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;
- 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.

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. 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 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;
- 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;

- 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 applicable to a device are premarket notification, also called 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 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 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, then the FDA will automatically classify the device as a Class III high risk 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 novo 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 novo request when it does not have a predicate to which it can claim substantial equivalence. The FDA reviews the request for a de 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 novo process, future devices from the company or a competitor may use that device as a 510(k) predicate. The advantage of the de 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 is increasingly moving devices with slightly different proposed indication statements or different technological features off the 510(k) path and on to the de 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. 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 premarket clearance 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, 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 novo classification;

- 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; 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 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, which altered 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 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 devices may only be promoted and sold for the indications for which they are approved or cleared. 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 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.

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 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 has been a recent trend of increased federal and state regulation of 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 and other 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 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 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 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 to 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. 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 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. 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 licensure could subject us to financial penalties and/or prohibit us from selling our current or future products to patients in such 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 and Entre systems are 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. 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.

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 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 or removed in time from the use of our products. 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.

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 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 are 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 and other 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

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 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 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. From April 1, 2021 through June 30, 2021, the reduction went back into effect at a 1% reduction level, and beginning July 1, 2021, 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.

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, 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 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;

- 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 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 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 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 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.

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 have 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 be 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. 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.

Our 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;

- limit our ability to obtain additional financing to fund future working capital, capital expenditures, research and development expenditures and other general corporate requirements;
- 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, 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 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;
- 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 individuals 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 products

We may be unable to collect all of our Medicare accounts receivable.

At December 31, 2022, we had approximately $33.2 million of accounts receivable for sales of our Flexitouch 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, we classified $23.1 million of our Medicare accounts receivable related to Flexitouch 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, 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 system sales.

Risks 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 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. 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.

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 respecct 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 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 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 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 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. 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;
- 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

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. 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.

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 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 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;
- 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 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 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.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements with our directors and officers provide that we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law; Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful and that we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We currently lease approximately 150,000 square feet of office space for our corporate headquarters in Minneapolis, Minnesota. The initial lease for this space of approximately 80,000 square feet commenced in September 2019 and had an initial expiration date in February 2030. Subsequently, we entered into amendments to our initial lease to include an additional approximately 70,000 square feet of office space and to extend the expiration date of the entire leased space to February 2031.

We also lease approximately 63,000 square feet of office, assembly and warehouse space at another facility in Minneapolis, Minnesota, that has an expiration date in March 2027.

We believe that these facilities are adequate to meet our business requirements for the near term and that additional space will be available on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

Information pertaining to certain legal proceedings in which we are involved can be found in Note 12 – “Commitments and Contingencies” to our consolidated financial statements included in Part II, Item 8 of this report and is incorporated herein by reference.

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market Information

Our common stock has been listed on The Nasdaq Stock Market LLC under the symbol "TCMD" since July 28, 2016.

Holders

As of February 17, 2023, there were approximately 31 holders of record of our common stock. The actual number of holders of common stock is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

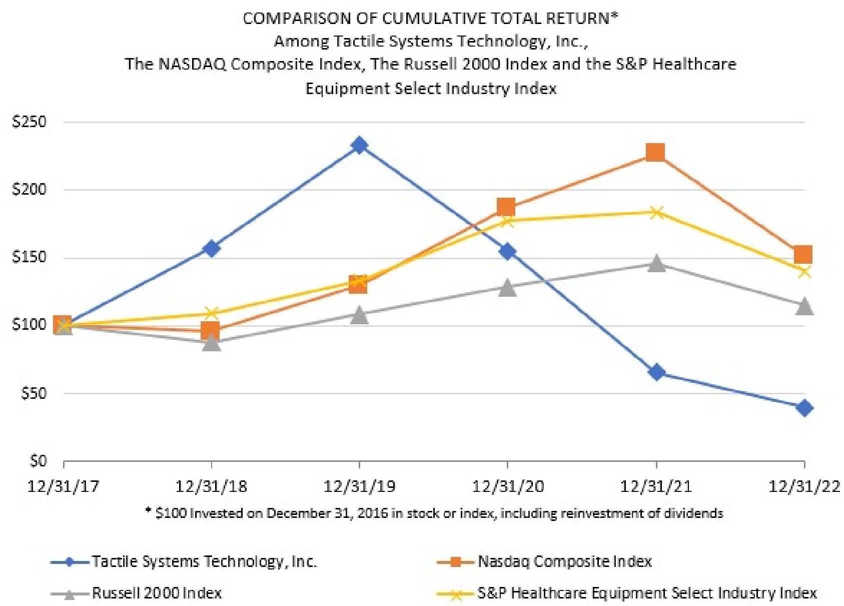
None.

Equity Compensation Plan Information

The information required by this Item concerning equity compensation plans is incorporated herein by reference from Part III, Item 12 of this report.

Stock Performance Graph

The graph below compares the cumulative total stockholder return on our common stock with the cumulative total stockholder returns on the Nasdaq Composite Index, Russell 2000 Index and S&P Healthcare Equipment Select Industry Index for the periods indicated. The graph assumes that $100 was invested on December 31, 2017, in our common stock and each of the indices and that all dividends, if any, were reinvested. No cash dividends have been declared on our common stock. Stockholder returns over the indicated periods should not be considered indicative of future stockholder returns.



Index	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
Tactile Systems Technology, Inc.	$ 100	$ 157	$ 233	$ 155	$ 66	$ 40
Nasdaq Composite Index	100	96	130	187	227	152
Russell 2000 Index	100	88	109	129	146	115
S&P Healthcare Equipment Select Industry Index	100	109	134	178	184	140

Item 6. [Reserved.]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes thereto included elsewhere in this report.

This Management's Discussion and Analysis of Financial Condition and Results of Operations focuses on discussion of year-over-year comparisons between 2022 and 2021. Discussion of 2020 results and year-over-year comparisons between 2021 and 2020 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 23, 2022.

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, particularly during most of 2021 and during the first quarter of 2022. 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 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.

Since the onset of COVID-19, we have remained proactive to ensure we continue to adapt to the needs of our employees, clinicians and patients. However, we cannot assure you these changes to our processes and practices will be successful in mitigating the impact of COVID-19 on our business. We continue to evaluate and, if appropriate, will adopt other measures in the future related to the ongoing safety of our employees, clinicians and patients.

Overview

We are a medical technology company that develops and provides innovative medical devices for the treatment of underserved chronic diseases. 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 setting 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.

Our current lymphedema products are the Flexitouch and Entre systems and our airway clearance product is the AffloVest. 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 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 2013. The Entre 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 system. Sales and rentals of our lymphedema products represented 86% and 98% of our revenue in the years ended December 31, 2022 and 2021, respectively.

On September 8, 2021, we acquired the assets of the AffloVest airway clearance product line from IBC, a privately-held company which developed and manufactured AffloVest. AffloVest is a portable, wearable vest that provides airway clearance to treat patients with chronic respiratory conditions such as bronchiectasis or conditions resulting from neuromuscular disorders. For the years ended December 31, 2022 and 2021, sales of AffloVest represented 14% and 2% of our revenue, respectively.

To support the growth of our business, we continue to invest in our commercial infrastructure, consisting of our direct sales force, training resources, reimbursement capabilities and clinical expertise. We market our lymphedema products in the United States using a direct-to-patient and -provider model. The AffloVest device is sold through respiratory durable medical equipment providers throughout the United States that service patients and bill third-party payers for the product. We also employ a small group of respiratory specialists, who educate DME representatives, provide product demonstrations for targeted clinicians and support technical questions related to the AffloVest. As of December 31, 2022, we employed a 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. This compares to a field staff of 262 as of December 31, 2021.

We invest in our reimbursement function to improve operational efficiencies and enhance individual payer expertise, while continuing our strategic focus of payer development. 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. Since the onset of COVID-19, our reimbursement function has been actively working with Medicare and a broad base of private payers to understand the ever-changing reimbursement criteria being introduced. While the U.S. government's declaration of a public health emergency (PHE) related to the COVID-19 pandemic has relaxed some Medicare criteria for respiratory patients, these circumstances are ever-changing, and the extent to which these changes will remain in place and the impact on our business in the future are not determinable at this time.

We also have a clinical team, consisting of a scientific advisory board, in-house therapists and nurses, and a Chief Medical Officer, that serves as a resource to clinicians and patients and guides the development of clinical evidence in support of our products. Most clinical studies require observation and interaction with clinicians and patients to monitor results and progress.

We rely on third-party contract manufacturers for the sourcing of parts, the assembly of our controllers and the manufacturing of the garments used with our systems. We conduct final assembly of the garments used with our products, perform quality assurance and ship our products from our facility in Minnesota. The AffloVest device continued to be manufactured and shipped by IBC on our behalf pursuant to a Transition Services Agreement through April 30, 2022. On May 1, 2022, we began manufacturing and shipping the AffloVest device from our Minnesota-based facility.

To date, our supply chain has not been materially impacted by COVID-19. We continue to receive our product on time and believe that we have enough safety stock to meet our short and mid-term demand. However, we cannot assure you that our supply chain will not be materially impacted in the future or that we will be able to meet any increased demand.

In July 2022, we launched Kylee™, a free mobile application that allows for patients to manage their conditions by tracking treatments and symptoms, as well as having direct access to educational resources.

For the year ended December 31, 2022, we generated revenue of $246.8 million and had a net loss of $17.9 million, compared to revenue of $208.1 million and a net loss of $11.8 million for the year ended

December 31, 2021, and revenue of $187.1 million and a net loss of $0.6 million for the year ended December 31, 2020.

Our primary sources of capital since our initial public offering in 2016 have been from operating income and bank financing.

We operate in one segment for financial reporting purposes.

Components of our Results of Operations

Revenue

We derive revenue from sales and rentals of our Flexitouch and Entre systems to patients in the United States. Revenue growth has been driven by increased clinician, patient and payer awareness of lymphedema and the clinical efficacy of our Flexitouch system, and the launch of our Entre system in 2013. We have expanded our direct sales force, which helps us drive and support our revenue growth and intend to continue this expansion. However, any reversal in these recent trends could have a negative impact on our future revenue.

We sell or rent our Flexitouch and Entre systems either directly to patients or to the Veterans Administration on behalf of patients, who are referred to us by physicians, therapists or nurses. We bill payers, such as private insurers, Medicare, or Medicaid, on behalf of our patients and bill patients directly for their cost-sharing amounts, including any portion of an unsatisfied deductible and any copayments or co-insurance. We bill the Veterans Administration directly for the purchase or lease of our product on behalf of the patient. Approximately 10% of our revenue in 2022 and 13% of our revenue in 2021 came from the Veterans Administration. Approximately 19% of our revenue in 2022 and 17% of our revenue in 2021 came from Medicare patients. Changes to the level of Medicare coverage for our products could reduce the number of Medicare patients who have access to our products. Our products currently are not subject to the competitive bidding process for supplying covered items to Medicare recipients.

We derive revenue from sales of our AffloVest product to accredited DME providers. These respiratory DME providers provide a full range of solutions for these patients with complex diseases, and represent a large, developed channel. Respiratory DME partners serve the role of receiving prescriptions, verifying coverage criteria, shipping, billing and training the patient. We intend to expand and support our respiratory DME partners, in an effort to help demonstrate HFCWO as a staple among the host of treatments they bring to chronic respiratory patients, thereby allowing us to continue to grow revenue from this product offering.

Our revenue has fluctuated, and we expect our revenue to continue to fluctuate, from quarter to quarter due to a variety of factors, including seasonality. See Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Seasonality” for a further discussion of factors contributing to our seasonality. Further, our revenue is impacted by fluctuations in the mix of products being sold and rented during each period and changes in the mix of our payers and contract pricing.

Furthermore, we expect our revenue to continue to increase in the future as a result of increased awareness of our solutions, expansion of our direct sales force, our DME partners, enhanced marketing and customer support efforts, continued focus on developing clinical and economic outcomes data, and efforts related to expanded third-party reimbursement. However, we also anticipate pricing pressure from private insurers, which will result in continued downward pressure on our revenue growth rate.

Cost of Revenue and Gross Margin

Cost of revenue consists primarily of component costs, direct labor, overhead costs, product warranties, provisions for slow-moving and obsolete inventory, delivery costs for items sold or rented, and amortization related to the intangible assets related to our products. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of revenue also includes depreciation expense for product tooling and equipment as well as shipping costs. We expect overhead costs as a percentage of revenue to decrease as a result of expected increases in production volume and yields. We expect cost of revenue to increase in absolute dollars primarily if, and to the extent, our revenue grows.

We provide a warranty for our products against defects in material and workmanship for a period of one to five years. We record a liability for future warranty claims at the time of sale for the warranty period offered to a customer in cost of revenue. If the assumptions used in calculating the provision were to materially change, such as incurring higher than anticipated warranty claims, an additional provision may be required.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, including product and payer mix, production volumes, manufacturing costs and cost-reduction strategies. We continue to work to reduce product manufacturing costs through enhanced product design efforts as well as supply chain initiatives in an effort to offset anticipated price erosion. Our gross margin will likely fluctuate from quarter to quarter.

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of personnel-related expenses, including salaries, bonuses, commissions and benefits for employees. They also include expenses for patient training, social media and advertising, informational kits, public relations and other promotional and marketing activities, field sales travel and entertainment expenses, trade shows and conferences, stock-based compensation, as well as customer service. We expect sales and marketing expenses to continue to increase in absolute dollars as we expand our commercial infrastructure to drive and support our planned revenue growth. To the extent our revenue grows, we expect sales and marketing expenses to decrease as a percentage of revenue over time.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of personnel-related expenses, third-party product development costs, laboratory supplies, consulting fees and related costs, clinical research expenses, expenses related to clinical and regulatory affairs, patent amortization costs, stock-based compensation and patent legal fees, including defense costs, and testing costs for new product launches. Clinical research expenses include clinical trial management and monitoring, payment to clinical investigators, consulting fees, data management, stock-based compensation, travel expenses and the cost of manufacturing products for clinical trials. We have made substantial investments in R&D since our inception. Our R&D efforts have focused primarily on activities designed to enhance our technologies and to support development and commercialization of new and existing products. We expect R&D expenses to increase for the foreseeable future as we continue to develop, enhance and commercialize new products and expand clinical trial efforts. We expect R&D expenses as a percentage of our revenue to vary over time depending on the level and timing of initiating new product development efforts, as well as our clinical trial activities.

Intangible Asset Amortization and Earn-Out

Amortization of intangible assets includes the amortization expense of our definite-lived intangible assets, consisting of patents, customer relationships, customer accounts, developed technology and defensive intangible assets. The costs of definite-lived intangibles are amortized to expense over their useful lives. Indefinite-lived intangible assets, such as goodwill and tradenames, are not amortized; we test for impairment on these assets annually.

The fair value of the earn-out, which is payable if certain future U.S. revenues of AffloVest are met, is recorded as a liability. On a quarterly basis the earn-out is revalued to fair value. Any gain or loss related to this revaluation is recorded through the income statement.

Reimbursement, General and Administrative Expenses

Reimbursement, general and administrative expenses consist primarily of compensation, including salaries, bonuses and benefits for employees in our patient services and advocacy, billing and collections, case management, payer relations and governmental affairs and reimbursement operations departments, as well as finance, human resources and administration, information technology, business development and general management functions, and facilities costs. Reimbursement expenses also include consulting, travel to payer case manager seminars, professional development and training, and certification expenses. General and administrative expenses also include professional services such as legal, consulting and accounting services, stock-based compensation, travel expenses, insurance and acquisition costs.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income related to investment income earned on our invested capital portfolio and interest expense related to our debt obligations.

Income Tax Expense (Benefit)

Our income tax expense (benefit) consists primarily of permanent differences related to share-based compensation activity, as well as deferred income taxes resulting from temporary differences between the reporting of amounts for financial statement purposes and income tax purposes.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, and related disclosure of contingent assets and liabilities, revenue and expenses at the date of the financial statements. Generally, we base our estimates on historical experience and on various other assumptions in accordance with GAAP that we believe to be reasonable under the circumstances. Actual results may differ from these estimates and such differences could be material to our financial position and results of operations. Critical accounting estimates are those that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition and results of operations.

While our significant accounting policies are more fully described in Note 3 to our consolidated financial statements included elsewhere in this report, we believe the following discussion addresses our most critical accounting estimates, which involve significant subjectivity and judgment, and changes to such estimates or assumptions could have a material impact on our financial condition or operating results. Therefore, we consider an understanding of the variability and judgment required in making these estimates and assumptions to be critical in fully understanding and evaluating our reported financial results.

Revenue Recognition

We derive revenue from the sales and rentals of our proprietary line of Flexitouch and Entre systems, and from sales of our AffloVest product. We recognize revenue when control of the product has been transferred to our customer, in the amount of the expected consideration to be received for the product. Expected consideration is estimated as follows:

- *Flexitouch and Entre systems.* Expected consideration to be received is estimated based on a detailed review of historical pricing adjustments and collections. Specifically, payment history of the applicable payer, as well as historical patient collections, serve as primary sources of information in estimating expected consideration.

We update our assessment of collectability on a quarterly basis, with any adjustments for Flexitouch and Entre systems being reflected as sales and rental revenue and AffloVest products being reflected as bad debt expense within reimbursement, general and administrative expenses in the Consolidated Statements of Operations in the period of adjustment.

If in the future we determine that another method is more reasonable, or if another method for calculating these input assumptions is prescribed by authoritative guidance, the expected consideration associated with the sales and rentals of our products could change significantly. Changes in contractual pricing, payment trends and rebate structures would impact, either positively or negatively, our sales and rental revenue.

Stock-Based Compensation

The fair value of stock options is estimated at the date of grant, using the Black-Scholes option-pricing model, except for the valuation of certain “CEO” related stock options subject to a market condition which uses the Monte Carlo Simulation model. We recognize the fair value of each award as an expense on a straight-line basis over the requisite service period, which is generally the vesting period of the equity grant.

The Monte Carlo Simulation and Black-Scholes valuation models require the input of highly subjective assumptions, including the expected term of the option, the expected volatility of the price of our common stock, the risk-free interest rate and the expected dividend yield. These estimates involve inherent uncertainties and the significant application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. We determined weighted-average valuation assumptions as follows:

- *Expected term*. We use the "simplified method" to determine the expected term of the stock option.

- *Expected volatility*. Expected volatility for grants issued in and prior to the first fiscal quarter of 2021 was estimated using the average historical volatility of public companies of similar size and industry over a similar period as the expected term assumption used for our options. Beginning in the second fiscal quarter of 2021, we had sufficient historical data to transition to utilizing our average historical volatility over a similar period as the expected term assumption used for our options as the expected volatility.

- *Risk-free interest rate*. The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.

- *Expected dividend yield*. We have never declared or paid any cash dividends on our common stock and do not presently plan to pay cash dividends on our common stock in the foreseeable future. Consequently, we use an expected dividend yield of zero.

If in the future we determine that another method is more reasonable, or if another method for calculating these input assumptions is prescribed by authoritative guidance, the fair value calculated for our stock options could change significantly. Higher volatility and longer expected lives would result in an increase to stock-based compensation expense determined at the date of grant. Stock-based compensation expense affects our cost of revenue, sales and marketing expenses, research and development expenses, and reimbursement, general and administrative expenses.

We estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover behavior and other factors. Quarterly changes in the estimated forfeiture rate can have a significant effect on reported stock-based compensation expense, as the cumulative effect of adjusting the rate for all expense amortization is recognized in the period the forfeiture estimate is changed. If a revised forfeiture rate is higher than the previously estimated forfeiture rate, an adjustment is made that will result in a decrease to the stock-based compensation expense recognized in the consolidated financial statements. If a revised forfeiture rate is lower than the previously estimated forfeiture rate, an adjustment is made that will result in an increase to the stock-based compensation expense recognized in the consolidated financial statements. The effect of forfeiture adjustments was insignificant for the years ended December 31, 2022, 2021 and 2020. We will continue to use significant judgment in evaluating the expected term, volatility and forfeiture rate related to our stock-based compensation.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table presents our results of operations for the periods indicated:

(In thousands)	Year Ended December 31, 2022		2021		Change $	%
Consolidated Statement of Operations Data:		% of revenue		% of revenue		
Revenue						
Sales revenue	$ 211,345	86 %	$ 177,914	86 %	$ 33,431	19 %
Rental revenue	35,440	14 %	30,143	14 %	5,297	18 %
Total revenue	246,785	100 %	208,057	100 %	38,728	19 %
Cost of revenue						
Cost of sales revenue	59,619	24 %	50,222	24 %	9,397	19 %
Cost of rental revenue	11,190	5 %	9,622	5 %	1,568	16 %
Total cost of revenue	70,809	29 %	59,844	29 %	10,965	18 %
Gross profit						
Gross profit - sales revenue	151,726	61 %	127,692	62 %	24,034	19 %
Gross profit - rental revenue	24,250	10 %	20,521	9 %	3,729	18 %
Gross profit	175,976	71 %	148,213	71 %	27,763	19 %
Operating expenses						
Sales and marketing	106,418	43 %	86,775	42 %	19,643	23 %
Research and development	7,088	3 %	5,659	3 %	1,429	25 %
Reimbursement, general and administrative	60,796	25 %	56,802	27 %	3,994	7 %
Intangible asset amortization and earn-out	14,432	5 %	739	— %	13,693	N.M. %
Total operating expenses	188,734	76 %	149,975	72 %	38,759	26 %
Loss from operations	(12,758)	(5)%	(1,762)	(1)%	(10,996)	N.M. %
Other expense	(2,715)	(1)%	(531)	— %	(2,184)	N.M. %
Loss before income taxes	(15,473)	(6)%	(2,293)	(1)%	(13,180)	N.M. %
Income tax expense	2,393	1 %	9,518	5 %	(7,125)	(75)%
Net loss	$ (17,866)	(7)%	$ (11,811)	(5)%	$ (6,055)	51 %

"N.M." Not Meaningful

Revenue

Revenue increased $38.7 million, or 19%, to $246.8 million in the year ended December 31, 2022, compared to $208.1 million in the year ended December 31, 2021. The increase in revenue was attributable to an increase of approximately $29.4 million in sales of our airway clearance product line, which consists of the AffloVest product we acquired on September 8, 2021, and an increase of $9.4 million, or 5%, in sales and rentals of the lymphedema product line compared to the year ended December 31, 2021. While we saw some level of recovery in 2022 after the first quarter, revenue in 2022 from the lymphedema product line was adversely affected by the fact that first quarter 2022 revenue was negatively impacted by the prolonged recovery from COVID-19, including the resurgence due to the Omicron variant during that period, which resulted in restricted access to clinics and hospitals and disrupted the recovery in patient visits versus the pre-COVID environment. In addition, the challenging labor market continued to impact our ability to recruit and retain quality candidates for our direct sales force, particularly during the first quarter of 2022.

Revenue from the Veterans Administration represented 10% and 12% of total revenue for the years ended December 31, 2022 and 2021, respectively. Revenue from Medicare represented 19% and 17% of total revenue for the years ended December 31, 2022 and 2021, respectively.

The following table summarizes our revenue by product for the years ended December 31, 2022 and 2021, both in dollars and percentage of total revenue:

(In thousands)	Year Ended December 31, 2022	2021	Change $	%
Revenue				
Lymphedema products	$ 212,266	$ 202,913	$ 9,353	5%
Airway clearance products	34,519	5,144	29,375	N.M.
Total	$ 246,785	$ 208,057	$ 38,728	19%
Percentage of total revenue				
Lymphedema products	86%	98%		
Airway clearance products	14%	2%		
Total	100%	100%		

Cost of Revenue and Gross Margin

Cost of revenue increased $11.0 million, or 18%, to $70.8 million during the year ended December 31, 2022, compared to $59.8 million during the year ended December 31, 2021. The increase in cost of revenue was primarily attributable to the additional cost of revenue related to AffloVest.

Gross margin was 71% for both of the years ended December 31, 2022 and 2021.

Sales and Marketing Expenses

Sales and marketing expenses increased $19.6 million, or 23%, to $106.4 million during the year ended December 31, 2022, compared to $86.8 million during the year ended December 31, 2021. The increase was primarily attributable to a:

- $15.8 million increase in personnel-related compensation expense as a result of the increased headcount in the collective field commercial team;
- $2.6 million increase in travel and entertainment expenses;
- $1.2 million increase related to our annual national sales training meeting;
- $0.6 million increase related to sales meetings and tradeshows; and
- $0.1 million increase in expenses for new product introductions.

These increases were partially offset by a $0.7 million decrease in professional services.

Research and Development Expenses

Research and development (“R&D”) expenses increased $1.4 million, or 25%, to $7.1 million during the year ended December 31, 2022, compared to $5.7 million during the year ended December 31, 2021, which was primarily attributable to an increase in personnel-related expense and R&D supplies.

Reimbursement, General and Administrative Expenses

Reimbursement, general and administrative expenses increased $4.0 million, or 7%, to $60.8 million during the year ended December 31, 2022, compared to $56.8 million during the year ended December 31, 2021. The increase was primarily attributable to a:

- $4.0 million increase in personnel-related compensation expense as a result of increased headcount in our reimbursement operations, payer relations and corporate functions;
- $0.7 million increase in occupancy costs, depreciation expense, and legal and professional fees; and
- $0.1 million increase in travel and entertainment.

These increases were partially offset by a $0.8 million decrease in acquisition costs.

Intangible Asset Amortization and Earn-out

Intangible asset amortization and earn-out expenses increased $13.7 million to $14.4 million during the year ended December 31, 2022, compared to $0.7 million during the year ended December 31, 2021. The increase in intangible asset amortization and earn-out expense was primarily attributable to the increase in the estimated fair value of our earn-out liability related to the AffloVest acquisition.

Other Expense, Net

Other expense, net was $2.7 million for the year ended December 31, 2022, compared to $0.5 million for the year ended December 31, 2021. The increase was primarily attributable to an increase in interest expense.

Income Tax Expense

We recorded an income tax expense of $2.4 million and $9.5 million for the years ended December 31, 2022 and 2021, respectively. The current year tax expense was primarily driven by the change in deferred tax assets and corresponding increase in the full valuation allowance which remains in place after an assessment of existing positive and negative evidence indicated these deferred tax assets would not be realizable.

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. Based on this evaluation, as of December 31, 2022 and 2021, a valuation allowance of $17.8 million and $12.0 million, respectively, was recorded to recognize only the residual portion of the existing deferred tax asset that are more likely than not to be realized and which comprises the assets that will not be offset by the reversal of deferred tax liabilities. The amount of the deferred tax asset considered realizable which will be offset by reversing deferred tax liabilities, however, could be adjusted in the future if estimates of taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as projections for growth.

Seasonality

Our business is affected by seasonality. 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 of the year 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.

Further, seasonality trends have been, and may continue to be, different than historical trends as a result of the COVID-19 pandemic and related impacts.

Liquidity and Capital Resources

Overview

As of December 31, 2022, we had cash and cash equivalents of $21.9 million and net accounts receivable of $77.9 million compared to cash and cash equivalents of $28.2 million and net accounts receivable of $62.3 million as of December 31, 2021. Our primary sources of capital since our initial public offering in 2016 have been from operating income and bank financing.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

(In thousands)	Year Ended December 31, 2022	2021	2020
Net cash provided by (used in):			
Operating activities	$ 5,209	$ 2,631	$ 2,794
Investing activities	(1,909)	(82,184)	20,179
Financing activities	(9,600)	59,927	2,112
Net (decrease) increase in cash and cash equivalents	$ (6,300)	$ (19,626)	$ 25,085

Net Cash Provided by Operating Activities

Net cash provided by operating activities during the year ended December 31, 2022, was $5.2 million, resulting from a net loss of $17.9 million and non-cash net income adjustments of $27.7 million, which were offset by a change in net operating assets and liabilities of $4.6 million. The non-cash net income adjustments primarily consisted of $11.9 million change in fair value of earn-out liability, $9.6 million of stock-based compensation expense, and $6.3 million of depreciation and amortization expense. Changes in operating assets and liabilities were unfavorably impacted by increasing accounts receivable, net investment in leases and continued investment in inventory designed to meet future projected demand, partially offset by an increase in current liabilities.

Net cash provided by operating activities during the year ended December 31, 2021, was $2.6 million, resulting from a net loss of $11.8 million and non-cash net income adjustments of $23.9 million, which were offset by an increase in net operating assets and liabilities of $9.5 million. The non-cash net income adjustments primarily consisted of $10.2 million of stock-based compensation expense, $10.2 million of deferred income tax expense and $3.7 million of depreciation and amortization expense. Changes in operating assets and liabilities were unfavorably impacted by increasing accounts receivable, net investment in leases and income taxes payable, partially offset by an increase in current liabilities.

Net Cash (Used in) Investing Activities

Net cash used in investing activities during the year ended December 31, 2022, was $1.9 million, primarily consisting of $1.8 million in purchases of property and equipment primarily related to office equipment, production tooling and tenant improvements and $0.1 million related to the acquisition of patents and other intangible assets.

Net cash used in investing activities during the year ended December 31, 2021, was $82.2 million, primarily consisting of acquisition-related payments of $79.8 million associated with the acquisition of the AffloVest business and $2.1 million in purchases of property and equipment primarily related to office equipment, production tooling and tenant improvements and $0.3 million related to the acquisition of patents and other intangible assets.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities during the year ended December 31, 2022, was $9.6 million, primarily consisting of payments of $6.0 million on notes payable and a payment of $5.0 million on the AffloVest earn-out, partially offset by $1.4 million in proceeds from exercises of common stock options and the issuance of common stock under the ESPP.

Net cash provided by financing activities during the year ended December 31, 2021, was $59.9 million, primarily consisting of borrowings of $54.8 million net of debt issuance costs incurred and $6.3 million in proceeds from exercises of common stock options and the issuance of common stock under the ESPP, partially offset by $1.2 million in taxes paid for the net share settlement of performance and restricted stock units.

Credit Agreement

On April 30, 2021, we entered into an Amended and Restated Credit Agreement (the “Restated Credit Agreement”) with the lenders from time to time party thereto, and Wells Fargo Bank, National Association, as Administrative Agent. The Restated Credit Agreement amended and restated in its entirety the prior credit agreement.

On September 8, 2021, we entered into a First Amendment Agreement (the “First Amendment”), which amends the Restated Credit Agreement (as amended by the First Amendment and the Second Amendment (as defined below), the “Credit Agreement”) with the lenders from time to time party thereto, and Wells Fargo Bank, National Association, as administrative agent. The First Amendment, among other things, adds a $30.0 million incremental term loan to the $25.0 million revolving credit facility provided by the Restated Credit Agreement. The term loan and the revolving credit facility mature on September 8, 2024. The Credit Agreement provides that, subject to satisfaction of certain conditions, we may increase the amount of the revolving loans available under the Credit Agreement and/or add one or more term loan facilities in an amount not to exceed $25.0 million in the aggregate, such that the total aggregate principal amount of loans available under the Credit Agreement (including under the revolving credit facility) does not exceed $80.0 million.

Our obligations under the Credit Agreement are secured by a security interest in substantially all of our and our subsidiaries’ assets and are also guaranteed by our subsidiaries. The Credit Agreement contains a number of restrictions and covenants, including that we maintain compliance with a maximum leverage ratio, minimum fixed charge coverage ratio and a minimum consolidated EBITDA covenant. As of December 31, 2022, we were in compliance with all financial covenants under the Credit Agreement.

On September 8, 2021, in connection with the closing of the acquisition of the AffloVest business, we borrowed the $30.0 million term loan and utilized that borrowing, together with a draw of $25.0 million under the revolving credit facility and cash on hand, to fund the purchase price. The principal of the term loan is required to be repaid in quarterly installments of $750,000 commencing January 7, 2022, through July 8, 2024, with the remaining outstanding balance due on September 8, 2024.

On February 22, 2022, we entered into a Second Amendment Agreement (the “Second Amendment”), which further amends the Credit Agreement. The Second Amendment modifies the maximum leverage ratio, the minimum fixed charge coverage ratio and the minimum consolidated EBITDA covenants under the Credit Agreement, and adds a minimum liquidity covenant. The Second Amendment also increases the applicable margin for LIBOR rate loans under the Credit Agreement during the period commencing on the date of the Second Amendment and ending on the last day of the fiscal quarter ending June 30, 2023.

Pursuant to the Second Amendment, on February 22, 2022, we made a mandatory principal prepayment of the term loan under the Credit Agreement of $3.0 million.

As of December 31, 2022, we had outstanding borrowings of $49.0 million under the Credit Agreement, comprised of $24.0 million under the term loan and $25.0 million under the revolving credit facility.

For additional information regarding the Credit Agreement, including interest rates, fees and maturities, see Note 11 – "Credit Agreement" of the consolidated financial statements contained in this report.

Future Cash Requirements

Our material estimated future cash requirements under our contractual obligations and commercial commitments as of December 31, 2022, in total and disaggregated into current (payable in 2023) and long-term (payable after 2023) obligations, are summarized as follows:

	Payments Due By Period				
(In thousands)	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Purchase commitments [1]	$ 33,478	$ 33,478	$ —	$ —	$ —
Operating lease obligations [2]	27,227	3,427	6,936	6,782	10,082
Note payable payments [3]	24,000	3,000	21,000	—	—
Revolving line of credit payments [4]	25,000	—	25,000	—	—
Interest payments [5]	5,778	3,539	2,239	—	—
Earn-out obligation [6]	13,050	13,050	—	—	—
Total	$ 128,533	$ 56,494	$ 55,175	$ 6,782	$ 10,082

(1) We issued purchase orders in 2022 totaling $33.5 million for goods that we expect to receive and pay for in 2023.

(2) We currently lease approximately 150,000 square feet of office space for our corporate headquarters in Minneapolis, Minnesota, under a lease that expires in February 2031 and approximately 63,000 square feet of office, assembly and warehouse space at another facility in Minneapolis, Minnesota, under a lease that expires in March 2027. We entered into a fleet vehicle program for certain members of our field sales organization in 2016. At December 31, 2022, we had two vehicles under this program with current lease commitments. Furthermore, we lease office equipment from time-to-time based on our needs and these commitments are classified as operating leases.

(3) Reflects principal payment obligations under our term loan. Refer to Note 11 "Credit Agreement" to our consolidated financial statements included in this report for additional information regarding the maturities of debt principal.

(4) Reflects repayment of the principal of outstanding borrowings under our revolving line of credit based on the scheduled maturity date.

(5) Interest payment amounts on long-term debt are calculated using outstanding balances and interest rates in effect on December 31, 2022.

(6) In connection with the acquisition of AffloVest, as of December 31, 2022, we were obligated to make an earn-out payment in the amount of $5.0 million (as well as an imputed interest payment of $250,000) by May 26, 2023, and may be obligated to make an additional earn-out payment of up to $10.0 million in cash, if certain future financial results of the AffloVest business are met. The fair value of this obligation at December 31, 2022 was $13.1 million, which is reflected on our Consolidated Balance Sheets.

Adequacy of Resources

Our future cash requirements may vary significantly from those now planned and will depend on many factors, including:

- the impact of the COVID-19 pandemic on our business;
- sales and marketing resources needed to further penetrate our market;
- expansion of our operations;
- response of competitors to our solutions and applications;
- costs associated with clinical research activities;
- increases in interest rates;
- labor shortages and wage inflation;

- costs to develop and implement new products; and
- use of capital for acquisitions or licenses, if any.

Historically, we have experienced increases in our expenditures consistent with the growth in our revenue, operations and personnel, and we anticipate that our expenditures will continue to increase as we expand our business.

Although the impact of the COVID-19 pandemic and other factors such as inflation and rising interest rates are difficult to predict, we believe our cash, cash equivalents and cash flows from operations will be sufficient to meet our working capital, capital expenditure, debt repayment and related interest, and other cash requirements for at least the next twelve months.

Inflation and changing prices did not have a material effect on our business during the year ended December 31, 2022, and we do not expect that inflation or changing prices will materially affect our business for at least the next twelve months.

Coronavirus Aid, Relief, and Economic Security (CARES) Act

On March 27, 2020 the CARES Act was signed into law. The CARES Act is a tax-and-spending package intended to provide economic relief to address the impact of the COVID-19 pandemic. The CARES Act includes several tax provisions that, among other things, allow businesses to carry back net operating losses ("NOLs") arising in 2018, 2019, and 2020 to the prior five tax years. In the third quarter of 2020, we collected $2.9 million related to the carry back of our NOLs arising from these prior tax years.

In addition, the CARES Act provided $100 billion in relief funds to hospitals and other healthcare providers on the front lines of the COVID-19 pandemic. An initial $30 billion of the funds were released for immediate infusion and were distributed to all facilities and providers that received Medicare fee-for-service ("FFS") reimbursements in 2019. On April 10, 2020, we received $1.2 million of the initial allotment to all facilities and providers which was determined to be our proportionate share. Within 45 days of each reporting period end, we complied with the reporting requirements confirming funds were utilized in a manner described within the terms and conditions outlined by the U.S. Department of Health & Human Services. As of December 31, 2020, we recognized all of the funds received in the initial allotment as other income.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under the applicable regulations.

Recent Accounting Pronouncements

Refer to Note 3 - "Summary of Significant Accounting Policies," of our consolidated financial statements contained in this report for a description of recently issued accounting pronouncements that are applicable to our business.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to market risk from changes in interest rates, primarily related to our investments and our borrowings. The principal objectives of our investment activities are to preserve principal, provide liquidity and maximize income consistent with minimizing risk of material loss. The recorded carrying amounts of cash and cash equivalents approximate fair value due to their short maturities. Our interest income is sensitive to changes in the general level of interest rates in the United States, particularly since our investments are generally short-term in nature. Based on the nature of our short-term investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio. We also have exposure to variable interest rates through our credit facility, as the interest expense related to any borrowings will fluctuate with changes in LIBOR and other benchmark rates. Therefore, increases in interest rates may impact our net income or loss by increasing the cost of carrying debt.

Inflation

Inflationary factors, such as increases in our cost of revenue, sales and marketing expenses and reimbursement expenses, may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial condition or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin, and on our sales and marketing and reimbursement expenses as a percentage of our revenue if the prices for our products do not increase as much or more than these increased costs.

Credit Risk

As of December 31, 2022 and 2021, our cash and cash equivalents were maintained with one financial institution in the United States. We perform periodic evaluations of the relative credit standing of this financial institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. We have not experienced any losses on our cash or cash equivalents to date.

Our accounts receivable primarily relate to revenue from the sale of our products to patients in the United States. As of December 31, 2022 and 2021, our accounts receivable were $77.9 million and $62.3 million, respectively. We had accounts receivable from two insurers representing approximately 45% and 21% of accounts receivable as of December 31, 2022. We had accounts receivable from two insurers representing approximately 33% and 24% of accounts receivable as of December 31, 2021. The credit risks associated with customers which for these purposes are insurers considers aggregation for entities that are known to be under common control.

Foreign Currency Risk

Our business is conducted in U.S. dollars and international transactions have been nominal. As we begin building relationships to commercialize our products internationally, our results of operations and cash flows may become increasingly subject to changes in foreign exchange rates.

Item 8. Financial Statements and Supplementary Data.

Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Tactile Systems Technology, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Tactile Systems Technology, Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 21, 2023 expressed an unqualified opinion.

Basis for opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical audit matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Transaction Price Adjustment – Uncollected Lymphedema Product Sales with Commercial Payers and Medicare

As described further in Note 3. Summary of Significant Accounting Policies – Revenue Recognition to the consolidated financial statements, revenue is recognized upon transfer of control of the product to the patient based on a transaction price determined to be the amount of expected consideration to be received for the product. In most cases, there is a contracted third-party payer, such as a commercial insurer, Medicare or the Veteran's Administration involved with the transaction. The transaction price is impacted by multiple factors including the terms and conditions contracted by third-party payers. Thus, payments from third-party payers typically are less than the Company's standard charge and represent an implicit price concession, resulting in variable consideration. The transaction price for commercial payers is determined based on the payment history of the payer drawn from actual write-off and collections experience over a rolling 12-month period, as well as historical patient collections by payer. The Company assesses the variable consideration for each Medicare claim as a percentage of the total invoice price based on ultimate approval and collection history. There is not variable consideration with sales to the Veterans Administration. The results of the variable consideration assessment are the primary source of information in estimating the recognition of net revenue and the net valuation of the related accounts receivable.

We identified the transaction price adjustment, as it relates to the uncollected Lymphedema product sales to commercial payers and Medicare, as a critical audit matter. The principal considerations for our determination of this as a critical audit matter are:

- The transaction price adjustment is related to material accounts and disclosures that are important to the users of the consolidated financial statements
- Significant judgment is required to estimate the expected amount of cash consideration to be collected, which is a key input into management's transaction price adjustment
- As it relates to sales with Medicare, the future collection could significantly differ from those subjective estimates given the payment uncertainty due to the appeals process for claims initially denied.

Our audit procedures related to the transaction price adjustment – uncollected Lymphedema product sales with commercial payers and Medicare included the following, among others:

- We tested the design and operating effectiveness of management's key controls relating to their Medicare and commercial payer transaction price assessments and commercial payer lookback analysis through reperformance, observation of the control being performed, and inspection of supporting documentation providing evidence of control performance.
- To test management's estimate of the commercial payer transaction price adjustment, we: (1) recomputed management's calculation of the historical collection amount by payer based on transactions that occurred during the year for a sample of commercial payers and (2) tested the completeness and accuracy of the underlying data used in management's calculation of the historical collection amount.
- For sales to patients insured by commercial payers, we assessed the reasonableness of management's year-end analysis of the transaction price adjustment recorded in the prior year compared to actual pricing adjustments experienced in the current period by recomputing the results of management's historical lookback analysis of collection amounts by payer portfolio and total reserve.
- For sales to patients covered by Medicare, we: (1) tested management's estimate by evaluating the determination of collection percentage assumptions, (2) recalculated the related transaction price adjustment based upon management's assumptions and (3) tested the completeness and accuracy of the underlying data inputs for the collection percentage determination.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2015.

Minneapolis, Minnesota
February 21, 2023

Tactile Systems Technology, Inc.
Consolidated Balance Sheets

(In thousands, except share and per share data)	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 21,929	$ 28,229
Accounts receivable	54,826	49,478
Net investment in leases	16,130	12,482
Inventories	23,124	19,217
Prepaid expenses and other current assets	3,754	4,141
Total current assets	119,763	113,547
Non-current assets		
Property and equipment, net	6,077	6,750
Right of use operating lease assets	21,322	23,984
Intangible assets, net	50,375	54,081
Goodwill	31,063	31,063
Accounts receivable, non-current	23,061	12,847
Other non-current assets	3,335	1,998
Total non-current assets	135,233	130,723
Total assets	$ 254,996	$ 244,270
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 9,984	$ 5,023
Note payable	2,968	2,960
Earn-out, current	13,050	3,250
Accrued payroll and related taxes	17,100	12,139
Accrued expenses	9,240	5,262
Income taxes payable	2,336	16
Operating lease liabilities	2,500	2,506
Other current liabilities	7,152	3,305
Total current liabilities	64,330	34,461
Non-current liabilities		
Revolving line of credit, non-current	24,916	24,857
Note payable, non-current	20,979	26,933
Earn-out, non-current	—	2,950
Accrued warranty reserve, non-current	2,207	3,108
Income taxes payable, non-current	298	348
Operating lease liabilities, non-current	20,866	23,354
Deferred income taxes	—	32
Total non-current liabilities	69,266	81,582
Total liabilities	133,596	116,043
Commitments and Contingencies (see Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 50,000,000 shares authorized; none issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized; 20,252,677 shares issued and outstanding as of December 31, 2022; 19,877,786 shares issued and outstanding as of December 31, 2021	20	20
Additional paid-in capital	131,001	119,962
(Accumulated deficit) retained earnings	(9,621)	8,245
Total stockholders' equity	121,400	128,227
Total liabilities and stockholders' equity	$ 254,996	$ 244,270

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

Tactile Systems Technology, Inc.
Consolidated Statements of Operations

(In thousands, except share and per share data)	Year Ended December 31, 2022	2021	2020
Revenue			
Sales revenue	$ 211,345	$ 177,914	$ 161,497
Rental revenue	35,440	30,143	25,633
Total revenue	246,785	208,057	187,130
Cost of revenue			
Cost of sales revenue	59,619	50,222	45,309
Cost of rental revenue	11,190	9,622	9,011
Total cost of revenue	70,809	59,844	54,320
Gross profit			
Gross profit - sales revenue	151,726	127,692	116,188
Gross profit - rental revenue	24,250	20,521	16,622
Gross profit	175,976	148,213	132,810
Operating expenses			
Sales and marketing	106,418	86,775	79,634
Research and development	7,088	5,659	5,264
Reimbursement, general and administrative	60,796	56,802	51,343
Intangible asset amortization and earn-out	14,432	739	197
Total operating expenses	188,734	149,975	136,438
Loss from operations	(12,758)	(1,762)	(3,628)
Other (expense) income	(2,715)	(531)	1,367
Loss before income taxes	(15,473)	(2,293)	(2,261)
Income tax expense (benefit)	2,393	9,518	(1,641)
Net loss	$ (17,866)	$ (11,811)	$ (620)
Net loss per common share			
Basic	$ (0.89)	$ (0.60)	$ (0.03)
Diluted	$ (0.89)	$ (0.60)	$ (0.03)
Weighted-average common shares used to compute net loss per common share			
Basic	20,067,969	19,719,485	19,346,929
Diluted	20,067,969	19,719,485	19,346,929

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

Tactile Systems Technology, Inc.
Consolidated Statements of Comprehensive Loss

(In thousands)	Year Ended December 31, 2022	2021	2020
Net loss	$ (17,866)	$ (11,811)	$ (620)
Other comprehensive loss			
Unrealized loss on marketable securities	—	—	(21)
Income tax related to items of other comprehensive loss	—	—	(5)
Total other comprehensive loss	—	—	(26)
Comprehensive loss	$ (17,866)	$ (11,811)	$ (646)

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

Tactile Systems Technology, Inc.
Consolidated Statements of Stockholders' Equity

(In thousands, except share data)	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	(Accumulated Deficit) Retained Earnings	Accumulated Other Comprehensive Loss	Total
Balances, December 31, 2019	19,152,715	$ 19	$ 91,874	$ 20,676	$ 26	$ 112,595
Stock-based compensation	—	—	10,689	—	—	10,689
Exercise of common stock options and vesting of restricted stock units	303,709	—	1,068	—	—	1,068
Taxes paid for net share settlement of restricted stock units	(37,790)	—	(1,854)	—	—	(1,854)
Common shares issued for employee stock purchase plan	74,084	—	2,898	—	—	2,898
Comprehensive loss for the period	—	—	—	(620)	(26)	(646)
Balances, December 31, 2020	19,492,718	$ 19	$ 104,675	$ 20,056	$ —	$ 124,750
Stock-based compensation	—	—	10,173	—	—	10,173
Exercise of common stock options and vesting of performance and restricted stock units	333,763	1	3,975	—	—	3,976
Taxes paid for net share settlement of restricted stock units	(22,357)	—	(1,173)	—	—	(1,173)
Common shares issued for employee stock purchase plan	73,662	—	2,312	—	—	2,312
Comprehensive loss for the period	—	—	—	(11,811)	—	(11,811)
Balances, December 31, 2021	19,877,786	$ 20	$ 119,962	$ 8,245	$ —	$ 128,227
Stock-based compensation	—	—	9,600	—	—	9,600
Exercise of common stock options and vesting of performance and restricted stock units	225,282	—	153	—	—	153
Common shares issued for employee stock purchase plan	149,609	—	1,286	—	—	1,286
Comprehensive loss for the period	—	—	—	(17,866)	—	(17,866)
Balances, December 31, 2022	20,252,677	$ 20	$ 131,001	$ (9,621)	$ —	$ 121,400

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

Tactile Systems Technology, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,		
(In thousands)	2022	2021	2020
Cash flows from operating activities			
Net loss	$ (17,866)	$ (11,811)	$ (620)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation and amortization	6,268	3,681	2,794
Net amortization of premiums and discounts on securities available-for-sale	—	—	(91)
Deferred income taxes	(32)	10,230	(1,233)
Stock-based compensation expense	9,600	10,173	10,689
Gain on other investments and maturities of marketable securities	—	—	(11)
Impairment losses	—	—	4,025
Loss on disposal of property and equipment and intangibles	20	20	—
Change in fair value of earn-out liability	11,850	(200)	—
Changes in assets and liabilities, net of acquisition:			
Accounts receivable	(5,348)	(5,629)	(10,405)
Net investment in leases	(3,648)	(1,774)	(2,561)
Inventories	(3,907)	972	318
Income taxes	2,270	(2,294)	1,972
Prepaid expenses and other assets	(950)	(1,489)	(528)
Right of use operating lease assets	168	614	559
Accounts receivable, non-current	(10,214)	(3,414)	(5,249)
Accounts payable	4,961	826	337
Accrued payroll and related taxes	4,961	551	1,490
Accrued expenses and other liabilities	7,076	2,175	1,308
Net cash provided by operating activities	5,209	2,631	2,794
Cash flows from investing activities			
Proceeds from maturities of securities available-for-sale	—	—	22,500
Payments related to acquisition	—	(79,829)	—
Purchases of property and equipment	(1,780)	(2,103)	(2,059)
Proceeds from sale of property and equipment	11	—	—
Intangible assets expenditures	(140)	(252)	(232)
Other investments	—	—	(30)
Net cash (used in) provided by investing activities	(1,909)	(82,184)	20,179
Cash flows from financing activities			
Proceeds from issuance of note payable	—	30,000	—
Proceeds from revolving line of credit	—	25,000	—
Payment on earn-out	(5,000)	—	—
Payments on note payable	(6,000)	—	
Payments of deferred debt issuance costs	(39)	(188)	—
Taxes paid for net share settlement of performance and restricted stock units	—	(1,173)	(1,854)
Proceeds from exercise of common stock options	153	3,976	1,068
Proceeds from the issuance of common stock from the employee stock purchase plan	1,286	2,312	2,898
Net cash (used in) provided by financing activities	(9,600)	59,927	2,112
Net (decrease) increase in cash and cash equivalents	(6,300)	(19,626)	25,085
Cash and cash equivalents – beginning of period	28,229	47,855	22,770
Cash and cash equivalents – end of period	$ 21,929	$ 28,229	$ 47,855
Supplemental cash flow disclosure			
Cash paid for interest	$ 2,186	$ 130	$ —
Cash paid for taxes	$ 44	$ 1,593	$ 543
Capital expenditures incurred but not yet paid	$ 38	$ 23	$ 17

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

Tactile Systems Technology, Inc.
Notes to the Consolidated Financial Statements

Note 1. Nature of Business and Operations

Tactile Systems Technology, Inc. ("we," "us," and "our") manufactures and distributes medical devices for the treatment of patients with underserved chronic diseases at home. We provide our Flexitouch and Entre systems, which help control symptoms of lymphedema, a chronic progressive medical condition, through our direct sales force for use in the home and sell or rent them through vascular, wound and lymphedema clinics throughout the United States.

On September 8, 2021, we acquired the assets of the AffloVest airway clearance business ("AffloVest Acquisition") from International Biophysics Corporation ("IBC"), a privately-held company which developed and manufactured AffloVest. AffloVest is a portable, wearable vest that treats patients with chronic respiratory conditions. We sell this device through home medical equipment and durable medical equipment ("DME") providers throughout the United States.

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. In September 2013, we began doing business as "Tactile Medical."

On August 2, 2016, we closed the initial public offering of our common stock, which resulted in the sale of 4,120,000 shares of our common stock at a public offering price of $10.00 per share. We received net proceeds from the initial public offering of approximately $35.4 million, after deducting underwriting discounts and approximately $2.9 million of transaction expenses.

Our business is affected by seasonality. 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 of the year when 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. Further, seasonality trends have been, and may continue to be, different than historical trends as a result of the COVID-19 pandemic and related impacts.

Note 2. Basis of Presentation

Our accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC.

The results for the year ended December 31, 2022, are not necessarily indicative of results to be expected for any future year.

Principles of Consolidation

Our accompanying consolidated financial statements include the accounts of Tactile Systems Technology, Inc. and its wholly owned subsidiary, Swelling Solutions, Inc. All intercompany balances and transactions have been eliminated in consolidation.

Risks and Uncertainties

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, particularly during 2020, most of 2021 and the first quarter of 2022. 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 some level of recovery in 2022, 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.

Since the onset of COVID-19, we have remained proactive to adapt to the needs of our employees, clinicians and patients. We cannot assure you that these changes to our processes and practices will be successful in mitigating the impact of COVID-19 on our business. We continue to evaluate and, if appropriate, will adopt other measures in the future related to the ongoing safety of our employees, clinicians and patients.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and to disclose contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Comprehensive Loss

Comprehensive loss reflects the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Our comprehensive loss represents net loss adjusted for unrealized gains and losses on available-for-sale marketable securities and the related taxes.

Note 3. Summary of Significant Accounting Policies

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash on hand and deposits. Our cash was held primarily in checking accounts as of December 31, 2022 and 2021. At times the amount of cash on deposit may exceed the federally insured limit of the bank. Deposit accounts at each of the institutions are insured up to $250,000 by the Federal Deposit Insurance Corporation (FDIC). At December 31, 2022 and 2021, the Company exceeded FDIC limits at various institutions. The Company has not experienced any losses in such accounts and believes there is little to no exposure to any significant credit risk.

Equity Investments

Equity investments (including equity securities) with readily determinable fair value are reported at fair value, with unrealized gains and losses included in the determination of net loss. For equity investments with no readily determinable fair value, we measure these investments at cost less impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Such observable price changes may include instances where the investee issues equity securities to new investors, thus creating a new indicator of fair value, as an example. As of each of December 31, 2022 and 2021, the total carrying value of our equity investments, with no readily determinable fair value, was $0.3 million, and are included in other non-current assets on our Consolidated Balance Sheets. On an annual basis, we perform a qualitative assessment considering impairment indicators to evaluate whether these investments are impaired and also monitor for any observable price changes. During the years ended December 31, 2022 and 2021, we did not have any impairment loss on these investments.

Accounts Receivable

The majority of our accounts receivable and revenue are from commercial insurance payers and government payers, such as Medicare, the Veterans Administration and Medicaid.

Accounts receivable are recorded based on management's assessment of the expected consideration to be received, based on a detailed review of historical pricing adjustments and collections. Management relies on the results of the assessment, which includes payment history of the applicable payer as well as historical patient collections, as a primary source of information in estimating the collectability of our accounts receivable. We update our assessment on a quarterly basis, which to date has not resulted in any material adjustments to the valuation of our accounts receivable. We believe the assessment provides reasonable estimates of our accounts receivable valuation, and therefore we believe that substantially all accounts receivable are fully collectible.

A portion of our claims to Medicare are initially denied and enter the appeals process, where many are ultimately reviewed by an Administrative Law Judge. After final adjudication of all claims, approximately 90% of the claims submitted are approved (this is on a number of claims, not a dollars claimed, basis across all our products). The appeals process can be lengthy, lasting more than a year in most cases. Accordingly, we classify a portion of our Medicare accounts receivable as non-current based on our experience with Medicare collections.

Inventories

Inventories are valued at the lower of cost (first-in, first-out method) or net realizable value.

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over their estimated useful lives of three to seven years. Leasehold improvements are depreciated over the remaining life of the respective building lease agreement.

Major expenditures for property and equipment are capitalized. Maintenance, repairs and minor renewals are expensed as incurred. When assets are retired or otherwise disposed of, their costs and related accumulated depreciation are removed from the accumulated depreciation accounts and the resulting gains or losses are included in income. The value of demonstration equipment in the possession of our field sales representatives is capitalized and depreciated over the estimated useful life of the equipment.

Revenue Recognition

We derive revenue from the sales and rentals of our Flexitouch and Entre systems, and from the sales of our AffloVest.

Flexitouch and Entre

We recognize revenue when control of the product has been transferred to our customer, in the amount of the expected consideration to be received for the product. In general, revenue from the sale or rental of a product is recognized upon shipment, unless circumstances dictate that control has not yet passed to the customer.

We provide a warranty for these products against defects in material and workmanship for a period of one to five years on garments and one to two years on controllers. In accordance with applicable accounting guidance, we have determined these were assurance warranties and therefore not considered a performance obligation. In addition, we did not evaluate immaterial promised goods or services in the context of the contract. As a result, the sale or rental of these products represent a single performance obligation that is satisfied at a point in time and is short-term in nature. In certain cases, we receive payment from Medicare sales over a period of time that may exceed one year. Despite these extended payment terms, no significant financing component is deemed to exist as the terms are not for the benefit of the patient with whom we have the contract. Rather, the extended payment terms occur as a result of an initial claim denial, which subsequently enters the Medicare appeals process as noted below.

We commercially distribute these products directly to patients who are referred to us by physicians, therapists or nurses. In most cases, there is a third-party payer, such as a commercial insurer, Medicare or the Veterans Administration, involved with the transaction. Our contractual relationship resides with the patient when the third-party payer is either a commercial insurer or Medicare and with the Veterans Administration if the patient is covered under their services. Revenue is recognized from such sales upon transfer of control of the product to the customer at a transaction price determined by collection history. As a result, the transaction price is impacted by multiple factors, including the terms and conditions contracted by various third-party payers, and therefore payments from third-party payers typically are less than our standard charge and represent an implicit price concession, resulting in variable consideration. As most contracts are with each individual sale to a patient, we have elected the portfolio approach to determine the transaction price, and ultimately the expected consideration. The portfolios used to determine transaction price are at the payer level, with pricing for each payer assessed based on the underlying similar characteristics.

For any of our products sold to patients covered by private payers, such as commercial insurance companies, revenue is recognized upon shipment. A product is not shipped until we have received a prescription from a physician for our products and, as applicable, receipt of prior authorization from payers. At shipment, we invoice the payer for the total product price, and we recognize revenue in the amount of cash consideration anticipated to be received based on the transaction price. After the insurance payer has remitted payment, we separately invoice the patient for their portion of the payment obligation, such as copayments and deductibles. The transaction price is determined based on the payment history of the applicable payer drawn from actual write-off and collections experience from the payer over a rolling 12-month period, as well as historical patient collections.

For our products sold to Medicare patients, we recognize revenue from such sales upon shipment of our products, which can occur only after we have received a prescription from a physician and all applicable patient documentation is obtained. The transaction price for our Entre systems is determined based on the payment history using the same methodology as our private insurers. A portion of our claims for our Flexitouch system are initially denied, and enter the appeals process, which can be lengthy. We assess the variable consideration for each of these claims as a percentage of the total invoice price based on ultimate approval and collection history.

For our products sold to the Veterans Administration on behalf of the patient, our contract is with the Veterans Administration rather than the patient. We enter into individual sales contracts with the Veterans Administration on behalf of each patient. These contracts determine the amount of consideration, which is typically paid in full within 2-3 days of shipment, and therefore there is no implicit price concession. In addition, the contracts provide for the right of control to transfer to the Veterans Administration upon delivery of the product to the patient, at which time revenue is recognized.

We incur incremental costs that directly relate to the sales of our products; however, as the amortization period would be less than one year, we have elected the practical expedient to expense these costs as incurred.

We sell and rent these products either directly to patients or the Veterans Administration on behalf of patients, who are referred to us by physicians, therapists or nurses. We bill private insurers and other payers, Medicare, and the Veterans Administration directly for purchases or rentals of our product on behalf of a patient and bill patients directly for their cost-sharing amounts, including any portion of an unsatisfied deductible and any copayments or co-insurance obligation.

A portion of our revenue is derived from patients who obtain our products under multiple-month rental arrangements. We bill these patients' insurance payers monthly over the duration of the rental term. Title to these products passes to the patients at the end of the rental period. Rental agreements are recorded as sales-type leases in accordance with Accounting Standards Update ("ASU") No. 2016-02, "Leases" (Topic 842) ("ASC 842"). Accordingly, as sales-type leases, the transaction price for the entire rental term is recognized upon transfer of control.

AffloVest

The AffloVest device is sold through durable medical equipment providers. Revenue is recognized when control of the promised goods or services is transferred to the distributors, in an amount that reflects the consideration we expect to be entitled to in exchange for transferring those goods or providing services. We account for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. When determining whether the distributor has obtained control of the goods or services, we consider any future performance obligations. Generally, there is no post-shipment obligation on products sold other than warranty obligations in the normal and ordinary course of business. Consequently, revenue from the sale of the AffloVest product is recognized at shipment, unless circumstances dictate that control has not yet passed to the distributor.

Certain of our contracts include volume-based incentives which involve rebates that are negotiated at or prior to the time of sale with the customer and are redeemable only if the customer achieves a specified cumulative level of sales or sales increase. Under these incentive programs, at the time of sale, we determine the most likely amount of the rebate to be paid based on forecasted sales levels. These forecasts are updated at least quarterly for applicable customers, and the transaction price is reduced for the anticipated cost of the rebate. If the forecasted sales for a customer change, the accrual for rebates is adjusted to reflect the new rebates expected to be earned by the customer.

Amounts billed to customers for shipping and handling activities after the customer obtains control are treated as a promised service performance obligation and recorded in revenue in the accompanying Consolidated Statements of Operations. Shipping and handling costs incurred for the delivery of goods to customers are considered a cost to fulfill the contract and are included in cost of revenue sold in the accompanying Consolidated Statements of Operations.

We provide a warranty for the AffloVest products against defects in material and workmanship for a period of five years. In accordance with applicable accounting guidance, we have determined these were assurance warranties and therefore not considered a performance obligation. In addition, we did not evaluate immaterial promised goods or services in the context of the contract. As a result, the sale of these products represents a single performance obligation that is satisfied at a point in time and is short-term in nature.

Advertising

Advertising costs are charged to operations when incurred. Advertising expense was $0.1 million for each of the years ended December 31, 2022, 2021 and 2020.

Research and Development Costs

We expense research and development costs as incurred, including expenses associated with clinical research studies and development.

Shipping and Handling Costs

Amounts billed to customers for shipping and handling activities after the customer obtains control are treated as a promised service performance obligation and recorded in total revenue in the accompanying Consolidated Statements of Operations. Shipping and handling costs incurred for the delivery of goods to customers are considered a cost to fulfill the contract and are included in cost of revenue in the accompanying Consolidated Statements of Operations.

Product Warranty

We provide a warranty for our products against defects in material and workmanship for a period of one to five years. We record a liability for future warranty claims at the time of sale for the warranty period offered to a customer. If the assumptions used in calculating the provision were to materially change, such as incurring higher than anticipated warranty claims, an additional provision may be required.

Impairment of Long-Lived Assets

We review long-lived assets, including property and equipment and patents, for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset may not be fully recoverable. We will assess long-lived assets used in operations for impairment indicators, including when undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount (see Note 8 – "Goodwill and Intangible Assets").

Goodwill

Goodwill represents the excess of the purchase price paid over the estimated fair value of the net assets acquired and liabilities assumed in the acquisition of a business. Goodwill is not amortized, but is tested for impairment at least annually or on an interim basis if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying value. We perform our annual assessment of goodwill for impairment as of July 1st of each fiscal year. See Note 8 – "Goodwill and Intangible Assets" for additional information.

Stock-Based Compensation

Stock options are valued using the Black-Scholes option-pricing model, except that the valuation of certain "CEO" related stock options subject to a market condition involve the use of the Monte Carlo Simulation model. The Monte Carlo Simulation and the Black-Scholes valuation models require the input of highly subjective assumptions. The assumptions include the expected term of the option, the expected volatility of the price of our common stock, expected dividend yield and the risk-free interest rate. These estimates involve inherent uncertainties and the significant application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. We recognize compensation expense for these options on a straight-line basis over the requisite service period (see Note 13 – "Stockholders' Equity").

Income Taxes

Income taxes are accounted for under the liability method. Deferred income taxes are provided for temporary differences between the financial reporting and the tax basis of assets and liabilities. If we determine in the future that it is more likely than not that we will not realize all or a portion of the deferred tax assets, we will record a valuation allowance in the period the determination is made (see Note 15 – "Income Taxes"). Changes in tax rates are reflected in the tax provision as they occur.

Net (Loss) Income Per Common Share

Basic net (loss) income per common share is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted net (loss) income per common share is computed based on the weighted average number of shares of common stock plus the effect of dilutive potential stock-based awards outstanding during the period using the treasury stock method. Dilutive potential stock-based awards include outstanding common stock options, time- and performance-based restricted stock units and employee stock purchase plan shares.

Business Segments

We operate and report in only one operating and reportable segment. Our chief operating decision maker does not use financial information below revenue to allocate resources.

Accounting Pronouncement Not Yet Adopted

In December 2022, the Financial Accounting Standards Board ("FASB") issued ASU No. 2022-06, "Reference Rate Reform (Topic 848) — Facilitation of the Effect of Reference Rate Reform on Financial Reporting" ("ASU 2022-06"), which provides optional expedients and exceptions for applying GAAP to transactions affected by reference rate (e.g., LIBOR) reform if certain criteria are met, for a limited period of time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. The ASU deferred the sunset date of Topic 848 from December 31, 2022 to December 31, 2024. The ASU is effective as of December 21, 2022 through December 31, 2024. We continue to evaluate transactions or contract modifications occurring as a result of reference rate reform and determine whether to apply the optional guidance on an ongoing basis. We have not elected any expedients to date and are currently evaluating any potential future impacts on the consolidated financial statements.

Note 4. Acquisitions

On September 8, 2021, we entered into an Asset Purchase Agreement ("AffloVest APA") to acquire the AffloVest therapy business from International Biophysics Corporation ("IBC"). Under the terms of the AffloVest APA, we agreed to pay IBC a total of up to $100.0 million for the purchase of substantially all of the assets related to its branded high frequency chest wall oscillation vest therapy business, other than specifically identified excluded assets. We acquired AffloVest to further expand our position as a leader in treating patients with underserved chronic conditions in the home. The acquired assets included inventory, tooling, intellectual property, permits and approvals, data and records, and customer and supplier information. At closing, $80.0 million of the purchase price was paid, of which a total of $0.5 million was deposited into an escrow account at closing for purposes of satisfying certain post-closing purchase price adjustments and indemnification claims. Subsequent to closing, $0.2 million was returned to us as a result of working capital adjustments. The AffloVest acquisition was funded through a combination of cash on hand and proceeds from borrowings.

On November 4, 2022, we entered into an Amendment to the AffloVest APA, the "Amendment" with IBC, which modifies the terms of the earn-out arrangement under the AffloVest APA, as follows:

- *Initial Earn-Out:* The AffloVest APA provided for an initial earn-out equal to 1.5 times the amount by which the AffloVest U.S. revenues in the period from October 1, 2021 to September 30, 2022 (the "Initial Earn-Out Period") exceed a specified amount; provided that in no event will the payment exceed $10.0 million.
    - The Amendment provides that the calculated amount of the initial earn-out payment is $10.0 million, of which the Company paid $5.0 million on or before November 28, 2022, and of which the Company will pay $5.0 million, plus an imputed interest payment of $250,000, on or before May 26, 2023.

- *Second Earn-Out:* The AffloVest APA provided for a second earn-out equal to 1.5 times the amount by which the AffloVest U.S. revenues in the period from October 1, 2022 to September 30, 2023 exceed the revenues recognized during the Initial Earn-Out Period; provided that in no event will the payment exceed $10.0 million.
    - The Amendment changes the 1.5 times multiplier to 3.0 times, but still provides that in no event will the second earn-out payment exceed $10.0 million.

The fair value of the earn-out as of the acquisition date was $6.4 million. The fair value of the earn-out, reflecting management's estimate of the likelihood of achieving these targets, was determined by employing a Monte Carlo Simulation model. This amount and the current versus non-current allocation will be remeasured at the end of each reporting period until the payment requirement ends, with any adjustments reported in income from operations (see Note 17 – "Fair Value Measurements").

On the date of AffloVest Acquisition, we allocated the assets acquired based on an estimate of their fair values. The following table summarizes the purchase price allocation:

(In millions)	Allocated Fair Value	
Inventories	$	1.6
Property and equipment[(1)]		—
Intangible assets		53.5
Goodwill		31.1
Purchase price	$	86.2

(1) The purchase price included less than $0.1 million of property and equipment.

The goodwill reflects expected synergies of combining the acquired products and customer information with our existing operations and is deductible for tax purposes over 15 years.

The following table reflects the allocation of purchase price to the acquired intangible assets and related estimated useful lives:

(In millions)	Allocated Fair Value		Estimated Useful Life
Customer relationships	$	31.0	13 years
Developed technology		13.0	11 years
Tradenames		9.5	Indefinite
Total intangible assets	$	53.5	

The weighted-average amortization period of the acquired intangible assets was 12.3 years.

The fair market valuations associated with the assets acquired fall within Level 3 of the fair value hierarchy, due to the use of significant unobservable inputs to determine fair value. The fair value measurements were calculated using unobservable inputs, primarily using the income approach, specifically the discounted cash flow method. The amount and timing of future cash flows within our analysis was based on our due diligence models, most recent operational budgets, long-range strategic plans and other estimates.

Transaction costs, such as legal and other costs, related to the acquisition aggregated approximately $0.8 million. These costs have been expensed as incurred and are included in reimbursement, general and administrative expenses in our Consolidated Statements of Operations for the year ended December 31, 2021.

The Consolidated Statements of Operations reflect the AffloVest operations beginning September 9, 2021. As the AffloVest business has been integrated with our existing operations, we are unable to determine the amount of AffloVest earnings from the acquisition date that is included in the Consolidated Statements of Operations. The following unaudited pro forma information for the years ended December 31, 2021 and 2020 presents the revenue and net income assuming the acquisition of AffloVest had occurred as of January 1, 2020. This information has been prepared for comparative purposes only and is not indicative of what actual results would have been if the acquisition had taken place at the beginning of fiscal 2020, or of future results.

	Year Ended December 31,			
(In thousands)	2021		2020	
Total revenue	$	219,414	$	203,193
Net (loss) income	$	(7,633)	$	11,832

These pro forma results include certain adjustments, primarily due to increases in amortization expense due to fair value adjustments of intangible assets, increases in interest expense due to additional borrowings incurred to finance the acquisition and amortization of debt issuance costs incurred to finance the transaction, acquisition related costs including transaction costs such as legal, accounting, valuation and other professional services, and related tax effects.

Note 5. Accounts Receivable

We had accounts receivable from two insurers representing approximately 45% and 21% of accounts receivable as of December 31, 2022. We had accounts receivable from two insurers representing approximately 33% and 24% of accounts receivable as of December 31, 2021. Revenue from these insurers accounted for 19% and 10% of our total revenue for the year ended December 31, 2022, and 17% and 12% for the year ended December 31, 2021. The credit risks associated with customers which for these purposes are insurers considers aggregation for entities that are known to be under common control.

Note 6. Inventories

Inventories consisted of the following:

(In thousands)	At December 31, 2022		At December 31, 2021	
Finished goods	$	5,100	$	8,242
Component parts and work-in-process		18,024		10,975
Total inventories	$	23,124	$	19,217

Note 7. Property and Equipment

Property and equipment consisted of the following:

	At December 31,			
(In thousands)	2022		2021	
Equipment	$	8,274	$	8,051
Tooling		3,390		2,545
Furniture and fixtures		2,087		2,104
Leasehold improvements		1,493		1,458
Demonstration equipment		1,012		632
Construction in progress		606		1,003
Subtotal		16,862		15,793
Less: accumulated depreciation		(10,785)		(9,043)
Property and equipment, net	$	6,077	$	6,750

Depreciation expense was $2.5 million, $2.3 million and $2.4 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Note 8. Goodwill and Intangible Assets

Goodwill

In the third quarter of fiscal 2021, we completed the AffloVest Acquisition. The purchase price of the AffloVest business exceeded the net acquisition-date estimated fair value amounts of the identifiable assets acquired and the liabilities assumed by $31.1 million, which was assigned to goodwill.

Intangible Assets

Our patents and other intangible assets are summarized as follows:

(In thousands)	Weighted-Average Amortization Period	At December 31, 2022 Gross Carrying Amount	Accumulated Amortization	Net Amount
Definite-lived intangible assets:				
Patents	12 years	$ 897	$ 173	$ 724
Defensive intangible assets	2 years	1,126	764	362
Customer accounts	< 1 year	125	114	11
Customer relationships	12 years	31,000	3,127	27,873
Developed technology	10 years	13,000	1,550	11,450
Subtotal		46,148	5,728	40,420
Unamortized intangible assets:				
Tradenames		9,500	—	9,500
Patents pending		455	—	455
Total intangible assets		$ 56,103	$ 5,728	$ 50,375

(In thousands)	Weighted-Average Amortization Period	At December 31, 2021 Gross Carrying Amount	Accumulated Amortization	Net Amount
Definite-lived intangible assets:				
Patents	12 years	$ 666	$ 109	$ 557
Defensive intangible assets	3 years	1,125	592	533
Customer accounts	1 year	125	89	36
Customer relationships	13 years	31,000	742	30,258
Developed technology	11 years	13,000	368	12,632
Subtotal		45,916	1,900	44,016
Unamortized intangible assets:				
Tradenames		9,500	—	9,500
Patents pending		565	—	565
Total intangible assets		$ 55,981	$ 1,900	$ 54,081

Amortization expense was $3.8 million, $1.4 million, and $0.4 million for the years ended December 31, 2022, 2021 and 2020, respectively. Future amortization expenses are expected as follows:

(In thousands)	
2023	$ 3,808
2024	3,787
2025	3,697
2026	3,633
2027	3,623
Thereafter	21,872
Total	$ 40,420

The weighted-average remaining amortization period for these intangible assets was 11.0 years as of December 31, 2022.

Note 9. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	At December 31, 2022	At December 31, 2021
In-transit inventory	$ 3,228	$ 416
Warranty	2,005	1,851
Travel	1,121	661
Legal and consulting	730	1,371
Clinical studies	276	113
Sales and use tax	147	106
Other	1,733	744
Total	$ 9,240	$ 5,262

Note 10. Warranty Reserves

The activity in the warranty reserve during and as of the end of the year presented was as follows:

	Year Ended December 31,		
(In thousands)	2022	2021	2020
Beginning balance	$ 4,959	$ 4,841	$ 3,759
Warranty provision	2,047	2,606	2,957
Processed warranty claims	(2,794)	(2,488)	(1,875)
Ending balance	$ 4,212	$ 4,959	$ 4,841
Accrued warranty reserve, current	$ 2,005	$ 1,851	$ 1,606
Accrued warranty reserve, non-current	2,207	3,108	3,235
Total accrued warranty reserve	$ 4,212	$ 4,959	$ 4,841

Note 11. Credit Agreement

On April 30, 2021, we entered into an Amended and Restated Credit Agreement (the “Restated Credit Agreement”) with the lenders from time to time party thereto, and Wells Fargo Bank, National Association, as Administrative Agent. The Restated Credit Agreement amended and restated in its entirety our prior credit agreement.

On September 8, 2021, we entered into a First Amendment Agreement (the “First Amendment”), which amends the Restated Credit Agreement (as amended by the First Amendment, the “Credit Agreement”) with the lenders from time to time party thereto and Wells Fargo Bank, National Association, as Administrative Agent. The First Amendment, among other things, adds a $30.0 million incremental term loan to the $25.0 million revolving credit facility provided by the Restated Credit Agreement. The term loan is reflected as a note payable on our Consolidated Balance Sheets. The term loan and the revolving credit facility mature on September 8, 2024. The Credit Agreement provides that, subject to satisfaction of certain conditions, we may increase the amount of the revolving loans available under the Credit Agreement and/or add one or more term loan facilities in an amount not to exceed $25.0 million in the aggregate, such that the total aggregate principal amount of loans available under the Credit Agreement (including under the revolving credit facility) does not exceed $80.0 million.

On September 8, 2021, in connection with the closing of the AffloVest Acquisition, we borrowed the $30.0 million term loan and utilized that borrowing, together with a draw of $25.0 million under the revolving credit facility and cash on hand, to fund the purchase price. As of both December 31, 2022 and 2021, there was no availability under our Credit Agreement.

On February 22, 2022, we entered into a Second Amendment Agreement (the "Second Amendment"), which further amends the Credit Agreement.

The principal of the term loan is required to be repaid in quarterly installments of $750,000 commencing January 7, 2022, through July 8, 2024, with the remaining outstanding balance due on September 8, 2024. Pursuant to the Second Amendment, we made a mandatory principal prepayment of the term loan of $3.0 million on February 22, 2022.

The term loan and amounts drawn under the revolving credit facility bear interest, at our option, at a rate equal to (a) the highest of (i) the prime rate, (ii) the federal funds rate plus 0.50% and (iii) LIBOR for an interest period of one month plus 1% (the "Base Rate") plus an applicable margin or (b) LIBOR for an interest period of one, three or six months, at our option, plus the applicable margin. The applicable margin is 0.75% to 2.25% on loans bearing interest at the Base Rate and 1.75% to 3.25% on loans bearing interest at LIBOR, in each case depending on our consolidated total leverage ratio; except that, pursuant to the Second Amendment, during the period commencing on February 22, 2022 and ending on the last day of the fiscal quarter ending June 30, 2023, the applicable margin for LIBOR rate loans is 3.50%. At December 31, 2022, all outstanding borrowings were subject to interest at a rate calculated at LIBOR plus an applicable margin, for an interest rate of 7.41%. Undrawn portions of the revolving credit facility are subject to an unused line fee at a rate per annum from 0.300% to 0.375%, depending on our consolidated total leverage ratio.

Maturities of the term loan for the next three years as of December 31, 2022, were as follows:

(In thousands)	Amount
2023	3,000
2024	21,000
Total	$ 24,000

Our obligations under the Credit Agreement are secured by a security interest in substantially all of our and our subsidiaries' assets and are also guaranteed by our subsidiaries. The Credit Agreement contains a number of restrictions and covenants, including that we maintain compliance with a maximum leverage ratio, minimum fixed charge coverage ratio and a minimum consolidated EBITDA covenant. As of December 31, 2022, we were in compliance with all financial covenants under the Credit Agreement.

Note 12. Commitments and Contingencies

Lease Obligations

We lease property and equipment under operating leases, typically with terms greater than 12 months, and determine if an arrangement contains a lease at inception. In general, an arrangement contains a lease if there is an identified asset and we have the right to direct the use of and obtain substantially all of the economic benefit from the use of the identified asset. We record an operating lease liability at the present value of lease payments over the lease term on the commencement date. The related right of use ("ROU") operating lease asset reflects rental escalation clauses, as well as renewal options and/or termination options. The exercise of lease renewal and/or termination options are at our discretion and are included in the determination of the lease term and lease payment obligations when it is deemed reasonably certain that the option will be exercised. When available, we use the rate implicit in the lease to discount lease payments to present value; however, certain leases do not provide a readily determinable implicit rate. Therefore, we must estimate our incremental borrowing rate to discount the lease payments based on information available at lease commencement.

We classify our leases as buildings, vehicles or computer and office equipment and do not separate lease and nonlease components of contracts for any of the aforementioned classifications. In accordance with applicable guidance, we do not record leases with terms that are less than one year on the Consolidated Balance Sheets.

None of our lease agreements contain material restrictive covenants or residual value guarantees.

Buildings

We lease certain office and warehouse space at various locations in the United States where we provide services. These leases are typically greater than one year with fixed, escalating rents over the noncancelable terms and, therefore, ROU operating lease assets and operating lease liabilities are recorded on the Consolidated Balance Sheets, with rent expense recognized on a straight-line basis over the term of the lease. The remaining lease terms vary from approximately one to eight years as of December 31, 2022.

We entered into a lease (“initial lease”) in October 2018, for approximately 80,000 square feet of office space for our new corporate headquarters in Minneapolis, Minnesota. In December 2018, we amended the initial lease to add approximately 29,000 square feet of additional office space, which is accounted for as a separate lease (“second lease”) in accordance with ASU No. 2016-02, “Leases” (Topic 842) (“ASC 842”). In December 2019, we further amended the lease which extended the expiration date of the initial lease, extended the expiration date of and added approximately 4,000 square feet to the second lease, as well as added approximately 37,000 square feet of additional office space, accounted for as a separate lease (“third lease”) in accordance with ASC 842. The portion of the space covered under the initial lease was placed in service in September 2019. This portion was recognized as an operating lease and included in the ROU operating lease assets and operating lease liabilities on the Consolidated Balance Sheets. The portion of the space covered under the second lease commenced in September 2020. Finally, the portion of the space covered under the third lease commenced in September 2021.

Vehicles

We lease vehicles for certain members of our field sales organization under a vehicle fleet program whereby the initial, noncancelable lease is for a term of 367 days, thus more than one year. Subsequent to the initial term, the lease becomes a month-to-month, cancelable lease. As of December 31, 2022, we had approximately two vehicles with agreements within the initial, noncancelable lease term that are recorded as ROU operating lease assets and operating lease liabilities. In addition to monthly rental fees specific to the vehicle, there are fixed monthly nonlease components that have been included in the ROU operating lease assets and operating lease liabilities. The nonlease components are not significant.

Computer and Office Equipment

We also have operating lease agreements for certain computer and office equipment. The remaining lease terms as of December 31, 2022, ranged from less than one year to approximately four years with fixed monthly payments that are included in the ROU operating lease assets and operating lease liabilities. The leases provide an option to purchase the related equipment at fair market value at the end of the lease. The leases will automatically renew as a month-to-month rental at the end of the lease if the equipment is not purchased or returned.

Lease Position, Undiscounted Cash Flow and Supplemental Information

The table below presents information related to our ROU operating lease assets and operating lease liabilities that we have recorded:

(In thousands)	At December 31, 2022	At December 31, 2021
Right of use operating lease assets	$ 21,322	$ 23,984
Operating lease liabilities:		
Current	$ 2,500	$ 2,506
Non-current	20,866	23,354
Total	$ 23,366	$ 25,860
Operating leases:		
Weighted average remaining lease term	7.7 years	8.6 years
Weighted average discount rate	4.2%	4.2%

	Year Ended December 31, 2022	Year Ended December 31, 2021
Supplemental cash flow information for our operating leases:		
Cash paid for operating lease liabilities	$ 3,575	$ 3,379
Non-cash right of use assets obtained in exchange for new operating lease obligations	$ 49	$ 6,920

The table below reconciles the undiscounted cash flows under the operating lease liabilities recorded on the Consolidated Balance Sheets for the periods presented:

(In thousands)	
2023	$ 3,427
2024	3,418
2025	3,517
2026	3,615
2027	3,167
Thereafter	10,082
Total minimum lease payments	27,226
Less: Amount of lease payments representing interest	(3,860)
Present value of future minimum lease payments	23,366
Less: Current obligations under operating lease liabilities	(2,500)
Non-current obligations under operating lease liabilities	$ 20,866

Operating lease costs were $3.8 million, $3.6 million and $3.0 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Major Vendors

We had purchases from one vendor that accounted for 18% of our total purchases for the year ended December 31, 2022 and purchases from two vendors that accounted for 32% of total purchases for the year ended December 31, 2021.

Purchase Commitment

We issued purchase orders in 2022 totaling $33.5 million for goods that we expect to receive within the next year.

Retirement Plan

We maintain a 401(k) retirement plan for our employees to which eligible employees can contribute a percentage of their pre-tax compensation. We recorded an expense related to our discretionary contributions to the 401(k) plan of $1.5 million, $1.2 million and $0.3 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Legal Proceedings

From time to time, we are subject to various claims and legal proceedings arising in the ordinary course of business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

We and certain of our present or former officers have been sued in a purported securities class action lawsuit that was filed in the United States District Court for the District of Minnesota on September 29, 2020, and that is pending under the caption *Brian Mart v. Tactile Systems Technology, Inc., et al*., File No. 0:20-cv-02074-NEB-BRT (the “Mart Lawsuit”). On April 19, 2021, the plaintiff filed an Amended Complaint against us and eight of our present and former officers and directors. Plaintiff seeks to represent a class consisting of investors who purchased our common stock in the market during the time period from May 7, 2018 through June 8, 2020 (“alleged class period”). The Amended Complaint alleges the following claims under the Securities Exchange Act of 1934, as amended (the “Exchange Act”): (1) that we and certain officer defendants made materially false or misleading public statements about our business, operational and compliance policies, and results during the alleged class period in violation of Section 10(b) of the Exchange Act; (2) that we and the individual defendants engaged in a scheme to defraud investors in order to allow the individual defendants to sell our stock in violation of Section 10(b) of the Exchange Act; (3) that the individual defendants engaged in improper insider trading of our stock in violation of Section 20A of the Exchange Act; and (4) that we and the individual defendants are liable under Section 20(a) of the Exchange Act because each defendant is a controlling person. On June 18, 2021, we and the individual defendants filed a motion to dismiss the Amended Complaint. On March 31, 2022, the court granted in part, and denied in part, the defendants’ motion to dismiss. All claims against three individual defendants were dismissed, and most claims against four other individual defendants were dismissed. On November 21, 2022, the company announced that it entered a Memorandum of Understanding to settle this matter. The Company does not expect to fund any portion of cash payments made in connection with the $5 million settlement amount. The settlement does not constitute an admission of liability or wrongdoing by the Company. The settlement is subject to the parties reaching agreement on various non-monetary terms and court approval of the final terms will be required.

On May 24, 2022, a stockholder derivative lawsuit was filed in the United States District Court for the District of Minnesota, purportedly on behalf of the Company against certain of our present and former officers and directors and the Company (as a nominal defendant), captioned *Jack Weaver v. Moen*, et al., File No. 0:22-cv-01403-NEB-BRT. This complaint generally arises out of the same subject matter as the Mart Lawsuit and alleges the following claims under the Exchange Act and common law: (1) that the director defendants made materially false or misleading public statements in proxy statements in violation of Section 14(a) of the Exchange Act; (2) that the director defendants’ stock and option awards should be rescinded under Section 29(b) of the Exchange Act; (3) that the officer defendants’ employment contract compensation should be rescinded under Section 29(b) of the Exchange Act; (4) that certain officer defendants are liable for contribution arising out of any liability incurred in the Mart Lawsuit, under Sections 10(b) and 21D of the Exchange Act; (5) that the individual defendants breached their fiduciary duties; and (6) that the individual defendants were unjustly enriched. The lawsuit seeks unspecified damages. In August, the matter was transferred to the United States District Court for the District of Delaware by order granting the Parties Stipulation to Transfer. On February 10, 2023, we filed a motion to dismiss the action. We are defending the action as it proceeds.

Note 13. Stockholders' Equity

We completed an initial public offering of our common stock on August 2, 2016, in which we sold 4,120,000 shares of our common stock at a public offering price of $10.00 per share. Immediately prior to the completion of the initial public offering, all then-outstanding shares of our Series A and Series B preferred stock were converted into 5,924,453 shares of our common stock. Our Series A preferred stock converted to common stock at a ratio of 1-for-1.03 and our Series B preferred stock converted to common stock at a ratio of 1-for-1. In addition, immediately prior to the completion of the initial public offering, we issued 2,354,323 additional shares of our common stock that our Series A and Series B preferred stockholders were entitled to receive in connection with the conversion of the preferred stock, and we issued 956,842 shares of our common stock to pay accrued dividends on our Series B preferred stock. We also paid $8.2 million in cumulative accrued dividends to our Series A convertible preferred stockholders in connection with the initial public offering, including $0.1 million of dividends paid to the holders of the common restricted shares.

Stock-Based Compensation

Our 2016 Equity Incentive Plan (the “2016 Plan”) authorizes us to grant stock options, stock appreciation rights, restricted stock, stock units and other stock-based awards to employees, non-employee directors and certain consultants and advisors. There were up to 4,800,000 shares of our common stock initially reserved for issuance pursuant to the 2016 Plan. The 2016 Plan provides that the number of shares reserved and available for issuance under the 2016 Plan will automatically increase annually on January 1 of each calendar year, commencing in 2017 and ending on and including January 1, 2026, by an amount equal to the lesser of: (a) 5% of the number of common shares of stock outstanding as of December 31 of the immediately preceding calendar year, or (b) 2,500,000 shares; provided, however, that our Board of Directors may determine that any annual increase be a lesser number. In addition, all awards granted under our 2007 Omnibus Stock Plan and our 2003 Stock Option Plan that were outstanding when the 2016 Plan became effective and that are forfeited, expire, are cancelled, are settled for cash or otherwise not issued, will become available for issuance under the 2016 Plan. Pursuant to the automatic increase feature of the 2016 Plan, 972,591 shares were added as available for issuance thereunder on January 1, 2021. Our Board of Directors exercised its prerogative to forego the automatic increase on each of January 1, 2023 and 2022. As of December 31, 2022, 5,957,683 shares were available for future grant pursuant to the 2016 Plan.

Upon adoption and approval of the 2016 Plan, all of our previous equity incentive compensation plans were terminated. However, existing awards under those plans continue to vest in accordance with the original vesting schedules and will expire at the end of their original terms.

In the second fiscal quarter of 2020, our Board of Directors appointed a new President and Chief Executive Officer (“CEO”), effective June 8, 2020. In conjunction with the acceptance of the written offer, our CEO received both restricted stock units and stock option awards under our 2016 Plan during the third fiscal quarter of 2020 and the stock options have a seven year term. A portion of the awards vested on June 30, 2021, with the remaining portion of the awards vesting over a period of three years from the date of grant. Further, the stock options were valued at the date of grant using the Monte Carlo Simulation model due to a market condition that required that our stock price exceed $40.15 for 20 consecutive trading days during the term of the option in order to vest. This condition was satisfied in the first quarter of 2021. The following table sets forth the estimated fair value of these stock options granted and the assumptions on which the fair value was determined:

	2020
Expected term	4.5 years
Expected volatility	45.39%
Risk-free interest rate	0.4%
Expected dividend yield	0%
Fair value on the date of grant	$13.60 - $14.70

We recorded total stock-based compensation expense of $9.6 million, $10.2 million and $10.7 million for the years ended December 31, 2022, 2021 and 2020, respectively. This expense was allocated as follows:

	Year Ended December 31,		
(In thousands)	2022	2021	2020
Cost of revenue	$ 367	$ 433	$ 539
Sales and marketing expenses	4,060	4,069	5,058
Research and development expenses	226	314	360
Reimbursement, general and administrative expenses	4,947	5,357	4,732
Total stock-based compensation expense	$ 9,600	$ 10,173	$ 10,689

Stock Options

Stock options issued to participants other than non-employees typically vest over three or four years and typically have a contractual term of seven or ten years. Stock-based compensation expense included in our Consolidated Statements of Operations for stock options was $2.5 million, $4.3 million and $4.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. The total grant date fair value of options vested during the year was $3.3 million, $4.3 million and $3.0 million for the years ended December 31, 2022, 2021 and 2020, respectively.

At December 31, 2022, there was approximately $1.6 million of total unrecognized pre-tax stock option expense under our equity compensation plans, which is expected to be recognized on a straight-line basis over a weighted-average period of 1.2 years.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model, other than options that have a market-based vesting condition, which are valued using the Monte Carlo Simulation model. Annually, we make predictive assumptions regarding future stock price volatility, dividend yield, expected term and forfeiture rate. The dividend yield assumption is based on expected annual dividend yield on the grant date. To date, no dividend on common stock has been paid by us. Expected volatility for grants issued in and prior to the first fiscal quarter of 2021 was estimated using the average historical volatility of public companies of similar size and industry over a similar period as the expected term assumption used for our options. Beginning in the second fiscal quarter of 2021, we had sufficient historical data to transition to utilizing our average historical volatility over a similar period as the expected term assumption used for our options as the expected volatility. The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group. We use the “simplified method” to determine the expected term of the stock option grants. We utilize this method because we do not have sufficient public company exercise data in which to make a reasonable estimate.

The following table sets forth the estimated fair values of our stock options granted in each of the years indicated, and the assumptions on which the fair values were determined:

	2022	2021	2020
Expected term	4.5 years	4.5 years	4.5 years
Expected volatility	59.2%	45.0 - 52.3%	44.1 - 46.4%
Risk-free interest rate	4.3%	0.6 - 1.1%	0.2 - 0.9%
Expected dividend yield	0%	0%	0%
Fair value on the date of grant	$ 8.11	$13.04 - $22.90	$13.45 - $18.64

Our stock option activity for the three years ended December 31, 2022, 2021 and 2020, was as follows:

(In thousands except options and per share data)	Options Outstanding	Weighted-Average Exercise Price Per Share (1)	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value (2)
Balance at December 31, 2019	866,955	$ 28.76	6.3 years	$ 33,957
Granted	378,695	$ 44.84		
Exercised	(147,741)	$ 7.24		$ 6,540
Forfeited	(54,824)	$ 50.25		
Cancelled/Expired	(3,376)	$ 63.61		
Balance at December 31, 2020	1,039,709	$ 36.43	5.6 years	$ 13,381
Granted	188,748	$ 49.33		
Exercised	(175,516)	$ 22.65		$ 4,901
Forfeited	(92,773)	$ 49.77		
Cancelled/Expired	(44,944)	$ 57.78		
Balance at December 31, 2021	915,224	$ 39.33	5.0 years	$ 2,068
Granted	47,280	$ 6.17		
Exercised	(90,878)	$ 1.68		$ 916
Forfeited	(92,981)	$ 36.28		
Cancelled/Expired	(163,338)	$ 37.65		
Balance at December 31, 2022	615,307	$ 43.25	4.7 years	$ 164
Options exercisable at December 31, 2022	435,363	$ 43.83	4.5 years	$ 84

(1) The exercise price of each option granted during the periods shown was equal to the market price of the underlying stock on the date of grant.

(2) The aggregate intrinsic value of options exercised represents the difference between the exercise price of the option and the closing stock price of our common stock on the date of exercise. The aggregate intrinsic value of options outstanding represents the difference between the exercise price of the option and the closing stock price of our common stock on the last trading day of the period.

Options exercisable of 517,316 at December 31, 2021, and 489,866 at December 31, 2020 had weighted average exercise prices of $32.60 and $25.39, respectively.

The following summarizes additional information about our stock options:

	Year Ended December 31,	
Number of:	**2022**	**2021**
Non-vested options, beginning of the year	397,908	549,843
Non-vested options, end of the year	179,944	397,908
Vested options, end of the year	435,363	517,316

	Year Ended December 31,	
Weighted-average grant date fair value of:	**2022**	**2021**
Non-vested options, beginning of the year	$ 18.02	$ 18.03
Non-vested options, end of the year	16.24	18.02
Vested options, end of the year	17.53	13.27
Forfeited options, during the year	14.73	19.26

Time-Based Restricted Stock Units

We have granted time-based restricted stock units to certain participants under the 2016 Plan that are stock-settled with common shares. Time-based restricted stock units granted under the 2016 Plan vest over one to three years. Stock-based compensation expense included in our Consolidated Statements of Operations for time-based restricted stock units was $5.8 million, $4.9 million and $5.2 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, there was approximately $7.8 million of total unrecognized pre-tax compensation expense related to outstanding time-based restricted stock units that is expected to be recognized over a weighted-average period of 1.9 years.

Our time-based restricted stock unit activity for the years ended December 31, 2022, 2021 and 2020 was as follows:

(In thousands except unit and per unit data)	Units Outstanding	Weighted-Average Grant Date Fair Value Per Unit	Aggregate Intrinsic Value [(1)]
Balance at December 31, 2019	171,687	$ 43.74	$ 11,591
Granted	175,582	$ 46.42	
Modification	2,288	$ 21.85	
Vested	(118,014)	$ 37.57	
Cancelled	(20,074)	$ 53.03	
Balance at December 31, 2020	211,469	$ 48.29	$ 9,503
Granted	189,762	$ 40.31	
Vested	(106,521)	$ 47.43	
Cancelled	(35,563)	$ 51.76	
Balance at December 31, 2021	259,147	$ 42.32	$ 4,932
Granted	539,525	$ 15.03	
Vested	(123,528)	$ 43.20	
Cancelled	(84,602)	$ 26.91	
Balance at December 31, 2022	590,542	$ 19.42	$ 6,779

(1) The aggregate intrinsic value of time-based restricted stock units outstanding was based on our closing stock price on the last trading day of the period.

Performance-Based Restricted Stock Units

We have granted performance-based restricted stock units (“PSUs”) to certain participants under the 2016 Plan. These PSUs have both performance-based and time-based vesting features. The PSUs granted in 2018 were earned to the extent performance goals based on revenue and adjusted EBITDA were achieved in 2019. The PSUs granted in 2019 were earned to the extent performance goals based on revenue and adjusted EBITDA were achieved in 2020. The PSUs granted in 2020 were earned to the extent performance goals based on revenue and adjusted EBITDA were achieved in 2021. The PSUs granted in 2021 will be earned if and to the extent performance goals based on revenue and adjusted EBITDA are achieved in 2022. The PSUs granted in 2022 will be earned if and to the extent performance goals based on revenue change and adjusted EBITDA margin are achieved in 2023. The number of PSUs earned will depend on the level at which the performance targets are achieved and can range from 50% of target if threshold performance is achieved and up to 150% of target if maximum performance is achieved. One-third of the earned PSUs will vest on the date the Compensation and Organization Committee certifies the number of PSUs earned, and the remaining two-thirds of the earned PSUs will vest on the first anniversary of that certification date. All earned and vested PSUs will be settled in shares of common stock.

Stock-based compensation expense included in our Consolidated Statements of Operations for PSUs was $0.5 million, $0.2 million, and $0.5 million for the years ended December 31, 2022, 2021 and 2020, respectively. The stock-based compensation expense for the year ended December 31, 2022 reflects an expense of $0.6 million related to the PSUs granted in 2022. The stock-based compensation expense for the year ended December 31, 2021 reflects a $0.5 million benefit due to a change in the estimated payout associated with PSUs granted in 2020 being below the minimum performance target threshold level, as defined, partially offset by an expense of $0.7 million related to the PSUs granted in 2018 and 2021. As of December 31, 2022, there was approximately $1.4 million of total unrecognized pre-tax compensation expense related to outstanding PSUs that is expected to be recognized over a weighted average period of 2.0 years.

Our performance-based restricted stock unit activity at the estimated payout of 100% of target for the years ended December 31, 2022, 2021 and 2020, was as follows:

(In thousands except unit and per unit data)	Performance-Based Units Outstanding	Weighted-Average Grant Date Fair Value Per Unit	Aggregate Intrinsic Value (1)
Balance at December 31, 2019	91,151	$ 44.63	$ 6,154
Granted	31,731	$ 50.41	
Vested	(26,204)	$ 33.58	
Cancelled	(17,375)	$ 52.87	
Balance at December 31, 2020	79,303	$ 47.83	$ 3,564
Granted	39,419	$ 51.82	
Vested	(34,159)	$ 33.98	
Cancelled	(30,246)	$ 64.39	
Balance at December 31, 2021	54,317	$ 50.22	$ 1,034
Granted	131,710	$ 18.54	
Vested	(4,407)	$ 12.31	
Cancelled	(26,002)	$ 42.53	
Balance at December 31, 2022	155,618	$ 25.05	$ 1,786

(1) The aggregate intrinsic value of performance-based restricted stock units outstanding was based on our closing stock price on the last trading day of the period

Employee Stock Purchase Plan

Our employee stock purchase plan ("ESPP"), which was approved by our Board of Directors on April 27, 2016, and by our stockholders on June 20, 2016, allows participating employees to purchase shares of our common stock at a discount through payroll deductions. The ESPP is available to all of our employees and employees of participating subsidiaries. Participating employees may purchase common stock, on a voluntary after-tax basis, at a price equal to 85% of the lower of the closing market price per share of our common stock on the first or last trading day of each stock purchase period. The ESPP provides for six-month purchase periods, beginning on May 16 and November 16 of each calendar year.

A total of 1,600,000 shares of common stock was initially reserved for issuance under the ESPP. This share reserve will automatically be supplemented each January 1, commencing in 2017 and ending on and including January 1, 2026, by an amount equal to the least of (a) 1% of the shares of our common stock outstanding on the immediately preceding December 31, (b) 500,000 shares or (c) such lesser amount as our Board of Directors may determine. Pursuant to the automatic increase feature of the ESPP, 194,518 shares were added as available for issuance thereunder on January 1, 2021. Our Board of Directors exercised its prerogative to forego the automatic increase on each of January 1, 2023 and 2022. As of December 31, 2022, 1,559,151 shares were available for future issuance under the ESPP. We recognized $0.8 million, $0.8 million and $0.9 million in stock-based compensation expense related to the ESPP for the years ended December 31, 2022, 2021 and 2020, respectively.

Note 14. Revenue

We derive our revenue from the sale and rental of our products to our customers in the United States. The following table presents our revenue, inclusive of sales and rental revenue, disaggregated by product:

(In thousands)	Year Ended December 31, 2022	2021	2020
Revenue			
Lymphedema products	$ 212,266	$ 202,913	$ 187,130
Airway clearance products	34,519	5,144	—
Total	$ 246,785	$ 208,057	$ 187,130
Percentage of total revenue			
Lymphedema products	86%	98%	100%
Airway clearance products	14%	2%	N.M.
Total	100%	100%	100%

Our revenue by channel, inclusive of sales and rental revenue, for the years ended December 31, 2022, 2021 and 2020 are summarized in the following table:

(In thousands)	Year Ended December 31, 2022	2021	2020
Private insurers and other payers	$ 139,087	$ 141,377	$ 132,789
Veterans Administration	25,507	25,654	24,485
Medicare	47,672	35,882	29,856
Durable medical equipment distributors	34,519	5,144	—
Total	$ 246,785	$ 208,057	$ 187,130

Our rental revenue is derived from rent-to-purchase arrangements that typically range from three to ten months. As title transfers to the patient, with whom we have the contract, upon the termination of the lease term and because collectability is probable, under ASC 842, these are recognized as sales-type leases. Each rental agreement contains two components, the controller and related garments, both of which are interdependent and recognized as one lease component.

The revenue and associated cost of revenue of sales-type leases are recognized on the lease commencement date and a net investment in leases is recorded on the Consolidated Balance Sheet. We bill the patients' insurance payers monthly over the duration of the rental term. We record the net investment in leases and recognize revenue upon commencement of the lease in the amount of the expected consideration to be received through the monthly payments. Similar to our sales revenue, the transaction price is impacted by multiple factors, including the terms and conditions contracted by various third party payers. As the rental contract resides with the patients, we have elected the portfolio approach, at the payer level, to determine the expected consideration, which considers the impact of early terminations. While the contract is with the patient, in certain circumstances, the third party payer elects an initial rental period with an option to extend. We assess the likelihood of extending the lease at the onset of the lease to determine if the option is reasonably certain to be exercised. As the lease is short-term in nature, we anticipate collection of substantially all of the net investment within the first year of the lease agreement. Completion of these payments represents the fair market value of the equipment, and as such, interest income is not applicable.

Rental revenue for the years ended December 31, 2022, 2021 and 2020, was primarily related to private insurers. Sales-type lease revenue and the associated cost of revenue for the years ended December 31, 2022, 2021 and 2020, was:

(In thousands)	Year Ended December 31, 2022	2021	2020
Sales-type lease revenue	$ 35,440	$ 30,143	$ 25,633
Cost of sales-type lease revenue	11,190	9,622	9,011
Gross profit	$ 24,250	$ 20,521	$ 16,622

Note 15. Income Taxes

The provision (benefit) for income tax expense consisted of the following:

(In thousands)	Year Ended December 31, 2022	2021	2020
Current income taxes, Federal	$ 1,838	$ (1,274)	$ (653)
Current income taxes, State	637	214	294
	2,475	(1,060)	(359)
Deferred income taxes, Federal	(32)	7,874	(833)
Deferred income taxes, State	—	2,356	(395)
	(32)	10,230	(1,228)
Unrecognized tax benefit, Federal	(50)	348	—
Unrecognized tax benefit, State	—	—	(54)
	(50)	348	(54)
Total provision (benefit) for income taxes	$ 2,393	$ 9,518	$ (1,641)

The components of our deferred tax assets and liabilities were as follows:

(In thousands)	At December 31, 2022	At December 31, 2021
Deferred tax assets:		
Operating lease liability	$ 5,945	$ 6,490
Net operating loss carryforwards	179	671
Accounts receivable and inventory reserves	6,013	4,658
Stock-based compensation	4,886	3,777
Accrued liabilities	1,914	1,104
Warranty reserves	1,071	1,245
Intangible assets	2,947	579
Business credits	536	682
R&D expenses	1,103	—
Other	183	199
Total deferred tax assets	24,777	19,405
Deferred tax liabilities:		
Right-of-use asset	(5,425)	(6,019)
Fixed assets	(1,080)	(914)
Prepaid expenses	(251)	(378)
Other	(186)	(87)
Total deferred tax liabilities	(6,942)	(7,398)
Valuation allowance	(17,835)	(12,039)
Net deferred tax assets	$ —	$ (32)

A reconciliation of income tax (benefit) expense to the statutory federal tax rate is as follows:

	Year Ended December 31, 2022	2021	2020
Tax expense at statutory rate	21.0 %	21.0 %	21.0 %
State income taxes, net of federal benefit	4.1	(1.1)	(7.9)
Executive compensation	—	(14.2)	(5.5)
Meals and entertainment	—	—	(10.6)
Incentive stock options	—	—	(0.4)
Employee Stock Purchase Plan	(1.0)	(7.5)	(8.6)
Federal business credits	1.6	10.9	—
Valuation allowance	(37.4)	(525.0)	8.0
Return to provision	(0.2)	(6.5)	3.6
Research and development credits	—	60.2	—
IRS exam	—	—	2.5
Deferred reprice - state	0.9	3.3	—
Federal carryback claim deferred rate differential	—	—	38.5
Unrecognized tax benefits	(0.3)	(2.2)	2.3
Excess benefit on non-qualified stock options and RSUs	(3.7)	47.2	28.0
Interest and penalties	—	(0.7)	1.9
Other	(0.5)	(0.5)	(0.2)
Net effective rate	(15.5) %	(415.1) %	72.6 %

A reconciliation of unrecognized tax benefits ("UTB") is as follows:

	December 31,		
(In thousands)	2022	2021	2020
Balance beginning of the year	$ 522	$ —	$ 54
Gross change — tax positions in prior year	90	522	(54)
Balance end of the year	$ 612	$ 522	$ —

Deferred income taxes result from temporary differences between the reporting of amounts for financial statement purposes and income tax purposes. These differences relate primarily to different methods used for income tax purposes including depreciation and amortization, warranty and vacation accruals, and deductions related to allowances for doubtful accounts receivable, and inventory reserves.

As of December 31, 2022, the Company had approximately $179 thousand of state net operating loss ("NOL") carryforwards. The state NOL carryforward amounts expire beginning in tax years 2027 if not utilized.

The Company is subject to income tax examinations in the U.S. federal jurisdiction as well as in various state jurisdictions. U.S. federal and state tax years prior to 2019 are closed to examination. In the event of any future tax assessments, we have elected to record the income taxes and any related interest and penalties as income tax expense on our Consolidated Statement of Operations. The Company is not under exam in any jurisdictions.

We recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more likely than not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority.

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss expected to be incurred over the three-year period ended December 31, 2022. Such objective evidence limits the ability to consider other subjective evidence, such as our projections for future growth.

On the basis of this evaluation, as of December 31, 2022, a valuation allowance of $17.8 million was recorded to recognize only the portion of the deferred tax assets that is more likely than not to be realized. The amount of the deferred tax assets considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

Note 16. Net (Loss) Income Per Common Share

The following table sets forth the computation of our basic and diluted net loss per share:

	Year Ended December 31,		
(In thousands, except share and per share data)	2022	2021	2020
Net loss	$ (17,866)	$ (11,811)	$ (620)
Weighted-average shares outstanding	20,067,969	19,719,485	19,346,929
Weighted-average shares used to compute diluted net loss per share	20,067,969	19,719,485	19,346,929
Net loss per share - Basic	$ (0.89)	$ (0.60)	$ (0.03)
Net loss per share - Diluted	$ (0.89)	$ (0.60)	$ (0.03)

The following common stock equivalents were excluded from the computation of diluted net loss per common share for the periods presented because including them would have been anti-dilutive:

	Year Ended December 31,		
	2022	2021	2020
Restricted stock units	590,542	265,616	218,686
Common stock options	615,307	915,224	1,039,709
Performance stock units	155,618	54,317	96,383
Employee stock purchase plan	100,506	34,809	53,205
Total	1,461,973	1,269,966	1,407,983

Note 17. Fair Value Measurements

We determine the fair value of our assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. We use a fair value hierarchy with three levels of inputs, of which the first two are considered observable and the last unobservable, to measure fair value. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1). The next highest priority is based on quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in non-active markets or other observable inputs (Level 2). The lowest priority is given to unobservable inputs (Level 3). As of December 31, 2021, we no longer had any money market mutual funds.

We have obligations to pay a $5.0 million agreed-upon earn-out payment in cash and up to an additional $10.0 million earn-out payment in cash if certain future U.S. revenues of the AffloVest are met. The earn-out liability was valued by employing a Monte Carlo Simulation model in a risk-neutral framework, which is a Level 3 input. The underlying simulated variable includes recognized revenue. The recognized revenue volatility estimate was based on a study of historical asset volatility for a set of comparable public companies. The model includes other assumptions including the market price of risk, which was calculated as the weighted average cost of capital less the long-term risk-free rate. The earn-out liability is adjusted to fair value at each reporting date until settled. Changes in fair value will be included in intangible asset amortization and earn-out expenses in our Consolidated Statements of Operations.

Changes in the earn-out liability measured at fair value using Level 3 inputs were as follows:

(In thousands)		
Earn-out liability at December 31, 2021	$	6,200
Addition for acquisition		—
Payment on earn-out		(5,000)
Fair value adjustments		11,850
Earn-out liability at December 31, 2022	$	13,050

As of December 31, 2022, the fair value of the earn-out liability accrued but not yet earned totaled $8.1 million and was classified as a current liability. The remaining $5.0 million of the earn-out liability had been earned and is to be paid by May 26, 2023.

The following provides information regarding fair value measurements for our remaining contingent earn-out liability as of December 31, 2022, and December 31, 2021, according to the three-level fair value hierarchy:

	At December 31, 2022			
(In thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Recurring Fair Value Measurements:				
Earn-out liability	$ —	—	$ 8,050	$ 8,050
Total	$ —	$ —	$ 8,050	$ 8,050

	At December 31, 2021			
(In thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Recurring Fair Value Measurements:				
Earn-out liability	$ —	$ —	$ 6,200	$ 6,200
Total	$ —	$ —	$ 6,200	$ 6,200

The carrying amounts of financial instruments such as cash equivalents, accounts receivable, other assets, accounts payable, accrued expenses and other liabilities approximate their related fair values due to the short-term maturities of these items. Non-financial assets, such as equipment and leasehold improvements, and intangible assets are subject to non-recurring fair value measurements if they are deemed impaired.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in the company's internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that occurred during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. It includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

Our independent registered public accounting firm has audited the effectiveness of our internal control over financial reporting as of December 31, 2022, as stated in its report which appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Tactile Systems Technology, Inc.

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of Tactile Systems Technology, Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2022, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 31, 2022, and our report dated February 21, 2023 expressed an unqualified opinion on those financial statements.

Basis for opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and limitations of internal control over financial reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP

Minneapolis, Minnesota
February 21, 2023

Item 9B. Other Information.

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information About our Executive Officers

Daniel Reuvers, age 59, has served as our President and Chief Executive Officer, and as a member of our Board of Directors, since June 2020. Previously, he was at Integra LifeSciences Holdings Corporation, where he has served as the Executive Vice President and President, Codman Specialty Surgical, since December 2016. His responsibilities there included global sales, marketing, product development, quality and regulatory, and service and repair. He joined Integra in 2008 as Vice President of Marketing & Product Development for the company's surgical instrument business, and held a series of roles with progressively increased responsibility. Among his accomplishments there, he led the $1B acquisition and integration of the Codman business from Johnson & Johnson. Previously, he served as President of Advanced Respiratory and Omni-Tract Surgical, both resulting in acquisitions by Hill-Rom and Integra, respectively. Mr. Reuvers served on the board of Respirtech, Inc. for 10 years, until their acquisition by Philips.

Kristie T. Burns, age 51, has served as our Senior Vice President, Marketing & Clinical Affairs since joining the company in March 2021. Prior to joining our company, Ms. Burns was the Chief Marketing Officer of Cala Health, Inc., a privately-held bioelectronic medicine company developing wearable neuromodulation therapies for chronic disease, from January 2017 until March 2021. At Cala Health, she organized the company's commercial functions and managed the U.S. commercial introduction of its lead product. Prior to joining Cala Health, Inc., Ms. Burns served as Vice President of Solutions Marketing, ResMed Americas of ResMed Inc. (NYSE: RMD), a global leader in digital health and cloud-connected medical devices focused on sleep apnea and other chronic diseases, from December 2003 to February 2016. Ms. Burns held various marketing and leadership roles of increasing responsibility with ResMed Inc. beginning in 2003. At ResMed Inc., her responsibilities included managing marketing and legal due diligence teams and leading the collaboration between multiple teams following a significant market reorganization. Ms. Burns previously served in consulting and business development roles of increasing responsibility at a privately-held cardiology consulting practice that was subsequently acquired by GE Medical Systems, from 1994 to 1999.

Brent A. Moen, age 55, has served as our Chief Financial Officer since joining the company in September 2018. Prior to joining our company, Mr. Moen served as Chief Financial Officer of Entellus Medical, Inc., a publicly held medical device company, from May 2016 until the company's acquisition by Stryker Corporation in February 2018. Prior to joining Entellus Medical, Mr. Moen served as Executive Vice President and Chief Financial Officer of ABRA Auto Body & Glass LP, an automotive collision repair company, from November 2013 to May 2015. Mr. Moen previously served as Senior Vice President and Chief Financial Officer of Regis Corporation, a publicly held owner, franchisor and operator of beauty salons, from January 2011 to December 2012. Mr. Moen held various financial roles of increasing responsibility with Regis Corporation, beginning in 2000. Mr. Moen holds a B.A. in Accounting from the University of North Dakota and is a Certified Public Accountant (inactive) and started his professional career with Coopers and Lybrand.

Eric Pauls, age 48, has served as our Senior Vice President, Sales since joining the company in May 2021. Prior to joining our company, Mr. Pauls served in positions of increasing responsibility at Royal Philips (NYSE: PHG; AEX: PHIA), a leading health technology company. He most recently held the position of Business Sales Leader for Sleep and Respiratory Care, North America. In this position, Mr. Pauls was responsible for a sleep and respiratory business, where he led a team of 500 sales and support personnel across multiple sales channels. From July 2017 to September 2019, he served as Business Segment Leader for RespirTech, a U.S.-based provider of an in-home wearable treatment for patients with chronic respiratory conditions, which was acquired by Philips in 2017. Mr. Pauls was Vice President of Sales for Key Accounts from January 2015 to June 2017 and Director of Sales for National Accounts from July 2012 to January 2014, leading targeted sales teams within Philips' Sleep and Respiratory Care business. He joined Philips Respironics as a Technical Sales Specialist in 2002, and was subsequently promoted to multiple positions within its sales organization over the following decade. Mr. Pauls holds a M.B.A. from Baker University and a B.S. in Respiratory Care from the University of Kansas.

Corporate Governance

Our board of directors has adopted a Code of Business Conduct and Ethics that applies to our directors, officers and employees. This code is available on the corporate governance section of our website (which is a subsection of the investor relations section of our website) at the following address: www.tactilemedical.com. We intend to disclose on our website any amendments or waivers to the Code that are required to be disclosed by SEC rules.

Other Information

Additional information required by this Item 10 will be contained in our definitive proxy statement for our 2023 Annual Meeting of Stockholders (the “Definitive Proxy Statement”) and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be contained in the Definitive Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 12 will be contained in the Definitive Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 13 will be contained in the Definitive Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be contained in the Definitive Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

1. *Financial Statements*

The following financial statements of Tactile Systems Technology, Inc. are set forth in Part II, Item 8:
Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2022 and 2021
Consolidated Statements of Operations for the years ended December 31, 2022, 2021 and 2020
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2022, 2021 and 2020
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2022, 2021 and 2020
Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021 and 2020
Notes to Consolidated Financial Statements

2. *Financial Statement Schedules*

Not applicable.

3. *Exhibits*

A list of exhibits required to be filed as part of this report is set forth in the Exhibit Index below.

EXHIBIT INDEX

		Incorporated by Reference			
Exhibit Number	**Description of Exhibit**	**Form**	**Date of Filing**	**Exhibit Number**	**Filed Herewith**
2.1	Asset Purchase Agreement, dated as of September 8, 2021, among Tactile Systems Technology, Inc., International Biophysics Corporation and H. David Shockley, Jr.	8-K	09/08/2021	2.1	
2.2	Amendment to Asset Purchase Agreement, dated as of November 4, 2022, by and between Tactile Systems Technology, Inc. and Movair, Inc. (f/k/a International Biophysics Corporation)	10-Q	11/07/2022	2.1	
3.1	Amended and Restated Certificate of Incorporation, as amended through May 9, 2019	8-K	05/09/2019	3.2	
3.2	Amended and Restated Bylaws, effective December 19, 2022				X
4.1	Description of the Registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	02/23/2022	4.1	
4.2	Specimen Certificate representing shares of common stock	S-1	05/06/2016	4.1	

4.3	Form of Senior Indenture	S-3	01/18/2023	4.3
4.4	Form of Subordinated Indenture	S-3	01/18/2023	4.4
10.1*	2007 Omnibus Stock Plan	S-1	01/25/2016	10.5
10.2*	Form of Incentive Stock Option Agreement under 2007 Omnibus Stock Plan	S-1	01/25/2016	10.6
10.3*	Form of Non-Statutory Stock Option Agreement (Employee) under 2007 Omnibus Stock Plan	S-1	01/25/2016	10.7
10.4*	Form of Non-Statutory Stock Option Agreement (Directors) under 2007 Omnibus Stock Plan	S-1	01/25/2016	10.8
10.5*	Form of Non-Statutory Stock Option Agreement (Consultants) under 2007 Omnibus Stock Plan	S-1	01/25/2016	10.9
10.6*	Form of Restricted Stock Agreement	S-1	01/25/2016	10.10
10.7*	2016 Equity Incentive Plan	S-1	06/09/2016	10.11
10.8*	Form of Non-Qualified Stock Option Agreement under 2016 Equity Incentive Plan	S-1	06/09/2016	10.12
10.9*	Form of Non-Qualified Stock Option Agreement under 2016 Equity Incentive Plan (to be used for awards beginning in 2020)	10-Q	05/04/2020	10.1
10.10*	Form of Incentive Stock Option Agreement under 2016 Equity Incentive Plan	S-1	06/09/2016	10.13
10.11*	Form of Incentive Stock Option Agreement under 2016 Equity Incentive Plan (to be used for awards beginning in 2020)	10-Q	05/04/2020	10.2
10.12*	Form of Restricted Stock Agreement under 2016 Equity Incentive Plan	S-1	06/09/2016	10.14
10.13*	Form of Restricted Stock Unit Award Agreement under 2016 Equity Incentive Plan	S-1	06/09/2016	10.15
10.14*	Form of Restricted Stock Unit Award Agreement under 2016 Equity Incentive Plan (to be used for awards beginning in 2019)	10-Q	05/06/2019	10.3
10.15*	Form of Restricted Stock Unit Award Agreement under 2016 Equity Incentive Plan (to be used for awards beginning in 2020)	10-Q	05/04/2020	10.3
10.16*	Form of Restricted Stock Unit Agreement under 2016 Equity Incentive Plan (Quarterly Awards)	S-1	06/09/2016	10.16

10.17*	Form of Performance Stock Unit Agreement under the 2016 Equity Incentive Plan to be used for awards beginning in 2018	8-K	02/27/2018	10.1
10.18*	Form of Performance Stock Unit Award Agreement under 2016 Equity Incentive Plan (to be used for awards beginning in 2019)	10-Q	05/06/2019	10.4
10.19*	Form of Performance Stock Unit Award Agreement under 2016 Equity Incentive Plan (to be used for awards beginning in 2020)	10-Q	05/04/2020	10.4
10.20*	Employee Stock Purchase Plan	S-1	06/09/2016	10.17
10.21*	First Declaration of Amendment to Employee Stock Purchase Plan	10-K	02/26/2018	10.18
10.22*	Management Incentive Plan	8-K	03/10/2017	10.1
10.23*	Non-Employee Director Compensation Policy	10-K	02/23/2022	10.23
10.24*	Form of Director and Officer Indemnification Agreement	S-1	05/06/2016	10.19
10.25*	Tactile Systems Technology, Inc. Executive Employee Severance Plan	10-Q	11/05/2018	10.2
10.26*	Form of Confidentiality, Assignment of Intellectual Property and Restrictive Covenants Agreement	10-Q	11/05/2018	10.3
10.27*	Offer letter between Daniel L. Reuvers and Tactile Systems Technology, Inc. dated May 20, 2020	8-K	05/22/2020	10.1
10.28*	Transition and Consulting Agreement, dated as of January 10, 2020, by and between Gerald R. Mattys and Tactile Systems Technology, Inc.	8-K	01/13/2020	10.1
10.29*	Offer letter between Eric Pauls and Tactile Systems Technology, Inc. dated April 19, 2021	10-K	02/23/2022	10.29
10.30*	Offer letter between Kristie Burns and Tactile Systems Technology, Inc. dated February 1, 2021	10-K	02/23/2022	10.30
10.31	Credit Agreement, dated as of August 3, 2018, by and among Tactile Systems Technology, Inc., the lenders from time to time party thereto and Wells Fargo Bank, National Association	10-Q	08/06/2018	10.1
10.32	First Amendment to Credit Agreement, dated as of February 12, 2019, by and among Tactile Systems Technology, Inc., the lenders party thereto and Wells Fargo Bank, National Association	10-K	02/28/2019	10.33

10.33	Waiver and Second Amendment to Credit Agreement, dated as of March 25, 2019, by and among Tactile Systems Technology, Inc., the lenders party thereto and Wells Fargo Bank, National Association	10-Q	05/06/2019	10.2	
10.34	Third Amendment to Credit Agreement, dated as of August 2, 2019, by and among Tactile Systems Technology, Inc., the lenders party thereto and Wells Fargo Bank, National Association	10-Q	11/04/2019	10.1	
10.35	Amended and Restated Credit Agreement, dated as of April 30, 2021, by and among Tactile Systems Technology, Inc., the lenders from time to time party thereto and Wells Fargo Bank, National Association, as Administrative Agent	10-Q	05/03/2021	10.1	
10.36	First Amendment Agreement, dated as of September 8, 2021, among Tactile Systems Technology, Inc., the lenders signatory thereto and Wells Fargo Bank, National Association, as administrative agent	8-K	09/08/2021	10.1	
10.37	Second Amendment Agreement, dated as of February 22, 2022, among Tactile Systems Technology, Inc., the lenders signatory thereto and Wells Fargo Bank, National Association, as administrative agent	10-K	02/23/2022	10.37	
21.1	Subsidiaries	S-1	01/25/2016	21.1	
23.1	Consent of Grant Thornton LLP				X
24.1	Power of Attorney (included in signature page)				X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) / 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) / 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X

101.1	The following financial statements from the Company’s Annual Report on Form 10-K for the year ended December 31, 2022, formatted in Inline XBRL: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Comprehensive Loss, (iv) Statements of Stockholders’ Equity, (v) Statements of Cash Flows, and (vi) Notes to the Financial Statements	X
104.1	Cover page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101.1)	X

* Indicates management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Tactile Systems Technology, Inc.

Date: February 21, 2023

By: /s/ Daniel L. Reuvers
Daniel L. Reuvers
Chief Executive Officer
(Principal executive officer)

Each of the undersigned hereby appoints Daniel L. Reuvers and Brent A. Moen, and each of them (with full power to act alone), as attorneys and agents for the undersigned, with full power of substitution, for and in the name, place and stead of the undersigned, to sign and file with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, any and all amendments and exhibits to this annual report on Form 10-K and any and all applications, instruments and other documents to be filed with the Securities and Exchange Commission pertaining to this annual report on Form 10-K or any amendments thereto, with full power and authority to do and perform any and all acts and things whatsoever requisite and necessary or desirable. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on February 21, 2023.

Name	Title
/s/ Daniel L. Reuvers Daniel L. Reuvers	Chief Executive Officer (principal executive officer) and Director
/s/ Brent A. Moen Brent A. Moen	Chief Financial Officer (principal financial officer and principal accounting officer)
/s/ William W. Burke William W. Burke	Chairman of the Board of Directors
/s/ Valerie L. Asbury Valerie L. Asbury	Director
/s/ Sheri L. Dodd Sheri L. Dodd	Director
/s/ Raymond O. Huggenberger Raymond O. Huggenberger	Director
/s/ Deepti Jain Deepti Jain	Director
/s/ D. Brent Shafer D. Brent Shafer	Director
/s/ Carmen B. Volkart Carmen B. Volkart	Director

TACTILE SYSTEMS TECHNOLOGY, INC.

AMENDED AND RESTATED BYLAWS

Effective: December 19, 2022

ARTICLE I
OFFICES

Section 1.1 REGISTERED OFFICE. The Corporation shall maintain a registered office and registered agent within the State of Delaware at such place within such State as may be designated from time to time by the board of directors of the Corporation.

Section 1.2 OTHER OFFICES. The Corporation may also have offices in such other places, either within or without the State of Delaware, as the board of directors may from time to time designate or the business of the Corporation may from time to time require.

ARTICLE II
STOCKHOLDERS

Section 2.1 MEETINGS OF STOCKHOLDERS.

(a) *ANNUAL MEETINGS.* Annual meetings of the stockholders, at which they shall elect members of the board of directors and transact such other business as may properly come before the meeting, shall be held on such date and at such time as the board of directors may designate.

(b) *SPECIAL MEETINGS.* Except as otherwise required by law, special meetings of stockholders of the Corporation for any purpose or purposes may be called only by the board of directors, the Chair of the board or the Chief Executive Officer of the Corporation. Special meetings of the stockholders may not be called by any other person or persons.

(c) *PLACE OF MEETINGS.* Meetings of the stockholders shall be held at such place, either within or without the State of Delaware, or solely by means of remote communication, as the board of directors shall determine.

(d) *NOTICE OF MEETING.* Notice, stating the place, if any, day and time of the meeting, and the means of remote communication, if any, shall be delivered by the Corporation not less than ten days nor more than 60 days before the date of the meeting to each stockholder of record entitled to vote at such meeting. Notice of a special meeting shall also state the purpose or purposes for which the meeting has been called. Without limiting the manner by which notice may otherwise be given, notice may be given by a form of electronic transmission that satisfies the requirements of the Delaware General Corporation Law. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail with postage thereon prepaid, addressed to the stockholder at his or her address as it appears in the Corporation's records. Meetings may be held without notice if all stockholders entitled to vote are present, or if notice is waived by those not present in accordance with Article VIII of these Bylaws. Any previously scheduled meeting of the stockholders may be postponed, and any special meeting of the stockholders may be cancelled, by resolution of the board of directors upon public notice given prior to the date previously scheduled for such meeting of stockholders. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting (or any supplement thereto).

(e) *CHAIR OF STOCKHOLDERS MEETING.* The Chair of the board, or in the Chair's absence, a Vice Chair, or in the absence of any Vice Chair, the Chief Executive Officer, or in the absence of the Chief Executive Officer, the Secretary, or in the absence of the Secretary, a chair chosen by a majority of the directors present, shall act as chair of the meetings of the stockholders.

(f) *CONDUCT OF MEETINGS*. The board of directors shall be entitled to make such rules and regulations for the conduct of meetings of stockholders as it shall deem necessary, appropriate, or convenient. Subject to such rules and regulations of the board of directors, if any, the chair of any meeting of stockholders shall have the right and authority to prescribe such rules, regulations, and procedures and to do all such acts as, in the judgment of such chair, are necessary, appropriate, or convenient for the proper conduct of the meeting, including, without limitation, establishing an agenda or order of business for the meeting, rules and procedures for maintaining order at the meeting and the safety of those present, limitations on participation in the meeting to stockholders of record of the Corporation, their duly authorized and constituted proxies, and such other persons as the chair shall permit, restrictions on entry to the meeting after the time fixed for the commencement thereof, limitations on the time allotted to questions or comments by participants, and regulation of the opening and closing of the polls for balloting and matters which are to be voted on by ballot.

Section 2.2 QUORUM OF STOCKHOLDERS; ADJOURNMENT; REQUIRED VOTE; PROXIES.

(a) *QUORUM OF STOCKHOLDERS; ADJOURNMENT.* Except as otherwise provided by law, by the Amended and Restated Certificate of Incorporation of the Corporation (the "*Certificate of Incorporation*") or by these Bylaws, the holders of a majority of the voting power of the shares of stock of the Corporation issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders, except that when specified business is to be voted on by a class or series of stock voting as a class, the holders of a majority of the shares of such class or series issued and outstanding and entitled to vote shall constitute a quorum of such class or series for the transaction of such business. The chair of the meeting or a majority of the shares so represented may adjourn the meeting from time to time, whether or not there is such a quorum. No notice of the time and place of adjourned meetings need be given, except that notice of the adjourned meeting shall be required if the adjournment is for more than 30 days or if after the adjournment a new record date is fixed for the adjourned meeting. The stockholders present at a duly called meeting at which a quorum is present may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum.

(b) *REQUIRED VOTE.* Except as is otherwise required by law, the Certificate of Incorporation or these Bylaws, each holder of record of shares of stock of the Corporation having voting powers shall be entitled, at each meeting of the stockholders, to one vote for every share of such stock standing in his or her name on the record of stockholders of the Corporation and, if a quorum is present and unless otherwise required by the Certificate of Incorporation, the affirmative vote of a majority of the shares of stock represented at the meeting and entitled to vote on the subject matter shall be the act of the stockholders, except with respect to the election of directors. Election of directors at all meetings of the stockholders at which directors are to be elected shall, subject to the rights of the holders of any series of Preferred Stock to elect directors under specified circumstances, be elected by a plurality of the votes cast.

(c) *PROXIES.* Each stockholder of record entitled to vote at any meeting may do so in person or by proxy authorized by an instrument in writing or in such other manner or form, such as electronic transmission, permitted by the Delaware General Corporation Law, by such stockholder or his or her duly authorized attorney in fact. Any stockholder directly or indirectly soliciting proxies from other stockholders must use a proxy card color other than white, which shall be reserved for the exclusive use by the board of directors.

Section 2.3 LIST OF STOCKHOLDERS. At least ten days before each meeting of stockholders, the Secretary or agent having charge of the stock transfer book shall make a complete list of the stockholders entitled to vote at such meeting, arranged in alphabetical order, with the address of each and the number of shares held by each. Such list shall be subject to inspection by any stockholder for a period of ten days prior to such meeting, for any purpose related to the meeting, at the principal office of the Corporation at any time during usual business hours or on a reasonably accessible electronic network.

Section 2.4 NOTICE OF STOCKHOLDER BUSINESS AND NOMINATIONS.

(a) *ANNUAL MEETINGS OF STOCKHOLDERS.*

(1) Nominations of persons for election to the board of directors of the Corporation and the proposal of business to be considered by the stockholders may be made at an annual meeting of stockholders (A) pursuant to the Corporation's notice of meeting, (B) by or at the direction of the board of directors, or (C) by any stockholder of the Corporation who was a stockholder of record at the time of giving of notice provided for in this Section 2.4, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 2.4.

(2) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (C) of paragraph (a)(1) of this Section 2.4, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation and such other business must otherwise be a proper matter for stockholder action. To be timely, a stockholder's notice shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; <u>provided</u>, <u>however</u>, that in the event that the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to the date of such annual meeting and not later than the close of business on the later of the 90th day prior to the date of such annual meeting or the 10th day following the day on which public announcement of the date of such meeting is first made by the Corporation. In no event shall any adjournment or postponement of an annual meeting or the public announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. Such stockholder's notice must set forth:

(A) as to each person whom the stockholder proposes to nominate for election or reelection as a director, (i) all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "*Exchange Act*") (including such person's written consent to being named in any proxy materials as a nominee and to serving as a director if elected), and (ii) information relating to any agreement, arrangement or understanding, including a voting commitment, or any relationship, including financial transactions and compensation, between such person and the stockholder or any Stockholder Associated Person (as defined in Section 2.4(c)(2) below); provided, that the Corporation may also require any proposed nominee to furnish such other information as the Corporation may reasonably require to determine the eligibility of such proposed nominee to serve as a director;

(B) as to any business, other than the nomination of a director or directors, that the stockholder proposes to bring before the meeting, (i) a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting and any material interest of such stockholder and any Stockholder Associated Person in such business, (ii) a description of all agreements, arrangements and understandings between such stockholder and any Stockholder Associated Person and any other person or persons (including their names) in connection with the proposal of such business by such stockholder, and (iii) if the proposal or business is to be included in the Corporation's proxy statement, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend these Bylaws, the language of the proposed amendment); and

(C) as to the stockholder giving the notice and any Stockholder Associated Person, (i) the name and address of such stockholder, as they appear on the Corporation's stock ledger, and the name and address, if different, of such Stockholder Associated Person, (ii) the class, series and number of all shares of stock of the Corporation which are held of record or are beneficially owned by such stockholder and by such Stockholder Associated Person, (iii) the nominee holder for, and the number of, shares owned beneficially but not of record by such stockholder and by such Stockholder Associated Person, (iv) any derivative position, including without limitation any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Corporation or with a value derived in whole or in part from the value of any class or series of shares of the Corporation, directly or indirectly held or beneficially held by such stockholder and such Stockholder Associated Person, and whether and the extent to which any hedging, equity swap or other transaction or series of transactions has been entered into by or on behalf of, or any other agreement, arrangement or understanding (including any short position or interest or any borrowing or lending of shares of stock) has been made by, such stockholder or such Stockholder Associated Person with respect to any shares of stock of the Corporation, or whether such stockholder or Stockholder Associated Person has an economic interest in the Corporation not reported as record or beneficial ownership, (v) any proxy, contract, arrangement, understanding or relationship pursuant to which such stockholder or Stockholder Associated Person has a right to vote any shares of stock of the Corporation, (vi) any rights to dividends on the shares of the Corporation owned beneficially by such stockholder or Stockholder Associated Person that are separated or separable from the underlying shares of the Corporation, (vii) a representation that the stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or through a qualified representative at the meeting to propose such nomination or business, and (viii) as to any business, other than the nomination of a director or directors, a representation whether such stockholder or Stockholder Associated Person intends or is part of a group which intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to elect the nominee or to approve or adopt the proposal and/or (y) otherwise to solicit proxies from stockholders in support of such nomination or proposal, and the information called for by this paragraph (2)(C) shall be supplemented by such stockholder and Stockholder Associated Person not later than 10 days after the record date for the meeting to disclose such information as of the record date.

(D) A stockholder who intends to solicit proxies in support of director nominees other than the Corporation's director nominees and who has delivered a notice of nomination pursuant to this Section 2.4 shall promptly certify to the Corporation, and notify the Corporation in writing, that it has complied with or will comply with the requirements of Rule 14a-19 under the Exchange Act, and upon request of the Corporation, shall, not later than five business days prior to the date of the applicable meeting of stockholders, deliver to the Corporation reasonable evidence of such compliance.

(3) Notwithstanding anything in the second sentence of paragraph (a)(2) of this Section 2.4 to the contrary, in the event that the number of directors to be elected to the board of directors of the Corporation is increased and there is no public announcement by the Corporation naming all of the nominees for director or specifying the size of the increased board of directors at least 100 days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice required by this Section 2.4 shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the Corporation.

(b) *SPECIAL MEETINGS OF STOCKHOLDERS*. The business to be transacted at any special meeting shall be limited to the purposes stated in the notice of such meetings. Nominations of persons for election to the board of directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting (1) by or at the direction of the board of directors or (2) provided that the board of directors has determined that directors shall be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time of giving of notice provided for in this Section 2.4 and is a stockholder of record at the time of the special meeting, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 2.4. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the board of directors, any such stockholder may nominate a person or persons (as the case may be), for election to such position(s) as specified in the Corporation's notice of meeting, if the stockholder's notice required by paragraph (a)(2) of this Section 2.4 shall be delivered to the Secretary at the principal executive offices of the Corporation not earlier than the close of business on the 120th day prior to the date of such special meeting and not later than the close of business on the later of the 90th day prior to the date of such special meeting or the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the board of directors to be elected at such meeting. In no event shall any adjournment or postponement of a special meeting or the public announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) *GENERAL.*

(1) Only such persons who are nominated in accordance with the procedures set forth in this Section 2.4 shall be eligible to serve as directors and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 2.4. Except as otherwise provided by law, the Certificate of Incorporation or these Bylaws, the chair of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 2.4 and, if any proposed nomination or business is not in compliance with this Section 2.4, to declare that such defective nomination or proposal shall be disregarded. Notwithstanding the foregoing provisions of this Section 2.4, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or proposal, such nomination or proposed business shall be disregarded, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Unless otherwise required by law, if any stockholder (i) provides notice pursuant to Rule 14a-19 under the Exchange Act and (ii) subsequently (A) notifies the Corporation that such stockholder no longer intends to solicit proxies in support of director nominees other than the Corporation's director nominees in accordance with Rule 14a-19, (B) fails to comply with the requirements of Rule 14a-19, or (C) fails to provide reasonable evidence sufficient to satisfy the Corporation that such requirements have been met, then such stockholder's nominations shall be deemed null and void and the Corporation shall disregard any proxies or votes solicited for any nominee proposed by such stockholder.

(2) For purposes of this Bylaw, (A) "*public announcement*" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or other national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act; and (B) *"Stockholder Associated Person"* of any stockholder shall mean (i) any person or entity controlling, controlled by or under common control with, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the Corporation owned of record or beneficially by such stockholder, and (iii) any person or entity controlling, controlled by or under common control with a Stockholder Associated Person as defined in the foregoing clauses (B)(i) or (B)(ii).

(3) Notwithstanding the foregoing provisions of this Section 2.4, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder (including Rule 14a-19) with respect to the matters set forth in this Section 2.4. Nothing in this Section 2.4 shall be deemed to affect any rights (A) of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act or (B) of the holders of any series of Preferred Stock to elect directors under specified circumstances.

Section 2.5 <u>INSPECTORS OF ELECTIONS</u>. The board of directors by resolution shall appoint one or more inspectors, which inspector or inspectors may include individuals who serve the Corporation in other capacities, including, without limitation, as officers, employees, agents or representatives, to act at the meetings of stockholders and make a written report thereof. One or more persons may be designated as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate has been appointed to act or is able to act at a meeting of stockholders, the chair of the meeting shall appoint one or more inspectors to act at the meeting. Each inspector, before discharging his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. The inspectors shall have the duties prescribed by law.

ARTICLE III
BOARD OF DIRECTORS

Section 3.1 GENERAL POWERS. The business and affairs of the Corporation shall be managed under the direction of the board of directors. In addition to the powers and authorities by these Bylaws expressly conferred upon them, the board of directors may exercise all such powers of the Corporation and do all such lawful acts and things as are not by statute or by the Certificate of Incorporation or by these Bylaws required to be exercised or done by the stockholders.

Section 3.2 NUMBER. Subject to the rights of the holders of any series of Preferred Stock to elect directors under specified circumstances, the number of directors of the Corporation shall be fixed, and may be increased or decreased from time to time, exclusively by the board of directors; provided, however, that no decrease in the number comprising the entire board of directors made pursuant to this Section 3.2 shall shorten the term of any incumbent director. The directors shall hold office until their successors are elected and qualified. At each annual meeting of the stockholders of the Corporation, the directors whose term expires at that meeting shall be elected for a term expiring at the next annual meeting of stockholders.

Section 3.3 SPECIAL MEETINGS. Special meetings of the board of directors may be called by the Chair of the board, the Chief Executive Officer or the board of directors. The person or persons authorized to call special meetings of the board of directors may fix the place and time of the meetings. Notice of any special meeting shall be given to each director and shall state the time and place for the special meeting.

Section 3.4 NOTICE. If notice of a board of directors' meeting is required to be given, notice of shall be given to each director at his or her business or residence in writing by hand delivery, first-class or overnight mail or courier service, electronic transmission (including, without limitation, via facsimile transmission or electronic mail), or orally by telephone. If mailed by first-class mail, such notice shall be deemed adequately delivered when deposited in the United States mails so addressed, with postage thereon prepaid, no later than the third business day preceding the date of such meeting. If by overnight mail or courier service, such notice shall be deemed adequately delivered when the notice is delivered to the overnight mail or courier service company at least twenty-four hours before such meeting. If by electronic transmission, such notice shall be deemed adequately delivered when the notice is transmitted at least 12 hours before such meeting. If by telephone or by hand delivery, the notice shall be given at least 12 hours prior to the time set for the meeting. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the board of directors need be specified in the notice of such meeting, except for amendments to these Bylaws, as provided under Article IX of these Bylaws. A meeting may be held at any time without notice if all the directors are present or if those not present waive notice of the meeting in accordance with Article VIII of these Bylaws.

Section 3.5 QUORUM. Subject to Section 3.8 of these Bylaws and except as may be otherwise specifically provided by law or the Certificate of Incorporation, a majority of the board of directors then in office shall constitute a quorum for the transaction of business, but if at any meeting of the board of directors there shall be less than a quorum present, a majority of the directors present may adjourn the meeting from time to time without further notice. The act of the majority of the directors present at a meeting at which a quorum is present shall be the act of the board of directors, except as may be otherwise specifically provided by law or the Certificate of Incorporation. The directors present at a duly organized meeting may continue to transact business until adjournment, notwithstanding the withdrawal of enough directors to leave less than a quorum.

Section 3.6 USE OF COMMUNICATIONS EQUIPMENT. Directors may participate in a meeting of the board of directors or any committee thereof by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

Section 3.7 ACTION BY CONSENT OF THE BOARD OF DIRECTORS. Any action required or permitted to be taken at any meeting of the board of directors or of any committee thereof may be taken without a meeting if all members of the board or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the board or committee.

Section 3.8 VACANCIES. Subject to applicable law and the rights of the holders of any series of Preferred Stock with respect to such series of Preferred Stock, and unless the board of directors otherwise determines, vacancies resulting from death, resignation, retirement, disqualification, removal from office or other cause, and newly created directorships resulting from any increase in the authorized number of directors, may be filled only by the affirmative vote of a majority of the remaining directors, though less than a quorum of the board of directors, or by the sole remaining director, and each director so chosen shall hold office for a term expiring at the annual meeting of stockholders at which the term of the class to which he or she has been elected expires and until such director's successor shall have been duly elected and qualified.

Section 3.9 COMMITTEES.

The board of directors may designate one or more committees, each of which shall consist of one or more directors. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of any member of such committee or committees, the member or members thereof present at any meeting and not disqualified from voting, whether or not constituting a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member.

Any committee shall, to the extent provided in a resolution of the board of directors and subject to the limitations contained in the Delaware General Corporation Law, have and may exercise all the powers and authority of the board of directors in the management of the business and affairs of the Corporation. Each committee shall keep such records and report to the board of directors in such manner as the board of directors may from time to time determine. Except as the board of directors may otherwise determine, any committee may make rules for the conduct of its business. Except as provided in the next sentence, and unless otherwise provided in a resolution of the board of directors or in rules adopted by the committee, each committee shall conduct its business as nearly as possible in the same manner as provided in these Bylaws for the board of directors. A majority of the members of a committee shall constitute a quorum, and the act of a majority of the members of a committee present at any meeting at which a quorum is present shall be the act of the committee.

The board of directors shall have power at any time to fill vacancies in, to change the membership of, or to dissolve any such committee. The term of office of the members of each committee shall be as fixed from time to time by the board of directors; provided, however, that any committee member who ceases to be a member of the board of directors shall automatically cease to be a committee member.

Nothing herein shall be deemed to prevent the board of directors from appointing one or more committees consisting in whole or in part of persons who are not directors of the Corporation; provided, however, that no such committee shall have or may exercise any authority of the board of directors.

ARTICLE IV
BOOKS AND RECORDS

The board of directors shall cause to be kept a record containing the minutes of the proceedings of the meetings of the board and of the stockholders, appropriate stock books and registers and such books of records and accounts as may be necessary for the proper conduct of the business of the Corporation. Unless otherwise required by the laws of Delaware, the books and records of the Corporation may be kept at the principal office of the Corporation, or at any other place or places inside or outside the State of Delaware.

ARTICLE V
OFFICERS

Section 5.1 OFFICERS; ELECTION OR APPOINTMENT. The board of directors shall take such action as may be necessary from time to time to ensure that the Corporation has such officers as are necessary, under Section 6.1 of these Bylaws and the Delaware General Corporation Law as currently in effect or as the same may hereafter be amended, to enable it to sign stock certificates. In addition, the board of directors at any time and from time to time may elect (a) one or more Chair of the board and/or one or more Vice Chairs of the board, (b) one or more Chief Executive Officers, one or more Presidents and/or one or more Chief Operating Officers, (c) one or more Vice Presidents, one or more Treasurers and/or one or more Secretaries and/or (d) one or more other officers, in each case if and to the extent the board of directors deems desirable. The board of directors may give any officer such further designations or alternate titles as it considers desirable. In addition, the board of directors at any time and from time to time may authorize the Chair of the board or the Chief Executive Officer of the Corporation to appoint one or more officers of the kind described in clauses (c) and (d) above. Any number of offices may be held by the same person and directors may hold any office unless the Certificate of Incorporation or these Bylaws otherwise provide.

Section 5.2 TERM OF OFFICE; RESIGNATION; REMOVAL; VACANCIES. Unless otherwise provided in the resolution of the board of directors electing or authorizing the appointment of any officer, each officer shall hold office until his or her successor is elected or appointed and qualified or until his or her earlier resignation or removal. Any officer may resign at any time upon written notice to the board of directors or to such person or persons as the board of directors may designate. Such resignation shall take effect at the time specified therein or, if not so specified, upon receipt, and unless otherwise specified therein no acceptance of such resignation shall be necessary to make it effective. The board of directors may remove any officer with or without cause at any time. The Chair of the board or the Chief Executive Officer authorized by the board of directors to appoint a person to hold an office of the Corporation may also remove such person from such office with or without cause at any time, unless otherwise provided in the resolution of the board providing such authorization. Any such removal shall be without prejudice to the contractual rights of such officer, if any, with the Corporation, but the election or appointment of an officer shall not of itself create contractual rights. Any vacancy occurring in any office of the Corporation by death, resignation, removal or otherwise may be filled by the board of directors at any regular or special meeting or by the Chair of the board or the Chief Executive Officer authorized by the board of directors to appoint a person to hold such office.

Section 5.3 POWERS AND DUTIES. The officers of the Corporation shall have such powers and duties in the management of the Corporation as shall be stated in these Bylaws or in a resolution of the board of directors which is not inconsistent with these Bylaws and, to the extent not so stated, as generally pertain to their respective offices, subject to the control of the board of directors. A Secretary or such other officer appointed to do so by the board of directors shall have the duty to record the proceedings of the meetings of the stockholders, the board of directors and any committees in a book to be kept for that purpose.

ARTICLE VI
STOCK

Section 6.1 STOCK CERTIFICATES. The shares of the Corporation may be either in certificated or in uncertificated form. If shares are issued in uncertificated form, each stockholder shall be entitled upon written request to a stock certificate or certificates duly numbered, certifying the number and class of shares in the Corporation owned by him and otherwise as specified in this Section 6.1. Each certificate for shares of stock shall be in such form as may be prescribed by the board of directors and shall be signed in the name of the Corporation by (a) the Chair of the board, the Chief Executive Officer, the President or a Vice President, and (b) by the Secretary or an Assistant Secretary or the Treasurer or an Assistant Treasurer. Any or all of the signatures on a certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue. Each certificate will include any legends required by law or deemed necessary or advisable by the board of directors.

Section 6.2 LOST, STOLEN OR DESTROYED CERTIFICATES. The Corporation may issue a new certificate of stock or uncertificated shares in place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation and/or the board of directors may require the owner of such lost, stolen or destroyed certificate, or his or her legal representatives, to make an affidavit of that fact and/or to give the Corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of any such certificate or issuance of any such new certificate or uncertificated shares. Anything herein to the contrary notwithstanding, the board of directors, in its absolute discretion, may refuse to issue any such new certificate or uncertificated shares, except pursuant to legal proceedings under the laws of the State of Delaware.

Section 6.3 TRANSFERS OF STOCK. The shares of the stock of the Corporation shall be transferable on the books of the Corporation by the holder thereof in person or by his or her attorney upon surrender for cancellation of a certificate or certificates for at least the same number of shares, or other evidence of ownership if no certificates shall have been issued, with an assignment and power of transfer endorsed thereon or attached thereto, duly executed, and with such proof of the validity and authenticity of the signature as the Corporation or its agents may reasonably require.

Section 6.4 REGISTERED STOCKHOLDERS. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and to hold liable for calls and assessments a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or legal claim or claims to or interest in such shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of the State of Delaware.

Section 6.5 REGULATIONS. Except as otherwise provided by law, the board of directors may make such additional rules and regulations, not inconsistent with the Bylaws, as it may deem expedient concerning the issue, transfer and registration of the securities of the Corporation. The board of directors may appoint, or authorize any officer or officers to appoint, one or more transfer agents and one or more registrars and may require all certificates for shares of capital stock to bear the signature or signatures of any of them.

Section 6.6 RECORD DATE. For the purpose of determining stockholders entitled to notice of, or to vote at, any meeting of stockholders or any adjournment thereof, or for the purpose of determining stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitlements to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix, in advance, a record date. Such date shall not be more than 60 nor less than ten days before the date of any such meeting, nor more than 60 days prior to any other action.

ARTICLE VII
DEPOSITARIES AND CHECKS

Depositaries of the funds of the Corporation shall be designated by the board of directors; and all checks on such funds shall be signed by such officers or other employees of the Corporation as the board of directors from time to time may designate.

ARTICLE VIII
WAIVER OF NOTICE

Any notice of a meeting required to be given by law, by the Certificate of Incorporation, or by these Bylaws may be waived by the person entitled thereto, either before or after the time of such meeting stated in such notice. Neither the business to be transacted at, nor the purpose of, any annual or special meeting of the stockholders or the board of directors or committee thereof need be specified in any waiver of notice of such meeting. Attendance at any meeting shall constitute waiver of notice except attendance for the express purpose of objecting, at the beginning of the meeting, to the transaction of business because the meeting is not lawfully called or convened.

ARTICLE IX
AMENDMENT

In furtherance and not in limitation of the powers conferred by law, the board of directors is expressly authorized to adopt, amend and repeal these Bylaws, subject to the power of the holders of capital stock of the Corporation to adopt, amend or repeal the Bylaws; provided, however, that, with respect to the power of holders of the capital stock to adopt, amend and repeal Bylaws of the Corporation, notwithstanding any other provision of these Bylaws or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the capital stock of the Corporation required by law, these Bylaws or any preferred stock, the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of these Bylaws.

ARTICLE X
INDEMNIFICATION AND INSURANCE

Section 10.1 RIGHT TO INDEMNIFICATION. Each person who was or is made a party or is threatened to be made a party to or is involved in any action, suit, claim or proceeding, whether civil, criminal, administrative or investigative (hereinafter a "*proceeding*"), by reason of the fact that he or she or a person of whom he or she is the legal representative is or was a director or officer of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans maintained or sponsored by the Corporation, whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent or in any other capacity while serving as a director, officer, employee or agent, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the Delaware General Corporation Law as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than said law permitted the Corporation to provide prior to such amendment), against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such person in connection therewith and such indemnification shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of his or her heirs, executors and administrators; provided, however, that except as provided in Section 10.4 of this Article X, the Corporation shall indemnify any such person seeking indemnification in connection with a proceeding (or part thereof) initiated by such person only if such proceeding (or part thereof) was authorized by the board of directors.

Section 10.2 ADVANCEMENT OF EXPENSES. The right to indemnification conferred in this Article X shall be a contract right and shall include the right to be paid by the Corporation the expenses incurred in defending any such proceeding in advance of its final disposition, such advances to be paid by the Corporation after receipt by the Corporation of a written statement or statements from the claimant requesting such advance or advances; provided, however, that if the Delaware General Corporation Law requires, the payment of such expenses incurred by a director or officer in his or her capacity as a director or officer (and not in any other capacity in which service was or is rendered by such person while a director or officer, including, without limitation, service to an employee benefit plan) in advance of the final disposition of a proceeding, shall be made only upon delivery to the Corporation of an undertaking by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified under this Article X or otherwise.

Section 10.3 OBTAINING INDEMNIFICATION. To obtain indemnification under this Article X, a claimant shall submit to the Corporation a written request, including therein or therewith such documentation and information as is reasonably available to the claimant and is reasonably necessary to determine whether and to what extent the claimant is entitled to indemnification. Upon written request by a claimant for indemnification pursuant to the first sentence of this Section 10.3, a determination, if required by applicable law, with respect to the claimant's entitlement thereto shall be made as follows: (1) if requested by the claimant, by Independent Counsel (as hereinafter defined), or (2) if no request is made by the claimant for a determination by Independent Counsel, (i) by the board of directors by a majority vote of a quorum consisting of Disinterested Directors (as hereinafter defined), or (ii) if a quorum of the board of directors consisting of Disinterested Directors is not obtainable or, even if obtainable, such quorum of Disinterested Directors so directs, by Independent Counsel in a written opinion to the board of directors, a copy of which shall be delivered to the claimant, or (iii) if a quorum of Disinterested Directors so directs, by the stockholders of the Corporation. In the event the determination of entitlement to indemnification is to be made by Independent Counsel at the request of the claimant, the Independent Counsel shall be selected by the board of directors unless there shall have occurred within two years prior to the date of the commencement of the action, suit or proceeding for which indemnification is claimed a Change in Control (as defined below), in which case the Independent Counsel shall be selected by the claimant unless the claimant shall request that such selection be made by the board of directors. If it is so determined that the claimant is entitled to indemnification, payment to the claimant shall be made within 30 days after such determination. If a claimant is successful, in whole or in part, in any suit brought against the Corporation to recover the unpaid amount of any written claim to indemnification, the claimant shall be entitled to be paid also the expense of prosecuting such claim.

Section 10.4 RIGHT OF CLAIMANT TO BRING SUIT. If a claim under Section 10.1 of this Article X is not paid in full by the Corporation within thirty days after a written claim pursuant to Section 10.3 of this Article X has been received by the Corporation, the claimant may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim and, if successful in whole or in part, the claimant shall be entitled to be paid also the expense of prosecuting such claim. It shall be a defense to any such action (other than an action brought to enforce a claim for expenses incurred in defending any proceeding in advance of its final disposition where the required undertaking, if any is required, has been tendered to the Corporation) that the claimant has not met the standard of conduct which makes it permissible under the Delaware General Corporation Law for the Corporation to indemnify the claimant for the amount claimed, but the burden of proving such defense shall be on the Corporation. Neither the failure of the Corporation (including its board of directors, Independent Counsel or stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because he or she has met the applicable standard of conduct set forth in the Delaware General Corporation Law, nor an actual determination by the Corporation (including its board of directors, Independent Counsel or stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that the claimant has not met the applicable standard of conduct.

Section 10.5 CORPORATION'S OBLIGATION TO INDEMNIFY. If a determination shall have been made pursuant to Section 10.3 of this Article X that the claimant is entitled to indemnification, the Corporation shall be bound by such determination in any judicial proceeding commenced pursuant to Section 10.4 of this Article X.

Section 10.6 PRECLUSION FROM CHALLENGING ARTICLE X. The Corporation shall be precluded from asserting in any judicial proceeding commenced pursuant to Section 10.4 of this Article X that the procedures and presumptions of this Article X are not valid, binding and enforceable and shall stipulate in such proceeding that the Corporation is bound by all the provisions of this Article X.

For purposes of this Article X:

(a) "*Change in Control*" shall be deemed to occur only if a majority of the members of the board of directors shall not be (i) individuals elected as directors of the Corporation for whose election proxies shall have been solicited by the board of directors of the Corporation or (ii) individuals elected or appointed by the board of directors of the Corporation to fill vacancies on the board of directors caused by death or resignation (but not by removal) or to fill newly created directorships.

(b) "*Disinterested Director*" means a director of the Corporation who is not and was not a party to the matter in respect of which indemnification is sought by the claimant.

(c) "*Independent Counsel*" means a law firm, a member of a law firm, or an independent practitioner, that is experienced in matters of corporation law and shall include any person who, under the applicable standards of professional conduct then prevailing, would not have a conflict of interest in representing either the Corporation or the claimant in an action to determine the claimant's rights under this Article X.

Section 10.7 NON-EXCLUSIVITY OF RIGHTS. The right to indemnification and the payment of expenses incurred in defending a proceeding in advance of its final disposition conferred in this Article X shall not be exclusive of any other right which any person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote of stockholders or otherwise. No repeal or modification of this Article X shall in any way diminish or adversely affect the rights of any director, officer, employee or agent of the Corporation hereunder in respect of any occurrence or matter arising prior to any such repeal or modification.

Section 10.8 INSURANCE. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another Corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the Delaware General Corporation Law. To the extent that the Corporation maintains any policy or policies providing such insurance, each such director or officer, and each such agent or employee to which rights to indemnification have been granted as provided in Section 10.9 of this Article X, shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage thereunder for any such director, officer, employee or agent.

Section 10.9 OTHER EMPLOYEES AND AGENTS. The Corporation may, to the extent authorized from time to time by the board of directors, grant rights to indemnification, and rights to be paid by the Corporation the expenses incurred in defending any proceeding in advance of its final disposition, to any employee or agent or class of employees or agents of the Corporation (including the heirs, executors, administrators or estate of each such person) to the fullest extent of the provisions of this Article X with respect to the indemnification and advancement of expenses of directors and officers of the Corporation.

Section 10.10 VALIDITY OF ARTICLE X. If any provision or provisions of this Article X shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Article X (including, without limitation, each portion of any paragraph of this Article X containing any such provision held to be invalid, illegal or unenforceable, that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby; and (b) to the fullest extent possible, the provisions of this Article X (including, without limitation, each such portion of any paragraph of this Article X containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.

ARTICLE XI
MISCELLANEOUS PROVISIONS

Section 11.1 FISCAL YEAR. The fiscal year of the Corporation shall be as fixed by the board of directors.

Section 11.2 DIVIDENDS. The board of directors may from time to time declare, and the Corporation may pay, dividends on its outstanding shares in the manner and upon the terms and conditions provided by law and the Certificate of Incorporation.

Section 11.3 EXCLUSIVE FORUM FOR SECURITIES ACT CLAIMS. Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated February 21, 2023, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Tactile Systems Technology, Inc. on Form 10-K for the year ended December 31, 2022. We consent to the incorporation by reference of said reports in the Registration Statements of Tactile Systems Technology, Inc. on Forms S-8 (File Nos. 333-212704, 333-216278, 333-223249, 333-236681, and 333-253449) and on Form S-3 (File No. 333-269287).

/s/ Grant Thornton LLP

Minneapolis, Minnesota
February 21, 2023

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel L. Reuvers, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tactile Systems Technology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Daniel L. Reuvers
Daniel L. Reuvers
Chief Executive Officer

Date: February 21, 2023

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brent A. Moen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tactile Systems Technology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Brent A. Moen
Brent A. Moen
Chief Financial Officer

Date: February 21, 2023

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Tactile Systems Technology, Inc. (the "Company") for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel L. Reuvers, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Daniel L. Reuvers
Daniel L. Reuvers
Chief Executive Officer

Date: February 21, 2023

Exhibit 32.2

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Tactile Systems Technology, Inc. (the "Company") for the period ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Brent A. Moen, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Brent A. Moen
Brent A. Moen
Chief Financial Officer

Date: February 21, 2023