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, 2018

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)	**1331 Tyler Street NE, Suite 200** **Minneapolis, Minnesota 55413** (Address and zip code of principal executive offices)	**41-1801204** (I.R.S. Employer Identification Number)

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

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

Common Stock, Par Value $0.001 Per Share (Title of each class)	**The Nasdaq Stock Market** (Name of each exchange on which registered)

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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. (Check one):

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 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 $52.00, the closing price of the shares of common stock on June 29, 2018 (the last business day of the registrant's most recently completed second fiscal quarter) as reported by the Nasdaq Global Market on such date, was $905,226,400.

The number of shares of registrant's Common Stock outstanding as of February 26, 2019 was 18,741,105.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Stockholders, scheduled to be held on May 9, 2019, 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. 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. 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," "target," "ongoing," "plan," "potential," "predict," "project," "should," "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 adequacy of our liquidity to pursue our complete business objectives;
- our ability to obtain reimbursement from third-party payers for our products;
- loss or retirement of key executives;
- adverse economic conditions or intense competition;
- loss of a key supplier;
- entry of new competitors and products;
- adverse federal, state and local government regulation;
- 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;
- price increases for supplies and components;
- 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 undertake no obligation to update or revise these forward-looking statements, even though our situation may change in the future. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

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 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 chronic diseases in the home setting to improve patient outcomes and quality of life and help control rising healthcare expenditures. We possess a unique, scalable platform to deliver at-home healthcare solutions directly to patients throughout the United States. This evolving home care delivery model is recognized by policy-makers 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 believe that our clinically proven, at-home treatment options for lymphedema and venous leg ulcers provide a continuity of care, service and support that improves outcomes, reduces costs and gives people their lives back.

We employ a direct-to-patient and -provider model, 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 in their homes. This model allows us to directly approach patients and clinicians, whereby we disintermediate the traditional durable medical equipment channel and capture both the manufacturer and distributor margins. For the year ended December 31, 2018, we generated revenues of $143.8 million and had net income of $6.6 million. Our revenues increased 32% during the year ended December 31, 2018 compared to the year ended December 31, 2017.

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). 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 system is a clinically proven at-home solution for patients with vascular disorders like lymphedema. Our proprietary Actitouch system is an ambulatory, home-based solution for chronic venous insufficiency patients that may be worn throughout the day. Our products deliver cost-effective, clinically proven, long-term treatment of chronic diseases. Patients with lymphedema or chronic venous insufficiency are typically treated by vascular surgeons, vascular medicine physicians, wound physicians, wound nurses and lymphedema therapists.

Our advanced at-home Flexitouch system provides effective automated, at-home lymphatic drainage therapy. Its patented, curved chambers stimulate the lymphatic system to remove excess fluid and reduce swelling. The pneumatic chambers sequentially inflate and deflate for only a few seconds each, creating a gentle wave-like application of pressure to stimulate the movement of lymphatic fluid and direct it towards properly functioning areas of the body. Peer-reviewed, published studies have shown that our Flexitouch system provides improved patient quality of life and clinical outcomes, and delivers significant cost savings to payers and patients. The first generation of our Flexitouch system received 510(k) clearance from the U.S. Food and Drug Administration, or the FDA, in July 2002 and our second-generation Flexitouch system received 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 in 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. Our Flexitouch system generated $131.9 million, or 92%, of our revenues in 2018, and

$100.3 million, or 92%, of our revenues in 2017.

Our Actitouch system provides precise, consistent and wearable compression that a patient may apply, remove and reapply at home. This system was developed to provide maximum convenience for patients by providing them with the freedom to remain active while simultaneously receiving the clinically proven benefits of sustained and intermittent pneumatic compression, which we refer to as dual-compression. Our Actitouch system received 510(k) clearance from the FDA in June 2013 and we began selling the product in September 2013. Due to a decrease in the demand for and sales volume of our Actitouch system, we plan to discontinue this product line in the second half of 2019, see "Our Products – Actitouch System" below for further discussion. We also introduced the Entre system in the United States in February 2013. The Entre system is sold to patients for whom a basic pump is suitable or who do not yet qualify for insurance reimbursement for an advanced compression device such as our Flexitouch system. Our Entre and Actitouch systems combined generated $11.8 million, or 8%, of our revenues in 2018, and $8.9 million, or 8%, of our revenues in 2017.

In October 2018, we licensed the intellectual property rights related to the Airwear Gradient Compression Wrap, or the Airwear wrap, in the U.S. and Canada, for use in all medical applications, including but not limited to swelling/edema and ulcers (including lymphedema and chronic venous insufficiency conditions), but excluding the use of the intellectual property in the field of prophylaxis for deep vein thrombosis. The Airwear wrap is indicated for the management of venous insufficiency, venous hypertension, venous ulcerations and lymphedema. Compression therapy is the standard of care for these conditions and the Airwear wrap works by delivering precise gradient compression to the lower leg. We plan to begin selling the Airwear wrap in the second half of 2019.

To support the growth of our business, we invest heavily in our commercial infrastructure, consisting of our direct sales force, 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 direct sales force is focused on increasing clinician awareness of our solutions and has grown to over 200 sales representatives as of December 31, 2018, compared to over 160 representatives as of December 31, 2017. We also utilize over 560 licensed, independent healthcare practitioners as home trainers who educate patients on the proper use of our solutions. Our Reimbursement Department, composed of over 70 employees, was reorganized in 2018 to improve operational efficiencies and enhance individual payer expertise, while continuing our strategic focus on payer development. The Reimbursement Department is now composed of our Payer Development and Reimbursement Operations groups. Our Payer Development group is composed of both strategic and analytical teams, with focus on payer decision-maker relationships and education, payer policy development and revision, payer contract negotiations, and payer data analysis. Our experienced Reimbursement Operations group is responsible for verifying patient insurance benefits, individual patient case development, prior authorization submissons, case follow-up, and appeals when necessary. Our clinical team, consisting of a scientific advisory board, in-house therapists and nurses, and a medical director (part-time), 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, physician and patient adoption of our technologies, and together with our commercial infrastructure, represent a significant competitive advantage.

Health insurance coverage for our Flexitouch, Entre and Actitouch 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 over 275 million lives in the United States. Over 120,000 patients have been treated with our Flexitouch system since its launch in 2004, and over 32,000 Flexitouch systems were shipped in 2018. More than 29,000 patients have been treated with our Entre and Actitouch systems since their launch in 2013, and over 8,000 Entre and Actitouch systems were shipped in 2018. We do not currently have any operations or sales outside the United States.

Overview of the Lymphedema and Chronic Venous Insufficiency Markets

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 decreased mobility, skin breakdown, pain, increased risk of serious infection and marked psychosocial impairment, resulting in significant negative implications for a patient's health and quality of life. 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 it 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

Chronic venous insufficiency 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. The disease 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 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 chronic venous insufficiency are costly and lifelong conditions with debilitating physical and psychological impacts on patients. We estimate that more than five million people in the United States are living with lymphedema. Based on an analysis of claims data commissioned by us, we estimated that approximately 1.1 million patients were diagnosed with lymphedema during the 12 months ended December 31, 2018. Based on a similar analysis of claims data commissioned by us, we estimated that there were approximately 700,000 patients diagnosed with lymphedema during the 12 months ended June 30, 2014. This represents a 10.6% average annual increase in the number of patients diagnosed with lymphedema over the period from June 30, 2014 to December 31, 2018. We estimate that the addressable market opportunity for our Flexitouch system exceeds $4.2 billion in the United States, which is based on the number of patients diagnosed with lymphedema and our average selling price per device.

We believe that chronic venous insufficiency, or CVI, afflicts approximately 3-11% of the U.S. population, and this percentage may rise due to the growing prevalence of obesity, cancer, and smoking, as well as an aging population. We estimate the addressable market opportunity for our Airwear wrap is in excess of 3.1 million patients in the United States, which is based on an analysis of claims data commissioned by us of patients diagnosed with CVI.

In the fourth quarter of 2016 we expanded the indications for 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 400,000 people in the United States suffer from cancers of the head and neck, and more than 60,000 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 will 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.

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 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. At that point, 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 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 chronic venous insufficiency is compression therapy. 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 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 and other activities. Treatment efficacy is inconsistent because bandages can lose their precise pressure between treatments. Patients use our Actitouch system to administer intermittent pneumatic compression therapy to assist with the circulation of blood through affected veins. Our Actitouch system provides precise, sustained and wearable compression that a patient may apply, remove and reapply at home, allowing patients to bathe, sleep comfortably and increase mobility. In a clinical study, our Actitouch system was shown to have comparable efficacy in healing venous leg ulcers and achieved higher patient quality of life scores as compared to multilayered bandages.

Our Strategy

Our goal is to become a leader in the at-home treatment of 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 and chronic venous insufficiency are undiagnosed or undertreated, and we intend to further educate physicians, wound nurses, lymphedema therapists, patients and payers 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. We intend to continue promoting this awareness through advertising campaigns, exhibiting at tradeshows and physician meetings, training and educating clinicians 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 venous and lymphatic diseases. 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.

- ***Expand our direct sales and customer support teams.*** We plan to expand our direct sales and marketing organization to drive greater product adoption by patients and their clinicians. We intend to strengthen our distribution network by continuing to recruit, train and retain talented sales representatives and increasing the number of licensed home trainers. With an expanded sales force, we believe we could target additional clinical call points.

- ***Introduce new features and products to grow our technology platform.*** We are actively exploring 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.*** Our products are covered under existing reimbursement codes, and we have secured coverage for our solutions with private 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.

- ***Introduce our solutions outside the United States.*** We currently sell our products only within the United States. While our plan is to continue to focus our direct sales efforts on penetrating the U.S. market, we plan to pursue future international expansion. We have European CE Mark approval for our current Flexitouch system. We also have a Medical Device License in Canada for our Flexitouch system.

Our Products

We market our Flexitouch, Entre and Actitouch systems, and we plan to market the Airwear wrap, as at-home therapies for the treatment of lymphedema and chronic venous insufficiency. 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 system is a fully automated, programmable, advanced pneumatic compression device designed for treatment of lymphedema in the home setting. Our Flexitouch system has received 510(k) clearance for the treatment of lymphedema, certain types of 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 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 one hour, with additional treatment options available if prescribed by a clinician.

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.

Actitouch System

We introduced our Actitouch system in the United States in September 2013. Our wearable Actitouch system combines intermittent pneumatic compression with sustained gradient compression to the lower leg and foot to improve and accelerate wound healing, as compared to the current standard of care, which involves sustained compression applied with compression wraps or multilayered bandages.

Actitouch consists of a compression sleeve, a control unit, an undersock and a power adapter/charger. The compression sleeve has four chambers that inflate to apply pressure to the leg, is designed with hook and loop fasteners to accommodate a wide range of leg shapes and sizes and may be worn under clothing and with most shoes. The control unit is concealed within the compression sleeve and monitors and adjusts the air pressure to ensure the correct level of compression is applied to the leg throughout the day. It offers a therapy tracker that monitors and displays average daily use to reinforce therapy goals. The undersock is designed to draw perspiration and moisture away from the skin and has padding in key areas to provide additional comfort. The system comes with a power adapter/charger that is used to power the device directly during intermittent pneumatic compression mode or to charge the battery for ambulatory use. The battery life allows the patient to wear the system all day without recharging.

Our Actitouch system operates in intermittent pneumatic compression mode or sustained compression mode. In sustained compression mode, the system provides sustained, graduated compression to the leg at preset pressures, and the compact, lightweight design gives patients the freedom to stay active while experiencing the benefits of a more comfortable compression therapy. The system ensures consistent compression regardless of variations in sleeve application, and monitors and adjusts pressure automatically every 30 minutes in response to changes in leg circumference. In intermittent pneumatic compression mode, the system performs cyclic inflation/deflation sequences to preset gradient pressures. Standard daily treatment involves two hours of intermittent compression while seated or reclining and 10 hours of sustained compression while active. The system is worn throughout the day and has the advantage of being removable for bathing or showering, changing primary bandaging, and when driving or operating machinery. The patient removes the system for sleep, allowing the battery to be recharged overnight.

We have observed a steady decrease in the demand for and sales volume of our Actitouch system over the past three years, reflecting a reduction in the overall future marketability of the product line. As a result, the current Actitouch system and corresponding product line will be discontinued in the second half of 2019. Due to the planned discontinuation of the current product line, we recorded a $2.5 million non-cash impairment charge to fully write off the inventory and intangible assets related to our Actitouch system. We believe the Airwear gradient compression wrap provides access to a larger population of patients with chronic venous insufficiency and does so earlier in their treatment pathway, while providing enhanced benefits as compared to the Actitouch system.

Airwear Gradient Compression Wrap

The Airwear Gradient Compression Wrap, or the “Airwear wrap”, was introduced in the United States in 2007, under the trade name Aero-Wrap, to provide precise compression from the foot up to the knee. The intellectual property rights related to the Airwear wrap are owned by Sun Scientific, Inc., or Sun Scientific. In October 2018, we entered into a license agreement with Sun Scientific pursuant to which we licensed certain intellectual property of Sun Scientific, including related to the Airwear wrap, in the U.S. and Canada, for use in all medical applications, including but not limited to swelling/edema and ulcers (including lymphedema and chronic venous insufficiency conditions), but excluding the use of the intellectual property in the field of prophylaxis for deep vein thrombosis.

The Airwear wrap is indicated for the management of venous insufficiency, venous hypertension, venous ulcerations and lymphedema. Compression therapy is the standard of care for these conditions and the Airwear wrap works by delivering sustained gradient compression to the lower leg. Compression helps by mechanically squeezing the leg to improve blood flow and fluid return, thereby reducing swelling and other associated symptoms. However, traditional static compression therapy products (e.g. stockings, competitive wraps, bandages, etc.) are often difficult to apply, require precise application to achieve the desired pressure and are generally not user-friendly, resulting in poor user compliance. By utilizing an easy to apply hook and loop fastening system on the Airwear wrap, patients do not need to struggle with stockings or bandages to receive the compression therapy they require. In addition, a unique and patented inflation system enables consistent and precise pressure to be applied without professional application. While our other products have certain reimbursement-related requirements that can delay the receipt of a prescription for them, the Airwear wrap is not subject to those additional reimbursement requirements and therefore can be prescribed by a healthcare provider at the time of a patient’s visit, or the Airwear wrap can be obtained by patients over-the-counter without a prescription. The Airwear wrap can also be added as a complementary therapy option to our

Flexitouch Plus and Entre systems by providing lower extremity compression that can be worn throughout the day.

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, 22 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.

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, manual 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<.001) and in the non-cancer-related lymphedema patients of 75% (from 28.8% to 7.3%; p<.001). The inpatient hospitalization rate declined 22% in the cancer-related group (from 2.7% to 2.1%; p=.63) and declined 54% in the non-cancer-related group (from 7.0% to 3.2%; p=.02). The manual therapy rate decreased 30% in the cancer-related lymphedema patients (from 35.6% to 24.9%; p=.001) and decreased 34% in the non-cancer-related lymphedema patients (from 32.3% to 21.2%; p=.001). In addition, outpatient hospital visits declined 29% in the cancer-related patients (from 58.6% to 41.4%; p<.001) and 40% in the non-cancer-related patients (from 52.6% to 31.4%; p<.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=.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<.001). Total costs per non-cancer-related lymphedema patients, excluding durable medical equipment costs, were reduced by 36% from $2,937 to $1,883 (p=.007). Outpatient hospital costs for the non-cancer patients declined by 65% from $1,726 to $606 (p<.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 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. 86% 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. 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 ($P = 0.257$).

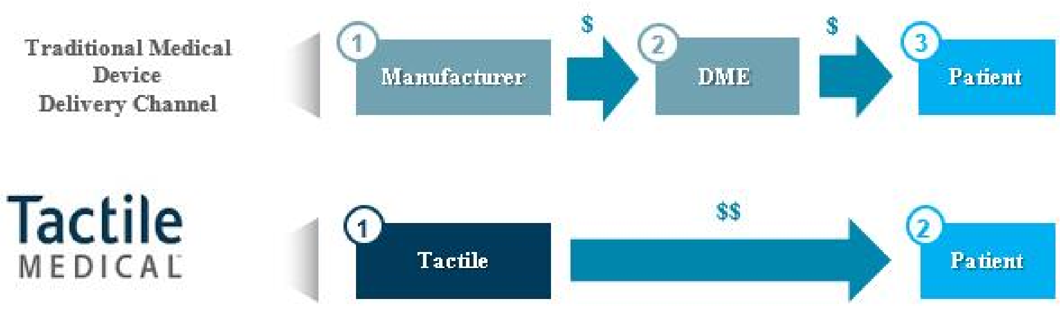
Comparison of Conventional Treatment for Venous Leg Ulcers with our Actitouch System

A prospective, randomized study published in the *International Wound Journal* demonstrated that our Actitouch system provides a comparable degree of effectiveness in venous leg ulcer healing to conventional treatment and an improved quality of life for patients. The study was conducted in the United States and Europe, involving a total of 90 patients over a 12-week period. The primary objective of the study was to evaluate the efficacy, functionality, safety, patient perceptions and impact on patient quality of life of two compression methods for venous leg ulcers, including our Actitouch system and a traditional four-layer bandage system. Of the 90 patients, 38 patients used our Actitouch system and 52 patients used a traditional four-layer bandage system.

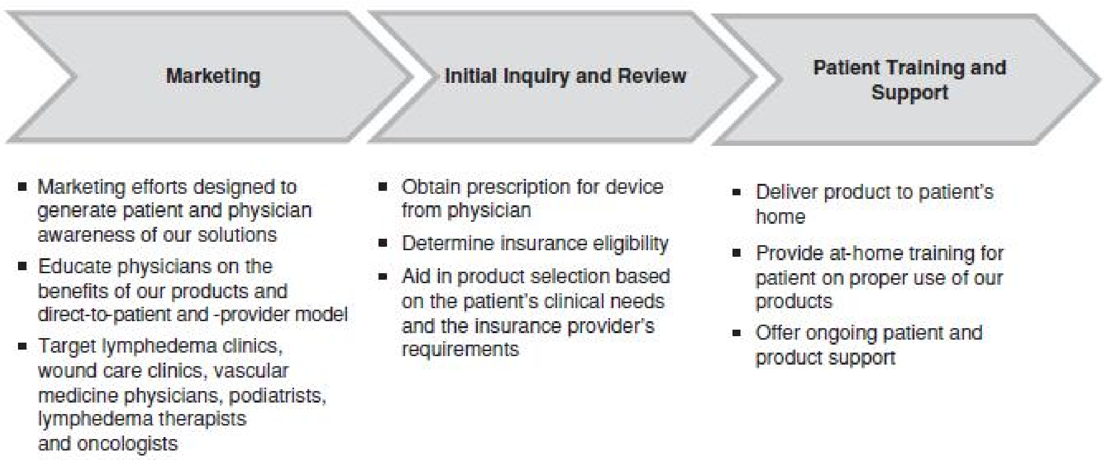
The study demonstrated a comparable degree of effectiveness in venous leg ulcer healing, with healing rate differences not reaching statistical significance. The type and frequency of adverse events reported were similar between the treatment groups and there were no serious adverse events related to treatment in either group. In addition to demonstrating a comparable degree of effectiveness in venous leg ulcer healing, this study also demonstrated that using our Actitouch system yielded greater improvements in quality of life as compared to those using the bandage system. The only area that our Actitouch system did not rate higher than the bandage system was discreteness under clothing.

Sales and Marketing

Unlike many of our competitors, we utilize a direct-to-patient and -provider model to market our solutions directly to patients and clinics, whereby we disintermediate the traditional durable medical equipment channel, providing high-quality customer service and capturing both the manufacturer and distributor margins. The below chart shows this disintermediation:



Our direct-to-patient and -provider model is composed of a direct sales force, contract at-home trainers, reimbursement capabilities and medical expertise to expand awareness, garner referrals and obtain payment for our products. As of December 31, 2018, we employed over 200 full-time sales representatives, including eight sales managers, who provide coverage throughout the United States. The below chart describes our U.S. direct-to-patient and -provider model.



Our marketing team leads our efforts in brand development, product messaging, tradeshow attendance, educational forums, website development, social media and advertising.

Reimbursement, Payer Relations and Customer Support Process

Private insurers and other payers represented approximately 71% and 74% of our revenues in 2018 and 2017, respectively, while Veterans Administration hospitals represented 20% and 18% of our revenues in 2018 and 2017, respectively, and Medicare represented approximately 9% and 8% of our revenues in 2018 and 2017, 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. Any policy, regulatory or legislative developments that eliminate or reduce reimbursement rates for our products could harm our ability to sell our products or cause increasing downward pressure on the prices of our products, either of which would negatively affect our ability to generate the revenues necessary to support our business. For example, changes to the level of Medicare coverage for our products could reduce the number of Medicare patients who have access to our products. Changes to, or repeal of, the Patient Protection and Affordable Care Act, or the ACA, could also potentially impact the number of patients who have access to our products.

As a nationwide provider, we have developed a broad expertise in obtaining billing codes, 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 Department, composed of over 70 employees, was reorganized in 2018 to improve operational efficiencies and enhance individual payer expertise, while continuing our strategic focus on payer development. The Reimbursement Department is now composed of our Payer Development and Reimbursement Operations groups. The Payer Development group is composed of both strategic and analytical teams with focus on payer decision-maker relationships and education, payer policy development and revision, payer contract negotiations, and payer data analysis. The Reimbursement Operations group, which is responsible for verifying patient insurance benefits, individual patient case development, prior authorization submissions, case follow-up and appeals when necessary, is organized into “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 over 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 ten years, and a greater than 90% Medicare claims submitted approval rate (post-arbitration and based on the number of claims, not dollar amount of claims, submitted across all our products) since 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 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 of care to enhance patient comfort, satisfaction, compliance and safety with our products.

Our Flexitouch Plus system controller is reimbursed under HCPCS code E0652, and our Actitouch system and Entre system controllers are 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 Airwear wrap is reimbursed under HCPCS code A6545. As of December 31, 2018, over 1,100 payers have paid for our products.

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 and chronic venous insufficiency. As of December 31, 2018, our research and development and clinical operations staff included more than 15 engineers, scientists, clinical monitors and project managers with expertise in trial management, pneumatics, electronics, garment design, embedded software, mechanical design, sensors and manufacturing technologies. Our research and development expenses, including spending on our clinical evidence development efforts, totaled $5.3 million and $5.1 million for the years ended December 31, 2018 and 2017, respectively. 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.

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 short 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 certain 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. As of December 31, 2018, we had over 45 employees in operations, manufacturing and quality assurance. Our quality management system has been certified to ISO in 2012, 2014 and 2017, including ISO 13485:2003. Many of our manufacturers' quality management systems also have been certified to ISO.

Order Fulfillment and Patient Education

Once we have a complete order and appropriate documentation from the payer, we package and ship a system, configured to their physician's prescription, directly to the patient. Our primary logistics partner is United Parcel Service, which we use for delivery and pick up of our devices. After delivery and when requested by our patient, we coordinate a visit from one of our over 560 licensed, independent contract trainers to provide education, clinical support or customer service. These trainers are healthcare professionals, licensed in their state of residence, who we have identified through our sales and marketing interest 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. Upon completion of the patient visit, the independent contractor submits an invoice to us for payment for the patient's training and their travel expenses.

Competition

The pneumatic compression pump market is composed of a number of manufacturers and distributors of pneumatic compression pumps. Our most significant manufacturing competitor is Bio Compression Systems, Inc. Other competitors are Lympha Press USA, Devon Medical Products, Inc. and NormaTec Industries. If we expand internationally, we expect that Arjo AB would become a competitor, in addition to other potential international competitors.

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 home medical equipment distribution intermediaries compresses their margins and limits their ability to invest in 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.

Some of our competitors and potential competitors are large, well-capitalized companies with greater resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we can. Some of these competitors have:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payers;
- established distribution networks;
- additional lines of products, the ability to offer rebates, bundle products to offer higher discounts or offer 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.

As a result, our current and future competitors may be able to find ways to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. Therefore, even if our technology and direct-to-patient and -provider marketing strategy is more effective than the technology and marketing strategy of our competitors, current or potential customers might accept competitor products and services in lieu of purchasing our products. We anticipate that 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. We may not be able to compete effectively against these organizations. 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. Increased competition in the future could adversely affect our revenues, revenue growth rate, margins and market share.

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. The FDA classifies medical devices into one of three classes — Class I, Class II or Class III — 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. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification and adherence to the FDA's Good Manufacturing Practices. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries, or post-market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general controls or if the device is a life-sustaining, life-supporting or a device of substantial importance in preventing impairment of human health, or which presents a potential, unreasonable risk of illness or injury and special controls are not adequate to assure safety and effectiveness.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Most Class II devices (and certain Class I devices that are not exempt) are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval or 510(k) de novo clearance prior to commercial marketing. The premarket approval process is more stringent, time-consuming and expensive than the 510(k) clearance process. However, the 510(k) clearance process has also become increasingly stringent and expensive.

510(k) Clearance Pathway 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." A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. 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. By law, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. 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. 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. We obtained 510(k) clearance for our Actitouch system in June 2013 and our Entre system in May 2015.

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.

The FDA has 45 days from its receipt of a premarket approval application to determine whether the application will be accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. After the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application and begin its in-depth review. The FDA has 180 days to review an "accepted" premarket approval application, although this process typically takes significantly longer and may require several years to complete. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. The FDA may delay, limit or deny approval of a premarket approval application for many reasons, including:

- 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.

If the FDA evaluations of both the premarket approval application and the manufacturing facilities are favorable, the FDA will either issue an approval order or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the premarket approval application. If the FDA's evaluation of the premarket approval application or manufacturing facilities is not favorable, the FDA will deny approval of the premarket approval application or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the premarket approval application. The FDA may also determine that additional clinical trials are necessary, in which case the premarket approval application may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the premarket approval application. Once granted, the premarket approval application may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

Clinical Trials Clinical trials are almost always required to support premarket approval and are sometimes required for 510(k) clearance. In the United States, these trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The FDA must approve the IDE in advance of trials for a specific number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements or the clinical investigation is exempt from the IDE regulations. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. We, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

FDA Ongoing Regulation 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.

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. The FDA requires each manufacturer to make this determination, but the FDA can review any such decision and can disagree with a manufacturer's determination. We have modified various aspects of our systems since receiving regulatory clearance, but we believe that new 510(k) clearances are not required for these modifications. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may retroactively require us to seek 510(k) clearance or premarket approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or premarket approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

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, refusing 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 product 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 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 Medicare supplier by the Accreditation Commission for Health Care for our solutions. Our Medicare accreditation must be renewed every three years through passage of an on-site inspection. We last renewed our accreditation with Medicare in May 2017. Maintaining our accreditation and Medicare enrollment requires that we comply with numerous business and customer support standards. If we are found to be 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. Although we believe we are in compliance with all applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could lose our licensure in that state, which could prohibit us from selling our current or future products to patients in that state. In addition, we are subject to certain state laws regarding professional licensure. We believe that our certified clinicians are in compliance with all such state laws. If our clinicians were to be found non-compliant in a given state, we would need to modify our approach to providing education, clinical support and customer service in such state.

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.

There are a number of safe harbors to the Federal Anti-Kickback Statute. Such safe harbors permit certain payments and business practices that, although they would otherwise potentially implicate the Federal Anti-Kickback Statute, are not treated as an offense under the same if the requirements of the specific applicable safe harbor are met.

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. Although we believe that we have structured such arrangements to be in compliance with the Anti-Kickback Statute and other applicable laws, regulatory authorities may determine that our marketing, pricing, or other activities violate the Federal Anti-Kickback Statute or other applicable laws. 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. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business, our financial condition and our results of 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. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these requirements are highly technical and there can be no guarantee that regulatory authorities will not determine or assert that our arrangements do not meet applicable Stark Law exceptions.

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, a 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 who has knowingly retained an overpayment. In addition, amendments in 1986 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.

Although we believe that we are in compliance with the Federal False Claims Act as well as the Civil Monetary Penalties laws, if we are found in violation of the same, penalties include fines ranging from $11,181 to $22,363 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 by physicians and other clinicians 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.

To the extent we are found to not be in compliance, we may be required to curtail or restructure our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business, our financial condition and our results of operations.

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). The FCPA also obligates companies with securities listed in the United States to comply with certain accounting provisions. Those provisions require a company such as ours to (i) maintain books and records that accurately and fairly reflect all transactions, expenses and asset dispositions, and (ii) devise and maintain an adequate system of internal accounting controls sufficient to provide reasonable assurances that transactions are properly authorized, executed and recorded. The FCPA is subject to broad interpretation by the U.S. government. The past decade has seen a significant increase in enforcement activity. In addition to the FCPA, there are a number of 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 the countries in which we conduct activities have their own domestic and international anti-corruption laws, such as the UK Bribery Act 2010. There have been cases where companies have faced multi-jurisdictional liability under the FCPA and the anti-corruption laws of other countries for the same illegal act.

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. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, financial condition and results of operations could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, financial condition and results of operations.

State and federal transparency/reporting requirements. As part of the 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 and certain ownership and investment interests held by physicians and their immediate family members. 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 following standards have been promulgated under HIPAA's regulations:

- the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of individually identifiable health information, or "protected health information";

- the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures;

- the Security Standards, which 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

- the breach notification rules, which 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.

In 2009, Congress passed the American Recovery and Reinvestment Act of 2009, or ARRA, which included sweeping changes to HIPAA, including an expansion of 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. 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 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, some 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 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. Although the costs to comply with applicable laws and regulations, including requirements in the European Union relating to the restriction of use of hazardous substances in products, have not been material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits. Also, we cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages and suspension of our operations.

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 and has promulgated voluntary 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 will be entitled to bear the CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. The method of assessing conformity varies depending on the type and class of the product, but typically involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system, technical or design file and specific testing of the manufacturer's device. Such an assessment may be required in order for a manufacturer to commercially distribute the product throughout these countries. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. We have the authorization to affix the CE Mark to our Flexitouch system and our Entre system and to commercialize these devices in the European Union. The notified body who inspected us issued our ISO 13485 certification in October 2014 and our EC-Certificate in December 2014.

In March 2012, we received our Medical Device License in Canada for our Flexitouch system. Before we are permitted to sell our devices in Canada, we must submit and obtain clearance of a license application, implement and comply with ISO Standard 13485, the Canadian Medical Device Regulations, and undergo an audit by a registrar accredited by Health Canada.

General Regulatory Compliance and Health Care Reform

The evolving regulatory and compliance environment and the need to build and maintain robust systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and administrative penalties, damages, fines, disgorgement, imprisonment, 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, any of which could adversely affect our ability to operate our business, financial condition and our results of operations.

In March 2010, the ACA was enacted into law in the United States. This healthcare reform, which included a number of provisions aimed at improving the quality and decreasing the cost of healthcare, has resulted in significant reimbursement cuts in Medicare payments to hospitals and other healthcare providers and in the healthcare reimbursement system, evolving toward value- and outcomes-based reimbursement methodologies. It is uncertain what long-term consequences these provisions will have on patient access to new technologies and what impacts these provisions will have on Medicare reimbursement rates. Other elements of the ACA, including comparative effectiveness research, an independent payment advisory board and payment systems reform, including shared savings pilots and other reforms, may result in fundamental changes to federal healthcare reimbursement programs. Changes to the ACA could impact the number of patients who have access to our products. Existing and additional legislative or administrative reforms, or any repeal of provisions, of the U.S. healthcare reimbursement systems may significantly reduce reimbursement or otherwise impact coverage for our medical devices, or adverse decisions relating to our products by administrators of such systems in coverage or reimbursement issues could have an adverse impact on our financial condition and results of operations.

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 has remained steady at 9% of revenue in 2018 compared to 8% in 2017.

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 both NCD and LCD 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 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.

On September 14, 2012, we completed an acquisition of certain assets, including inventory, equipment and tooling and patents for the Actitouch system and a technology known as SMM from ConvaTec, Inc. and ConvaTec Technologies, Inc., or the Sellers. In addition to $5.0 million of earlier payments, we were required to pay quarterly royalty payments to the Sellers through September 1, 2017 equal to 9% of sales for the Actitouch system and 7% of sales of SMM. For each quarterly calculation period beginning thereafter and ending on September 1, 2023, we are required to make quarterly payments to the Sellers equal to at least 6% of the sales of the Actitouch system and 5% of the sales of SMM. If Actitouch system and SMM sales in any calendar year beginning in 2018 exceed $40.0 million, the sales percentage amount relating to Actitouch system sales that we must pay shall equal 6% of the sales of the Actitouch system up to $40.0 million and 7% on the sales of the Actitouch system over $40.0 million.

Patents

Our patent portfolio consists of three sets of patents, including patents relating to our Flexitouch system, Actitouch system and other compression-related technologies, each of which is described in further detail below. As of December 31, 2018, we owned more than 150 issued patents globally, of which 27 were issued U.S. patents. As of December 31, 2018, we owned 65 patent applications pending globally, of which 27 were patent applications pending in the United States. Our U.S. issued patents have varying patent terms, expiring between 2022 and through at least 2033, subject to payment of required maintenance fees, annuities and other charges. U.S. patents covering various aspects of our Flexitouch system expired in 2017.

Flexitouch System Patent Family

Since 2014, many patent applications, including utility and design patent applications, have been filed in the U.S. and internationally, directed to various aspects, designs and functionality of the Flexitouch system. For example:

- In 2015, a patent application was filed internationally directed to compression garments using various configurations and types of tightening apparatus. A U.S. patent application claiming priority to the international application was filed in 2016 (U.S. Pub. No. 2017/0128306-A1).

- In 2016, multiple patent applications were filed in the U.S. and internationally directed to head and neck compression therapy (U.S. Pub. No. 2017/0095393-A1), head and neck compression garments (U.S. Pub. No. 2017/0095395-A1), and static and dynamic compression therapy (U.S. Pub. No. 2017/0095394-A1).

- In 2017 and 2018, multiple patent applications were filed in the U.S. and internationally directed to chest and arm compression garments (U.S. Pub. No. 2017/0258672-A1), therapy using head and torso compression garments and torso compression garments (U.S. Pub. No. 2017/0209332-A1), compression therapy fill processes, compression therapy graphical user interfaces, and trunk and leg compression garments and therapy.

- In 2018, multiple U.S. and international patents and patents applications were acquired from Wright Therapy Products directed to compression pump construction (U.S. Pat. No. 8,182,437 B2), fill and calibration processes (U.S. Pat. No. 8,202,236 B2 & U.S. Pub. No. 2013/0237889-A1), patient compliance (U.S. Pat. No. 9,889,063 B2), compression therapy processes, and garment construction.

Actitouch System Patents

The following is a summary of our patent families relating to our Actitouch system:

- On October 14, 2008, a "Medical Compress" patent directed to the ornamental aspects of the compression sleeve was issued (U.S. Design Pat. No. D578,652). Similar patents have been issued in Europe, Japan, Canada, Mexico, Australia, China and Taiwan.

- On June 22, 2010, a "Proximity Detection Apparatus" patent directed to control unit proximity detection allowing a different mode of operation was issued (U.S. Pat. No. 7,741,966). Similar patents have been issued in Japan, Canada, Mexico, China and Taiwan, and an application is pending in Europe.

- On March 22, 2011, a "Compression Device for the Limb" patent directed to the storage of data related to duration of use was issued (U.S. Pat. No. 7,909,786). Similar patents have been issued in Japan, Canada, Mexico, China, the United Kingdom, Germany, France, Ireland, Italy, Sweden and Taiwan.

- On May 24, 2011, a "Pressurized Medical Device" patent directed to the detection of malfunctioning pressure sensors was issued (U.S. Pat. No. 7,947,003). Similar patents have been issued in Japan, Canada, Mexico, China, Taiwan and Europe.

- On December 13, 2011, a "Relating to Socks" patent directed to a sock and compression device kit was issued (U.S. Pat. No. 8,075,507). Similar patents issued remain active in Japan, Mexico and Ireland.

- On July 23, 2013, a "Medical Compress" patent directed to the ornamental aspects of the compression sleeve and control unit was issued (U.S. Design Pat. No. D686,738). Similar patents have been issued in Europe, Canada, Mexico, Australia, China and Taiwan.

- On November 5, 2013, a "Compression Device for the Foot" patent directed to a Y-shaped foot wrap was issued (U.S. Pat. No. 8,574,180). Similar patents have been issued in Japan, Canada, China, the United Kingdom, Germany, France, Ireland, Sweden and Taiwan. A continuation application directed to the subject matter of this patent family issued in the United States as U.S. Patent No. 9,463,135. Another continuation application (U.S. Pub. No. 2017/0020770-A1) directed to the subject matter of this patent family is pending in the United States.

- On January 28, 2014, a "Compression Device for the Limb" patent directed to the compression sleeve configuration was issued (U.S. Pat. No. 8,636,679). Similar patents have been issued in Japan, Canada, Mexico and Taiwan, an application for similar subject matter is pending in Europe, and a continuation application (U.S. Pub. No. 2014/0128787) is pending in the United States.

- On March 8, 2016, a "Cuff for Providing Compression to a Limb" patent directed to a compression cuff including an abutting spacer configuration was issued (U.S. Patent No. 9,278,043). Similar patents have been issued in Japan, Canada, China, the United Kingdom, Germany, France, Ireland, Sweden and Taiwan.

- On January 10, 2017, a “Compression Device for the Limb” patent directed to a compression device including silent mode was issued (U.S. Pat. No. 9,539,166). Similar patents have been issued in France, Germany, Ireland, Sweden, and the United Kingdom. Another U.S. patent directed to the subject matter of this patent family has issued (U.S. Pat. No. 9,044,372), and a U.S. continuation application (U.S. Pub. No. 2017/0112709-A1) also directed to the subject matter of this patent family is pending.

Licensed Patents

In 2018, we licensed multiple U.S. and international patents and patent applications directed to static (continuous) leg compression therapy products from Sun Scientific, Inc.

Trademarks

We have registered the trademarks Flexitouch, the Flexitouch logo design and Actitouch with the United States Patent and Trademark Office on the Principal Register. We have filed an application to register the trademark Airwear in the United States. We rely in the United States on common law rights to the Entre, Tactile Medical and Tactile Medical design trademarks and have applied to register the Tactile Medical trademark in the United States, Australia, China, the European Union and Japan.

Seasonality

Our business is affected by seasonality. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Seasonality."

Employees

As of December 31, 2018, we had 499 employees, including 280 in sales and marketing; 123 in reimbursement and payer relations; 56 in manufacturing, quality assurance, and research and development; 32 in general administration, finance, information technology and human resources; and 8 in clinical research and operations. None of our employees are represented by a collective bargaining agreement. We believe that our employee relations are positive, as evidenced by our being selected as a Top Workplace in Minnesota by our employees for the last nine years.

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

Changes in United States or Chinese trade policy, including the imposition of tariffs and the resulting consequences, may have a material adverse impact on our business and results of operations.

The United States government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements. It has also initiated or is considering the imposition of tariffs on certain foreign goods, including certain raw materials that are included in our products, or on our products directly. Changes in U.S. trade policy could result in one or more of its trading partners adopting responsive trade policy 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 could result in increased costs for 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 lowering our margin on products sold.

China has announced a plan to impose tariffs on a wide range of U.S. products in retaliation for new U.S. tariffs. Additional tariffs could be imposed by China in response to proposed increased tariffs on products imported from China. There is also a concern that the imposition of additional tariffs by the United States, including the increases proposed for raw materials utilized in our products, or our products themselves, 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 revenues 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.

As of December 31, 2018, we are no longer an emerging growth company and, as a result, we now must comply with increased disclosure and compliance requirements which may increase our costs.

As a result of the market value of our common stock held by non-affiliates exceeding $700 million as of the last business day of our second fiscal quarter of 2018, we are deemed a large accelerated filer and we no longer qualify as an emerging growth company as of December 31, 2018. Accordingly, we are subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. These requirements include:

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;

- that we adopt new or revised accounting standards when they are applicable to public companies, instead of delaying their adoption until they are applicable to private companies;

- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- the requirement that we provide full and more detailed disclosures regarding executive compensation; and

- the requirement that we hold a non-binding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved.

We expect that the loss of emerging growth company status and compliance with the additional requirements of being a large accelerated filer will increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources.

We are incurring increased costs and are subject to additional regulations and requirements as a result of being a public company, which costs and requirements will increase in connection with us no longer qualifying as an emerging growth company, which could lower our profits or make it more difficult to run our business.

As a public company, we have incurred, and are continuing to incur, significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements and costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and Nasdaq. These expenses and costs will increase as we no longer qualify as an emerging growth company as of December 31, 2018. These expenses could lower our profits or make it more difficult to run our business.

Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

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 revolving 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 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 that 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.

Our revenues are primarily generated from our Flexitouch system and we are therefore highly dependent on only one product.

Our Flexitouch system accounted for 92% of our revenues for each of the years ended December 31, 2018 and 2017. We expect that sales of this product will continue to account for the substantial majority of our revenues 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 Flexitouch system 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 Flexitouch system. If our Flexitouch system fails to achieve wide market acceptance for any reason, our business, financial condition and results of operations could be adversely affected.

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 lymphedema and chronic venous insufficiency. In order to achieve this growth strategy, we must:

- increase clinician and consumer awareness of these diseases, which are often undertreated;
- 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 and chronic venous insufficiency 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 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 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 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, both in the United States and in international markets. 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.

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 revenues.

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 revenues from our Flexitouch system and, in fact, our revenues could be substantially reduced, causing a material adverse effect on our business.

If we are unable to expand, manage and maintain our direct sales and marketing organizations, we may not be able to generate anticipated revenues.

Our operating results are directly dependent upon the sales and marketing efforts of our employees. If our direct sales force fails to adequately promote, market and sell our products, our sales may suffer. Our direct sales force has grown from three representatives in March 2005 to a team of over 200 people as of December 31, 2018.

In order to generate future sales growth, we will need to expand the size and geographic scope of our direct sales organization. Accordingly, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales personnel with significant technical knowledge of lymphedema and chronic venous insufficiency. Because the competition for their services is high, we cannot assure you we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales personnel would prevent us from building awareness of our solutions, expanding our business and generating additional sales. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products, which could have an adverse impact on our business.

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 and are likely to remain constant or decrease due, in part, to federal and state government budgetary constraints. As a result, with respect to Medicare and Medicaid related revenues, 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. As such, we must control our operating costs, particularly labor and related costs, and failing to do so 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;
- 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, including no longer qualifying as an emerging growth company; and
- costs associated with entering 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 and chronic venous insufficiency or for market adjacencies. Any product we develop will have to compete for market acceptance and market share. We face significant competition in the United States, and we expect the intensity of competition will increase over time. Our primary competitors are Bio Compression Systems, Inc. and Lympha Press USA. Other competitors include Wright Therapy Products (which was acquired by BSN Medical GmbH in 2015), Devon Medical Products and NormaTec Industries. If we expand internationally, we expect that Arjo AB would become a competitor, in addition to other potential international competitors. 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.

Physicians and payers may require additional clinical studies prior to prescribing our products or 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 or chronic venous insufficiency. 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.

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. 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 an effective and dedicated sales and marketing team.

If we are unsuccessful in developing and commercializing new products, our ability to increase our revenues 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.

Our limited operating history and commercial experience make it difficult for us to predict future performance. A number of factors over which we have limited control, such as seasonal variations in revenues, may contribute to fluctuations in our financial results. In the first quarter, our results of operations typically have been negatively impacted by the resetting of annual patient healthcare insurance plan deductibles, which may cause patients to delay purchases of elective products. In the third and fourth quarters, our revenues typically have been higher because patients often spend the remaining balances in their flexible-spending accounts or because of lower out-of-pocket costs to patients who have met their annual deductibles under their health insurance plans. 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 revenues 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 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 revenues 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.

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 Actitouch systems and in our Airwear wrap. 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.

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.

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

At December 31, 2018, we had approximately $2.6 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 more than a year in most cases. At December 31, 2018, we classified $1.9 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, 2018, 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.

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 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 by physicians and other clinicians 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 payer relations group is responsible for verifying and managing patient claims. This group works with physicians and other clinicians to educate physicians and other clinicians on their record keeping responsibilities. From time to time our payer relations group identifies situations where the physician documentation could be questioned by Medicare or other insurers, and revises its procedures to strengthen our 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 physicians and other clinicians document the medical necessity support for prescribing our products, we could face potential liabilities for submitting claims based on inadequate records, even though those records are prepared and maintained by physicians and other clinicians.

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. For example, an LCD released in December 2015 added restrictive criteria that impacts Medicare coverage of our Flexitouch system and our Entre system for certain patients. Additional LCDs or changes in 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 on-going 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.

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 and chronic venous insufficiency. 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 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, which have become more complex since we no longer qualify as an emerging growth company as of December 31, 2018. 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.

Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock.

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, if cleared or approved, 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 revenues.

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 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.

Changes in reimbursement coding could impair our ability to receive reimbursement for our products.

Our Flexitouch Plus system controller is reimbursed under HCPCS code E0652, and our Actitouch system and Entre system controllers are 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 Airwear wrap is reimbursed under HCPCS code A6545. 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 with those physicians or patients 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 two locations 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, including, but not limited to, tornadoes, flooding, fire and power outages, 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, 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 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.

We may pursue acquisitions and our potential inability to successfully integrate newly acquired companies or businesses could adversely affect our financial results.

We may pursue acquisitions of other companies or their businesses in the future. If we complete acquisitions, we face many risks commonly encountered with growth through acquisitions. These risks include:

- 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;

- 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.

We are increasingly dependent on sophisticated information technology and if we fail to effectively maintain or protect our information systems or data, including from 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 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 and customer 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). Cyber-attacks, such as those involving the deployment of malware, are increasing in their frequency, sophistication and intensity and have become increasingly difficult to detect. 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;
- 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;
- incur expenses or lose revenues 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. If we or our third-party credit card payment processor fail to comply with these rules or requirements, we may be subject to fines and higher transaction fees and lose our ability to accept credit and debit card payments from our patients, and there may be an adverse impact on our business.

We have no experience selling our products outside of the United States and cannot predict if we will be successful in achieving adoption of our products and revenue growth outside of the United States in a timely manner or at all. 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.

We expect that we would be subject to additional risks related to entering into international markets, including:

- 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 revenues, 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;
- 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.

If we experience any of these risks, our strategy to expand internationally could be impacted and our future growth could be adversely affected.

Our employees, 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 and other third parties may engage in fraudulent conduct or other illegal activity. Misconduct by employees 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 precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, 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.

A reclassification of our independent contractor home trainers by tax authorities could require us to pay retroactive taxes and penalties, which could have a material adverse effect on our business, financial condition and operating results.

We contract with over 560 licensed healthcare practitioners as home trainers, who educate our patients on the proper use of our solutions. Because we consider these licensed practitioners to be independent contractors, as opposed to employees, 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. In the event federal or state taxing authorities determine that the healthcare practitioners are employees, our business may be adversely affected and subject to retroactive taxes and penalties. Under current federal tax law, a safe harbor from reclassification, and consequently retroactive taxes and penalties, is available if our current treatment is consistent with a long-standing practice of a significant segment of our industry and if we meet certain other requirements. If challenged, we may not prevail in demonstrating the applicability of the safe harbor to our operations. Further, in the future there could be changes to the laws and rules in this area, including new or different interpretations or guidance, or the modification or elimination of the safe harbor. Any such changes in the law, rules or safe harbor, or new or different interpretations or guidance, could impact our classification of healthcare practitioners as independent contractors, which 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 have been required to conduct a good faith reasonable country of origin analysis on our potential use of conflict minerals, which has imposed and may impose additional costs on us and could raise reputational and other risks.

The SEC has promulgated final rules in connection with the Dodd-Frank Wall Street Reform and Consumer Protection Act regarding disclosure of the use of certain minerals, known as conflict minerals, mined from the Democratic Republic of the Congo and adjoining countries. While the status of these rules is uncertain, we have incurred and will continue to incur costs associated with complying with these disclosure requirements, including costs to determine the source of any conflict minerals used in our products. We have adopted a policy relating to conflict minerals, incorporating the standards set forth in the Organization for Economic Co-operation and Development Due Diligence Guidance, which affects the sourcing, supply and pricing of materials used in our products. As we continue our due diligence, we may face reputational challenges if we are unable to verify the origins for all metals used in our products through the procedures we have and may continue to implement. We may also encounter challenges in our efforts to satisfy customers that may require all of the components of products purchased to be certified as conflict-free. If we are not able to meet customer requirements, customers may choose to disqualify us as a supplier.

Risks Relating to Government Regulation

We are subject to extensive federal and state regulation, and if we fail to comply with applicable regulations, we 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 each state to act as a durable medical equipment supplier.

As a healthcare provider participating in governmental healthcare programs, we are subject to laws 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. Government agencies or their contractors also periodically open investigations and obtain information from healthcare providers. 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 alters 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 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 marketing and direct sales force to not promote our products for uses outside of the FDA-cleared indications for use, known as "off-label uses." 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, 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. As noted above, 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. Similarly, in an effort to decrease costs, physicians may also reuse those of our products that are intended for a single use or may purchase reprocessed products from third-party reprocessors in lieu of purchasing new products from us, which could result in product failure and liability. As described immediately above, 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.

If we begin selling our products outside the United States, our products and 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.

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 future 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. 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.

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. The ACA, among other things, imposed a new excise tax on entities that manufacture, produce or import medical devices in an amount equal to 2.3% of the price for which such devices are sold in the United States. However, the Consolidated Appropriations Act of 2016 included a two-year moratorium on the medical device excise tax. Due to the moratorium, the medical device excise tax did not apply to the sale of a taxable medical device by the manufacturer, producer or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2017. Additionally, H.R. 195 (Pub. L. 115-120), signed into law on January 22, 2018, extended for an additional two years the moratorium on the medical device excise tax. Because of the moratorium, the medical device excise tax does not apply to the sale of taxable medical devices by the manufacturer, producer or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2019. While we believe that our current products will be exempt from this tax under an exemption for retail products when the moratorium ends, if our belief is determined to be incorrect, we could be subject to additional tax liabilities, which could have a material adverse effect on our results of operations and cash position. Moreover, products that we introduce or acquire in the future could be subject to this tax.

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. 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 revenues and profitability and the future revenues 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. 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 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, it is possible that 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. Any 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 HITECH, govern the collection, dissemination, security, use and confidentiality of patient-identifiable health 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 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.

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. If we begin selling our products outside the United States, we will need to comply with applicable laws in those jurisdictions that regulate the use and disclosure of individually identifiable information.

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 get a false claim paid. 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. We were recently served with a *qui tam* action, which alleges that we violated the Federal Anti-Kickback Statute and the Federal False Claims Act. See Item 3., “Legal Proceedings,” for additional information regarding this action.

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, it is possible that 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. 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 many 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 or our operations could harm our ability to operate our business and our financial results. Any 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 license and certification from the Accreditation Commission for Health Care. In May 2008, we became a Durable, Medical Equipment, Prosthetics, Orthotics, and Supplies accredited Medicare supplier by the Accreditation Commission for Health Care for our solutions and our Medicare accreditation must be renewed every three years through passage of an on-site inspection. We last renewed our accreditation with Medicare in May 2017. In addition to maintaining our Durable Medical Equipment license and 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 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.

For our products to be eligible for reimbursement by the Veterans Administration, we must participate in the Department of Veterans Affairs 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 Veterans Administration, our business, financial condition and results of operations could be adversely affected.

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.

Any future 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 these distributors experience delays in receiving necessary registrations or approvals to market our products outside the United States, or if they fail to receive those registrations or approvals, 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.

Risks Related to Our Financial Condition

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 existing cash and cash equivalents and revenues will be sufficient to meet our capital requirements and fund our operations indefinitely. 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 cost and effort associated with our relocation to a new corporate headquarters, which we expect will occur in the fourth quarter of 2019;
- the extent to which we acquire or invest in products, technologies and businesses; and
- the costs of operating as a public company and losing our emerging growth status.

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.

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 revenues.

The patents for our products have varying expiration dates and, if 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 revenues 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 respect to our patents and patent applications or those of our current or future collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Third-party claims of intellectual property infringement or misappropriation may adversely affect our business and could prevent us from developing or commercializing our products.

Our commercial success depends in part on us not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the medical device industry, including patent infringement lawsuits, interferences, oppositions, *ex-parte* review and *inter partes* reexamination and post-grant review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending 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 products 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 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 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 recently enacted and is currently implementing wide-ranging patent reform legislation. Further, several recent 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.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted, reviewed after issuance, and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third-party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours, even if we had made the invention before it was made by the third-party. This will require us to be cognizant, going forward, of the time from invention to filing of a patent application, but early filing of patent applications may not always be possible. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (a) file any patent application related to our products or (b) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid as unpatentable, even though the same evidence may be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action.

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.

We do not intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. In addition, our credit agreement contains terms restricting our ability to pay dividends on our common stock. Any return to stockholders will therefore be limited to any appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders purchased their shares.

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. Since we are a "large accelerated filer" as of December 31, 2018 and are no longer an "emerging growth company," our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting beginning with this Annual Report on Form 10-K. 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.

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 requirements for nominations for election to the board of directors 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;

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

- 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;

- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;

- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and

- we may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We lease approximately 52,000 square feet of office space for our current corporate headquarters in Minneapolis, Minnesota under a lease that expires in July 2021. We lease an additional 44,000 square feet of office, assembly and warehouse space at another leased facility in Minneapolis, Minnesota under a lease that expires in February 2024. We entered into a lease in October 2018 for approximately 110,000 square feet of office space for our future corporate headquarters in Minneapolis, Minnesota which will commence upon our move in the fourth quarter of 2019. That lease expires in February 2030. 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.

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.

On February 13, 2019, we were served with a sealed amended complaint venued in the United States District Court in the Southern District of Texas, Houston Division, captioned *United States ex rel Veterans First Medical Supply, LLC vs. Tactile Medical Systems Technology, Inc.,* Case No. 18-2871, which had been filed on January 23, 2019. The complaint is a *qui tam* action on behalf of the United States brought by one of our competitors. The United States has declined to intervene in this action. The complaint alleges that we violated the Federal Anti-Kickback Statute claiming that we submitted false claims and made false statements in connection with the Medicare and Medicaid programs, and that we engaged in unlawful retaliation in violation of the Federal False Claims Act. The complaint seeks damages, statutory penalties, attorneys' fees, treble damages and costs. We believe that the allegations in the lawsuit are without merit and we intend to vigorously defend against the lawsuit.

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 Global Market under the symbol "TCMD" since July 28, 2016.

Holders

As of February 19, 2019, there were approximately 46 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.

Use of Proceeds from Registered Securities

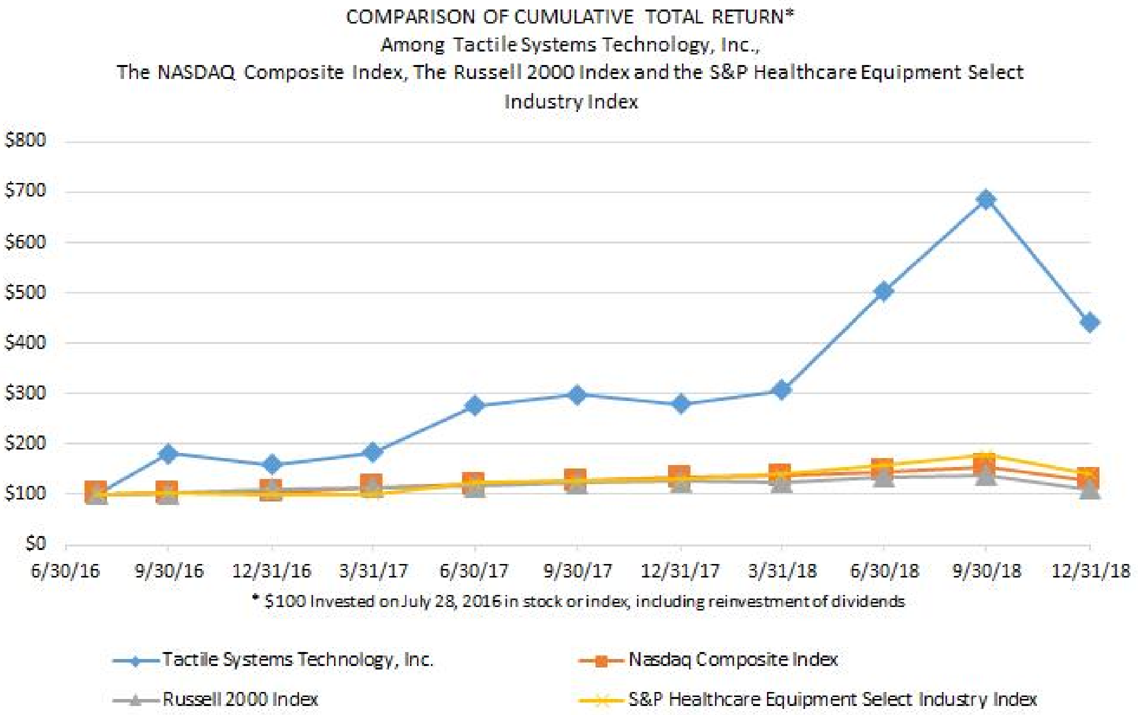
On August 2, 2016, we issued and sold 4,120,000 shares of our common stock in the initial public offering at a public offering price of $10.00 per share, for aggregate gross proceeds of $41.2 million. All of the shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-209115), which was declared effective by the SEC on July 27, 2016. Piper Jaffray & Co. and William Blair & Company, L.L.C. acted as joint book-running managers for the offering. The offering terminated on August 2, 2016.

The net offering proceeds to us, after deducting underwriting discounts of approximately $2.9 million and offering expenses paid by us totaling approximately $2.9 million, were approximately $35.4 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates. We also paid $8.2 million in cumulative accrued dividends to our Series A preferred stockholders from the issuance proceeds.

At December 31, 2018, the net proceeds from our initial public offering were held in a diversified portfolio of bank deposits, government money market funds, government securities (U.S. Treasury and U.S. government agency securities) and high-grade short-term corporate bonds. All investments were in compliance with our Investment Policy and are highly liquid, with liquidity and capital preservation being the primary investment objectives. There has been no material change in our planned uses of the net proceeds from those described in the Prospectus dated July 27, 2016.

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 July 28, 2016, 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.



	2016			2017				2018			
Index	Jul. 28	Sep. 30	Dec. 31	Mar. 31	Jun. 30	Sep. 30	Dec. 31	Mar. 31	Jun. 30	Sep. 30	Dec. 31
Tactile Systems Technology, Inc.	$ 100	$ 181	$ 159	$ 183	$ 276	$ 299	$ 280	$ 307	$ 502	$ 686	$ 440
Nasdaq Composite Index	100	103	105	115	119	126	134	137	146	156	129
Russell 2000 Index	100	103	111	114	116	122	126	125	135	139	111
S&P Healthcare Equipment Select Industry Index	100	104	100	100	123	126	130	141	159	178	142

Item 6. Selected Financial Data.

The following tables set forth our selected historical consolidated financial data as of and for the periods indicated. The selected consolidated statements of operations data for the years ended December 31, 2018, 2017, 2016, 2015 and 2014, and the selected consolidated balance sheet data as of December 31, 2018, 2017, 2016, 2015 and 2014 have been derived from our audited consolidated financial statements. Our historical results are not indicative of the results to be expected in the future. The following financial data should be read in conjunction with, and are qualified in their entirety by reference to, “Management's Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this report.

	Year Ended December 31,				
(In thousands, except share and per share data)	2018	2017	2016	2015	2014
Consolidated Statements of Operations Data:					
Revenues, net	$ 143,751	$ 109,283	$ 84,542	$ 62,872	$ 47,736
Cost of goods sold	41,493	29,015	22,940	16,908	12,715
Gross profit	102,258	80,268	61,602	45,964	35,021
Operating expenses					
Sales and marketing	60,371	44,396	33,794	24,485	18,154
Research and development	5,289	5,060	4,476	4,312	2,843
Reimbursement, general and administrative	33,608	26,914	19,060	13,716	10,225
Total operating expenses	99,268	76,370	57,330	42,513	31,222
Income from operations	2,990	3,898	4,272	3,451	3,799
Other income (expense)	486	292	38	(194)	(4)
Income before income taxes	3,476	4,190	4,310	3,257	3,795
Income tax (benefit) expense	(3,147)	(1,665)	1,431	1,864	1,725
Net income	6,623	5,855	2,879	1,393	2,070
Convertible preferred stock dividends	—	—	1,247	1,845	1,761
Allocation of undistributed earnings to preferred stockholders	—	—	—	—	216
Net income (loss) attributable to common stockholders	$ 6,623	$ 5,855	$ 1,632	$ (452)	$ 93
Net income (loss) per common share attributable to common stockholders[1]					
Basic	$ 0.36	$ 0.34	$ 0.18	$ (0.15)	$ 0.04
Diluted	$ 0.34	$ 0.31	$ 0.15	$ (0.15)	$ 0.02
Weighted-average common shares used to compute net income (loss) per common share attributable to common stockholders					
Basic	18,252,689	17,355,175	8,913,042	2,929,438	2,491,108
Diluted	19,347,632	18,877,863	10,758,684	2,929,438	3,797,688

(In thousands)	At December 31, 2018	2017	2016	2015	2014
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 20,099	$ 23,968	$ 30,701	$ 7,060	$ 5,416
Working capital	68,885	62,353	50,440	19,858	18,927
Total assets	107,071	88,447	73,935	36,973	31,494
Total debt	—	—	—	—	13
Convertible preferred stock	—	—	—	32,927	21,082
Retained earnings (accumulated deficit)	9,705	3,082	(2,773)	(5,652)	(6,872)
Total stockholders' equity (deficit)	89,270	72,787	59,639	(5,649)	(6,427)

(1) Net income (loss) per common share attributable to common stockholders was calculated under the two-class method prior to our initial public offering in 2016, as our convertible preferred stock participated in our undistributed earnings prior to our initial public offering. The two-class method requires earnings for the period to be allocated based upon their respective rights to receive distributed and undistributed earnings. No adjustment is made during periods with a net loss, as the holders of the convertible preferred stock have no obligation to fund losses.

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.

Overview

We are a medical technology company that develops and provides innovative medical devices for the treatment of 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 chronic diseases in the home setting to improve patient outcomes and quality of life and help control rising healthcare expenditures. Our initial area of therapeutic focus is vascular disease, with a goal of advancing the standard of care in treating lymphedema and chronic venous insufficiency. 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 policy-makers 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 proprietary products are the Flexitouch, Entre, and Actitouch 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. We derive the vast majority of our revenues from our Flexitouch system. Sales of our Flexitouch system represented 92% of our revenues in each of the years ended December 2018 and 2017.

In September 2012, we acquired our second proprietary product, the Actitouch system. The system received 510(k) clearance from the FDA in June 2013 and we began selling the product in September 2013 to address the many limitations of multilayered bandages that are worn by patients suffering from venous leg ulcers. We also introduced our Entre system in the United States in February 2013. The Entre system is sold to patients who need a more basic pump or who do not yet qualify for insurance reimbursement for an advanced compression device such as our Flexitouch system. For the years ended December 31, 2018 and 2017, sales of our Entre and Actitouch systems combined represented 8% of our revenues. During fiscal year 2018, we recorded a $2.5 million non-cash impairment charge to fully impair the inventory and intangible assets related to our Actitouch system, and we intend to discontinue this product line in the second half of 2019. See Note 3 - "Summary of Significant Accounting Policies" to the consolidated financial statements in this report for more information regarding this impairment charge and discontinuation.

In October 2018, we licensed the intellectual property rights related to the Airwear Gradient Compression Wrap, or the Airwear wrap, in the U.S. and Canada, for use in all medical applications, including but not limited to swelling/edema and ulcers (including lymphedema and chronic venous insufficiency conditions), but excluding the use of the intellectual property in the field of prophylaxis for deep vein thrombosis. The Airwear wrap is indicated for the management of venous insufficiency, venous hypertension, venous ulcerations and lymphedema. We plan to begin selling the Airwear wrap in the second half of 2019.

To support the growth of our business, we invest heavily in our commercial infrastructure, consisting of our direct salesforce, home training resources, reimbursement capabilities and clinical expertise. We market our products in the United States using a direct-to-patient and -provider model. Our direct salesforce has grown to a team of over 200 employees as of December 31, 2018, compared to over 160 employees as of December 31, 2017. This model allows us to directly approach patients and clinicians, whereby we disintermediate the traditional durable medical equipment channel, allowing us to capture both the manufacturer and distributor margins. We also utilize over 560 licensed, independent healthcare practitioners as home trainers who educate patients on the proper use of our systems. We invest substantial resources in our Reimbursement Department, which was reorganized in 2018 to improve operational efficiencies and enhance individual payer expertise, while continuing our strategic focus of payer development. The Reimbursement Department, composed of over 70 employees, now consists of our Payer Development and Reimbursement Operations groups. Our Payer Development group is composed of both strategic and analytical teams, with focus on payer decision-maker relationships and education, payer policy development and revision, payer contract negotiations, and payer data analysis. Our experienced Reimbursement Operations group is responsible for verifying patient insurance benefits, individual patient case development, prior authorization submissons, case follow-up, and appeals when necessary. We also have a clinical team, consisting of a scientific advisory board, in-house therapists and nurses, and a medical director (part-time), that serves as a resource to clinicians and patients and guides the development of clinical evidence in support of our products.

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 Flexitouch system, perform quality assurance, and ship our products from our facility in Minneapolis, Minnesota.

For the year ended December 31, 2018, we generated revenues of $143.8 million and had net income of $6.6 million, compared to revenues of $109.3 million and net income of $5.9 million for the year ended December 31, 2017, and revenues of $84.5 million and net income of $2.9 million for the year ended December 31, 2016.

Our primary sources of capital to date have been from operating income and private placements of our capital stock, as well as our initial public offering, which closed on August 2, 2016.

In August 2017, we filed a shelf registration statement on Form S-3 with the SEC. Under the shelf registration statement, we may offer and sell from time to time up to $200 million of common stock, preferred stock, debt securities, warrants, rights or units. The shelf registration statement also registered for resale from time to time up to 5,703,534 shares of our common stock held by the selling stockholders named therein. In September 2017, certain of the selling stockholders completed a secondary offering of 3,795,000 shares of our common stock at a public offering price of $33.00 per share. We did not receive any proceeds from the sale of the shares by the selling stockholders.

We operate in one segment for financial reporting purposes.

Components of our Results of Operations

Revenues

We derive our revenues from the sale of our Flexitouch, Entre and Actitouch 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 and Actitouch systems 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 revenues.

Our revenues have fluctuated, and we expect our revenues to continue to fluctuate, from quarter to quarter due to a variety of factors. For instance, our fourth quarter is consistently our strongest quarter of the year. 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 revenues are impacted by fluctuations in the mix of products being sold during each period and changes in the mix of our payers and contract pricing.

We sell our products 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 of our product on behalf of the patient. Approximately 20% of our revenues in 2018 and 18% of our revenues in 2017 came from the Veterans Administration. Approximately 9% of our revenues in 2018 and 8% of our revenues in 2017 came from Medicare patients. Changes to the level of Medicare coverage for our products, including the 2015 LCD modification to the criteria for Medicare coverage, 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 expect our revenues to continue to increase in the future as a result of increased awareness of our solutions, expansion of our direct sales force, enhanced marketing and customer support efforts, continued focus on developing clinical and economic outcomes data, expanded third-party reimbursement and introduction of our solutions outside the United States. We also anticipate pricing pressure from commercial insurance payers, which will result in continued downward pressure on our revenue growth rate.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of component costs, direct labor, overhead costs, product warranties, provisions for slow-moving and obsolete inventory, delivery costs for items sold, and amortization related to the intangible assets we licensed from Sun Scientific Inc. A significant portion of our cost of goods sold consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for product tooling, production equipment and shipping costs. We expect overhead costs as a percentage of revenues to decrease as a result of expected increases in production volume and yields. We expect cost of goods sold to increase in absolute dollars primarily if, and to the extent, our revenues grow.

We provide a warranty on our device controllers ranging from one to two years for commercially insured patients and five years for Medicare patients, as required by CMS. We also provide replacement garments to our patients for up to five years after purchase. We establish a reserve for warranty claims based on historical warranty repair and replacement costs incurred. Provisions for warranty obligations, which are included in cost of goods sold, are recorded at the time of shipment.

We calculate gross margin as gross profit divided by revenues. 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. In 2018, our gross margin was also impacted by a $0.7 million inventory write-off related to the impairment of our Actitouch assets. In addition, the up-front payment we made under our license agreement with Sun Scientific Inc. will also be amortized as a cost of goods sold. We expect our gross margin to decrease slightly over the near term as we experience pricing pressure from third-party payers. We continue to work to reduce product manufacturing cost 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 support our direct-to-patient and -provider model. These expenses consist primarily of personnel-related expenses, including salaries, bonuses, commissions and benefits for employees. They also include expenses for patient home 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 revenues grow, we expect sales and marketing expenses to decrease as a percentage of revenues 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 in absolute dollars 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 revenues to vary over time depending on the level and timing of initiating new product development efforts, as well as our clinical trial activities.

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. Our experienced Reimbursement Department of over 70 employees consists of our Payer Development and Reimbursement Operations groups. Our Payer Development group focuses on payer decision-maker relationships and education, payer policy development and revision, payer contract negotiations, and payer data analysis. Our Reimbursement Operations group focuses on verifying patient insurance benefits, individual patient case development, prior authorization submissons, case follow-up, and appeals when necessary. 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 and insurance costs. We expect to continue to incur additional legal, accounting, insurance and other professional service fees associated with being a public company, which may increase further now that we are no longer an emerging growth company, as defined under the JOBS Act. In 2018, our reimbursement, general and administrative expense was impacted by a $1.8 million intangible asset impairment charge related to our Actitouch assets.

Other Income (Expense), Net

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

Income Tax (Benefit) Expense

Our income tax (benefit) expense 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 Policies and Significant 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, revenues 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.

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 policies, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue Recognition

We derive revenue from the sales and rentals of our products, which consist of our proprietary line of Flexitouch, Entre and Actitouch systems.

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 of a product is recognized upon shipment, unless circumstances dictate that control has not yet passed to the customer.

We provide a warranty for our 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 sales of our products represent a single performance obligation that is satisfied at a point in time and are 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 distribute our 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 revenues 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 Actitouch and 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 thereupon 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 our products 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 private insurers and other payers, Medicare, and the Veterans Administration directly for purchase 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 revenues 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. Patients may return the product before the end of the rental period, and as such these arrangements are deemed to be month-to-month cancelable leases in accordance with Accounting Standards Codification, or ASC 840, "Leases," through December 31, 2018. Accordingly, we recognize the related revenue for these rental arrangements monthly, on a pro rata basis, over the lesser of the duration of the rental period or the period during which the patient possesses the product.

Accounts Receivable, Net

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

Accounts receivable are recorded at 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.

Stock-Based Compensation

We account for stock-based compensation awards at the fair value on the date of grant, expensed over the applicable vesting period. The fair value of options on the grant date is estimated using the Black-Scholes option-pricing 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 Black-Scholes option-pricing model requires 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. Our expected volatility is derived using the average historical volatility of public companies of similar size and industry because we believe the expected volatility will approximate historical volatility, due to the fact that we had no trading history prior to our initial public offering.

- *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.

The following table sets forth the estimated fair values of our stock options granted in the years ended December 31, 2018, 2017 and 2016, and the assumptions on which they were based:

	2018	2017	2016
Expected term	4 - 6 years	4 - 6 years	4 - 6 years
Expected volatility	42.7 - 43.4%	43.5 - 45.9%	43%
Risk-free interest rate	2.6 - 3.1%	1.7 - 2.3%	1%
Expected dividend yield	0%	0%	0%
Fair value on the date of grant	\$12.46 - \$29.07	\$7.82 - \$16.23	\$3.48 - \$7.16

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 goods sold, 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, 2018, 2017 and 2016. We will continue to use significant judgment in evaluating the expected term, volatility and forfeiture rate related to our stock-based compensation.

Prior to our initial public offering, the fair value of the common stock underlying our equity compensation awards was historically determined by our board of directors, with input from management and third-party valuations on an annual basis. Given the absence of a public trading market for our common stock prior to our initial public offering, our board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series: *Valuation of Privately Held Company Equity Securities Issued as Compensation*, known as the AICPA Accounting and Valuation Guide. The following factors, among others, were considered:

- our results of operations, history of losses and other financial metrics;
- our capital resources and financial condition;
- the contemporaneous valuations of our common stock by an unrelated third-party valuation firm;
- the prices of our convertible redeemable preferred stock sold to outside investors in arms-length transactions;
- the rights, preferences and privileges of our preferred stock relative to those of our common stock;
- the rights of freestanding warrants and other similar instruments related to our securities that are redeemable;
- the hiring of key personnel;
- the introduction of new products;
- the fact that the common stock underlying the option grants involves illiquid securities in a private company;
- the risks inherent in the development and expansion of our products and services; and
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, given prevailing market conditions.

In valuing our common stock, from January 1, 2014, until our initial public offering, our board of directors determined the equity value of our business using the market approach valuation method and the income approach valuation method to determine the enterprise value. For 2014, our board of directors exclusively used the market approach valuation method. For 2015, these two approaches were initially weighted equally. During 2015, we received a summary valuation from the lead underwriters for our initial public offering. In the second half of 2015 we reviewed our fair value determinations for 2015, effectively modifying our valuation approach for 2015 to include this summary valuation as a third factor in determining fair value, along with the other approaches previously considered. Our board of directors then considered the factors set forth above in reaching its determination of the fair value.

Since our initial public offering, we determine the fair value of our common stock based on the closing market price on The Nasdaq Global Market on the date of grant.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

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

(In thousands)	Year Ended December 31, 2018		Year Ended December 31, 2017		Change $	Change %
Condensed Consolidated Statement of Operations Data:		% of revenue		% of revenue		
Revenues	$ 143,751	100 %	$ 109,283	100 %	$ 34,468	32 %
Cost of goods sold	41,493	29 %	29,015	27 %	12,478	43 %
Gross profit	102,258	71 %	80,268	73 %	21,990	27 %
Operating expenses						
Sales and marketing	60,371	42 %	44,396	40 %	15,975	36 %
Research and development	5,289	4 %	5,060	5 %	229	5 %
Reimbursement, general and administrative	33,608	23 %	26,914	25 %	6,694	25 %
Total operating expenses	99,268	69 %	76,370	70 %	22,898	30 %
Income from operations	2,990	2 %	3,898	3 %	(908)	(23)%
Other income	486	— %	292	— %	194	66 %
Income before income taxes	3,476	2 %	4,190	3 %	(714)	(17)%
Income tax benefit	(3,147)	(3)%	(1,665)	(2)%	(1,482)	89 %
Net income	$ 6,623	5 %	$ 5,855	5 %	$ 768	13 %

Revenues

Revenues increased $34.5 million, or 32%, to $143.8 million in the year ended December 31, 2018, compared to $109.3 million in the year ended December 31, 2017. The growth in revenues was attributable to an increase of approximately $31.6 million, or 31%, in sales of our Flexitouch system and an increase of approximately $2.9 million, or 32%, in sales of our Entre and Actitouch systems in the year ended December 31, 2018. The increase in Flexitouch system sales was largely driven by expansion of our sales force, increased volume due to a new contract with a large private insurer, the launch of the Flexitouch Plus product, our third-generation Flexitouch product, and sales growth in the Veterans Administration channel. The increase in Entre and Actitouch systems sales was largely driven by our creation of a separate inside sales team. The inside sales team is dedicated to selling the Entre and Actitouch systems, allowing us to focus on selling these systems more efficiently.

The following table summarizes our revenues by product for the years ended December 31, 2018, and December 31, 2017, both in dollars and percentage of total revenues:

(In thousands)	Year Ended December 31, 2018	Year Ended December 31, 2017	Change $	Change %
Revenues				
Flexitouch system	$ 131,935	$ 100,344	$ 31,591	31 %
Entre/Actitouch systems	11,816	8,939	2,877	32 %
Total	$ 143,751	$ 109,283	$ 34,468	32 %
Percentage of total revenues				
Flexitouch system	92 %	92 %		
Entre/Actitouch systems	8 %	8 %		
Total	100 %	100 %		

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $12.5 million, or 43%, to $41.5 million during the year ended December 31, 2018, compared to $29.0 million during the year ended December 31, 2017. The increase in cost of goods sold was primarily attributable to an increase in the number of systems sold, additional manufacturing headcount to support increased volumes, incremental manufacturing costs specific to the introduction of the Flexitouch Plus, and the $0.7 million write-off of Actitouch inventory. Gross margin was 71% and 73% for the years ended December 31, 2018 and 2017, respectively. The decrease in gross margin was primarily attributable to lower pricing under a new contract with a large private insurer.

Sales and Marketing Expenses

Sales and marketing expenses increased $16.0 million, or 36%, to $60.4 million during the year ended December 31, 2018, compared to $44.4 million during the year ended December 31, 2017. The increase was driven by a $5.4 million increase in variable sales compensation expense, a $4.7 million increase in personnel-related compensation expense due to higher sales and marketing headcount, a $4.2 million increase in travel and entertainment, recruitment, consulting, and patient training costs, and $1.7 million of incremental stock-based compensation expense.

Research and Development Expenses

R&D expenses increased $0.2 million, or 5%, to $5.3 million during the year ended December 31, 2018, compared to $5.1 million during the year ended December 31, 2017. The increase in R&D expenses was primarily attributable to a $0.2 million increase in clinical studies, consulting and product development costs, including those related to the development of our Flexitouch Plus.

Reimbursement, General and Administrative Expenses

Reimbursement, general and administrative expenses increased $6.7 million, or 25%, to $33.6 million during the year ended December 31, 2018, compared to $26.9 million during the year ended December 31, 2017. The increase in reimbursement, general and administrative expenses for the year ended December 31, 2018, was primarily attributable to a $2.5 million increase in personnel-related expenses, resulting from increased headcount in our reimbursement operations, payer relations, patient services and corporate functions, a $1.9 million increase in stock-based compensation expense, an impairment charge of $1.8 million due to the determination that the carrying amount of the intangible assets related to our Actitouch system would not be recoverable, a $1.3 million increase in other operating expenses, including facilities, depreciation and service charges and an increase of $0.2 million in professional fees, legal, accounting, audit and tax expenses and software fees, which were partially offset by a decrease of $0.8 million in accrued sales and use and franchise taxes due to one-time related sales and use taxes in 2017.

Other Income (Expense), Net

Other income, net was $0.5 million for the year ended December 31, 2018, compared to $0.3 million for the year ended December 31, 2017. The increase in other income was due to investment income earned on the capital derived from our initial public offering proceeds.

Income Tax Benefit

We recorded an income tax benefit of $3.1 million and $1.7 million for each of the years ended December 31, 2018 and 2017, respectively. The current year tax benefit was primarily due to a significant increase related to tax-deductible share-based compensation activity, as compared with the previous year. This activity included vesting of restricted stock units, excess tax benefits associated with exercises of non-qualified stock options, and disqualifying dispositions of incentive stock options and employee stock purchase plan, or ESPP, shares. The prior year income tax benefit was partially offset by approximately $1.2 million of incremental tax expense associated with revaluation of our deferred tax assets and liabilities, resulting from the enactment of the Tax Cuts and Jobs Act in December 2017. The net income tax benefit in the current year resulted in a significant increase in our net income for the year ended December 31, 2018.

Comparison of the Years Ended December 31, 2017 and 2016

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

(In thousands)	Year Ended December 31, 2017		2016		Change $	%
Condensed Consolidated Statement of Operations Data:		% of revenue		% of revenue		
Revenues	$ 109,283	100 %	$ 84,542	100 %	$ 24,741	29 %
Cost of goods sold	29,015	27 %	22,940	27 %	6,075	26 %
Gross profit	80,268	73 %	61,602	73 %	18,666	30 %
Operating expenses						
Sales and marketing	44,396	40 %	33,794	40 %	10,602	31 %
Research and development	5,060	5 %	4,476	5 %	584	13 %
Reimbursement, general and administrative	26,914	25 %	19,060	23 %	7,854	41 %
Total operating expenses	76,370	70 %	57,330	68 %	19,040	33 %
Income from operations	3,898	3 %	4,272	5 %	(374)	(9)%
Other income	292	— %	38	— %	254	N.M.
Income before income taxes	4,190	3 %	4,310	5 %	(120)	(3)%
Income tax (benefit) expense	(1,665)	(2)%	1,431	2 %	(3,096)	N.M.
Net income	$ 5,855	5 %	$ 2,879	3 %	$ 2,976	103 %

N.M. (not meaningful)

Revenues

Revenues increased $24.7 million, or 29%, to $109.3 million in the year ended December 31, 2017, compared to $84.5 million in the year ended December 31, 2016. The growth in revenues was attributable to an increase of approximately $26.9 million, or 37%, in sales of our Flexitouch system in the year ended December 31, 2017. The increase in Flexitouch system sales was largely driven by expansion of our sales force and increased physician and patient awareness of the treatment options for lymphedema, as well as increased contractual coverage with national and regional insurance payers. The increase in sales of our Flexitouch system were partially offset by a decrease of 20% in sales of our Entre and Actitouch systems in the year ended December 31, 2017.

The following table summarizes our revenues by product for the years ended December 31, 2017 and December 31, 2016, both in dollars and percentage of total revenues:

(In thousands)	Year Ended December 31, 2017	2016	Change $	%
Revenues				
Flexitouch system	$ 100,344	$ 73,413	$ 26,931	37 %
Entre/Actitouch systems	8,939	11,129	(2,190)	(20)%
Total	$ 109,283	$ 84,542	$ 24,741	29 %
Percentage of total revenues				
Flexitouch system	92 %	87 %		
Entre/Actitouch systems	8 %	13 %		
Total	100 %	100 %		

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $6.1 million, or 26%, to $29.0 million during the year ended December 31, 2017, compared to $22.9 million during the year ended December 31, 2016. The increase in cost of goods sold was primarily attributable to an increase in the number of systems sold and additional manufacturing headcount to support increased volumes. Gross margin for each of the years ended December 31, 2017 and 2016, was 73%.

Sales and Marketing Expenses

Sales and marketing expenses increased $10.6 million, or 31%, to $44.4 million during the year ended December 31, 2017, compared to $33.8 million during the year ended December 31, 2016. The increase was primarily driven by a $2.7 million increase in personnel-related compensation expense due to increased sales and marketing headcount, a $2.5 million increase in variable sales compensation expense and $1.0 million of incremental stock-based compensation expense. In addition, sales and marketing expenses increased $4.4 million due to increased travel and entertainment, recruitment, consulting, and patient training costs.

Research and Development Expenses

R&D expenses increased $0.6 million, or 13%, to $5.1 million during the year ended December 31, 2017, compared to $4.5 million during the year ended December 31, 2016. The increase in R&D expenses was due to a $0.2 million increase in personnel-related expenses and a $0.4 million increase in clinical studies and product development costs, including those related to the development of our Flexitouch Plus, the third-generation version of our Flexitouch system.

Reimbursement, General and Administrative Expenses

Reimbursement, general and administrative expenses increased $7.9 million, or 41%, to $26.9 million during the year ended December 31, 2017, compared to $19.1 million during the year ended December 31, 2016. The increase in reimbursement, general and administrative expenses for the year ended December 31, 2017 was primarily attributable to a $2.4 million increase in personnel-related expenses, including variable compensation resulting from increased headcount in our reimbursement operations, payer relations, patient services and corporate functions, an increase of $1.5 million in professional fees, including legal, accounting and audit expenses associated with public company requirements, a $1.3 million increase in other operating expenses, including facilities, depreciation and service charges, a $1.2 million increase in stock-based compensation expense, an increase of $1.0 million related to accrued sales and use and franchise taxes, and $0.5 million of expense associated with our September 2017 secondary offering.

Other Income (Expense), Net

Other income, net was $0.3 million for the year ended December 31, 2017, compared to $38,000 for the year ended December 31, 2016. The increase in other income was due to investment income earned on the capital derived from our initial public offering proceeds.

Income Tax (Benefit) Expense

We recorded an income tax benefit of $1.7 million and income tax expense of $1.4 million for the years ended December 31, 2017 and 2016, respectively. The tax benefit in 2017 was primarily due to a significant increase in tax benefits related to tax-deductible share-based compensation activity compared with the previous year. This activity included vesting of restricted stock awards and restricted stock units, excess tax benefits associated with exercises of non-qualified stock options, and disqualifying dispositions of incentive stock options and ESPP shares. It was partially offset by approximately $1.2 million of incremental tax expense associated with revaluation of our deferred tax assets and liabilities, resulting from the enactment of the Tax Cuts and Jobs Act in December 2017. The net income tax benefit resulted in a significant increase in our earnings per share for the year ended December 31, 2017.

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 sales in the third and fourth quarters as a result of patients having paid their annual insurance deductibles in full, thereby reducing their out-of-pocket costs for our products, and because patients often spend the remaining balances in their healthcare flexible spending accounts at that time. This seasonality applies only to purchases 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 or do not have plans that include patient deductibles for purchases of our products.

Liquidity and Capital Resources

Overview

As of December 31, 2018, we had cash and cash equivalents of $20.1 million and marketable securities of $25.8 million, compared with cash and cash equivalents of $24.0 million and marketable securities of $19.9 million as of December 31, 2017. Our primary sources of capital to date have been from operating income and private placements of our capital stock, as well as proceeds from our initial public offering, which closed on August 2, 2016.

Cash Flows

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

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Net cash provided by (used in):			
Operating activities	$ 9,007	$ 4,192	$ 7,033
Investing activities	(14,726)	(14,016)	(11,844)
Financing activities	1,850	3,091	28,452
Net (decrease) increase in cash and cash equivalents	$ (3,869)	$ (6,733)	$ 23,641

Net Cash Provided by Operating Activities

Net cash provided by operating activities during the year ended December 31, 2018, was $9.0 million, resulting from net income of $6.6 million and non-cash net income adjustments of $7.7 million, which were partially offset by an increase in net operating assets of $5.9 million. The non-cash net income adjustments primarily consisted of $8.0 million of stock-based compensation expense, $3.6 million of depreciation and amortization and a $2.5 million non-cash impairment charge to fully write off the inventory and intangible assets related to our Actitouch product, partially offset by an increase of $6.2 million in deferred tax assets driven by the current period tax benefit associated with tax-deductible stock-based compensation activity. The uses of cash related to changes in operating assets primarily consisted of an increase in accounts receivable. The changes in operating liabilities primarily consisted of increases in accounts payable and other liabilities. These changes generally were driven by our increased business volume year-over-year, which resulted in increases to customer accounts receivable and other expenditures, including compensation and personnel-related costs.

Net cash provided by operating activities during the year ended December 31, 2017, was $4.2 million, resulting from net income of $5.9 million, net non-cash expense add-backs of $6.5 million, and a net increase in operating liabilities of $2.7 million, partially offset by a net increase in operating assets of $10.9 million. The non-cash expense add-back items consisted primarily of $4.2 million of stock-based compensation, $1.8 million of depreciation and amortization, and a $0.3 million increase in our allowance for doubtful accounts. The uses of cash related to changes in operating assets primarily consisted of increases in accounts receivable, inventories and income taxes. The changes in operating liabilities primarily consisted of increases in accounts payable and accrued expenses and other liabilities. These changes generally were driven by our increased business volume year-over-year, which resulted in increases to customer accounts receivable and required increases to our levels of inventory and other expenditures, including compensation and personnel-related costs.

Net cash provided by operating activities during the year ended December 31, 2016, was $7.0 million, resulting from net income of $2.9 million, net non-cash expense add-backs of $2.6 million and a net increase in operating liabilities of $4.6 million, partially offset by a net increase in operating assets $3.1 million. The net non-cash expense add-back items consisted of $1.9 million of stock-based compensation, $0.8 million of depreciation and amortization, and a $0.6 million increase in our allowance for doubtful accounts, partially offset by an increase in net deferred income tax assets of $0.6 million. The changes in operating assets primarily consisted of increases in accounts receivable, inventories, income taxes receivable, and prepaid expenses and other assets. The changes in operating liabilities primarily consisted of increases in accounts payable and accrued expenses and other liabilities, partially offset by decreases in future product royalties. These changes generally were driven by our increased business volume year-over-year, which resulted in increases to customer accounts receivable and required increases to our levels of inventory and other expenditures, including compensation and personnel-related costs.

Net Cash Used in Investing Activities

Net cash used in investing activities during the year ended December 31, 2018, was $14.7 million, consisting primarily of $5.4 million related to the acquisition of patents and other intangible assets, $4.7 million in net purchases of securities available-for-sale, $2.1 million in purchases of rental and demonstration equipment, $2.0 million in purchases of product tooling and computer and manufacturing equipment, leasehold improvements and furniture and fixtures and $0.5 million of other investments.

Net cash used in investing activities during the year ended December 31, 2017, was $14.0 million, consisting primarily of net purchases of marketable securities of $10.1 million, $3.7 million in purchases of product tooling and computer and manufacturing equipment, $0.1 million of patent costs, and $0.1 million of other investments.

Net cash used in investing activities during the year ended December 31, 2016, was $11.8 million, consisting primarily of net purchases of marketable securities of $11.0 million, $0.8 million in purchases of product tooling and computer and manufacturing equipment, and $0.1 million in patent costs.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the year ended December 31, 2018, was $1.9 million, consisting of proceeds from the issuance of common stock under the ESPP of $2.7 million and proceeds from exercises of common stock options of $1.5 million, partially offset by $2.4 million in taxes paid for the net share settlement of restricted stock units.

Net cash provided by financing activities during the year ended December 31, 2017, was $3.1 million, which was primarily due to $3.1 million of proceeds from the issuance of common stock under the ESPP and $0.8 million of proceeds from exercises of common stock options and warrants, partially offset by $0.5 million in purchases of treasury stock to cover withholding taxes upon the lapse of restrictions on restricted stock awards and $0.4 million in taxes paid for the net share settlement of restricted stock units that vested during the year.

Net cash provided by financing activities during the year ended December 31, 2016, was $28.5 million, which was primarily generated by gross proceeds of $41.2 million from our initial public offering, partially offset by $8.2 million in payments of accrued dividends on preferred stock and $4.8 million of underwriting costs and expenses associated with our initial public offering. Until August 2016, when we closed on our initial public offering, we historically funded our operations through the issuance of capital stock.

Credit Agreement

On August 3, 2018, we entered into a credit agreement with Wells Fargo Bank, National Association, which was amended by a First Amendment dated February 12, 2019, or the “Credit Agreement”, which expires on August 3, 2021. The Credit Agreement provides for a $10,000,000 revolving credit facility, with the ability to increase the amount of the revolving loans available and/or add one or more term loan facilities not to exceed an incremental $25,000,000, subject to satisfaction of certain conditions. As of December 31, 2018, and the date on which we filed this report, we did not have any outstanding borrowings under the Credit Agreement.

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 and a minimum liquidity covenant. As of December 31, 2018, we were in compliance with all financial covenants under the Credit Agreement. For additional information on the Credit Agreement, see Note 12 – "Credit Agreement" to the consolidated financial statements in this report.

Adequacy of Capital Resources

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

- sales and marketing resources needed to further penetrate our market;
- expansion of our operations domestically and/or internationally;
- response of competitors to our solutions and applications;
- costs associated with clinical research activities;
- 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 revenues, operations and personnel, and we anticipate that our expenditures will continue to increase as we expand our business.

We believe our cash, cash equivalents, marketable securities and cash flows from operations, together with the Credit Agreement, will be sufficient to meet our working capital and capital expenditure 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, 2018, and we do not expect that inflation or changing prices will materially affect our business for at least the next twelve months.

In August 2017 we filed a shelf registration statement on Form S-3 with the SEC. Under the shelf registration statement, we may offer and sell from time to time up to $200 million of common stock, preferred stock, debt securities, warrants, rights or units. The shelf registration statement also registered for resale from time to time up to 5,703,534 shares of our common stock held by the selling stockholders named therein. In September 2017 certain of the selling stockholders completed a secondary offering of 3,795,000 shares of our common stock at a public offering price of $33.00 per share. We did not receive any proceeds from the sale of the shares by the selling stockholders.

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.

Contractual and Commercial Commitments Summary

Our contractual obligations and commercial commitments as of December 31, 2018 are summarized below:

(In thousands)	Payments Due By Period Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Purchase commitments [(1)]	$ 14,894	$ 14,894	$ —	$ —	$ —
Operating lease obligations [(2)]	25,082	1,664	5,145	4,695	13,578
Future product royalties [(3)]	5	5	—	—	—
Total	$ 39,981	$ 16,563	$ 5,145	$ 4,695	$ 13,578

(1) We issued purchase orders in 2018 totaling $14.9 million for goods that we expect to receive in 2019.

(2) We currently lease approximately 52,000 square feet of office space for our corporate headquarters in Minneapolis, Minnesota, under a lease that expires in July 2021 and 44,000 square feet of office, assembly and warehouse space at another leased facility in Minneapolis, Minnesota, under a lease that expires in February 2024. We entered into a lease in October 2018 for approximately 110,000 square feet of office space for our future corporate headquarters in Minneapolis, Minnesota, which will commence upon our move in the fourth quarter in 2019. That lease expires in February 2030. We entered into a fleet vehicle program for certain members of our field sales organization in 2016.

(3) We are required to make quarterly royalty payments to a third-party for our Actitouch system revenue through August 2023. Beginning in September 2017, the payments are equal to 6% of our quarterly revenues attributable to our Actitouch system. In any year that these revenues exceed $40.0 million, we are required to pay 7% on revenues over $40.0 million and 6% on revenues of $40.0 million and under. Because our revenues attributable to our Actitouch system, and therefore the amount of royalty payments we will be required to pay in the future, are unknown, this amount only reflects royalties due associated with a portion of our 2018 Actitouch revenues.

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.

JOBS Act

Prior to December 31, 2018, we were an “emerging growth company” as defined by the JOBS Act. The JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We elected to avail ourselves of this exemption prior to December 31, 2018, and as a result, our financial statements prior to that date may not have been comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies.

Subject to certain conditions, as an emerging growth company we also were able to rely on certain of the exemptions and reduced reporting requirements of the JOBS Act, including without limitation, from providing an auditor's attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. Because the market value of our common stock that was held by non-affiliates as of the last business day of our second fiscal quarter of 2018 exceeded $700 million, we were deemed a large accelerated filer and no longer qualify as an emerging growth company as of December 31, 2018. As a result, we no longer are able to take advantage of the extended transition period for the adoption of certain accounting standards or of the reduced disclosure and other benefits available to emerging growth companies, including our exemption from providing our auditor’s attestation on our system of internal control over financial reporting, which is included for the first time in this Annual Report on Form 10-K.

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 investment activities. 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.

Inflation

Inflationary factors, such as increases in our cost of goods sold, 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 revenues if the selling prices of our products do not increase as much or more than these increased costs.

Credit Risk

As of December 31, 2018 and 2017, our cash, cash equivalents and marketable securities were maintained with three and two, respectively, financial institutions in the United States. We perform periodic evaluations of the relative credit standing of these financial institutions and believe they have sufficient assets and liquidity to conduct their 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 revenues from the sale of our products to patients in the United States. As of December 31, 2018 and 2017, our accounts receivable were $26.2 million and $20.3 million, respectively. We had accounts receivable from three insurers representing approximately 29%, 11% and 8% of accounts receivable as of December 31, 2018. We had accounts receivable from three insurers representing approximately 32%, 15% and 8% of accounts receivable as of December 31, 2017.

Foreign Currency Risk

Our business is conducted in U.S. dollars and international transactions have been minimal. 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.

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 its subsidiary (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 28, 2019 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 supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Grant Thornton LLP

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

Minneapolis, Minnesota
February 28, 2019

Tactile Systems Technology, Inc.
Consolidated Balance Sheets

(In thousands, except share and per share data)	At December 31, 2018	At December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 20,099	$ 23,968
Marketable securities	25,786	19,944
Accounts receivable, net	24,332	17,623
Inventories	11,189	11,040
Income taxes receivable	1,793	2,119
Prepaid expenses and other current assets	1,762	2,178
Total current assets	84,961	76,872
Property and equipment, net	4,810	3,776
Other assets		
Intangible assets, net	5,339	2,218
Medicare accounts receivable, long-term	1,884	2,718
Deferred income taxes	8,820	2,662
Other non-current assets	1,257	201
Total other assets	17,300	7,799
Total assets	$ 107,071	$ 88,447
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,110	$ 4,253
Accrued payroll and related taxes	7,421	6,706
Accrued expenses	2,780	2,598
Future product royalties	5	17
Income taxes	51	212
Other current liabilities	709	733
Total current liabilities	16,076	14,519
Long-term liabilities		
Accrued warranty reserve, long-term	1,725	1,141
Total liabilities	17,801	15,660
Commitments and Contingencies (see Note 13)		
Stockholders' equity		
Preferred stock, $0.001 par value, 50,000,000 shares authorized; none issued and outstanding as of December 31, 2018 and 2017	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized; 18,631,127 shares issued and outstanding as of December 31, 2018; 17,872,465 shares issued and 17,846,379 shares outstanding as of December 31, 2017	19	18
Additional paid-in capital	79,554	70,224
Retained earnings	9,705	3,082
Accumulated other comprehensive loss	(8)	(44)
Less: treasury stock, at cost — none as of December 31, 2018 and 26,086 shares as of December 31, 2017	—	(493)
Total stockholders' equity	89,270	72,787
Total liabilities and stockholders' equity	$ 107,071	$ 88,447

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, 2018	2017	2016
Revenues, net	$ 143,751	$ 109,283	$ 84,542
Cost of goods sold	41,493	29,015	22,940
Gross profit	102,258	80,268	61,602
Operating expenses			
Sales and marketing	60,371	44,396	33,794
Research and development	5,289	5,060	4,476
Reimbursement, general and administrative	33,608	26,914	19,060
Total operating expenses	99,268	76,370	57,330
Income from operations	2,990	3,898	4,272
Other income	486	292	38
Income before income taxes	3,476	4,190	4,310
Income tax (benefit) expense	(3,147)	(1,665)	1,431
Net income	6,623	5,855	2,879
Convertible preferred stock dividends	—	—	1,247
Net income attributable to common stockholders	$ 6,623	$ 5,855	$ 1,632
Net income per common share			
Basic	$ 0.36	$ 0.34	$ 0.18
Diluted	$ 0.34	$ 0.31	$ 0.15
Weighted-average common shares used to compute net income per common share			
Basic	18,252,689	17,355,175	8,913,042
Diluted	19,347,632	18,877,863	10,758,684

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

Tactile Systems Technology, Inc.
Consolidated Statements of Comprehensive Income

(In thousands)	Year Ended December 31, 2018	2017	2016
Net income	$ 6,623	$ 5,855	$ 2,879
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities	60	(53)	(17)
Income tax related to items of other comprehensive income (loss)	(24)	20	6
Total other comprehensive income (loss)	36	(33)	(11)
Comprehensive income	$ 6,659	$ 5,822	$ 2,868

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

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

(In thousands, except share data)	Series B Preferred Stock		Series A Preferred Stock		Common Stock		Additional	Retained Earnings	Accumulated Other	Treasury	
	Shares	Amount	Shares	Amount	Shares	Par Value	Paid-In Capital	(Accumulated Deficit)	Comprehensive Loss	Stock	Total
Balances, December 31, 2015	2,733,468	$ 12,599	3,061,488	$ 20,328	3,222,902	$ 3	$ —	$ (5,652)	$ —	$ —	$ (5,649)
Stock-based compensation	—	—	—	—	—	—	2,082	—	—	—	2,082
Exercise of common stock options and warrants	—	—	—	—	255,217	1	235	—	—	—	236
Preferred stock dividends	—	436	—	811	—	—	(1,247)	—	—	—	(1,247)
Sale of common stock from initial public offering, net of offering expenses	—	—	—	—	4,120,000	4	35,378	—	—	—	35,382
Preferred stock dividends paid in cash	—	—	—	(8,207)	—	—	—	—	—	—	—
Common stock issued in lieu of series B preferred stock dividend	—	—	—	—	956,842	1	(1)	—	—	—	—
Conversion of series B preferred stock to common stock	(2,733,468)	(13,035)	—	—	2,733,468	3	13,032	—	—	—	13,035
Conversion of series A preferred stock to common stock	—	—	(3,061,488)	(12,932)	3,190,985	3	12,929	—	—	—	12,932
Common stock issued for series A & B preferred stock liquidation preference	—	—	—	—	2,354,323	2	(2)	—	—	—	—
Comprehensive income for the period	—	—	—	—	—	—	—	2,879	(11)	—	2,868
Balances, December 31, 2016	—	$ —	—	$ —	16,833,737	$ 17	$ 62,406	$ (2,773)	$ (11)	$ —	$ 59,639
Stock-based compensation	—	—	—	—	—	—	4,235	—	—	—	4,235
Exercise of common stock options and warrants and vesting of restricted stock units	—	—	—	—	731,596	1	833	—	—	—	834
Taxes paid for net share settlement of restricted stock units	—	—	—	—	—	—	(387)	—	—	—	(387)
Common shares issued for employee stock purchase plan	—	—	—	—	307,132	—	3,137	—	—	—	3,137
Shares repurchased to cover taxes from restricted stock award vesting	—	—	—	—	(26,086)	—	—	—	—	(493)	(493)
Comprehensive income for the period	—	—	—	—	—	—	—	5,855	(33)	—	5,822
Balances, December 31, 2017	—	$ —	—	$ —	17,846,379	$ 18	$ 70,224	$ 3,082	$ (44)	$ (493)	$ 72,787
Stock-based compensation	—	—	—	—	—	—	7,974	—	—	—	7,974
Exercise of common stock options and vesting of restricted stock units	—	—	—	—	661,568	1	1,514	—	—	—	1,515
Taxes paid for net share settlement of restricted stock units	—	—	—	—	—	—	(2,379)	—	—	—	(2,379)
Treasury stock issued for option exercises	—	—	—	—	26,086	—	(493)	—	—	493	—
Common shares issued for employee stock purchase plan	—	—	—	—	97,092	—	2,714	—	—	—	2,714
Comprehensive income for the period	—	—	—	—	—	—	—	6,623	36	—	6,659
Balances, December 31, 2018	—	$ —	—	$ —	18,631,125	$ 19	$ 79,554	$ 9,705	$ (8)	$ —	$ 89,270

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

Tactile Systems Technology, Inc.
Consolidated Statements of Cash Flows

(In thousands)	Year Ended December 31, 2018	2017	2016
Cash flows from operating activities			
Net income	$ 6,623	$ 5,855	$ 2,879
Adjustments to reconcile net income to net cash provided by operating activities			
Depreciation and amortization	3,635	1,849	799
Deferred income taxes	(6,182)	143	(611)
Stock-based compensation expense	7,974	4,235	1,889
Loss on disposal of equipment	3	—	—
Loss on sales of marketable securities	1	—	—
Impairment losses	2,534	—	—
Changes in assets and liabilities:			
Accounts receivable	(6,709)	(3,391)	(522)
Inventories	(870)	(4,486)	(773)
Income taxes	165	(2,942)	(81)
Prepaid expenses and other assets	(1,140)	146	(407)
Medicare accounts receivable – long-term	834	105	(784)
Accounts payable	690	462	1,407
Accrued payroll and related taxes	715	14	3,337
Accrued expenses and other liabilities	746	2,252	824
Future product royalties	(12)	(50)	(924)
Net cash provided by operating activities	9,007	4,192	7,033
Cash flows from investing activities			
Proceeds from sales of securities available-for-sale	2,000	1,000	—
Proceeds from maturities of securities available-for-sale	15,000	1,000	—
Purchases of securities available-for-sale	(21,680)	(12,051)	(11,011)
Purchases of property and equipment	(4,196)	(3,746)	(775)
Acquisition of intangible assets	(5,350)	(74)	(58)
Other investments	(500)	(145)	—
Net cash used in investing activities	(14,726)	(14,016)	(11,844)
Cash flows from financing activities			
Taxes paid for net share settlement of restricted stock units	(2,379)	(387)	—
Proceeds from exercise of common stock options and warrants	1,515	834	236
Proceeds from the issuance of common stock from the employee stock purchase plan	2,714	3,137	—
Shares repurchased to cover taxes from restricted stock award vesting	—	(493)	—
Dividends paid on preferred stock	—	—	(8,207)
Proceeds from IPO	—	—	41,200
Fees paid for IPO	—	—	(4,777)
Net cash provided by financing activities	1,850	3,091	28,452
Net change in cash and cash equivalents	(3,869)	(6,733)	23,641
Cash and cash equivalents – beginning of period	23,968	30,701	7,060
Cash and cash equivalents – end of period	$ 20,099	$ 23,968	$ 30,701
Supplemental cash flow disclosure			
Cash paid for interest	$ 9	$ —	$ —
Cash paid for taxes	$ 2,883	$ 923	$ 2,158
Capital expenditures incurred but not yet paid	$ 167	$ 15	$ 174

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") is the sole manufacturer and distributor of the Flexitouch and Entre systems, medical devices that help control symptoms of lymphedema, a chronic and progressive medical condition, the Actitouch system, a medical device used to treat venous leg ulcers and chronic venous insufficiency, and the Airwear wrap, a medical device used for the management of venous insufficiency, venous hypertension, venous ulcerations and lymphedema. We provide our products for use in the home and sell them through vascular, wound and lymphedema clinics throughout the United States. We do business as "Tactile Medical."

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. In connection with the closing of the initial public offering, all of our outstanding redeemable convertible preferred stock automatically converted to common stock on August 2, 2016. At August 2, 2016, we did not have any redeemable convertible preferred stock issued or outstanding.

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 sales in the third and fourth quarters as a result of patients having paid their annual insurance deductibles in full, thereby reducing their out-of-pocket costs for our products, and because patients often spend the remaining balances in their healthcare flexible spending accounts at that time. This seasonality applies only to purchases 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 or do not have plans that include patient deductibles for purchases of our products.

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. We have reclassified certain prior year amounts to conform to the current year's presentation.

The results for the year ended December 31, 2018, 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.

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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Comprehensive Income

Comprehensive income 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 income represents net income adjusted for unrealized gains and losses on available-for-sale marketable securities.

JOBS Act Accounting Election

Prior to December 31, 2018, we were an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), and as a result we were eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We elected to take advantage of the extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies. However, as of the last business day of our second fiscal quarter of 2018, the market value of our common stock that was held by non-affiliates exceeded $700 million, and as a result, we no longer qualify as an emerging growth company as of December 31, 2018. Therefore we no longer are able to take advantage of the extended transition period for adopting new or revised accounting standards.

Note 3. Summary of Significant Accounting Policies

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in available-for-sale securities with original maturities of three months or less at the time of purchase. At December 31, 2018 and 2017, our cash was held primarily in checking and money market accounts.

Marketable Securities and Equity Investments

We determine the appropriate classification of our marketable securities as available-for-sale or held-to-maturity at the time of purchase and periodically reevaluate such classification. Debt securities are classified as held-to-maturity when we have the positive intent and ability to hold the securities to maturity. Debt securities for which we do not have the intent or ability to hold to maturity are classified as available-for-sale.

Debt securities not classified as held-to-maturity are classified as available-for-sale and are reported at fair value, with unrealized gains and losses included in the determination of comprehensive income, a component of stockholders' equity. We review our available-for-sale securities for impairment to determine if the impairment is temporary or other-than-temporary. A temporary impairment charge results in an unrealized loss being recorded in other comprehensive income. Other-than-temporary impairments are recorded in net income in the period the impairment is determined to be other-than-temporary. Realized gains and losses on the sale of marketable securities are determined using the specific-identification method.

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 income. 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 December 31, 2018 and 2017, the total carrying value of our equity investments, with no readily determinable fair value, were $0.65 million and $0.15 million, respectively, 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, 2018 and 2017, we did not have any impairment loss on these investments.

Accounts Receivable, Net

The majority of our accounts receivable and revenues 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. As such, effective December 31, 2018, management has reclassified certain related accounts which impacted the presentation of accounts receivable on the Consolidated Statements of Cash Flows. We have reclassified prior year amounts to conform with the current year presentation. As a result of this reclassification, the reserves for uncollectible schedule, previously disclosed in the Summary of Significant Accounting Policies, is no longer included in the Notes to the Consolidated Financial Statements.

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. Patient rental equipment is depreciated over the multiple month rental period.

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 accounts and the resulting gains or losses are included in income. The value of equipment for patients who obtain our products through a multiple month rental arrangement is capitalized and depreciated over the term of the rental period, after which time title to this equipment passes to the patient. 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 products, which consist of our proprietary line of Flexitouch, Entre and Actitouch systems.

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 of a product is recognized upon shipment, unless circumstances dictate that control has not yet passed to the customer.

We provide a warranty for our 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 sales of our 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 distribute our 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 revenues 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 Actitouch and 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 our 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 purchase 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 revenues are 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. Patients may return the product before the end of the rental period, and as such, these arrangements are deemed to be month-to-month cancelable leases in accordance with Accounting Standards Codification, or ASC 840, "Leases," through December 31, 2018. Accordingly, we recognize the related revenue for these rental arrangements monthly, on a pro rata basis, over the lesser of the duration of the rental period or the period during which the patient possesses the product.

Advertising

Advertising costs are charged to operations when incurred. Advertising expense was $0.1 million for each of the years ended December 31, 2018, 2017, and 2016.

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

We do not charge any shipping and handling costs to our customers. Shipping and handling costs incurred are included in cost of goods sold.

Product Warranty

We provide a warranty for our products against defects in material and workmanship for a period of one to five years on garments and one to two years on controllers. 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, resulting in more defects than anticipated, 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.

As of December 31, 2018, indicators existed, including the calculation of an undiscounted cash flow in comparison to carrying amount, that indicated the patent-related intangible assets for our Actitouch system were impaired. The primary valuation technique used in estimating the fair value of patent intangible assets is a discounted cash flow approach. Specifically, we used a relief of royalty rate method which applies a royalty rate to estimated sales, with the resulting amounts then discounted using an appropriate market discount rate. The relief of royalty rate is the estimated royalty rate a market participant would pay to acquire the right to market/produce the product. If the resulting discounted cash flows are less than the book value of the intangible asset, impairment exists, and the asset value must be written down. Based on impairment testing performed in the fourth quarter of 2018, the Actitouch assets were deemed to be fully impaired. The impairment was due to an evaluation of projected future demand and sales volume in the context of results over the past three years, which resulted in the determination this product would be discontinued in the second half of 2019. As such, we wrote off $1.8 million of intangible assets book value, classified within the reimbursement, general and administrative line of the Consolidated Statements of Operations, as well as $0.7 million in inventory related assets, classified within the cost of goods sold line.

Stock-Based Compensation

The valuation of stock options involves the use of the Black-Scholes option-pricing model, which requires 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 14).

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 bases 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 16). Changes in tax rates are reflected in the tax provision as they occur.

Net Income (Loss) per Share Attributable to Common Stockholders

For the reporting periods prior to our initial public offering, we used the two-class method to compute net income (loss) per common share attributable to common stockholders because we had issued securities, other than common stock, that contractually entitled the holders to participate in our dividends and earnings prior to our initial public offering. The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive distributed and undistributed earnings. All series of our convertible preferred stock were considered participating securities.

Under the two-class method, for periods with net income, basic net income per share attributable to common stockholders is computed by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net income per share attributable to common stockholders is computed by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Net income attributable to common stockholders is computed by subtracting from net income the portion of current year earnings that the participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss, as the holders of the participating securities have no obligation to fund losses.

Recent Accounting Pronouncements

Prior to December 31, 2018, we were an "emerging growth company" as defined by the JOBS Act. The JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, (the "Securities Act"), for complying with new or revised accounting standards. In other words, an emerging growth company can selectively delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. In accordance with the JOBS Act, we elected to participate in the exemption and, as a result, our financial statements may not have been comparable to the financial statements of issuers that are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. As of the last business day of our second fiscal quarter of 2018, the market value of our common stock that was held by non-affiliates exceeded $700 million, and as a result, we no longer qualified as an emerging growth company as of December 31, 2018 and will no longer be able to take advantage of the extended transition period. Therefore, as of December 31, 2018, we are required to adopt new or revised accounting standards when they are applicable to public companies that are not emerging growth companies.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "*Revenue from Contracts with Customers.*" The new standard replaces Section 605, "*Revenue Recognition*," and creates modifications to various other revenue accounting standards for specialized transactions and industries. The new standard is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard also requires additional disclosures about the nature, amount, timing, and uncertainty of revenue, cash flows arising from customer contracts, and enhanced disclosures related to disaggregated revenue information. We adopted this standard for our annual reporting period ended on December 31, 2018, and for interim reporting periods thereafter, due to the determination of our change in filing status. The adoption of this standard using the modified retrospective approach did not have a material or significant impact on our consolidated financial statements, and as such, no adjustment was required to the opening balance of retained earnings as of January 1, 2018. (See above in this Note 3 - Summary of Significant Accounting Policies and Note 15 - Revenue for additional information and disclosures.)

In January 2016, the FASB issued ASU No. 2016-01, "*Financial Instruments – Recognition and Measurement of Financial Assets and Financial Liabilities,*" which requires entities to measure certain investments in equity securities at fair value and recognize any changes in fair value within the statement of operations. Under the standard, equity investments that do not have readily determinable fair values are eligible for a measurement alternative that allows for these investments to be recorded at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The ASU is effective for us as of December 31, 2018 and interim periods thereafter. We have applied this ASU to our cost method investments as disclosed in Note 3. Summary of Significant Accounting Policies – *Marketable Securities and Equity Investments*. The adoption had no impact to the consolidated financial statements as of December 31, 2018.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases*" (Topic 842), which supersedes the existing guidance for lease accounting, "*Leases*" (Topic 840). ASU No. 2016-02 requires lessees to recognize a lease liability and a right-of-use asset for all leases that extend beyond one year. As a result of the change in our filing status, the amendments in this ASU will be effective for us for interim and annual periods beginning after December 15, 2018. The original guidance required application on a modified retrospective basis with the earliest period presented in the financial statements. In August 2018, the FASB issued ASU 2018-11, "*Targeted Improvements"* to ASC 842, which includes an option to not restate comparative periods in transition and instead to elect to use the effective date of ASC 842, "Leases", as the date of initial application of transition. Based on the effective date, this guidance will apply and we will adopt this ASU beginning on January 1, 2019, and we plan to elect the transition option provided under ASU 2018-11. We engaged an accounting firm to assist us with the related assessment and have completed the qualitative analysis from both the lessee and lessor perspectives. As part of our process, we elected to utilize certain practical expedients that were provided for transition relief. Accordingly, we are not reassessing expired or existing contracts, lease classifications or related initial direct costs as part of our assessment process. Additionally, we elected the practical expedient to treat lease and non-lease components of fixed payments due to the lessor as one, and therefore no separate allocation is required on the initial implementation date of January 1, 2019, and thereafter. We anticipate the adoption of this standard will result in an increase in our Right of Use assets and lease liabilities in the range of $2.5 to $3.5 million recorded on our Consolidated Balance Sheets on January 1, 2019. We anticipate the most significant impact to our Consolidated Statements of Operations will be related to our rental income, which was recognized as month-to-month, cancelable leases in accordance with ASC 840 through December 31, 2018 and will be recognized as a sales-type lease under ASC 842 thereafter. Rental sales agreements that commenced prior to December 31, 2018, will continue to be recognized as month-to-month, cancelable leases until they are completed, as we were not required to reassess the classification. Rental agreements commencing after January 1, 2019 will be recorded as sales-type leases with the associated revenue and cost of sales recognized on the lease commencement date, with a corresponding asset and liability recorded on the Consolidated Balance Sheet.

In June 2016, the FASB issued ASU No. 2016-13, "*Financial Instruments — Credit Losses*," to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The ASU will be effective for us for interim and annual periods beginning January 1, 2020. Therefore, we plan to further evaluate the anticipated impact of the adoption of this ASU on our consolidated financial statements in future periods.

In August 2016, the FASB issued ASU No. 2016-15, "*Statement of Cash Flows (Topic 230) — Classification of Certain Cash Receipts and Cash Payments*," to provide clarity on how certain cash receipt and cash payment transactions are presented and classified within the statement of cash flows. The ASU is effective for us for annual periods beginning December 31, 2018, and interim periods thereafter. We evaluated the adoption of this ASU on our consolidated financial statements in the current year and noted no impact.

In January 2017, the FASB issued ASU No. 2017-01 "*Business Combinations (Topic 805) — Clarifying the Definition of a Business*," to revise the definition of a business and provide new guidance to assist in the evaluation of transactions as either asset acquisitions (disposals) or business acquisitions (disposals). We elected to early-adopt this standard on January 1, 2018, for interim transactions that have not previously been included in issued financial statements, which is permitted under this standard. The adoption of this standard did not have a material impact on our consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-07 "*Improvements to Non-employee Share-Based Payment Accounting*," which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The ASU will be effective for us beginning January 1, 2019, including interim periods within that fiscal year. We do not anticipate any material impact on our consolidated financial statements in future periods as a result of the adoption of this ASU.

Note 4. Acquisitions

On May 22, 2018, we acquired certain assets and the intellectual property of Wright Therapy Products, Inc. ("WTP") for total consideration of approximately $875,000 plus a potential earn-out to be amortized on a straight-line basis over the life of the related asset. The earn-out is based on certain revenue metrics over the seven-month period beginning June 30, 2018, and will be capitalized to intangible assets if and when it is probable the earn-out will be achieved. As of December 31, 2018, the earn-out period had ended and the total amount accrued and capitalized as an intangible asset was $375,000. The assets include the rights to a portfolio of thirty-one issued and pending patents that includes intellectual property related to WTP's pneumatic compression therapy devices and five related trademarks, as well as certain customer accounts. Due to the nature of these patents and related trademarks, as well as our planned use, they have been classified as defensive intangible assets on the balance sheet. The acquisition was recorded as an asset acquisition, and an allocation of the purchase price, based on relative fair value, has been completed as reflected below:

(In thousands)		Gross Carrying Amount	Weighted-Average Amortization Period
Defensive intangible assets	$	788	7 years
Customer accounts		87	5 years
Total	$	875	

On October 15, 2018, we entered into a license agreement (the "License Agreement") with Sun Scientific, Inc. ("Sun Scientific"), pursuant to which we licensed certain intellectual property of Sun Scientific, including related to its Aero-Wrap product, in the United States and Canada for use in all medical applications, including but not limited to swelling/edema and ulcers (including the lymphedema and chronic venous insufficiency conditions), but excluding the use of the intellectual property in the field of prophylaxis for deep vein thrombosis.

Pursuant to the License Agreement, we paid Sun Scientific an initiation fee of $4.0 million. We have also agreed to pay Sun Scientific a royalty in a range of high single digits to low double digits as a percentage of the net sales of the products containing the licensed intellectual property and a contingent payment if the net sales of the Airwear wrap exceed $80.0 million within the first seven years of the term of the License Agreement. We have concluded as of December 31, 2018 that it is not probable the contingent payment threshold will be achieved, and it will be subsequently reassessed at each quarter-end. The contingent payment may be made, at our option, in cash or shares of our common stock

The License Agreement will continue until the date of expiration of the last to expire or be invalidated of the licensed patents, subject to earlier termination under certain circumstances. The license rights to the patents are to be amortized on a straight-line basis over the life of the License Agreement. The License Agreement was recorded as an asset acquisition, and an allocation of the purchase price, based on relative fair value, has been completed as reflected below:

(In thousands)	Gross Carrying Amount	Weighted-Average Amortization Period
Patents	$ 4,047	12 years

Note 5. Marketable Securities

Our investments in marketable securities, all of which have original contractual maturities of six to twenty-four months, are classified as available-for-sale and consist of the following:

	At December 31, 2018			
	Amortized	Unrealized		Fair
(In thousands)	Cost	Gains	Losses	Value
U.S. government and agency obligations	$ 19,332	$ 5	$ 17	$ 19,320
Corporate debt securities and certificates of deposit	6,464	7	5	6,466
Marketable securities	$ 25,796	$ 12	$ 22	$ 25,786

	At December 31, 2017			
	Amortized	Unrealized		Fair
(In thousands)	Cost	Gains	Losses	Value
U.S. government and agency obligations	$ 11,997	$ —	$ 56	$ 11,941
Corporate debt securities and certificates of deposit	8,017	—	14	8,003
Marketable securities	$ 20,014	$ —	$ 70	$ 19,944

Net pre-tax unrealized losses for marketable securities of $22 thousand at December 31, 2018, were recorded as a component of accumulated other comprehensive loss in stockholders' equity. Marketable securities valued at $16.0 million were sold during the year ended December 31, 2018, at a loss of $1 thousand.

Unrealized losses and fair value of securities available-for-sale aggregated by investment category and the length of time the securities were in a continuous loss position were as follows:

	At December 31, 2018					
	Less than 12 months		12 months or more		Total	
(In thousands)	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. government and agency obligations	$ 11,884	$ 11	$ 2,993	$ 6	$ 14,877	$ 17
Corporate debt securities and certificates of deposit	2,993	3	999	2	3,992	5
Marketable securities	$ 14,877	$ 14	$ 3,992	$ 8	$ 18,869	$ 22

(In thousands)	At December 31, 2017					
	Less than 12 months		12 months or more		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. government and agency obligations	$ 5,974	$ 25	$ 5,967	$ 31	$ 11,941	$ 56
Corporate debt securities and certificates of deposit	7,005	13	998	1	8,003	14
Marketable securities	$ 12,979	$ 38	$ 6,965	$ 32	$ 19,944	$ 70

Note 6. Accounts Receivable, Net

Accounts receivable include amounts due from Medicare totaling $2.6 million and $3.5 million relating to Flexitouch system sales to patients as of December 31, 2018 and 2017, respectively, which are waiting for insurance approval. This estimated amount is the portion of the accounts receivable we expect to collect based on approval and collection history from Medicare.

We classified $1.9 million and $2.7 million of this receivable as of December 31, 2018 and 2017, respectively, as non-current as we do not expect these claims will be paid within the next twelve months due to the anticipated timing of the appeals process.

We had accounts receivable from two insurers representing approximately 29% and 11% of accounts receivable as of December 31, 2018. We had accounts receivable from two insurers representing approximately 32% and 15% of accounts receivable as of December 31, 2017. Revenues from these insurance companies accounted for 29% and 9% of our total revenues for the year ended December 31, 2018, and 31% and 8% for the year ended December 31, 2017.

Note 7. Inventories

Inventories consisted of the following:

(In thousands)	At December 31, 2018	At December 31, 2017
Finished goods	$ 5,318	$ 4,267
Component parts and work-in-process	5,871	6,773
Total inventories	$ 11,189	$ 11,040

Note 8. Property and Equipment

Property and equipment consisted of the following:

(In thousands)	At December 31, 2018	At December 31, 2017
Equipment	$ 4,442	$ 3,235
Tooling	2,574	1,932
Furniture and fixtures	459	427
Demonstration equipment	632	460
Leasehold improvements	1,001	938
Patient rental equipment	1,342	1,131
Subtotal	10,450	8,123
Less: accumulated depreciation	(5,640)	(4,347)
Property and equipment, net	$ 4,810	$ 3,776

Depreciation expense was $3.3 million, $1.5 million and $0.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Note 9. Intangible Assets

Our patents and other intangible assets, all of which are subject to amortization, are summarized as follows:

		At December 31,					
		2018			2017		
(In thousands)	Weighted-Average Amortization Period	Gross Carrying Amount	Accumulated Amortization	Net Amount	Gross Carrying Amount	Accumulated Amortization	Net Amount
Patents	12 years	$ 4,253	$ 71	$ 4,182	$ 3,536	$ 1,318	$ 2,218
Defensive intangible assets	6 years	1,126	82	1,044	—	—	—
Customer accounts	4 years	125	12	113	—	—	—
Total		$ 5,504	$ 165	$ 5,339	$ 3,536	$ 1,318	$ 2,218

Amortization expense was $0.4 million for the year ended December 31, 2018, and $0.3 million for each of the years ended December 31, 2017 and 2016. Future amortization expenses are expected as follows:

(In thousands)	
2019	$ 558
2020	558
2021	558
2022	558
2023	491
Thereafter	2,616
Total	$ 5,339

The weighted-average remaining amortization period for these intangible assets was 7 years as of December 31, 2018.

Note 10. Accrued Expenses

Accrued expenses consisted of the following:

	At December 31,	
(In thousands)	2018	2017
Warranty	$ 841	$ 531
Travel and business	557	453
Acquisition earn-out	375	—
Legal and consulting	319	317
Deferred rent	155	173
Accrued taxes	115	1,070
Clinical studies	60	15
Other	358	39
Total	$ 2,780	$ 2,598

Note 11. Warranty Reserves

The reserve for warranties was as follows:

	Year Ended December 31,	
(In thousands)	2018	2017
Beginning balance	$ 1,672	$ 793
Warranty provision	1,720	1,487
Processed warranty claims	(826)	(608)
Ending balance	$ 2,566	$ 1,672
Accrued warranty reserve, current	$ 841	$ 531
Accrued warranty reserve, long-term	1,725	1,141
Total accrued warranty reserve	$ 2,566	$ 1,672

Note 12. Credit Agreement

On August 3, 2018, we entered into a credit agreement with Wells Fargo Bank, National Association. On February 12, 2019, we entered into a first amendment to our credit agreement, which provided for an increase in our annual capital expenditure limitations. We refer to the credit agreement, as amended, as the “Credit Agreement.”

The Credit Agreement provides for a $10,000,000 revolving credit facility. The revolving credit facility expires on August 3, 2021. 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 an incremental $25,000,000 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 $35,000,000.

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 plus the applicable margin. The applicable margin is 0.40% to 1.15% on loans bearing interest at the Base Rate and 1.40% to 2.15% on loans bearing interest at LIBOR, in each case depending on our consolidated total leverage ratio. Undrawn portions of the revolving credit facility are subject to an unused line fee at a rate per annum from 0.200% to 0.275%, depending on our consolidated total leverage ratio.

As of December 31, 2018, we did not have any outstanding borrowings under the Credit Agreement.

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 limits our ability to make capital expenditures during a fiscal year in excess of the amounts set forth in the Credit Agreement, which are $5.0 million for 2018, $15.0 million for 2019, $15.0 million for 2020 and $9.0 million for 2021. The Credit Agreement requires that we (i) not permit, as of the last day of each fiscal quarter, our consolidated total leverage ratio to exceed 3.00 to 1.00 and (ii) maintain minimum cash and cash equivalents, measured on the last day of each fiscal quarter, of not less than $7,500,000 (subject to a temporary reduction to $5,000,000 for the two fiscal quarters immediately following a permitted acquisition). As of December 31, 2018, we were in compliance with all financial covenants under the Credit Agreement.

The Credit Agreement also contains certain other 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.

Amounts due under the Credit Agreement may be accelerated upon an Event of Default (as defined in the Credit Agreement), such as breach of a representation, covenant or agreement of ours, defaults with respect to certain of our other material indebtedness or the occurrence of bankruptcy if not otherwise waived or cured.

We may use the proceeds from advances under the revolving credit facility (i) to finance capital expenditures, (ii) to pay fees, commissions and expenses in connection with the Credit Agreement and (iii) for working capital and general corporate purposes.

Note 13. Commitments and Contingencies

Lease Obligations

In March 2008, we entered into a non-cancelable operating lease agreement for building space for our corporate headquarters that provides for monthly rent, real estate taxes and operating expenses that was subsequently extended to July 31, 2021. We are looking to sub-lease this space for the remainder of our lease obligation due to our new headquarters lease described below.

In July 2016, we entered into a non-cancelable operating lease agreement for building space to accommodate the relocation of our manufacturing, quality, and research and development functions. In December 2018, we entered into an amendment to obtain additional space within the existing building. The amended lease agreement extends through February 2024 and provides for monthly rent, real estate taxes and operating expenses.

In October 2018, we entered into a non-cancelable office lease agreement for our new corporate headquarters space that provides for monthly rent, real estate taxes and operating expenses. The initial lease term is through February 2030, with an option to renew for two periods of five years each.

Rent expense was $1.5 million, $1.1 million and $1.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

In July 2016, we entered into a fleet vehicle lease program for certain members of our field sales organization.

We also have operating lease agreements for certain computer and office equipment that expire in 2021. The leases provide an option to purchase the related equipment at fair market value at the end of the lease.

Future base minimum lease payments for all lease obligations are expected to be as follows for the years ending December 31:

(In thousands)	Buildings	Computer/Office Equipment	Fleet Vehicle Program	Total
2019	$ 1,434	$ 51	$ 179	$ 1,664
2020	2,496	34	—	2,530
2021	2,612	3	—	2,615
2022	2,347	—	—	2,347
2023	2,348	—	—	2,348
Thereafter	13,578	—	—	13,578
Total	$ 24,815	$ 88	$ 179	$ 25,082

Major Vendors

We had purchases from two vendors that accounted for 46% of total purchases for the year ended December 31, 2018. We had purchases from three vendors that accounted for 40% of total purchases for the year ended December 31, 2017.

Purchase Commitment

We issued purchase orders in 2018 totaling $14.9 million for goods that we expect to receive between February and December of 2019.

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. Discretionary contributions to the 401(k) plan totaled $0.2 million for each of the years ended December 31, 2018, 2017 and 2016.

Note 14. 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, 892,318 and 841,686 shares were added as available for issuance thereunder on January 1, 2018 and 2017, respectively. Our Board of Directors exercised its prerogative to forego the automatic increase on January 1, 2019. As of December 31, 2018, 5,161,690 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.

We recorded stock-based compensation expense of $8.0 million, $4.2 million and $1.9 million for the years ended December 31, 2018, 2017 and 2016, respectively. This expense was allocated as follows:

(In thousands)	Year Ended December 31, 2018	2017	2016
Cost of goods sold	$ 160	$ 117	$ 112
Sales and marketing expenses	3,254	1,521	514
Research and development expenses	242	140	36
Reimbursement, general and administrative expenses	4,318	2,457	1,227
Total stock-based compensation expense	$ 7,974	$ 4,235	$ 1,889

Total stock-based compensation expense includes a modification of share-based awards held by a former executive resulting in a charge of $1.0 million for the year ended December 31, 2018. At December 31, 2018, there was approximately $0.1 million of estimated total unrecognized pre-tax compensation expense related to this modification that is expected to be recognized on a straight-line basis over 0.2 years.

Stock Options

Stock options issued to participants other than non-employees vest over three or four years and typically have a contractual term of seven or ten years. Annually, stock options are granted to our non-employee directors on the date of the annual meeting of stockholders and vest in full on the earlier of one year after the date of grant or on the date of the next year's annual meeting of stockholders. These options have a contractual term of seven years.

Stock-based compensation expense included in our Consolidated Statements of Operations for stock options was $2.1 million, $1.0 million and $1.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. The total grant date fair value of options vested during the year was $1.5 million, $0.8 million and $0.2 million for the years ended December 31, 2018, 2017 and 2016, respectively.

At December 31, 2018, there was approximately $5.9 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 2.4 years.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing 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 was estimated using the average historical volatility of public companies of similar size and industry over the similar period as the expected term assumption used for our options. 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:

	2018	2017	2016
Expected term	4 - 6 years	4 - 6 years	4 - 6 years
Expected volatility	42.7 - 43.4%	43.5 - 45.9%	43%
Risk-free interest rate	2.6 - 3.1%	1.7 - 2.3%	1%
Expected dividend yield	0%	0%	0%
Fair value on the date of grant	$12.46 - $29.07	$7.82 - $16.23	$3.48 - $7.16

Stock option activity for the three years ended December 31, 2018, is summarized 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, 2015	1,840,448	$ 1.18	5.8 years	$ 18,573
Granted	305,236	$ 10.60		
Exercised	(253,138)	$ 0.93		$ 2,447
Forfeited	(36,247)	$ 5.34		
Balance at December 31, 2016	1,856,299	$ 2.69	5.5 years	$ 25,467
Granted	345,995	$ 25.26		
Exercised	(657,916)	$ 1.23		$ 15,927
Forfeited	(56,658)	$ 7.22		
Balance at December 31, 2017	1,487,720	$ 8.41	6.2 years	$ 29,611
Granted	203,614	$ 47.25		
Exercised	(553,375)	$ 2.74		$ 25,393
Forfeited	(61,424)	$ 21.27		
Balance at December 31, 2018	1,076,535	$ 17.94	6.5 years	$ 31,172
Options exercisable at December 31, 2018	622,675	$ 6.75	5.2 years	$ 24,161

(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 998,269 at December 31, 2017, and 1,359,302 at December 31, 2016 had weighted average exercise prices of $2.45 and $1.06, respectively.

The following summarizes additional information about our stock options:

	Year Ended	
Number of:	**2018**	**2017**
Non-vested options beginning of the year	489,451	496,997
Non-vested options end of the year	453,860	489,451
Vested options	622,675	315,082

	Year Ended	
Weighted-average grant date fair value of:	**2018**	**2017**
Non-vested options beginning of the year	$ 9.57	$ 2.99
Non-vested options end of the year	14.80	9.57
Vested options	2.84	2.45
Forfeited options	9.45	3.25

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 $3.5 million, $2.5 million and $0.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, there was approximately $4.8 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 year ended December 31, 2018 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, 2015	—	$ —	$ —
Granted	327,454	$ 10.45	
Vested	(1,726)	$ 17.29	
Cancelled	(865)	$ 17.35	
Balance at December 31, 2016	324,863	$ 10.39	$ 1,972
Granted	240,070	$ 22.28	
Vested	(87,539)	$ 11.81	
Cancelled	(35,887)	$ 15.17	
Balance at December 31, 2017	441,507	$ 16.38	$ 12,795
Granted	103,417	$ 38.13	
Vested	(199,733)	$ 15.53	
Cancelled	(35,559)	$ 20.74	
Balance at December 31, 2018	309,632	$ 23.69	$ 14,104
Deferred and unissued at December 31, 2018(2)	3,865	$ 32.88	$ 176

(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.

(2) For the year ended December 31, 2018, there were 1,652 restricted stock units granted to non-employee directors in lieu of their quarterly cash retainer payments. These restricted stock units were fully vested upon grant and represent the right to receive one share of common stock, per unit, upon the earlier of the director's termination of service as a director of ours or the occurrence of a change of control of us. These restricted stock units are included in the "Granted" line in the table above and are also included in the "Vested" line in the table above due to their being fully vested upon grant. As of December 31, 2018, there were 3,865 outstanding restricted stock units that had been previously granted to non-employee directors in lieu of their quarterly director retainer payments. These restricted stock units are not included in the "Balance at December 31, 2018" line in the table above because they are fully vested.

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 will be earned if and to the extent performance goals based on revenue and adjusted EBITDA are achieved in 2019. 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 $0.7 million for the year ended December 31, 2018. As of December 31, 2018, there was approximately $1.5 million of total unrecognized pre-tax compensation expense related to outstanding PSUs that is expected to be recognized over a weighted average period of 2.4 years.

Our performance-based restricted stock unit activity for the year ended December 31, 2018 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, 2017	—	$ —	$ —
Granted	70,680	$ 33.53	
Vested	—	$ —	
Cancelled	(5,253)	$ 32.36	
Balance at December 31, 2018	65,427	$ 33.62	$ 2,980

(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 plan is available to all 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 plan provides for six-month purchase periods, beginning on May 16 and November 16 of each calendar year. The initial purchase period began on July 27, 2016 and ended on May 15, 2017.

A total of 1.6 million shares of common stock were initially reserved for issuance under the plan, and 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 (1) 1% of the shares of our common stock outstanding on the immediately preceding December 31, (2) 500,000 shares or (3) such lesser amount as our Board of Directors may determine. Pursuant to the automatic increase feature of the plan, 178,463 shares were added to the ESPP on January 1, 2018. Our Board of Directors exercised its prerogative to forego the automatic increase on January 1, 2019. On May 15, 2017, 259,981 shares were purchased, utilizing $2.2 million of employee contributions in the initial purchase period. On November 15, 2017, 47,151 shares were purchased, utilizing $0.9 million of employee contributions in the May 16, 2017 to November 15, 2017 purchase period. On May 15, 2018, 63,578 shares were purchased under the ESPP, utilizing $1.4 million of employee contributions in the November 16, 2017 to May 15, 2018 purchase period. On November 15, 2018, 33,514 shares were purchased, utilizing $1.3 million of employee contributions in the May 16, 2018 to November 15, 2018 purchase period. As of December 31, 2018, 1,542,576 shares were available for future issuance under the ESPP. We recognized $0.7 million, $0.7 million and $0.4 million in stock-based compensation expense related to the ESPP for the years ended December 31, 2018, 2017 and 2016, respectively.

Note 15. Revenue

We derive our revenues from the sale and rental of our Flexitouch, Entre and Actitouch systems to our customers in the United States. While our primary source of revenue is from the sale of our products, our rental revenue represents $13.6 million, $10.1 million, and $7.9 million for the years ended December 31, 2018, 2017 and 2016, respectively, and is primarily derived from rentals of the Flexitouch system. The following table presents our revenue, inclusive of sales and rental revenue, disaggregated by product:

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Revenues			
Flexitouch system	$ 131,935	$ 100,344	$ 73,413
Entre/Actitouch systems	11,816	8,939	11,129
Total	$ 143,751	$ 109,283	$ 84,542

	Year Ended December 31,		
	2018	2017	2016
Percentage of total revenues			
Flexitouch system	92 %	92 %	87 %
Entre/Actitouch systems	8 %	8 %	13 %
Total	100 %	100 %	100 %

Rental revenue for the years ended December 31, 2018 and 2017 was primarily related to private insurers. For the year ended December 31, 2016, rental revenue was primarily related to private insurers and the Veterans Administration. Our revenues from third-party payers, inclusive of sales and rental revenue, for the years ended December 31, 2018, 2017 and 2016 are summarized in the following table:

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Veterans Administration	$ 28,043	$ 19,727	$ 12,259
Medicare	13,536	8,641	10,063
Private insurers and other payers	102,172	80,915	62,220
Total	$ 143,751	$ 109,283	$ 84,542

Note 16. Income Taxes

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

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Current income taxes, Federal	$ 2,416	$ (2,283)	$ 1,809
Current income taxes, State	778	460	233
	3,194	(1,823)	2,042
Deferred income taxes, Federal	(4,804)	315	(435)
Deferred income taxes, State	(1,537)	(157)	(176)
	(6,341)	158	(611)
Total (benefit) provision for income taxes	$ (3,147)	$ (1,665)	$ 1,431

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

(In thousands)	At December 31, 2018	At December 31, 2017
Deferred tax assets:		
Net operating loss carryforwards	$ 4,038	$ 197
Accounts receivable and inventory reserves	1,729	846
Stock-based compensation	1,629	739
Accrued liabilities	946	71
Warranty reserves	634	410
Fixed assets	29	—
Intangible assets	—	515
Other	66	194
Total deferred tax assets	$ 9,071	$ 2,972
Deferred tax liabilities:		
Depreciation	(196)	(310)
Intangible assets	(55)	—
Total deferred tax liabilities	$ (251)	$ (310)
Net deferred tax assets	$ 8,820	$ 2,662

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

	Year Ended December 31, 2018	2017	2016
Tax expense at statutory rate	21.0 %	34.0 %	34.0 %
State income taxes, net of federal benefit	11.9	(4.4)	3.3
Executive compensation	11.8	—	—
Meals and entertainment	7.6	6.3	5.4
Incentive stock options	1.9	(89.1)	2.7
Employee Stock Purchase Plan	4.5	(4.6)	3.0
Transaction costs	—	3.8	—
Return to provision	3.6	1.4	—
IRS Exam	23.3	—	—
Deferred reprice - state	(0.3)	1.9	(0.3)
Deferred true-up	—	0.5	(7.9)
Deferred reprice - federal	—	28.0	—
Unrecognized tax benefits	(4.6)	5.1	—
Excess benefit on non-qualified stock options and RSUs	(177.6)	(22.8)	(8.0)
Interest and penalties	6.3	—	—
Other	0.1	0.2	1.0
Net effective rate	(90.5) %	(39.7) %	33.2 %

A reconciliation of unrecognized tax benefits is as follows:

(In thousands)	December 31, 2018	2017	2016
Balance beginning of the year	$ 212	$ —	$ —
Gross increases — tax positions in prior year	3,477	212	—
Settlement	(3,638)	—	—
Balance end of the year	$ 51	$ 212	$ —

As of December 31, 2018, we had $14.8 million of U.S. federal net operating loss (“NOL”) carry-forwards and approximately $0.9 million of state NOLs. The state NOL carry-forward amounts expire beginning in tax years 2024 if not utilized.

We are 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 2014 are closed to examination as of December 31, 2018. We are not currently under examination by any taxing authority. 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 statement of operations.

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 our 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. The Internal Revenue Service (“IRS”) commenced an examination of our 2016 U.S. income tax return in the first quarter of 2018. The examination was effectively settled in the fourth quarter of 2018. Management agreed to adjustments proposed by the IRS related to our bonus compensation accrual and Medicare accounts receivable reserves. We have recognized $0.2 million in interest and penalties related to the audit in income tax expense. The gross increases to our unrecognized tax benefits (“UTB”) for the tax, interest, and penalties associated with the proposed adjustments as well as the ultimate settlement with the IRS is reflected within our tabular reconciliation of unrecognized tax benefits above. As of December 31, 2018, we had a UTB with respect to state income taxes of approximately $0.1 million that, if recognized, would affect the effective tax rate. We recognize interest and penalties related to unrecognized tax benefits in tax expense.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act establishes new tax laws effective for tax years beginning after December 31, 2017, including, but not limited to, the reduction of the U.S. federal corporate income tax rate to 21%. The Securities and Exchange Commission staff issued Staff Accounting Bulletin No. 118 (“SAB 118”), which provides guidance on accounting for the tax effects of the Tax Act. SAB 118 provides for a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Tax Act for which the accounting under ASC 740 is complete. Our accounting for the Tax Act is complete, including the remeasurement of our deferred tax assets and liabilities using the reduced corporate federal income tax rate of 21%. 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.

Note 17. Net Income (Loss) Per Share Attributable to Common Stockholders

We adopted ASU 2016-09, “*Improvements to Employee Share-Based Payment Accounting*,” in the fourth quarter of 2016 on a retrospective basis, effective January 1, 2016. The following table sets forth the computation of our basic and diluted net income (loss) per share attributable to common stockholders and reflects the adoption of ASU 2016-09:

	Year Ended December 31,		
(In thousands, except share and per share data)	**2018**	**2017**	**2016**
Net income	$ 6,623	$ 5,855	$ 1,632
Weighted-average shares outstanding	18,252,689	17,355,175	8,913,042
Effect of restricted stock units, common stock options, warrants, and employee stock purchase plan shares	1,094,943	1,522,688	1,845,642
Weighted-average shares used to compute diluted net income per share	19,347,632	18,877,863	10,758,684
Net income per share - Basic	$ 0.36	$ 0.34	$ 0.18
Net income per share - Diluted	$ 0.34	$ 0.31	$ 0.15

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

	Year Ended December 31,		
	2018	2017	2016
Restricted stock units	16,283	1,184	—
Common stock options	111,565	63,066	1,840,447
Common stock warrants	—	—	5,800
Employee stock purchase plan	—	—	—
Total	127,848	64,250	7,641,204

Note 18. 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). The following provides information regarding fair value measurements for our cash equivalents and marketable securities as of December 31, 2018, and December 31, 2017, according to the three-level fair value hierarchy:

	At December 31, 2018			
(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:				
Money market mutual funds	$ 2,447	$ —	$ —	$ 2,447
U.S. government and agency obligations	16,326	2,994	—	19,320
Corporate debt securities	—	6,466	—	6,466
Total	$ 18,773	$ 9,460	$ —	$ 28,233

	At December 31, 2017			
(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:				
Money market mutual funds	$ 9,212	$ —	$ —	$ 9,212
U.S. government and agency obligations	1,000	10,941	—	11,941
Corporate debt securities	—	8,003	—	8,003
Total	$ 10,212	$ 18,944	$ —	$ 29,156

During the year ended December 31, 2018, there were no transfers within the three-level hierarchy. A significant transfer is recognized when the inputs used to value a security have been changed, which merits a transfer between the disclosed levels of the valuation hierarchy.

The fair values for our currency, money market mutual funds, U.S. government and agency obligations and corporate debt securities are determined based on valuations provided by external investment managers who obtain them from a variety of industry standard data providers.

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. As of December 31, 2018, we re-measured the value of our intangible assets related to the Actitouch product line to their fair value, which was deemed to be $0 using level 3 measurements. We had no re-measurements of non-financial assets to fair value in the years ended December 31, 2017.

Note 19. Quarterly Financial Information (Unaudited)

The quarterly financial data presented below should be read in conjunction with the consolidated financial statements and related notes:

	Three Months Ended			
(In thousands, except per share data)	Mar. 31, 2018	Jun. 30, 2018	Sep. 30, 2018	Dec. 31, 2018
Revenues	$ 26,848	$ 34,133	$ 36,322	$ 46,448
Gross profit	19,539	24,523	26,181	32,015
(Loss) income from operations	(1,827)	1,311	1,370	2,136
Net (loss) income	(50)	2,572	1,746	2,355
Net income per share - Basic(1)	0.00	0.14	0.10	0.13
Net income per share - Diluted(1)	0.00	0.13	0.09	0.12

	Three Months Ended			
(In thousands, except per share data)	Mar. 31, 2017	Jun. 30, 2017	Sep. 30, 2017	Dec. 31, 2017
Revenues	$ 19,850	$ 26,264	$ 28,283	$ 34,886
Gross profit	14,226	19,230	20,755	26,057
(Loss) income from operations	(2,932)	730	1,258	4,927
Net (loss) income	(1,504)	3,787	1,342	2,230
Net (loss) income per share - Basic(1)	(0.09)	0.22	0.08	0.13
Net (loss) income per share - Diluted(1)	(0.09)	0.20	0.07	0.12

(1) The summation of quarterly per share amounts may not equal the calculation for the full year, as each quarterly calculation is performed discretely.

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, 2018. 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, 2018, 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, 2018 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. Based on this assessment, management concluded that, as of December 31, 2018, 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, 2018, 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 its subsidiary (the "Company") as of December 31, 2018, 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, 2018, 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, 2018, and our report dated February 28, 2019 expressed an unqualified opinion on those consolidated 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 28, 2019

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

Peter H. Soderberg, age 72, has served as a member of our board of directors since September 2012. Mr. Soderberg currently is the Managing Partner of Worthy Venture Resources, LLC, a company that seeks to add intellectual and financial capital to post start-up companies transitioning to an established national market presence. Beginning in 2006, Mr. Soderberg served as the President and Chief Executive Officer of both Hillenbrand Industries and Hill-Rom. In 2008, Hillenbrand Industries separated its two subsidiaries creating two, separately traded, public companies. Mr. Soderberg continued his role as President and Chief Executive Officer of the medical technology company, Hill-Rom Holdings, Inc. until 2010. Mr. Soderberg served on the board of Hillenbrand Industries/Hill-Rom from 2002 until his semi-retirement in 2011. Previously, he was President and Chief Executive Officer at Welch Allyn, a manufacturer of medical diagnostic equipment, for six years, and served as Group Vice President and Chief Operating Officer from 1993 to 1999. Prior to his role at Welch Allyn Mr. Soderberg served 23 years at Johnson & Johnson in a variety of operations, marketing and management positions, including President of Johnson & Johnson Health Management. His career also includes roles as President and Chief Executive Officer of an industrial technology company and the founder and President of a venture capital business. Mr. Soderberg currently serves on the board of directors of Integer Holdings Corp. (NYSE: ITGR, formerly Greatbatch, Inc.), a medical technology company. Mr. Soderberg previously served on the boards of Constellation Brands, Inc. and the Advanced Medical Technology Association.

William W. Burke, age 59, has served as a member of our board of directors since September 2015. Since November 2015, Mr. Burke has served as President of Austin Highlands Advisors, LLC, a provider of corporate advisory services. He served as Executive Vice President and Chief Financial Officer of IDEV Technologies, a peripheral vascular devices company, from November 2009 until the company was acquired by Abbott Laboratories in August 2013. From August 2004 to December 2007, he served as Executive Vice President and Chief Financial Officer of ReAble Therapeutics, a diversified orthopedic device company that was sold to The Blackstone Group in a going private transaction in 2006 and subsequently merged with DJO Incorporated in November 2007. Mr. Burke remained with ReAble until June 2008. From 2001 to 2004, he served as Chief Financial Officer of Cholestech Corporation, a medical diagnostic products company. Mr. Burke has served on the board of directors of numerous public and private companies and currently serves on the board of directors of Adtalem Global Education Inc. and Myocardial Solutions, Inc. He previously served on the board of directors of Invuity, Inc. (acquired by Stryker Corporation in October 2018), LDR Holding Corporation (acquired by Zimmer Biomet in July 2016) and Medical Action Industries (acquired by Owens & Minor in October 2014).

Raymond O. Huggenberger, age 60, has served as a member of our board of directors since September 2017. Mr. Huggenberger has served as a member of the board of directors of Inogen, Inc. since 2008. Mr. Huggenberger served as Inogen’s Chief Executive Officer from 2008 to February 2017 and also served as Inogen’s President from 2008 until January 2016. Prior to joining Inogen, Mr. Huggenberger held various management positions with Sunrise Medical Inc., a global manufacturer and distributor of durable medical equipment, culminating as its President and Chief Operating Officer. Mr. Huggenberger also serves on the board of directors of private companies Wellfount Corporation, a pharmacy services company, Sommetrics, a medical device company, Clarify Medical, medical device company, Ebb Therapeutics, a medical device company, and previously served on the board of directors of IYIA Technologies, Inc., a healthcare company.

Gerald R. Mattys, age 60, has served as our Chief Executive Officer and as a member of our board of directors since 2005. From 2002 to 2004, he served as the Chief Executive Officer of Medisyn Technologies, Inc., a development stage biotechnology company. From 2000 to 2002, he was the President and Chief Executive Officer of Timm Medical Technologies, Inc., a medical device company. During the period from 1998 to 2000, he was Vice President and General Manager of Alternate Care for Mallinckrodt, Inc., a pharmaceutical and medical device company. Prior to that, he served 18 years in various roles in product management, sales, marketing and management at several medical device companies.

Richard J. Nigon, age 71, has served as a member of our board of directors since September 2012. Mr. Nigon is currently Senior Vice President of Cedar Point Capital, Inc., a private company that raises capital for early stage companies, where he has served since 2007. From February 2001 until December 2006, Mr. Nigon was a Director of Equity Corporate Finance for Miller Johnson Steichen Kinnard, a privately held investment firm, which was acquired in December 2006 by Stifel Nicolaus, a brokerage and investment banking firm. After that acquisition, Mr. Nigon became a Managing Director of Private Placements until May 2007. From February 2000 to February 2001, Mr. Nigon served as the Chief Financial Officer of Dantis, Inc., a web hosting company. Prior to joining Dantis, Mr. Nigon was employed by Ernst & Young LLP from 1970 to 2000, where he was a partner from 1981 to 2000. While at Ernst & Young, Mr. Nigon served as the Director of Ernst & Young's Twin Cities Entrepreneurial Services Group and was the coordinating partner on several publicly traded companies in the consumer retailing and manufacturing sectors. Mr. Nigon is a director of Northern Technologies International Corporation and Celcuity, Inc., and was previously a director of Vascular Solutions, Inc. before its acquisition by Teleflex, Incorporated in February 2017. Mr. Nigon also serves as a director of several private companies.

Cheryl Pegus, age 55, has served as a member of our board of directors since July 2017. Dr. Pegus is currently the SVP, Health Care Services and Chief Medical Officer at Cambia Health Solutions and leads the strategy for Cambia's enterprise and regional health plan business. Prior to joining Cambia, she served as the president of Caluent LLC, a health care data analytics company. She formerly served as the first Chief Medical Officer of Walgreen Co. ("Walgreens") from 2010 to 2013, where she assisted in the expansion of its healthcare services, new product launches and data analytics. Prior to joining Walgreens, Dr. Pegus was the General Manager and Chief Medical Officer of SymCare Personalized Health Solutions, Inc., a Johnson & Johnson start-up company, and the National Medical Director/Clinical Product Head for Aetna, Inc. Dr. Pegus currently serves as a director on the board of US Acute Care Solutions, a Welsh Carson portfolio company, and previously served as a director on the board of Cogentix Medical, Inc. before its acquisition by LM US Parent, Inc. in April 2018. Within the medical academic community, she currently serves as board chair for the Association of Black Cardiologists.

Kevin H. Roche, age 68, has served as a member of our board of directors since October 2004. Mr. Roche was General Counsel of UnitedHealth Group, a health insurance provider, from 1989 to 1996, at which time he founded and operated as the Chief Executive Officer of the Ingenix division of UnitedHealth Group, where he served until 2001. Following his retirement from UnitedHealth Group, Mr. Roche has spent several years assisting emerging growth companies as an investor, advisor and board member. He also serves as a Senior Advisor for Triple Tree, LLC. He currently serves as a director for several private healthcare companies. During the past five years, Mr. Roche served on the board of directors of Cogentix Medical, Inc.

Executive Officers

Information regarding our Chief Executive Officer, Gerald R. Mattys, is included above under the heading "Directors."

Robert J. Folkes, age 56, has served as our Chief Operating Officer since February 2015. He served as our Chief Financial Officer from 2005 until April 2016. Prior to joining our company in 2004, Mr. Folkes was the Chief Financial Officer for Advanced Respiratory, a medical device company, from 1997 until its sale in 2003. Prior to joining Advanced Respiratory, Mr. Folkes was an Audit Senior Manager for Ernst & Young LLP.

Brent A. Moen, age 51, 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.

Bryan F. Rishe, age 63, has served as our Senior Vice President, Sales since December 2017 and previously served as our Vice President, Sales since 2008. From 2004 to 2008, he served as the Vice President, Sales for BSN Medical, a medical soft goods manufacturer. Mr. Rishe also served as the Vice President, Sales and Marketing for TFX Medical, a surgical equipment manufacturer. Prior to that, Mr. Rishe was the Western Area Manager with Surgical Laser Technologies, a specialty laser company. Mr. Rishe has held other sales leadership and business development roles with Becton Dickinson, Baxter Travenol and American Hospital Supply.

Mary M. ("Maggie") Thompson, age 61, has served as our Senior Vice President, Reimbursement and Payer Relations, since November 2017 and previously served as our Vice President, Payer Relations and Government Affairs since 2006. Prior to joining our company, Ms. Thompson served as Director of Reimbursement for Uroplasty, Inc., a medical device company, from 2005 to 2006. From 1998 until 2005, Ms. Thompson served as Director of Payer Relations at Advanced Respiratory, a medical device company. A registered nurse, Ms. Thompson first practiced nursing at Gillette Children's Hospital and at a grant-funded community clinic in St. Paul, Minnesota. She then worked for the Minnesota Attorney General's Office as a nurse consultant until she joined a large health plan as the Government Programs Quality Regulatory Manager, working closely with the Centers for Medicare and Medicaid Services and Minnesota's Medicaid program. Ms. Thompson is active in the Alliance for Wound Care Stakeholders and is a member of Women Business Leaders in Healthcare.

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.

Additional information required by this Item 10 will be contained in our definitive proxy statement for our 2019 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, 2018 and 2017
   Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016
   Consolidated Statements of Comprehensive Income for the years ended December 31, 2018, 2017 and 2016
   Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2018, 2017 and 2016
   Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016
   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 Index to Exhibits below.

EXHIBIT INDEX

		Incorporated by Reference				
Exhibit Number	**Description of Exhibit**	**Form**	**File Number**	**Date of Filing**	**Exhibit Number**	**Filed Herewith**
2.1^	Asset Sale and Purchase Agreement, dated as of September 14, 2012, by and between Tactile Systems Technology, Inc., Swelling Solutions, Inc., ConvaTec Inc. and ConvaTec Technologies, Inc.	S-1	333-209115	01/25/2016	2.1	
3.1	Fourth Amended and Restated Certificate of Incorporation	S-1	333-209115	06/09/2016	3.1	
3.2	Amended and Restated By-laws	S-1	333-209115	05/06/2016	3.2	
4.1	Specimen Certificate representing shares of common stock	S-1	333-209115	05/06/2016	4.1	
4.3	Form of Senior Indenture	S-3	333-220132	08/23/2017	4.6	
4.4	Form of Subordinated Indenture	S-3	333-220132	08/23/2017	4.7	
10.1*	2003 Stock Option Plan	S-1	333-209115	01/25/2016	10.1	
10.2*	Form of Incentive Stock Option Agreement under 2003 Stock Option Plan	S-1	333-209115	01/25/2016	10.2	
10.3*	Form of Non-Statutory Stock Option Agreement (Employee) under 2003 Stock Option Plan	S-1	333-209115	01/25/2016	10.3	

10.4*	Form of Non-Statutory Stock Option Agreement (Director) under 2003 Stock Option Plan	S-1	333-209115	01/25/2016	10.4
10.5*	2007 Omnibus Stock Plan	S-1	333-209115	01/25/2016	10.5
10.6*	Form of Incentive Stock Option Agreement under 2007 Omnibus Stock Plan	S-1	333-209115	01/25/2016	10.6
10.7*	Form of Non-Statutory Stock Option Agreement (Employee) under 2007 Omnibus Stock Plan	S-1	333-209115	01/25/2016	10.7
10.8*	Form of Non-Statutory Stock Option Agreement (Directors) under 2007 Omnibus Stock Plan	S-1	333-209115	01/25/2016	10.8
10.9*	Form of Non-Statutory Stock Option Agreement (Consultants) under 2007 Omnibus Stock Plan	S-1	333-209115	01/25/2016	10.9
10.10*	Form of Restricted Stock Agreement	S-1	333-209115	01/25/2016	10.10
10.11*	2016 Equity Incentive Plan	S-1	333-209115	06/09/2016	10.11
10.12*	Form of Non-Qualified Stock Option Agreement under 2016 Equity Incentive Plan	S-1	333-209115	06/09/2016	10.12
10.13*	Form of Incentive Stock Option Agreement under 2016 Equity Incentive Plan	S-1	333-209115	06/09/2016	10.13
10.14*	Form of Restricted Stock Agreement under 2016 Equity Incentive Plan	S-1	333-209115	06/09/2016	10.14
10.15*	Form of Restricted Stock Unit Award Agreement under 2016 Equity Incentive Plan	S-1	333-209115	06/09/2016	10.15
10.16*	Form of Restricted Stock Unit Agreement under 2016 Equity Incentive Plan (Quarterly Awards)	S-1	333-209115	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	001-37799	02/27/2018	10.1
10.18*	Employee Stock Purchase Plan	S-1	333-209115	06/09/2016	10.17
10.19*	First Declaration of Amendment to Employee Stock Purchase Plan	10-K	001-37799	02/26/2018	10.18
10.20*	Management Incentive Plan	8-K	001-37799	03/10/2017	10.1

10.21*	Non-Employee Director Compensation Policy					X
10.22*	Form of Director and Officer Indemnification Agreement	S-1	333-209115	05/06/2016	10.19	
10.23*	Tactile Systems Technology, Inc. Executive Employee Severance Plan	10-Q	001-37799	11/05/2018	10.2	
10.24*	Form of Confidentiality, Assignment of Intellectual Property and Restricted Covenants Agreement	10-Q	001-37799	11/05/2018	10.3	
10.25*	Form of Employment Agreement between Tactile Systems Technology, Inc. and its named executive officers	S-1	333-209115	06/09/2016	10.20	
10.26*	Employment Agreement between Tactile Systems Technology, Inc. and Gerald Mattys	S-1	333-209115	06/09/2016	10.22	
10.27*	Employment Agreement between Tactile Systems Technology, Inc. and Lynn Blake	S-1	333-209115	06/09/2016	10.23	
10.28*	Employment Agreement between Tactile Systems Technology, Inc. and Bryan Rishe	S-1	333-209115	06/09/2016	10.24	
10.29*	Confidential Transition Agreement and Release, dated June 14, 2017, by and between Mary E. Anderson and Tactile Systems Technology, Inc.	10-Q	001-37799	08/07/2017	10.1	
10.30*	Separation and Consulting Agreement between Tactile Systems Technology, Inc. and Lynn L. Blake, dated as of August 1, 2018	8-K	001-37799	08/06/2018	10.1	
10.31	Line of credit documents, as amended May 11, 2016 by and between Tactile Systems Technology, Inc. and Venture Bank	S-1	333-209115	06/09/2016	10.21	
10.32	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	001-37799	08/06/2018	10.1	
10.33	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					X

10.34**	License Agreement, dated as of October 15, 2018, by and between Tactile Systems Technology, Inc. and Sun Scientific, Inc.	10-Q	001-37799	11/05/2018	10.1	
21.1	Subsidiaries	S-1	333-209115	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, 2018, formatted in XBRL: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Comprehensive Income, (iv) Statements of Stockholders' Equity (Deficit), (v) Statements of Cash Flows, and (vi) Notes to the Financial Statements					X

^ Schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule will be furnished supplementally to the Securities and Exchange Commission upon request.

* Indicates management contract or compensatory plan or arrangement.

** The Securities and Exchange Commission has granted the registrant's request that certain provisions of this exhibit be treated as confidential. Such material has been redacted from the exhibit as filed.

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 28, 2019	By: /s/ Gerald R. Mattys
	Gerald R. Mattys Chief Executive Officer (Principal executive officer)

Each of the undersigned hereby appoints Gerald R. Mattys 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 28, 2019.

Name	Title
/s/ Gerald R. Mattys Gerald R. Mattys	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/ Peter H. Soderberg Peter H. Soderberg	Chairman of the Board of Directors
/s/ William W. Burke William W. Burke	Director
/s/ Raymond O. Huggenberger Raymond O. Huggenberger	Director
/s/ Richard Nigon Richard Nigon	Director
/s/ Cheryl Pegus Cheryl Pegus	Director
/s/ Kevin H. Roche Kevin H. Roche	Director

Exhibit 10.21

TACTILE SYSTEMS TECHNOLOGY, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Adopted: January 1, 2019

Each non-management director of Tactile Systems Technology, Inc. (the "*Company*") will receive:

- An annual restricted stock unit (RSU) grant on the date of each annual meeting of stockholders at which the director is elected to the board or continues to serve as a director, the number of RSUs calculated by dividing $125,000 by the closing sale price for a share of the Company's common stock on the Company's principal stock exchange on the date of grant. Each grant will vest in full on the earlier of one year after the date of grant or the date of the next year's annual meeting of stockholders, provided the director remains a member of the board as of the vesting date. RSUs will settle in shares no later than March 15 of the calendar year following the date of vesting.
- An annual retainer of $40,000, payable in quarterly installments, in arrears, on the last business day of each calendar quarter. A non-management director may elect to receive a grant of fully vested RSUs in lieu of each such annual retainer installment, with the grant date being the last business day of each calendar quarter and the number of RSUs equal to the amount of the annual retainer installment divided by the closing sale price for a share of the Company's common stock on the Company's principal stock exchange on the date of grant. Each RSU will represent the right to receive one share of the Company's common stock upon the earlier of the director's separation from service as a director of the Company or the occurrence of a change in control of the Company. Any election to receive RSUs in lieu of cash, and the settlement of such RSUs shall be made in accordance with the requirements of Section 409A of the Internal Revenue Code.

Each non-management director of the Company that chairs a committee will receive an annual fee as follows:

Committee Chair	Annual Cash Fee
Audit	$20,000
Compensation and Organization	$15,000
Nominating and Corporate Governance	$ 10,000
Compliance and Reimbursement	$ 10,000

Each non-management director of the Company, other than the chair, that serves on a committee will receive an annual fee as follows:

Non-Chair Committee Members	Annual Cash Fee
Audit	$10,000
Compensation and Organization	$7,500
Nominating and Corporate Governance	$5,000
Compliance and Reimbursement	$5,000

The chair of the Company's board of directors will receive an additional annual fee of $50,000.

The Company will reimburse a director's reasonable expenses in connection with attending board and committee meetings.

For directors joining the Company during a period between annual meetings, all amounts will be prorated based on the percentage of the year until the next annual meeting.

Execution Version

FIRST AMENDMENT TO CREDIT AGREEMENT

This First Amendment to Credit Agreement (this "**Amendment**") is entered into as of February 12, 2019, by and among (a) Tactile Systems Technology, Inc., a Delaware corporation (dba Tactile Medical) ("**Borrower**"), (b) the Lenders who are party to this Amendment and the Lenders who may become a party to this Amendment pursuant to the terms of the Credit Agreement (defined below) (collectively, the "**Lenders**"), and (c) Wells Fargo Bank, National Association, a national banking association, as Administrative Agent for the Lenders ("**Agent**"). This Amendment is consented and agreed to by the Guarantors.

RECITALS

A. Borrower, Lenders and Agent are parties to that certain Credit Agreement dated as of August 3, 2018 (as the same may be amended, restated or modified from time to time, the "**Loan Agreement**"). Capitalized terms used but not defined in this Amendment have the meanings given to such terms in the Loan Agreement.

B. Borrower has requested that Lenders and Agent permit certain amendments and modifications to the Loan Agreement.

C. Lenders and Agent have agreed to such modifications, but only upon the terms and conditions outlined in this Amendment.

TERMS OF AGREEMENT

In consideration of the mutual covenants herein, and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, Borrower, Lenders and Agent hereby agree as follows:

1. Amendment and Restatement of Section 9.14. Section 9.14 of the Loan Agreement is amended and restated in its entirety as follows:

> Section 9.14 Capital Expenditures. Permit the aggregate amount of all Capital Expenditures in any Fiscal Year to exceed the amount set forth below for such Fiscal Year (or for the 2021 Fiscal Year, from January 1, 2021 through August 3, 2021):

Fiscal Year	**Amount**
2018	$5,000,000
2019	$15,000,000
2020	$15,000,000
2021	$9,000,000

2. Representations and Warranties. Borrower represents and warrants as follows:

(a) All warranties and representations made under the Loan Agreement and the other Loan Documents are true and correct in all material respects as of the date hereof(without duplication of any materiality qualifier contained therein), except to the extent such representation or warranty expressly relates to an earlier date (in which case, such representations and warranties were true and correct in all material respects (without duplication of any materiality qualifier contained therein) as of such earlier date).

(b) The execution and delivery by Borrower and Guarantor of this Amendment (i) are and will be within Borrower's and Guarantor's organizational powers; (ii) have been authorized by all necessary organizational action; (iii) are not and will not require any Governmental Approval or violate any Applicable Law relating to any Credit Party or any Subsidiary thereof where the failure to obtain such Governmental Approval or such violation could reasonably be expected to have a Material Adverse Effect; (iv) conflict with, result in a breach of or constitute a default under any indenture, agreement or other instrument evidencing Indebtedness or a payment obligation in excess of the Threshold Amount to which such Person is a party or by which any of its properties may be bound or any Governmental Approval relating to such Person, which could, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; or (v) result in or require the creation or imposition of any Lien upon or with respect to any property now owned or hereafter acquired by such Person other than Permitted Liens.

(c) This Amendment will be valid, binding and enforceable against Borrower and Guarantor in accordance with its respective terms.

(d) No Default or Event of Default has occurred under the Loan Agreement or any of the other Loan Documents.

3. Guaranties. All guaranties of the Obligations remain in full force and effect, and all Guarantors hereby (a) consent to the modifications and changes in terms to the Loan Agreement described herein; and (b) reaffirm their guaranty obligations described in such guaranties.

4. Release and Waiver of Claims. For purposes of this section, the term Lenders and Agents specifically include each of Lender's and Agent's predecessors, successors, affiliates, and all of their past, present and future officers, trustees, directors, members, agents, contractors, employees, consultants, attorneys, assigns, insurers, stockholders, and representatives, and each of them (whether or not any of the same were acting within or without the scope of employment or engagement). The release and waiver of claims of this section is to be construed broadly in favor of Lenders and Agent and against Borrower and Guarantor. Borrower and Guarantor hereby jointly and severally affirm that they do not have any defense, claim, offset, counterclaim or other claim or action (whether known or unknown) against Lenders or Agent including, but not limited to, with respect to the Loans, the Loan Agreement or the Loan Documents, or arising out of negotiations prior to and/or contemporaneous with the execution of this Amendment, and that even if such claim, action, defense, offset or counterclaim exists or might exist on the date hereof (whether known or unknown), Borrower and Guarantor hereby knowingly and jointly and severally forever waive, release and relinquish the same. Borrower and Guarantor acknowledge that the relationship between Borrower and Guarantor, on the one hand, and Lenders and Agent, on the other hand, has been solely a borrower-lender relationship, that Lenders and Agent have not exercised control over Borrower, Guarantor or any of their respective operations, and that Borrower and Guarantor are not acting under any duress or coercion in connection with the execution of this Amendment. Borrower and Guarantor represent and warrant that they have obtained the advice of independent legal counsel, or have had the opportunity to obtain their own legal counsel and have knowingly declined to obtain such legal counsel, with respect to their execution of this Amendment and the matters set forth herein.

5. Effectiveness of Prior Documents. Except as specifically amended hereby, the Loan Agreement and the other Loan Documents shall remain in full force and effect in accordance with their respective terms. All covenants, warranties and representations contained in the Loan Agreement and the other Loan Documents are hereby reconfirmed as of the date hereof. All Collateral previously provided to

secure the Loan Agreement and the Loan Documents continues as security, and Borrower and Guarantor reaffirm all of their obligations under any Loan Document to which it is a party. This is an amendment, not a novation.

6. Reimbursement of Agent's Expenses. Borrower hereby agrees to reimburse Agent for all reasonable and documented out of pocket costs and expenses relating to this Amendment. Borrower hereby authorizes Agent, at its option, to debit any account of Borrower held with the Lenders for the payment of such fees, costs and expenses.

7. No Waiver of Defaults; Warranties. The execution of this Amendment shall not be deemed to be a waiver of any Default or Event of Default under the Loan Agreement or Loan Documents, whether or not known and whether or not existing on the date of this Amendment. Lenders and Agent expressly reserve all of their rights and remedies under the Loan Agreement and Loan Documents with respect to any existing or future Defaults or Events of Default under the Loan Agreement or other Loan Documents, including this Amendment. All agreements, representations and warranties made herein shall survive the execution of this Amendment.

8. Counterparts. This Amendment may be signed in any number of counterparts, each of which shall be considered an original, but when taken together shall constitute one document.

9. Final Expression. This written Amendment is a final expression of the agreement between Lenders, Agent, Borrower and Guarantor relating to the subject matter hereof, and this written agreement may not be contradicted by evidence of any alleged oral agreement.

10. Governing Law. The governing law, submission to jurisdiction, waiver of venue, service of process and waiver of jury trial provisions set forth in Sections 12.5 and 12.6 of the Loan Agreement are incorporated herein by reference and apply to this Amendment.

[*Signature Page to Follow*]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the day and year first above written.

BORROWER:

TACTILE SYSTEMS TECHNOLOGY, INC.

By: /s/ Brent Moen
Name: Brent Moen
Title: CFO

Consented and Agreed to By:

GUARANTOR:

SWELLING SOLUTIONS, INC.

By: /s/ Brent Moen
Name: Brent Moen
Title: CFO

[Borrower and Guarantor Signature Page to First Amendment to Credit Agreement]

AGENT AND LENDERS:

WELLS FARGO BANK, NATIONAL ASSOCIATION, as Administrative Agent, Swingline Lender, Issuing Lender and Lender

By: /s/ Sara Barton
Name: Sara Barton
Title: Vice President

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated February 28, 2019, 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, 2018. We consent to the incorporation by reference of said reports in the Registration Statements of Tactile Systems Technology, Inc. on Form S-3 (File No. 333-220132) and Forms S-8 (File No. 333-216278, File No. 333-212704 and File No. 333-223249).

/s/ Grant Thornton LLP

Minneapolis, Minnesota
February 28, 2019

Exhibit 31.1

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, Gerald R. Mattys, 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/ Gerald R. Mattys
Gerald R. Mattys
Chief Executive Officer

Date: February 28, 2019

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 28, 2019

Exhibit 32.1

**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, 2018, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Gerald R. Mattys, 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/ Gerald R. Mattys
Gerald R. Mattys
Chief Executive Officer

Date: February 28, 2019

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, 2018, 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 28, 2019