Electromed, Inc.
Form 10-K
September 28, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2010

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

For the transition period from _____ to _____.

Commission File No.: 001-34839

Electromed, Inc.

(Exact name of Registrant as specified in its charter)

Minnesota	**41-1732920**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

500 Sixth Avenue NW, New Prague, MN

(Address of principal executive offices)

(952) 758-9299

(Registrant s telephone number, including area code)

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

Common Stock $0.01 par value	Nasdaq Capital Market
(Title of each class)	(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Exchange Act: None

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

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

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 o No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files).
Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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. x

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if smaller reporting company)	Smaller Reporting Company x

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

The registrant completed the initial public offering of its common stock on August 18, 2010. Accordingly, there was no public market for the registrant s common stock as of December 31, 2009, the last day of the registrant s most recently completed second fiscal quarter.

There were 7,887,885 shares of the registrant s common stock outstanding as of September 16, 2010.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant s Fiscal 2011 Annual Meeting of Shareholders, to be filed within 120 days of June 30, 2010, are incorporated by reference into Part III of this Form 10-K.

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INFORMATION REGARDING FORWARD LOOKING STATEMENTS

Some of the statements in this report may contain forward-looking statements that reflect our current view on future events, future business, industry and other conditions, our future performance, and our plans and expectations for future operations and actions. In some cases, you can identify forward-looking statements by the following words: anticipate, believe, continue, could, estimate, expect, intend, ma 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. Our forward-looking statements in this report relate to the following: our business and growth strategy, our business strengths and competitive advantages, our intent to increase international sales and distribution, our expectation that our products will be prescribed for an increasing number of conditions, our plan to continue to increase investment in research and development, our intent to continue improvement of our product offerings through innovation, our intent to add sales staff and other employees, our belief that we will continue to expand our intellectual property portfolio, our expectations with respect to our settlement with Hill-Rom, and our anticipated revenues, offering proceeds, expenses, and capital requirements. Many of these forward-looking statements are located in this report under Item 1. BUSINESS; Item 2. PROPERTIES and Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS, but they may appear in other sections as well. These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry s actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management s beliefs and assumptions, which in turn are based on currently available information.

You should read this report thoroughly with the understanding that our actual results may differ materially from those set forth in the forward-looking statements for many reasons, including events beyond our control and assumptions that prove to be inaccurate or unfounded. We cannot provide any assurance with respect to our future performance or results. Our actual results or actions could and likely will differ materially from those anticipated in the forward-looking statements for many reasons, including the reasons described in this report. These factors include, but are not limited to:

the competitive nature of our market;

the risks associated with expansion into international markets;

changes to Medicare, Medicaid, or private insurance reimbursement policies;

changes to health care laws;

changes affecting the medical device industry;

our need to maintain regulatory compliance and to gain future regulatory approvals and clearances;

our ability to protect our intellectual property;

the outcome of current and future litigation, including our ability to reach a definitive settlement agreement with Hill-Rom in the timeframe expected; and

general economic and business conditions.

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PART I

Item 1. Business.

Overview

Electromed, Inc. (we, us, Electromed or the Company) was founded by Mr. Robert Hansen and Mr. Craig Hansen and incorporated in Minnesota in 1992. In August 2010 we completed an initial public offering of 1,700,000 shares of our common stock. Our common stock is traded on the Nasdaq Capital Market under the ticker symbol ELMD.

We manufacture, market and sell products that provide airway clearance therapy, including the SmartVest® Airway Clearance System (SmartVest System) and related products, to patients with compromised pulmonary function. The SmartVest System generates High Frequency Chest Wall Oscillation (HFCWO), also known as High Frequency Chest Compression, a technique for airway clearance therapy. HFCWO facilitates airway clearance by loosening and mobilizing respiratory secretions in a patient s lungs. A vest is worn over the torso that repeatedly compresses and releases the chest at frequencies from 5 to 20 cycles per second. Each compression (or oscillation) produces pulsations within the lungs that shear secretions from the surfaces of the airways and propels them toward the mouth where they can be removed by normal coughing. Unlike traditional chest physio-therapy, which must be performed on the patient while he or she is placed in a series of often uncomfortable positions, HFCWO can be performed with the patient sitting upright.

Studies show that HFCWO therapy is as effective an airway clearance method for patients who have cystic fibrosis or other forms of compromised pulmonary function as traditional chest physio-therapy administered by a respiratory therapist. However, HFCWO can be self-administered, relieving a caregiver of participation in the therapy, and eliminating the attendant cost of an in-home care provider. We believe the treatments are cost-effective primarily because they reduce a patient s risk of respiratory infections and other secondary complications that are associated with impaired mucus transport. Secondary complications, such as pneumonia, may be serious or life-threatening and often result in costly hospital visits.

The SmartVest System is a portable, programmable, and multi-positional airway clearance machine that generates HFCWO and has been approved by the FDA to treat the condition of excess lung secretions. Consequently, it may be prescribed to patients suffering from cystic fibrosis, chronic obstructive pulmonary disease, muscular dystrophy, post-surgical airway complications and a variety of other diseases and conditions associated with impaired lung and airway capacity. By clearing airways, patients are able to rid their lungs of retained secretions and are therefore less likely to develop lung infections such as pneumonia.

The SmartVest System features a programmable electro-mechanical pulse generator and a pneumatic therapy garment, which together provide safe, comfortable, and effective airway clearance therapy. We believe that the lightweight, portable design allows patients greater freedom to travel and enjoy activities of daily living, resulting in enhanced quality of life for patients using our SmartVest System. A broad range of vest sizes for children and adults allow for tailored fit and function. User-friendly controls allow children to administer their own daily therapy under adult supervision. Our goal has been to make the HFCWO airway clearance treatments as comfortable and convenient as possible so our patients can more easily tolerate their regimen and be able to perform their treatments as readily as possible.

In order to maintain and expand our position in the market for airway clearance therapy products, we have assembled an experienced team of employees with expertise in health care, product development, manufacturing, marketing, sales, and financial management. For example, more than 30% of our employees are respiratory therapists. In addition, we engage over 300 respiratory therapists and health professionals on a non-exclusive independent contractor basis to educate and train customers on the SmartVest System. Our team also includes several consultants who advise us on quality assurance, product development, and financing, and who keep us apprised of industry developments and opportunities in Europe.

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Growth Strategy

We believe we are poised for significant sales and earnings growth, predicated on the following objectives:

Expanding and repositioning our sales staff within the U.S. We select experienced medical professionals, usually respiratory therapists, to represent our products in the field. Our sales representatives, which we identify as Clinical Area Managers (CAMs), are employed full-time by Electromed, are assigned an exclusive territory, and under the supervision of a regional manager, serve discrete geographic areas of the U.S. They are equipped with demonstration models, and, where appropriate, arrange for such models to be accessed by patients through a demonstration program to physicians, clinics, and hospitals. We believe this approach is an effective sales model and ensures that patients, physicians, clinics, and hospitals receive reliable and correct training for our products. We intend to recruit additional CAMs and expect that doing so will increase our domestic sales. As we gain sales and industry contacts within each territory, we intend to continue to actively monitor sales opportunities by repositioning certain of our current CAMs to serve smaller geographic areas.

Establishing and strengthening sales relationships in Europe and Asia. Internationally, we have made sales in more than ten countries. We are actively identifying distributors and other sales opportunities. Our historical practice and continued intent includes developing long-term relationships with distributors who possess the knowledge, experience, and financial maturity to serve pulmonary patients and reliably satisfy payment obligations. Our agreements typically allow us to terminate the relationship if the distributor does not meet particular sales thresholds on an annual basis. We believe that expanding our distributor relationships in Europe and Asia will generate revenue growth because it will allow us to establish our SmartVest System as the preferred airway clearance therapy product in regions where HFCWO therapy is not yet widely used. Attention is given to a distributor candidate s knowledge and experience in serving respiratory physicians and patients in the host country. We then designate members of our regulatory staff to actively monitor the distributor s conformity with all applicable regulations and good practices in the host country. We support our distributors by providing advertising materials and direct training opportunities at our headquarters.

Maintaining leadership in product innovation. We have pursued our goal of continuous improvement through an active research and product development program, and plan to develop and introduce future advancements in HFCWO products for patient use. Each product will be designed to provide compact, portable, and user-friendly features. In addition, we expect to continue enhancing our Single Patient Use Vest and SmartVest Wrap, which we market to hospitals and health care providers.

Business Strengths

Intellectual Property

Our intellectual property represents one of our most significant business strengths. It allowed us to pioneer an HFCWO device with a single-hose and flow-through system design, leading to the competitive advantages described below. We currently hold 19 issued U.S. patents and 5 issued foreign patents covering the SmartVest System and its underlying technology, and have 33 additional U.S. and foreign patent applications pending. These patents and patent applications offer coverage in the field of air pressure pulse delivery to a human in support of airway clearance. These patents and patent applications are described in more detail below, under the heading Intellectual Property.

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Competitive Advantages of SmartVest System

We believe that the SmartVest System offers competitive advantages in improved patient comfort and satisfaction. Unlike our competitors products, which are primarily dependent upon a two-hose, closed system for attaining consistent air pulse transmission to the vest and lungs, the SmartVest System relies on a single-hose, flow-through system. We believe a single-hose, flow-through system provides the following benefits:

The single-hose system simplifies delivery of the air pulse energy to the lungs. The pulse is delivered evenly from the base of our vest, extending the force pulses upward and inward in strong but smooth cycles of 360-degree latitudes, which delivers simultaneous treatment to the patient s chest and back and all lobes of the lungs. In addition, the single hose is less obtrusive than a two-hose system and is longer than the hoses used by competing products, allowing the patient greater comfort during the course of treatment.

The flow-through system design provides a continuous accommodation grid of air release holes in the vest air bladder. No matter what resistance a patient s chest may be creating in normal aspiration (breathing), air release adjusts accordingly in the bladder. This can prevent lags in pulse pressure accommodation as compared to a closed system, in which electronic signal generators must continuously send changes in air fill instruction to the air pump. We believe greater patient comfort is realized in our flow-through system design.

Industry Contacts

Our management team has significant business experience and has developed industry relationships, resulting from memberships in various respiratory care professional groups and attendance, sponsorship and participation in numerous medical conferences in the U.S., Europe, and Asia. We believe these investments of time and capital have increased visibility of the SmartVest System and established a favorable reputation and perception of Electromed. In addition, participation in industry conferences allows us to educate and train health care professionals on the SmartVest System.

In addition to relationships developed at the management level, our staff and contractors, who often play a key role in the education of current and potential customers, have developed trusted relationships across the U.S. with physicians and other caregivers over the course of their careers. Over 30% of our full-time employees, including our entire Patient Services Department and nearly all of our sales representatives, are respiratory therapists. Many of these individuals have extensive experience in the field of respiratory care, and their relationships and experience are of great worth to us. These individuals maintain a dialogue with clinics, patients, patient families, and respiratory therapist trainers to ensure that our products are being properly operated and are performing effectively. Additionally, our sales representatives participate in various events, such as family days held by the Cystic Fibrosis Foundation for cystic fibrosis patients, at which they have an opportunity to demonstrate the effectiveness of the SmartVest System and further develop relationships with patients, patient families, physicians and hospitals. We believe that the relationships and reputation for service that our staff and contractors have developed are key factors in our ability to gain patients and secure reimbursement.

Engineering and Manufacturing Departments

Another significant business strength is the valuable know-how of our Engineering and Manufacturing Departments. The experience of the individuals in these departments helps ensure the efficient production of high-quality products. In addition, we have established a network of vendors who permit us to integrate all assembly and quality assurance on a single campus. We believe that our efficient product development and manufacturing processes create a business strength because they allow us to offer our products at competitive prices and respond quickly to increases in demand.

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Our Products

Our products are primarily used in the home health care market. We also sell our products for use in hospitals, which we refer to as institutional sales. Accordingly, our points of contact are home health care use, hospitals, clinics, and pulmonary rehabilitation centers, both domestically and internationally. The SmartVest System is a doctor-prescribed therapy and, depending on the circumstances of the patient, its cost to an individual is generally reimbursable by Medicare, Medicaid and private insurance, or a combination of the three. Our products have been cleared for market by the FDA.

The SmartVest System

The SmartVest System consists of a pneumatic therapy garment, an electronic pulse generator for creating and controlling force pulses, and a single hose which extends the force pulses from the generator to the pneumatic vest. The SmartVest System is a portable airway clearance therapy system that gives the patient direct control over the most difficult and time-consuming aspects of respiratory therapy, and provides caregivers an easier and more reproducible means of administering therapy to disabled or bedridden patients. The SmartVest System also has other appealing practical features, including improved ease of use and a non-clinical appearance. We believe these attributes particularly appeal to children, teenagers and young adults who represent the majority of the cystic fibrosis patient population. Our system allows the patient to be relatively mobile while therapy is being given, unlike manual chest physical therapy in which the patient must remain in a fixed position.

We believe the SmartVest System s therapy garment is unique in its:

Design: We have pioneered a vest design that provides consistent and controlled pulse pressure that is distributed throughout the vest and treats the entire front and back thoracic (chest) cavity. The vest is low profile, featuring a soft, breathable fabric. Some competitive models have reduced weight and size of their vests by reducing coverage area of the chest and applying pressure to the chest only. We do not endorse or employ a partial coverage vest, and all of our products offer 360-degree coverage. Our vest uses a flow-through system design, which improves patient comfort by providing a continuous accommodation grid of air release holes in the vest air bladder, allowing air releases to automatically adjust. This can prevent lags in pulse pressure accommodation as compared to a closed system, in which electronic signal generators must continuously send changes in air fill instruction to the air pump. We believe heightened patient comfort is realized because of our flow-through design.

Size and Ease of Use: The SmartVest System is available in eight sizes to accommodate children and adults. The simple design of the Velcro and overlap closure system creates a broad size adjustment range to insure a properly tailored fit. It also makes the vest easier to clean and disinfect than some competitors products, which often use straps and buckles. The patented design includes a removable bladder, permitting the therapy garment to be easily washed and dried. This feature also helps improve infection control efforts.

Material: An attractive washable nylon shell with quick fit Velcro provides an appealing non-clinical look and feel, which we believe enhances self-esteem and patient compliance.

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Modular Assembly: The vest s modular assembly allows the custom modification of the manifold to enhance pulsation and avoid local areas of sensitivity such as incisions and catheters.

The SmartVest System s electronic pulse generator features the following important aspects:

Portable Design: The pulse generator for the SmartVest System is streamlined and fits into a roller bag for easy transport. The vest and hose are carried in a small companion bag. The unit is relatively lightweight and can be readily carried or rolled by an individual. The system complies with airline carry-on size limits and can be carried onto an airplane or stowed in the trunk of a car, allowing patients greater freedom to travel.

Single-Hose System: When the SmartVest System is in use, a single hose delivers the pulsation to the vest, which we believe provides therapy in a more comfortable and unobtrusive manner than a two-hose system. In addition to facilitating patient comfort, the single-hose system provides effective treatment by simplifying delivery of the air pulse energy to the lungs. The pulse is delivered evenly from the base of the SmartVest therapy garment, extending the force pulses upward and inward in strong but smooth cycles of 360-degree latitudes, which delivers simultaneous treatment to the patient s chest and back and all lobes of the lungs.

Programmable Pulse Generation: The SmartVest System uses a pulse generator with an internal programmable memory feature to generate a pneumatic pulse electronically. The pulse frequency can be adjusted from 5 to 20 cycles per second, which accommodates the required therapeutic range. The range can be preset, by programmable controls, to assure patient safety and specific treatment requirements. For example, the unit can be programmed to deliver a varying pulse frequency during the course of a treatment session without requiring manually directed changes. We believe this feature adds convenience and enhances patient compliance with treatment protocol choices. For more information about the complexity of treatments typically offered to patients with chronic pulmonary dysfunction, please refer to the information under the heading Customers.

Power Supply: The SmartVest System also includes a power supply suitable for use in international markets, such that voltage and amperage are accommodated automatically.

In order to maintain and expand our position in the airway clearance therapy industry, we plan to develop and introduce future advancements in HFCWO products. Our goal is to provide effective treatment while improving the quality of life for patients who suffer from chronic pulmonary conditions resulting in impaired airway clearance. Therefore, we plan to make each product progressively more compact, portable, and user-friendly. Our goal is to seek improvements in design that will result in a relatively lower manufacturing cost for each subsequent generation of the SmartVest System.

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Other Products

We market our Single Patient Use Vest (SPUV) and SmartVest Wrap® to health care providers, particularly those working in intensive care units. Hospitals issue the SPUV or SmartVest Wrap to one patient for the duration of his or her stay. Both products facilitate continuity of care because they introduce the patient to our product line and may encourage use of the home care SmartVest System, which can be provided to the chronic condition patient upon discharge. Both products provide full coverage pulsation. The SPUV is a full-sized vest that is often used for patients undergoing institutional treatment who are already accustomed to using a SmartVest System. The SPUV is intended for short-term, in-patient use and allows the patient to avoid contaminating his or her home-use vest while continuing treatment in a hospital or other facility.

The SmartVest Wrap, which we introduced in 2007, is lightweight, convenient, and well-suited for patients recovering from surgery and short-term illnesses. We believe that the design of the SmartVest Wrap, which lacks a vest outer shell, makes it easy for the health care professional to operate because it does not need to go over the patient s head, minimizing the need to move post-surgical patients and avoiding interference with other apparatuses the patient may be using. In addition, the wrap is reversible, which allows the air pulse generator to be aligned on either side of a hospital bed. We believe that our ability to provide a relatively more comfortable therapy alternative to patients results in a higher likelihood of patient cooperation and consistent use.

We have designed and patented a mobile pedestal, which we manufacture and provide with sales of our institutional models of the SmartVest System. The mobile pedestal allows for easy transport within the medical facility. This unit includes a pneumatic feature, permitting ease of movement in raising and lowering the vertical position of the generator.

Our Markets

Overview

We market our HFCWO products to a broad patient population. For patients with a chronic pulmonary condition, many hours per day may be dedicated to a variety of treatments. The SmartVest System provides effective airway clearance therapy in a comfortable and portable design which allows patients greater independence and speed of treatment. Building from a foundation of product quality, as well as our dedication to customer service, our goal is to be a consistent innovator in providing airway clearance therapy to patients with compromised pulmonary function.

Because sale of the SmartVest System is by physician s prescription only, we market to health care professionals, such as doctors, nurses, respiratory therapists, and clinic coordinators. However, with respect to both our in-home and institutional products, the health care professionals decisions may be based on preferences expressed by patients. Therefore, we believe that it is also important to market our products to patients and caregivers. In addition, because the availability of reimbursement is an important consideration for health care professionals and patients, we must also prove the effectiveness of our product to public and private insurance providers.

Our SmartVest System is currently prescribed to patients who suffer from cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), bronchiectasis, neuro-muscular disorders or post-surgical complications and patients who are ventilator dependent or have other conditions involving excess secretion and impaired mucus transport. When we entered the market in 2000, we focused on providing our product to CF patients because we felt those individuals could greatly benefit from treatment from our HFCWO system and it was the indication most likely to qualify for reimbursement at that time. We expect that the CF patient population will remain an important customer population in the future but seek to continuously expand our product offerings to a broader patient population, which now includes post-surgical and intensive care patients at risk of developing pneumonia, patients with end-stage neuromuscular disease, and ventilator-dependent patients. We believe that our greatest opportunities for growth are in emerging areas of application, such as COPD, bronchiectasis, neuro-muscular disorders, and acute care. We also believe that international populations present a key market opportunity, as HFCWO is not yet a prevalent form of therapy outside of the U.S.

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When evaluating market expansion for the SmartVest System, it is important to understand the needs of the patients requiring airway clearance therapy and, in some instances, their care providers. The essential requirements that make a patient a candidate for airway clearance therapy are compromised respiratory function with a need to:

- secure airway clearance therapy on a cost-effective long-term basis, confidently and with relative ease;
- maintain and/or improve pulmonary status;
- mobilize secretions several times per day; and
- carry out activities of daily living.

The SmartVest System is designed to meet the individual patient s needs by providing a therapy that is efficient, is easy to administer, and can be performed independently. Electromed s established marketing and product support services provide education, training, and follow-up with the patient population to insure the product is integrated into their daily treatment regimen. We believe advantages of the SmartVest System to the independent patient include:

- usually can be reimbursed by private insurance, by federal or state government programs or combinations of the foregoing;
- consistent treatments at home;
- independence from a dedicated caregiver;
- portability;
- improved comfort during therapy; and
- improved self-image.

Cystic Fibrosis

CF is a genetic defect that disrupts chloride (salt) transfer in and out of cells, causing the normal secretions from the exocrine glands to become very thick and sticky, eventually blocking ducts of the glands in the pancreas, lungs and liver. The thick mucus accumulates in the lung s respiratory tracts, causing chronic infections, scarring, and decreased vital capacity. Normal coughing is often not sufficient to dislodge these secretions. Cystic fibrosis symptoms usually appear in early childhood. The median life expectancy for CF patients in the U.S. is approximately thirty-seven years, although some patients live into their fifties and beyond.

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Approximately 30,000 people in the U.S. currently have cystic fibrosis, with an estimated 1,000 new cases diagnosed each year. We estimate that during our 2010 fiscal year, sales to CF patients comprised approximately 19% of our net revenue, although overlap in patient populations makes it difficult to attribute revenue to any particular condition with certainty.

All patients with cystic fibrosis require respiratory therapy as a daily part of their care regimen. Traditionally, care providers perform Chest Physical Therapy (CPT) one to four times per day. CPT consists of a patient lying in one of twelve positions (most with the head pointed downward) while a caregiver claps or pounds on the chest and back over each lobe of the lung. To treat all areas of the lung in all twelve positions requires pounding for 30 to 45 minutes along with inhalation therapy. CPT clears the secretions by shaking loose airway secretions through chest percussions and draining the loosened secretions towards the mouth. Active coughing is required to ultimately remove the loosened secretions.

The SmartVest System provides a convenient means to mobilize secretions. Although some patients may prefer CPT based on their preference to avoid the reimbursement process for the SmartVest System, the necessity to learn to use the system and adjust to a new treatment method, and the potential that the patient may temporarily be without the equipment if it needs to be repaired, many patients feel that CPT limits their independence by requiring the presence and assistance of a second person. Attending college, working a job, traveling on business, and having a normal social life are all adversely impacted by the need for CPT. Although some older patients can learn to perform some elements of CPT on themselves, many adults do not, and must forego regular CPT in order to meet the requirements of school and employment with concomitant risk to their health. Moreover, CPT is a physically exhausting process for both the patient and the caregiver. Patient and caregiver non-compliance with prescribed protocols is a well-recognized problem that diminishes the effectiveness of this method. CPT effectiveness is also highly technique sensitive and degrades as the giver becomes tired.

Bronchiectasis

Bronchiectasis is a chronic lung condition characterized by abnormal widening of the bronchial tubes, or, as defined by Medicare, a productive cough that occurs more than twice per year or lasts longer than six months. In a patient with bronchiectasis, the bronchial tubes are damaged by the abnormal widening, which impairs their ability to clear mucus from the lungs and causes a chronic cough. Bronchiectasis may affect multiple areas of one or both lungs. The condition is often caused by inflammation and infection of the airways, for example due to bacterial lung infections (chronic bronchitis or pneumonia) or inhaling foreign objects. Cystic fibrosis causes about half of all bronchiectasis in the U.S. The effects of bronchiectasis include excessive coughing, shortness of breath, fatigue, and recurring pneumonias. Depending on the severity of a patient s condition, treatments range from bronchodilator medications (inhalers), antibiotics, daily CPT and drainage, or surgical removal of the affected lung tissue. We believe that our success in the CF market suggests that our SmartVest System can provide effective treatment to patients with bronchiectasis, as clearing the airways of secretions is central to the treatment of both conditions. We estimate that during our 2010 fiscal year, sales to bronchiectasis patients comprised approximately 39% of our net revenue, although overlap in patient populations makes it difficult to attribute revenue to any particular condition with certainty.

Chronic Obstructive Pulmonary Disease

COPD is a progressive disease that, over time, makes it more and more difficult for a patient to breathe. According to statistics published by the World Health Organization in November 2008, COPD is the fourth leading cause of death in the world, and some experts expect that it will be the largest cause of disability and death due to respiratory disease in the year 2020.

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People with COPD may have chronic inflammation of the bronchial tubes, emphysema or, more likely, both. In emphysema, the walls between the air sacs in the lungs are damaged, causing them to lose their shape and become deflated. This damage can also destroy the walls of the air sacs, leading to fewer and larger air sacs instead of many tiny ones. In chronic obstructive bronchitis, the lining of the airways is constantly irritated and inflamed. This causes the lining to thicken. The patient s immune system reacts by increasing secretions, making it difficult to breathe. Thus, patients with COPD slowly suffocate over a period of years. Using auxiliary muscles, people can inhale with considerable effort but are unable to exhale. Even a mild case of COPD can have an impact on the heart. Heart failure is also associated with severe COPD.

COPD has no cure, and traditional treatments are inconvenient for the patient and have limited effectiveness. These treatments consist of inhaled dilator and steroid medications, physical therapy exercises, major surgery, such as a lung transplant or lung volume reduction surgery, and oxygen therapy, either constantly through nasal prongs or for several hours per day through a mask. For some patients, the primary course of action is merely to manage the risks and complications that result from the disease, such as by obtaining pneumonia and influenza vaccines, since infections may suddenly increase the severity of COPD. We believe that the combination of excess secretions and the inability to forcibly exhale to clear the lungs make COPD patients ideal candidates for our airway clearance therapy.

Neuro-Muscular Diseases

Neuro-muscular diseases include muscular dystrophy, spinal muscular atrophy, and multiple sclerosis. Patients with neuro-muscular diseases have difficulty breathing, as well as difficulty clearing their lungs of accumulated mucus. The conditions often cause a patient s diaphragm muscles to deteriorate and lead to poor spinal alignment, each of which impairs the patient s ability to fully inhale. In addition, poor muscle coordination makes it difficult for the patient to forcefully exhale or cough. Due to this difficulty, patients with neuro-muscular diseases have an exceptionally high risk of developing serious secondary complications, such as pneumonia and respiratory failure. Secretion management is a critical aspect of the respiratory care of these patients. We believe that our SmartVest System aids in producing effective coughs, and thereby improves breathing and reduces the risk of infection.

New Markets

Acute Care

The acute care market includes ventilator-dependent patients and post-surgical patients at risk for pulmonary complications. Patients at risk include smokers, those with a history of lung disease, asthma, or chronic bronchitis, the overweight, the elderly, those immobilized by illness or injury, and those who have an adverse reaction to anesthesia. Specific problems may include pneumonia, infection, atelectasis (collapsed lung), and/or respiratory failure all of which increase mucus retention in the lungs.

We have worked with health care professionals to create products for acute care patients, including our Single Patient Use Vest, or SPUV, and our SmartVest Wrap. We market both of these products to health care providers, particularly those working in intensive care units. Hospitals issue the SPUV or SmartVest Wrap to one patient for the duration of his or her hospital stay. Both products facilitate continuity of care, because they introduce the patient to our product line and may encourage use of the home care SmartVest System, which can be provided to the chronic condition patient upon discharge. Both products provide full coverage pulsation. The SPUV is a full-sized vest that is often used for patients undergoing institutional treatment who are already accustomed to using a SmartVest System. The SmartVest Wrap, which we introduced in 2007, is lightweight, convenient and well-suited for patients recovering from surgery and short-term illnesses. We believe that the lightweight nature of the SmartVest Wrap makes it easy for the health care professional to operate. In addition, we believe that our ability to provide a relatively more comfortable therapy alternative to patients results in a higher level of patient cooperation and consistent use.

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Other Indications

The benefits of airway clearance therapy using the SmartVest System are not disease-specific. They apply to a broad range of conditions characterized by lung congestion. One currently underserved group of patients are those with underlying medical conditions and circumstances, such as severe down syndrome, demobilizing injuries and severe muscular distrophy. Patients with severe underlying conditions often suffer from multiple physical problems and may be non-ambulatory. Their inability to move predisposes them to lung congestion, which often progresses to more serious medical conditions such as pneumonia. We believe these patients could improve their lung functionality and reduce their incidence of infection by using airway clearance therapy with the SmartVest System, and that the consistently higher oxygen levels that result from improvements to breathing could offer ancillary benefits for their conditions.

Marketing, Sales and Distribution

We believe that we can achieve future earnings and sales growth through expanding and repositioning our domestic sales staff, focusing on continuing education opportunities and industry relationships, building distributor relationships in Europe and Asia, and maintaining leadership in product innovation. Each of these objectives is described in more detail above in the section entitled Growth Strategy.

Because sale of the SmartVest System is by physician s prescription only, we focus our marketing efforts on physicians and health care professionals such as physician s assistants, nurses, nurse practitioners, and respiratory therapists, as well as directly to their patients. In addition to increasing the visibility and acceptance of our products through participating in medical conferences and maintaining industry contacts, as explained in more detail above in the section entitled Business Strengths Industry Contacts, we have a designated Marketing Department and place advertisements in leading medical magazines and journals in the U.S. and Europe. We also believe that the Internet has provided us with a marketing benefit in recent years, as several overseas distributors have contacted us after visiting our website.

In addition to distributors overseas, as explained in more detail below under the heading Our Markets International Marketing, we have established our own sales force in the U.S., nearly all of whom are respiratory therapists. Each sales representative, or Clinical Area Manager (CAM), is responsible for introducing our products, principally the SmartVest System, to clinics and hospitals within a specific geographical area, and are also able to provide training and continued support to customers. As of June 30, 2010, we had 20 total sales representatives, including a national sales manager, 3 regional sales managers, and 16 clinical area managers. Collectively, our sales force covers the entire United States and portions of Canada, which we have divided into West, Midwest, and East regions. Each clinical area manager is assigned to a particular territory within one of the three regions. We have also developed a network of over 300 respiratory therapists and health care professionals to assist with training patients across the U.S. on a non-exclusive independent contractor basis. We believe that the professional understanding of the Clinical Area Managers and trainers demonstrates our commitment to customer service and facilitates sales. We expect that with expanded funding, our current and future Clinical Area Managers can capture additional market share.

International Marketing

The international market for HFCWO therapy devices is emerging and we believe represents a major growth opportunity for us. In fiscal 2010, our international sales comprised approximately 4.5% of net revenue. Internationally, we have made sales in more than ten countries. In addition to sales made in Canada, the principal countries in which we have made sales internationally, and the countries in which our principal distributors are located, are Italy, Spain and Japan. We are actively identifying distributors and other sales opportunities.

Our historical practice and continued intent includes developing long-term relationships with distributors who have knowledge and experience in serving respiratory physicians and patients in the host country. Units are sold at a consistent price with payment made directly from the distributor. For all international sales, our Quality Assurance Department and Chief Financial Officer monitor pricing, payments and conforming regulatory practice. Our Chief Executive Officer and Marketing Director oversee the growth and performance of international sales.

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We obtained ISO 9001 Certification in January 2005, which provides assurance to our international distributors and customers that our products conform with uniform standards for manufacturing quality and that our business meets certain professional standards. Securing certification from the International Organization for Standardization (ISO) provides assurance across national boundaries that the goods imparted are of a reliable and predictable quality, consistent with the representations of the manufacturer.

We have also obtained clearance to use the European Union CE Mark on our products. The CE Mark is required for medical device sales in countries within the European Economic Area, which includes the twenty-seven member countries of the European Union as well as Iceland, Liechtenstein, Norway, Switzerland, and Turkey, and other European countries that may adopt EU standards voluntarily. We also require all of our distributors to comply with their home country regulations. We originally obtained clearance to use the CE Mark in April 2005. Renewal is required every five years, and our notified body performs an annual audit to ensure that we are in compliance with all applicable regulations. We have maintained our CE Mark in good standing since originally receiving it and most recently renewed it in January 2010.

Competition

High Frequency Chest Wall Oscillation (HFCWO) was first developed for CF patients at the University of Minnesota. The purpose of HFCWO is to provide more effective mucus clearance in a form that could be performed independently of a caregiver. The original technology was licensed to American Biosystems, Inc. (now Advanced Respiratory, Inc. (ARI), part of Hill-Rom Holdings, Inc., a publicly traded company) which, until the introduction of our original MedPulse Respiratory Vest System® in 2000, was the only manufacturer of this technology. All of ARI s products use a two-hose, closed system, in contrast to the single-hose, flow-through system that we designed, which we believe provides greater ease of use and patient comfort. In 2005, Respiratory Technologies, Inc., a privately held company doing business as RespirTech, received FDA clearance to market their inCourage system (the inCourage System), which includes a HFWCO vest. Like our SmartVest System, ARI s The Vest and RespirTech s inCourage System are cleared for market by the FDA.

From a clinical performance perspective, all HFCWO products meet a common standard of substantial equivalence. As a result, features and benefits such as number of hoses required to deliver the therapy (one hose versus two hoses), construction quality, appearance of the generator, reputation for patient services, and sales effectiveness of field personnel have become key variables. We believe that the product features of our SmartVest System enable us to compete effectively, particularly when health care professionals, patients, and caregivers are provided with demonstrations of product choices prior to committing to a specific product. We often provide demonstration units to encourage such comparisons. Unlike our competitors products, the SmartVest System has a single-hose, flow-through system design and an adjustable vest made from soft, breathable and washable fabric. We use Velcro in our patented vest to provide a tailored fit, as opposed to an inflatable fit model. In addition to product features, our focus on providing exemplary customer training and service, along with our commitment to engage and retain highly motivated employees and contractors, many of whom are medical professionals, provides a valuable competitive advantage.

Alternative products for administering pulmonary therapy include:

Positive Expiratory Pressure (PEP) mask, which provides backpressure into the lungs on expiration to keep respiratory tracts open longer to drain;

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The Flutter® (Scandipharm), a tube which vibrates on expiration;

Acapella® Vibratory PEP Therapy System (Smiths Medical), a handheld device that combines PEP with oscillations;

Intrapulmonary Percussive Ventilation Device, generally comprised of a ventilator that combines positive air pressure with nebulisation as appropriate; and

Traditional Chest Physical Therapy (CPT), which is usually performed one to four times per day.

Physicians may prescribe some or all of these devices and techniques, depending upon each patient s health status, severity of disease, compliance, or personal preference. We believe our primary competitive advantage over alternative treatments is patient comfort, ease of use, and the effectiveness of HFCWO treatment as compared to CPT and other alternative treatments. Because HFCWO is not technique dependent, as compared to most other pulmonary therapy products, therapy begins automatically once power is provided and remains consistent and controlled for the duration of the session. We strive to make the SmartVest System an increasingly attractive and comfortable form of HFCWO therapy. We believe that HFCWO therapy generally, and our SmartVest System in particular, produces less interference with daily activities, which increases the likelihood of regular use. We believe these advantages encourage physicians to prescribe and patients to request the SmartVest System for pulmonary therapy. Reimbursement for the diverse patient populations for each of these pulmonary therapies varies greatly because a patient s medical care costs are typically addressed by a combination of private insurance and government benefit schedules, as well as state health care policies and programs.

Research and Development

We have demonstrated our commitment to product development by introducing several new products and product enhancements since we first entered the market in 2000. In addition to the 19 U.S. patents and 5 foreign patents that we currently hold, we have a number of pending patent applications domestically and internationally.

As of June 30, 2010, our research and development staff consisted of three full-time employee engineers. We also receive engineering support from several consultants, including Mr. Craig Hansen, pursuant to an agreement with Hansen Engine Corporation. See Part III, Item 13, Certain Relationships and Related Transactions, and Director Independence. Our team, the majority of whom have experience in respiratory therapy and medical device development, has a demonstrated record of developing new products which receive the appropriate product approvals and regulatory clearances, with our products having been approved or cleared in the U.S., Canada, and the member countries of the European Economic Area.

During the fiscal years ended June 30, 2010 and 2009 we incurred research and development expenses of $601,000 and $358,000, respectively. As a result of our expected investments in enhancing the SmartVest System, we expect the amount we spend on research and development to increase in the future to approximately 5% of revenue.

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Intellectual Property

As of June 30, 2010, we held 19 issued U.S. patents and 5 foreign patents covering the SmartVest System and its underlying technology, and had 33 pending U.S. and foreign patent applications. The pending U.S. patent applications primarily relate to additional aspects of the underlying technology for the SmartVest System and the pending foreign patent applications correspond to our existing U.S. patents and pending U.S. patent applications. We believe it will take several years, or possibly longer, for pending patent applications to result in issued patents, if at all. Our first U.S. patent expires in 2013 and in Canada in 2016.

Our patents and patent applications offer coverage in the field of air pressure pulse delivery to a human in support of airway clearance. The following table provides information about our issued U.S. patents:

U.S. PATENT NUMBER	TITLE	ISSUED
5,453,081	Pulsator	September 26, 1995
5,569,170	Pulsator	October 29, 1996
6,254,556	Repetitive Pressure Pulse Jacket	July 3, 2001
D456,591	Human Body Pulsating Jacket	May 7, 2002
D461,897	Human Body Respiratory Vest	August 20, 2002
6,488,641	Body Pulsating Apparatus	December 3, 2002
D469,876	Human Respiratory Bladder	February 4, 2003
6,547,749	Body Pulsating Method and Apparatus	April 15, 2003
6,605,050	Body Pulsating Jacket	August 12, 2003
D478,989	Supine Respiratory Vest	August 26, 2003
6,676,614	Vest for Body Pulsating Method and Apparatus	January 13, 2004
D531,728	Combined Human Body Pulsator and Movable Pedestal	November 7, 2006
D547,718	Air Pulsating Generator	July 31, 2007
7,278,978	Respiratory Vest with Inflatable Bladder	October 9, 2007
7,374,550	Respiratory Vest for Repetitive Pressure Pulses	May 20, 2008
D585,991	Combined Air Pulsator and Movable Pedestal	February 3, 2009
7,537,575	Body Pulsating Method and Apparatus	May 26, 2009
7,713,219	Combined Air Pulsator and Movable Pedestal	May 11, 2010
7,736,324	Portable Human Body Pulsating Apparatus Mounted on a Pedestal	June 15, 2010

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We have also received the following U.S. trademark and service mark registrations: MEDPULSE, MEDPULSE RESPIRATORY VEST SYSTEM, SMARTVEST, SMARTVEST WRAP, SMARTWRAP, FACT, SOFT START, TRIMLINE, and CREATING SUPERIOR CARE THROUGH INNOVATION.

We generally pursue patent protection for patentable subject matter in our proprietary devices in foreign countries in which we make regular sales. We have been granted patent protection in Canada, New Zealand and South Africa. We have additional patent applications pending in Canada, Japan, and South Korea and with the European Patent Organization, whose member states include Spain, Croatia, Greece, Italy, Portugal, and Romania.

In addition to our patent and trademark protected intellectual property, we seek to protect proprietary information and know-how through confidentiality and non-competition provisions in the agreements with our executives and employees. We cannot provide assurance that these persons will abide by the terms of these agreements. In addition, despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary.

We intend to continue expanding our intellectual property portfolio, and particularly our patent position, as our business grows. However, our patent applications may not result in issued patents, and we cannot assure you that any patents that have been issued or might be issued will be broad enough to prevent competitors from emulating our products, or that all of our patents will be upheld if asserted against third parties, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

Our industry is characterized by the existence of a large number of patents and frequent litigation based on assertions of patent infringement. For a description of litigation relating to our intellectual property, please refer to Part I, Item 3 of this Report, entitled Legal Proceedings.

Manufacturing

Our headquarters in New Prague, Minnesota include a dedicated manufacturing and engineering facility of more than 10,000 square feet. Our site has been regularly audited by the FDA, in accordance with FDA practices, and we maintain our operations in a manner consistent with FDA requirements for a medical device manufacturer. Our manufacturing processes emphasize simplicity, cost-effectiveness, and a capacity to realize increases in production volume with escalation in demand. All employees are responsible for maintaining specific manufacturing and quality standards, which are monitored by our quality assurance manager under an extensive system designed to satisfy FDA and ISO standards.

Electromed staff is responsible for manufacturing each SmartVest System. While components are outsourced based upon detailed specifications, each SmartVest System is assembled, tested, and approved for final shipment at our manufacturing site in New Prague, Minnesota, under careful control consistent with FDA, Underwriters Laboratory (UL), and ISO standards. While all third-party vendors present some degree of risk of supply or impairment issues, many of our vendors are located within 100 miles of our headquarters, which enables us to closely monitor the supply chain. We maintain at least a two-month supply of all of our critical components, and the materials used in the SmartVest System are generally available from a number of suppliers.

A rigorous quality standard is applied to components received from vendors. Any adverse findings result in the quarantine of any out of specification components. Before a SmartVest System is shipped to a patient, rigorous testing is again applied to match the performance of the air pulse generator with the particular vest size stipulated for the patient.

Seasonality

Our business is not materially affected by seasonality.

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Product Warranties

We provide a warranty on the SmartVest System that covers the cost of replacement parts and labor, or a new SmartVest System in the event we determine a full replacement is necessary. For SmartVest Systems initially purchased and currently located in the United States and Canada, we provide a lifetime warranty to the individual patient for whom the system is prescribed. For products sold to patients in Greece, we provide a five-year warranty. For sales to institutions within the United States and Canada, and for all other sales to individuals and institutions made outside of the United States and Canada, we provide a three-year warranty. Our warranties provide that if a newer model of our systems has been developed and sold between the time of purchase of the original system and we determine the need for replacement, we may replace the system with a newer model at our discretion.

Third-Party Reimbursement

Much of our growth is dependent on continued acceptance of HFCWO technology by third-party payers. In the U.S., individuals who use the SmartVest System will generally rely on third-party payers, including private payers and governmental payers such as Medicare and Medicaid, to cover and reimburse all or part of the cost of using the SmartVest System. Reimbursement for HFCWO therapy and our SmartVest System varies among public and private insurance providers.

Most patients are able to qualify for reimbursement and payment from Medicare, Medicaid, private insurance or combinations of the foregoing. We believe that subsequent generations of HFCWO products will also qualify for reimbursement under Medicare Plan B and most major health plans. However, some third-party payers must also approve coverage for new or innovative devices or therapies before they will reimburse health care providers who use the medical devices or therapies. In addition, we face the risk that new or modified products could have a lower reimbursement rate, or that the levels of reimbursement currently available for our existing products could decrease, which would hamper our ability to market and sell that product. Consequently, our sales will continue to depend in part on the availability of coverage and reimbursement from third-party payers, even though our devices may have been cleared for commercial distribution by the FDA. The manner in which reimbursement is sought and obtained varies based upon the type of payer involved and the setting in which the procedure is furnished. The nature of any future legislation is uncertain, making it difficult for us to predict the impact of cost-containment trends on operating results.

A key element in our customer support strategy has been achieved by establishing an effective Reimbursement Department to seek insurance authorization and process claims on behalf of the patient. The skill and knowledge gained and offered by our Reimbursement Department is an important factor in building our revenue and serving patients financial interests. Our payment terms allow patients to acquire the SmartVest System over a period of 1 to 15 months, which is consistent with reimbursement procedures followed by Medicare and other third parties. The amount we receive for any single unit is based on reimbursement schedules and may vary based on a number of factors, including Medicare and third-party reimbursement processes and policies. The patient maintains the risk of reimbursement to the Company in the event of non-payment by third-party payers.

Payments for overseas sales are made directly by the distributor, and we are not involved in the reimbursement process. Overseas sales were approximately 4.5% of our net revenue in fiscal 2010, as explained in more detail below under the heading International Marketing.

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Governmental Regulation

Medicare and Medicaid

Recent government and private sector initiatives in the U.S. and foreign countries are aimed to limit the growth of health care costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments, and managed-care arrangements, and are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical devices. Government programs, including Medicare and Medicaid, have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments, restricting coverage for certain products or services, and implementing other mechanisms designed to constrain utilization and contain costs. In addition, many private insurance programs look to Medicare as a guideline in setting their coverage policies and payment amounts. This has created an increasing level of price sensitivity among customers. If we develop new or modified products that have a lower reimbursement rate, or the levels of reimbursement currently available for our existing products decrease, demand for our products would be affected. We believe, however, that HFCWO can reduce the risk of secondary complications and required hospitalizations from excess secretion, and is therefore a cost-effective alternative to traditional treatments. We expect that the cost-saving aspects of the SmartVest System will increase in importance as cost control measures become more prevalent in the health care industry.

FDA Requirements

We have received clearance from the U.S. Food and Drug Administration to market our products, including the SmartVest System, as a powered percussor. Since inception, management has retained the necessary clinical, medical and legal expertise to support required clearances and approvals to market our products. On April 7, 2004, our Model 2000ez SMARTVEST was cleared to market by the FDA pursuant to a 510(k) submission.

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices. A full-time quality assurance manager as well as a consulting regulatory and clinical expert provide detailed oversight of their respective areas of responsibility.

Premarket Clearance and Approval Requirements

All of our current products have been cleared for sale in the U.S. by the FDA under the premarket notification (510(k) clearance process). However, unless an exemption applies, if we develop new medical devices or modifications to existing products that would affect the product s safety or effectiveness, we must obtain FDA clearance before marketing the new or modified product in the U.S., either through the 510(k) clearance process or the more complex Premarket Approval Application (PMA) process.

The 510(k) clearance process would be available if we could demonstrate that our new medical device is substantially equivalent to a legally marketed medical device. In this process, we would be required to submit data that supports our equivalence claim. While human clinical data has not been routinely required for 510(k) products in the past, the FDA is increasingly requiring it for new technologies. If human clinical data is required, it must be gathered in compliance with FDA investigational device exemption regulations. We must receive an order from the FDA finding substantial equivalence to another legally marketed medical device before we can commercially distribute the new medical device. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness. A very small number of our devices are exempt from pre-market review.

