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.

The second, more rigorous process, known as pre-market approval (PMA), would require us to independently demonstrate that the new medical device is safe and effective. We would do this by collecting data regarding design, materials, bench and animal testing, and human clinical data for the medical device. The FDA will authorize commercial release if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on benefit outweighing risk for the population intended to be treated with the device. This process is much more detailed, time-consuming and expensive than the 510(k) clearance process.

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510(k) Clearance Pathway

When a 510(k) clearance is required, we will be required to submit a 510(k) demonstrating that our proposed device is substantially equivalent to a previously cleared 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 PMAs. In cases where no predicate is available, we can request a de novo classification of the product. If the FDA classifies the device as substantially equivalent to a predicate device, we will receive an order that allows us to market the device.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use.

There is no guarantee that the FDA will grant 510(k) clearance to new or modified products that we develop in the future. Failure to obtain such clearances or approvals could adversely affect our ability to grow our business. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business.

Clinical Trials

We were able to obtain FDA clearance by demonstrating substantial equivalence to preexisting products, and therefore new clinical trials were not required to obtain FDA clearance for our current products. However, clinical trials are increasingly required for 510(k) clearance and therefore may be required to obtain FDA clearance for future products. If the device presents a significant risk, as defined by the FDA, to human health, the FDA requires the device sponsor to file an investigational device exemption (an IDE) application with the FDA and obtain IDE approval prior to commencing the human clinical trials. Such trials generally require an IDE application approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements.

Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board (IRB) for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. If the clinical trial is not performed in accordance with the FDA s IDE regulations, the FDA could seek an enforcement action against the sponsor and the investigators. In addition, the sponsor, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance to market the product in the U.S. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

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Quality System Regulation (QSR), which is the medical device term for good manufacturing practices, 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 FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

clearance of product modifications that could significantly affect safety or efficacy or that would constitute a significant change in the safety or efficacy of our cleared devices;

medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

post-approval or post-clearance restrictions or conditions, including post-approval or post-clearance study commitments;

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

the FDA s recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under health care reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

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Furthermore, we could face product recalls, FDA enforcement actions, and user lawsuits if any of our products are found to pose a risk of injury or otherwise be defective. We believe that our products pose a low risk of injury because they are non-invasive, and we maintain an active training program that we expect would provide early identification of any product defects. Nevertheless, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death.

The FDA has broad post-market and regulatory enforcement powers. Our facilities have been and will continue to be subject to unannounced inspections by the FDA to determine our level of compliance with the QSR and other regulations. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

warning letters or untitled letters;

fines and civil penalties;

unanticipated expenditures to address or defend such actions;

delays in clearing or approving, or refusal to clear or approve, our products;

withdrawal or suspension of approval or clearance of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

product recall or seizure;

orders for physician notification or device repair, replacement or refund;

injunctions; and

criminal prosecution.

Fraud and Abuse Laws

Federal health care laws apply when we or customers submit claims for items or services that are reimbursed under Medicare, Medicaid or other federally-funded health care programs. The principal federal laws include: the False Claims Act which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; the Anti-Kickback Statute which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of items or services reimbursable by a federal health care program; and health care fraud statutes that prohibit false statements and improper claims with any third-party payer. There are often similar state false claims, anti-kickback, and anti-self referral and insurance laws that apply to state-funded Medicaid and other health care programs and private third-party payers. In addition, the U.S. Foreign Corrupt Practices Act can be used to prosecute companies in the U.S. for arrangements with physicians, or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country.

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The laws applicable to us are subject to change, and to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including substantial penalties, fines and damages, and exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

The Federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as Medicare or Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, improper discounts, the furnishing of free supplies, equipment or services, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. In addition, some anti-kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, to issue a series of regulations, known as safe harbors. These safe harbors, issued by the OIG beginning in July 1991, set forth provisions that, if all their applicable requirements are met, will assure health care providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on marketing of health care services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Another development affecting the health care industry is the increased use of the Federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act s whistleblower or *qui tam* provisions. The False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought against health care providers by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the Civil False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal health care program.

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When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, companies have been prosecuted under the False Claims Act in connection with alleged off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices for our products, the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

HIPAA and Other Fraud and Privacy Regulations

Among other things, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: health care fraud and false statements relating to health care matters. The HIPAA health care fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

In addition to creating the two new federal health care crimes, regulations implementing HIPAA also establish uniform standards governing the conduct of certain electronic health care transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by health care providers, health plans and health care clearinghouses, which are referred to as covered entities. Three standards have been promulgated under HIPAA s regulations: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establish standards for common health care transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards, which require covered entities to implement and maintain certain security measures to safeguard certain electronic health information. Because we provide our products directly to patients and bill third-party payers such as Medicare, Medicaid, and insurance companies, we are a covered entity and must comply with these standards. The government intended this legislation to reduce administrative expenses and burdens for the health care industry; however, our compliance with certain provisions of these standards entails significant costs for us. Although the HIPAA regulations allow disclosure to medical device companies for purposes of complying with FDA regulations, treatment, and payment, HIPAA may have a chilling effect on disclosure in some cases, limiting information that is available to us.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some 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. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

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Environmental Laws

We are also subject to various environmental laws and regulations both within and outside the U.S. Like other medical device companies, our operations involve the use of substances regulated under environmental laws, primarily manufacturing and sterilization processes. To the best of our knowledge at this time, we do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position, or cash flows.

Employees

As of June 30, 2010, we employed 70 total employees, 66 of which are full-time employees. Of our 70 employees, more than 30% are respiratory therapists who are licensed by the appropriate state professional organization, including all of the employees in our Patient Services Department and nearly all of our sales representatives. In addition, we retain as independent contractors several expert consultants, who assist with quality assurance, product development, marketing, and international opportunities. We also retain over 300 respiratory therapists and health care professionals on a non-exclusive independent contractor basis to provide training to our customers in the U.S. Approximately 75% of these independent contractors are credentialed by the National Board for Respiratory Care as either Certified Respiratory Therapists or Registered Respiratory Therapists. The remainder of these respiratory therapists are licensed at the state level in fields such as respiratory care, nursing, physical therapy and occupational therapy. We believe that providing our customers with the opportunity to obtain support and training from health care professionals underscores our commitment to professional service and high quality.

None of our employees is covered by a collective bargaining agreement. We believe our relations with our employees are good.

Executive Officers of the Registrant

Set forth below are the names, titles, periods of service, and business experience of our executive officers.

Name	Age	Title
Robert D. Hansen	70	Chairman and Chief Executive Officer
Terry Belford	59	Chief Financial Officer

Robert D. Hansen Chairman and Chief Executive Officer

Mr. Hansen co-founded Electromed in 1992 and is responsible for the strategic direction and development of the Company. Mr. Hansen is also a co-founder and is President and Chief Executive Officer of Hansen Engine Corporation, a research and development company that provides research and development services to Electromed. Mr. Hansen joined Hansen Engine Corporation in January 1983 and has over forty years of business leadership and investment industry experience. Mr. Hansen devotes approximately 5% of his time attending to matters related to Hansen Engine Corporation where he is primarily responsible for corporate governance matters through his service as a member of Hansen Engine Corporation s board of directors. He was also the founder and CEO of LockerMate Corporation until January 1995. Mr. Hansen received a BA Degree from Dana College (1964), Masters of Arts Degree from the University of Cincinnati in U.S. History (1966), and a Masters of Divinity Degree (1976) from Luther Theological Seminary. He completed additional graduate studies in U.S. economic history and foreign policy at the University of Cincinnati. In 1996, Mr. Hansen was awarded a Mini-MBA in Managing Growing Companies from the University of St. Thomas. Among other attributes, skills, experiences and qualifications, our Board believes that Mr. Hansen s history with Electromed and management and investment industry experience allow him to make a valuable contribution as a director. Mr. Hansen is the brother of Craig Hansen, one of our directors.

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Terry M. Belford, CPA, CMA Chief Financial Officer

Mr. Belford joined Electromed in January 2004 as its Chief Financial Officer. Before joining Electromed, Mr. Belford worked for ten years as an independent accountant and consultant, serving clients in the distributing, importing, and manufacturing industries. Prior to that he served for several years as a controller and chief financial officer for both established and start-up companies in the above mentioned industries. Mr. Belford earned a Bachelor of Science degree from the University of Missouri and also holds both CPA and CMA designations. He is a member of the American Institute of Certified Public Accountants, the Minnesota Society of Certified Public Accountants and the Institute of Certified Management Accountants.

Item 1A. Risk Factors.

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

Item 1B. Unresolved Staff Comments.

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

Item 2. Properties.

We own our principal headquarters and manufacturing facilities, consisting of approximately 24,000 total square feet, which are located on an approximately 2.3 acre parcel at 500 Sixth Avenue NW, New Prague, Minnesota 56071 and 502 Sixth Avenue NW, New Prague, Minnesota 56071. Management considers the current facilities to be satisfactory for our growth plans. In addition, we believe there is sufficient space within the lot in New Prague for additions to the most recently constructed building.

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 are maintained in such a way as to emphasize simplicity, cost-effectiveness, and a capacity to realize increases in production volume with escalation in demand.

Item 3. Legal Proceedings.

Our industry is characterized by the existence of a large number of patents and trademarks and frequent litigation based on assertions of patent and trademark infringement. Hill-Rom Services, Inc., ARI, Hill-Rom Company, Inc. and Hill-Rom Services Pte. Ltd. (collectively, Hill-Rom), subsidiaries of Hill-Rom Holdings, Inc., brought an action on August 21, 2009, against us in the Southern District of Indiana alleging that our use of the term SmartVest infringes on its alleged trademarks The Vest and Vest. We answered the allegations and brought counter-claims against Hill-Rom alleging, among other things, defamation and libel. On September 16, 2010, we reached a settlement in principle with respect to our litigation with Hill-Rom. The terms of the settlement are confidential. We expect to enter a definitive settlement agreement within the next month and anticipate that a stipulation of dismissal will be filed at that time. The Company has no plans to change its use of the SmartVest marks.

In addition to the foregoing, we may be party to legal actions, proceedings, or claims in the ordinary course of business. Corresponding costs are accrued when it is more likely than not that loss will be incurred and the amount can be precisely or reasonably estimated. We are not aware of any undisclosed actual or threatened litigation that would have a material adverse effect on our financial condition or results of operations.

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Item 4. (Removed and Reserved).

PART II

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

Market Information

Our common stock began trading on the NASDAQ Capital Market on August 13, 2010 under the symbol ELMD in connection with our initial public offering. Our stock was not publicly traded during fiscal 2010.

As of June 30, 2010, there were 198 registered holders of our common stock.

Dividends

We have never paid cash dividends on any of our securities. We currently intend to retain any earnings for use in operations and do not anticipate paying cash dividends in the foreseeable future. Currently, the agreement governing our credit facility restricts our ability to pay cash dividends.

Recent Sales of Unregistered Equity Securities

In August 2009, we issued an aggregate of 13,733 shares of common stock to 19 accredited investors pursuant to warrant exercises, for aggregate cash consideration of approximately $34,333.

In August 2009, we issued 5,000 shares of common stock to an employee pursuant to a warrant exercise, for aggregate cash consideration of $15,000.

In September 2009, we issued 5,000 shares of common stock to a service provider in exchange for services.

In December 2009 and January 2010, we issued warrants to purchase an aggregate of 10,000 shares of common stock to 2 employees. The warrants vest in full one year from the date of issuance, have a four-year term and have an exercise price of $4.50 per share.

In November 2009, we issued 12,000 shares of common stock to an employee pursuant to a warrant exercise, for cash consideration of $24,000.

From April 2010 to June 2010, we issued warrants to purchase an aggregate of 15,000 shares of common stock to 3 employees. The warrants vest in full one year from the date of issuance, have a four-year term and have an exercise price of $4.50 per share.

In June 2010, we issued 100,000 shares of common stock to an employee pursuant to a warrant exercise, for cash consideration of $300,000.

In June 2010, we issued 5,000 shares of common stock to a service provider pursuant to a warrant exercise, for cash consideration of $17,500.

Purchase of Equity Securities by the Company

None.

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Use of Proceeds

We completed our initial public offering of shares of common stock, $0.01 par value (the Offering) during the first quarter of our 2011 fiscal year. The effective date of our registration statement relating to the Offering, filed on Form S-1 under the Securities Act of 1933 (File No. 333-166470), was August 12, 2010. A total of 1,700,000 shares of our common stock were registered and sold in the Offering. In addition, we granted Feltl and Company, Inc. (Feltl), the underwriter of the Offering, warrants to purchase up to 170,000 additional shares of our common stock at a price of $4.80 per share and an over-allotment option to purchase 255,000 shares at $4.00 per share, less an underwriting discount of $0.30 per share. On September 23, 2010, Feltl provided notice of its intent to acquire 200,000 additional shares of our common stock pursuant to exercise of its over-allotment option. As a result of this exercise, Feltl will also receive warrants to purchase up to 20,000 additional shares of our common stock.

The aggregate offering price of our securities sold, including the shares sold to Feltl upon exercise of its overallotment option, equals $7,600,000. The aggregate underwriting discount for shares sold in the offering and pursuant to the overallotment option equals $570,000, none of which was or will be paid to our affiliates. We incurred approximately $1,040,000 of offering costs in connection with the Offering. We expect to receive net proceeds from this Offering of approximately $5,990,000. We have used $500,000 to reduce the amount of our existing indebtedness under our credit facility with U.S. Bank, National Association. We have used and intend to use the remainder of the proceeds from the offering to add employees to our Reimbursement, Patient Services and Administrative Departments; add members to our sales force and further develop our focus on institutional sales; continue our research and development efforts; and for general corporate purposes, including to finance equipment purchases and other capital expenditures in the ordinary course of business and to satisfy working capital needs.

Item 6. Selected Financial Data.

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

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 financial statements and the accompanying notes included elsewhere in this Report. The forward-looking statements include statements that reflect management s beliefs, plans, objectives, goals, expectations, anticipations and intentions with respect to our future development plans, capital resources and requirements, results of operations, and future business performance. Our actual results could differ materially from those anticipated in the forward-looking statements included in this discussion as a result of certain factors, including, but not limited to, those discussed in the section entitled Information Regarding Forward-Looking Statements immediately preceding Part I of this Report.

Overview

Electromed, Inc. was incorporated in 1992. We are engaged in the business of providing innovative airway clearance products applying High Frequency Chest Wall Oscillation (HFCWO) technologies in pulmonary care for patients of all ages.

We manufacture, market and sell products that provide HFCWO, including the SmartVest® Airway Clearance System (SmartVest System) and related products, to patients with compromised pulmonary function. Our products are sold for both the home health care market and the institutional market for use by patients in hospitals, which we refer to as institutional sales. For approximately ten years, we have marketed the SmartVest System and its predecessor products to patients suffering from cystic fibrosis, chronic obstructive pulmonary disease (COPD), bronchiectasis and repeated episodes of pneumonia. Additionally, we offer our products to a patient population that includes post-surgical and intensive care patients at risk of developing pneumonia, patients with end-stage neuromuscular disease, and ventilator-dependent patients. Our goal is to be a consistent innovator in providing HFCWO to patients with compromised pulmonary function.

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Because sale of the SmartVest System is by a physician s prescription only, we focus our marketing efforts on physicians as well as directly to patients. In addition to distributors overseas, we have established our own domestic sales force, nearly all of whom are respiratory therapists, who we believe are able to provide superior support and training to our customers. In addition, we have non-exclusive independent contractor arrangements with over 300 respiratory therapists and health care professionals who also provide education and training to our customers. Further, although the reimbursement process is subject to many contingencies, the SmartVest System is often eligible for reimbursement from major private insurance providers, HMOs, state Medicaid systems, and the federal Medicare system, which is an important consideration for patients considering an HFCWO course of therapy. We believe that our SmartVest System has created a solid foundation to support our entry into larger markets for airway clearance therapy.

The SmartVest System may be reimbursed under the Medicare-assigned billing code for High Frequency Chest Wall Oscillation devices if the patient has cystic fibrosis, bronchiectasis (including chronic bronchitis or COPD that has resulted in a diagnosis of bronchiectasis), or any one of certain enumerated neuro-muscular diseases, and can demonstrate that another less expensive physical or mechanical treatment did not adequately mobilize retained secretions. Private payers consider a variety of sources, including Medicare, as guidelines in setting their coverage policies and payment amounts.

We have been generating revenue from the sale of our SmartVest System or its predecessor products since 2000 and have generated net income since the fiscal year ended June 30, 2006. For the fiscal year ended June 30, 2010, we generated revenue of approximately $14,300,000 and net income of approximately $916,000. Our sales growth rate was 10.0% for the 2010 fiscal year compared to the 2009 fiscal year and was 48.5% for the 2009 fiscal year compared to the 2008 fiscal year. Management believes the decrease in net income in dollars and as a percentage of revenues was primarily the result of certain events that restricted management s available time to recruit additional sales representatives and distributors, combined with increased expenditures on sales and marketing and increased research and development expense. The events that drew the focus of management included a 60-day suspension in all of Medicare reimbursements (which was favorably resolved on December 4, 2009), securing a new bank financing facility, and the Company s initial public offering. Management was also required to address a trademark lawsuit initiated by a competitor (see Part I, Item 3, Legal Proceedings).

Critical Accounting Policies and Estimates

During the preparation of our consolidated financial statements, we are required to make estimates, assumptions and judgments that affect reported amounts. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. We update these estimates, assumptions and judgments as appropriate, which in most cases is at least quarterly. We use our technical accounting knowledge, cumulative business experience, judgment and other factors in the selection and application of our accounting policies. While we believe the estimates, assumptions and judgments we use in preparing our consolidated financial statements are appropriate, they are subject to factors and uncertainties regarding their outcome and therefore, actual results may materially differ from these estimates. The following is a summary of our primary critical accounting policies and estimates. Please also refer to Note 1 to the Consolidated Financial Statements, included in Part II, Item 8 of this Report.

Revenue Recognition and Allowance for Doubtful Accounts

Revenues from direct patient sales are recorded at the amount to be received from patients under their arrangements with third-party payers, including private insurers, prepaid health plans, Medicare and Medicaid. In addition, we record an estimate for selling price adjustments which often arise from changes in a patient s insurance coverage, changes in a patient s state of domicile, insurance company coverage limitations or patient death. We periodically review originally billed amounts and our collection history and make changes to the estimation process by considering any changes in recent collection or sales allowance experience, but have not made material adjustments to previously recorded revenues and receivables.

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Other than the installment sales as discussed below, we expect to receive payment on the vast majority of accounts receivable within one year and therefore classify all receivables as current assets. However, in some instances, payment for direct patient sales can be delayed or interrupted resulting in a small portion of collections occurring later than one year. In the event receivables are expected to be paid over longer intervals than one year, we recognize revenue under the installment method.

Certain third-party reimbursement agencies pay us on a monthly installment basis, which can span from 18 to 60 months in the cases of Wisconsin, New York and Texas Medicaid, which constitute the majority of our installment method sales. Due to the length of time over which reimbursement is received, we believe that the inherent uncertainty of collection due to external factors noted above precludes us from making a reasonable estimate of revenue at the time the product is shipped. In certain circumstances, the patient must periodically attest that the unit continues to be utilized as a prerequisite to continued reimbursement coverage. Therefore, we believe the installment method is appropriate for these sales. If the third party reimbursement agency discontinues payment and we determine no further payments will be made from the patient, the carrying value of the account receivable is written off as a period adjustment against the previously recognized sales. Under the installment method, we do not record accounts receivable or revenue at the time of product shipment. We defer and amortize the costs associated with the sale and, as each installment is received, that amount is recognized as revenue. Deferred costs associated with the sale are amortized to cost of revenue ratably over the estimated period in which collections are scheduled to occur.

Accounts receivable are also net of an allowance for doubtful accounts, which are accounts from which payment is not expected to be received although product was provided and revenue was earned. Management determines the allowance for doubtful accounts by regularly evaluating individual customer receivables and considering a customer s financial condition and credit history. Receivables are written off when deemed uncollectible. Recoveries of receivables previously written off are recorded when received.

We request that customers return to us previously-sold units that are no longer in use, in order to limit the possibility that such units would be resold by unauthorized parties or used by individuals without a prescription. The customer is under no obligation to return the product; however, we do reclaim the majority of previously sold units upon the discontinuance of patient usage. We have not obtained certification to recondition and resell returned units. Returned units are primarily used for warranty replacement parts and demonstration equipment. Returned products do not have significant value to us as the costs of becoming certified to resell, reclamation and reconditioning typically exceed the costs of producing a new unit.

Valuation of Long-lived and Intangible Assets

Long-lived assets, such as property and equipment and finite-life intangible assets are evaluated for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. In evaluating recoverability, the following factors, among others, are considered: a significant change in the circumstances used to determine the amortization period, an adverse change in legal factors or in the business climate, a transition to a new product or service strategy, a significant change in customer base, and a realization of failed marketing efforts. The recoverability of an asset is measured by a comparison of the unamortized balance of the asset to future undiscounted cash flows. If we believe the unamortized balance is unrecoverable, we would recognize an impairment charge necessary to reduce the unamortized balance to the estimated fair value of the asset. The amount of such impairment would be charged to operations at the time of determination.

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Property and equipment are stated at cost less accumulated depreciation. We use the straight-line method for depreciating property and equipment over their estimated useful lives, which range from 3 to 39 years. Our finite-life intangibles consist of patents and trademarks and their carrying costs include the original cost of obtaining the patents, periodic renewal fees, and other costs associated with maintaining and defending patent and trademark rights. Patents and trademarks are amortized over their estimated useful lives, generally 15 and 12 years using the straight-line method. During the year ended June 30, 2010 we incurred legal defense costs associated with a trademark infringement lawsuit filed against us (see Note 9 to the Consolidated Financial Statements included in Part II, Item 8 of this Report). Such legal defense costs are being capitalized and amortized over the remaining useful life of the trademark. In the event we are unsuccessful in defending our trademark, such capitalized legal defense costs of approximately $880,000 as of June, 2010 will be immediately expensed. We expect future amortization expense to increase as we incur additional costs associated with our patents and trademarks, including the trademark defense costs.

Allowance for Excess and Slow-moving Inventory

An allowance for potentially slow-moving or excess inventories is made based on our analysis of inventory levels on hand and comparing it to expected future production requirements, sales forecasts and current estimated market values.

Income Taxes

We recognize deferred tax assets and liabilities based on the differences between the financial statement carrying amounts and the tax basis of assets and liabilities. We provide a valuation allowance for deferred tax assets if we determine, based on the weight of available evidence, that it is more likely than not that some or all of the deferred tax assets will not be realized.

Warranty Reserve

We provide a lifetime warranty on products sold to patients in the United States and Canada, a three-year warranty for institutional sales within the United States and Canada, a five-year warranty on products sold to patients in Greece, and a three-year warranty on all other sales to individuals and institutions outside of the United States and Canada. We estimate, based upon a review of historical warranty claim experience, the costs that may be incurred under our warranty policies and record a liability in the amount of such estimate at the time a product is sold. The warranty cost is based upon future product performance and durability, and is estimated largely based upon historical experience. We estimate the average useful life of our products to be approximately five years. Factors that affect our warranty liability include the number of units sold, historical and anticipated rates of warranty claims, the product useful life, and cost per claim. At our discretion, based upon the cost to either repair or replace a product, we have occasionally replaced such products covered under warranty with a new model. We periodically assess the adequacy of our recorded warranty liability and make adjustments to the accrual as claim data and historical experience warrant.

Share-Based Compensation

Share-based payment awards consist of warrants issued to employees for services, and to nonemployees in lieu of cash payment for products or services. Expense is estimated using the Black-Scholes pricing model at the date of grant and the portion of the award that is ultimately expected to vest is recognized on a straight-line basis over the requisite service or vesting period of the award. In determining the fair value of our share-based payment awards, we make various assumptions when using the Black-Scholes pricing model including expected risk free interest rate, stock price volatility, life and forfeitures.

Results of Operations

Fiscal Year Ended June 30, 2010 Compared to Fiscal Year Ended June 30, 2009

Revenues

Revenue results for the twelve month periods are summarized in the table below (dollar amounts in thousands).

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	Twelve Months Ended June 30, 2010	2009	Increase (Decrease)	
Total Revenue	$ 14,304	$ 12,999	$ 1,305	10.0%
Home Care Revenue	$ 13,109	$ 11,651	$ 1,458	12.5%
International Revenue	$ 647	$ 919	($ 272)	(29.6%)
Government/Institutional Revenue	$ 548	$ 429	$ 119	27.7%

Home Care Revenue. Our home care revenue increased by 12.5% or approximately $1,458,000 in fiscal 2010 compared to fiscal 2009. This primarily resulted from a 17% increase in referrals, from 1,773 in 2009 to 2,076 in 2010, and a 19% increase in approvals, from 1,108 in 2009 to 1,323 in 2010. We attribute this increase primarily to an increase in productivity by our existing sales staff as they continued to expand and strengthen their relationships with customers. In addition, we employed approximately 36% more sales representatives as of June 30, 2010 as compared to June 30, 2009. The increase to our sales force facilitated higher revenues through deeper penetration of the market.

International Revenue. International revenue decreased by 29.6% in fiscal 2010, or $272,000. Revenue from sales in Greece was down by $193,000, from $206,000 in fiscal 2009 to $13,000 in 2010, and revenue from sales in Spain was down by $59,000, from $123,000 in 2009 to $64,000 in 2010. This reflects the reductions in health care spending instituted by those governments concerning purchases of medical devices. Revenue from sales in Japan also decreased by $89,000, from $217,000 in 2009 to $128,000 in 2010. Revenue from sales in Italy increased by $92,000, to $315,000 in 2010 compared to $223,000 in 2009, as our distributor continued to make inroads into that market.

Government/Institutional Revenue. Revenue from government institutions increased to approximately $124,000 in fiscal 2010, compared to approximately $116,000 in fiscal 2009. Institutional revenue rose by $111,000, to approximately $424,000 in 2010 compared to approximately $313,000 in 2009, reflecting increased sales to hospital group purchasing organizations resulting from targeted sales and marketing efforts. Revenue from institutional sales of the SmartVest Wrap increased by $79,000, to approximately $169,000 in fiscal 2010 compared to approximately $90,000 in fiscal 2009 reflecting the popularity and acceptance of that product. We believe the SmartVest Wrap, along with our Single Patient Use Vest, provide synergies with our home care SmartVest System, because they introduce the hospital patient to our product line and make it more likely that patients will continue to use our products for subsequent in-home care.

Gross Profit

Gross profit increased to $10,600,000, or 74.1% of net revenues, for the fiscal year ended June 30, 2010, from approximately $9,700,000 million, or 74.3% of net revenues, for the fiscal year ended June 30, 2009. The increase in gross profit resulted primarily from the increase in sales volume.

Operating expenses

Selling, general and administrative expenses. Selling, general and administrative expenses for the fiscal year ended June 30, 2010 were approximately $8,200,000, compared to approximately $6,800,000 for the same period in the prior year. Travel, meals and entertainment, and trade show expenses were $209,000 higher in fiscal 2010 than in 2009, an increase of 22%. This increase reflects the 23% increase in the average number of sales representatives in 2010 compared to 2009. SG&A payroll and compensation related expenses increased by 21%, or approximately $664,000, to $3,790,000 million in fiscal 2010, compared to $3,126,000 in fiscal 2009. This increase reflects a 34% increase in total employees from an average of 44 employees in 2009 compared to an average of 59 employees in 2010. Health insurance costs for SG&A employees rose by $146,000, or 43%, to $484,000 in 2010, compared to $338,000 in 2009. This increase resulted from a combination of a 15% rate increase, and an increase in the number of employees participating in the health insurance plan. Advertising and marketing expenses for the fiscal year ended June 30, 2010 increased $237,000 to approximately $904,000 in fiscal 2010 from $667,000 in fiscal 2009, or approximately 35.5%. These expenditures related to providing marketing support to a larger sales team.

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Research and development expenses. Research and development expenses were approximately $601,000 and $358,000 for the fiscal years ended June 30, 2010 and 2009, respectively. The increase was related to various research projects that began in fiscal 2009 and related to system design and performance, development of new colored therapy garments and a new disposable hose for the SmartVest System. Research and development costs in 2010 were 4.2% of revenue, as a result of our continued investments in enhancing our products. We expect research and development expense to increase to approximately 5% or greater of revenue in the future.

Interest expense

Interest expense decreased to approximately $263,000 in fiscal 2010, compared to $270,000 in fiscal 2009. The decrease was due to a combination of a decrease in average debt outstanding due to payments on term loans and lower average interest rates on outstanding debt, offset by amortization of loan charges of approximately $53,000 in fiscal 2010 compared to approximately $10,000 of loan charges in fiscal 2009.

Income tax expense

Income tax expense was approximately $599,000 in fiscal 2010, compared to approximately $830,000 in the 2009 fiscal year. In fiscal 2010, our income tax expense was down as a result of lower pre-tax income. The effective income tax rate in 2010 was approximately 39.5% compared to approximately 38.5% in 2009. The increase in the effective rate was due to increases in non-deductible expenses as a percentage of pre-tax income in 2010 over 2009.

Net income

Net income for the twelve months ended June 30, 2010 was approximately $916,000, or 6.4% of revenues, compared to approximately $1,333,000, or 10.3% of revenues, in the same period in fiscal 2009. The decrease in net income in dollars and as a percentage of revenues was primarily the result of certain events that restricted management s available time to recruit additional sales representatives and distributors, combined with increased expenditures on sales and marketing and increased research and development expense, as noted above. The events that drew the focus of management included a 60-day suspension of all Medicare reimbursements (which was favorably resolved on December 4, 2009), the of securing a new bank financing facility, and the Company s initial public offering. Management was also required to address a trademark lawsuit initiated by a competitor (see Part I, Item 3, Legal Proceedings).

Liquidity and Capital Resources

Cash Flows and Sources of Liquidity

We currently have a credit facility with U.S. Bank, National Association (U.S. Bank) that provides for a $3,500,000 revolving line of credit and $2,520,000 in term debt. A $1,520,000 term loan bears interest at 5.79% (Term Loan A). The remaining $1,000,000 term loan bears interest at 4.28% (Term Loan B). The operating line of credit has an interest rate of LIBOR plus 2.75%. The amount eligible for borrowing on our line of credit is limited to 60 percent of eligible accounts receivable less the outstanding balance on our Term Loan B. The operating line of credit requires monthly payments of interest due and has a maturity date of November 30, 2010, which we expect will be renewed. Term Loan A requires monthly payments of principal and interest of approximately $10,700 and has a maturity date of December 9, 2014. Term Loan B requires monthly payments of principal and interest of approximately $29,600 and has a maturity date of December 9, 2012. Our obligations under the U.S. Bank credit facility are secured by substantially all of our assets and are guaranteed by our wholly-owned subsidiary, Electromed Financial, LLC. As of June 30, 2010, we had $1,768,000 outstanding on the operating line of credit and $2,309,000 outstanding on the term debt for a total outstanding under the U.S. Bank credit facility of $4,077,000. As of June 30, 2010, we had net unused availability of $883,000 under our line of credit.

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The agreement governing the credit facility contains certain covenants that restrict our ability to, among other things, pay cash dividends, incur indebtedness or liens, change Chief Executive Officer or Chief Financial Officer, merge or consolidate with any person, or sell, lease, assign, transfer or otherwise dispose of any assets other than in the ordinary course of business. The agreement also contains financial covenants that require maintenance of certain fixed charge and cash flow leverage ratios.

Subsequent to the end of our 2010 fiscal year, on August 13, 2010, we completed an initial public stock offering (IPO) of 1,700,000 shares of common stock, par value $0.01 per share, at an offering price of $4.00 per share. In addition, we received notice on September 23, 2010 that the underwriter in the IPO would acquire an additional 200,000 pursuant to exercise of a portion of its over-allotment option. After deducting the payment of underwriting discounts and commissions and offering expenses, we expect the net proceeds from the sale of shares in our IPO and pursuant to the over-allotment option to be approximately $5,990,000. The terms of the U.S. Bank credit facility require us to immediately prepay the outstanding loan amounts to the extent of net proceeds received from any equity offering. Management discussed this requirement with U.S. Bank prior to closing the IPO. U.S. Bank agreed to waive this requirement in connection with the IPO and granted a formal waiver on September 23, 2010, as discussed in Note 11 to the Consolidated Financial Statements, contained in Part II, Item 8 of this Report. See Part II, Item 5, Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities, for a discussion of our use of the IPO proceeds.

Cash Flows from Operating Activities

For the fiscal year ended June 30, 2010, our net cash provided by operating activities was approximately $608,000. Cash flows provided by operations were primarily a result of net income adjusted for non-cash expenses offset by approximately $229,000, $292,000 and $111,000 increases in accounts receivable, inventories, prepaid expenses and other current assets, respectively.

For the fiscal year ended June 30, 2009, our net cash used by operating activities was approximately $1,158,000. Our cash flows used by operations were primarily the result of a decrease in accounts payable and accrued liabilities of approximately $571,000 and an increase in accounts receivable of approximately $2,419,000, driven by the increase in sales and timing differences associated with collection of those sales, offset by net income adjusted for noncash expenses.

Cash Flows from Investing Activities

For the fiscal year ended June 30, 2010 cash used in investing activities was approximately $909,000. During the fiscal year ended June 30, 2010, we paid approximately $515,000 in costs related to defending our SmartVest trademark, $270,000 for purchases of property and equipment, and $125,000 for the purchase of the minority interest in Electromed Financial, LLC.

For the fiscal year ended June 30, 2009, cash used for investing activities was $712,000. Cash of approximately $649,000 was used for expanding and equipping our new manufacturing building and approximately $62,000 was used for payment of patent costs.

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Cash Flows From Financing Activities

For the fiscal year ended June 30, 2010, cash provided by financing activities was approximately $550,000. Short- and long-term borrowings during the period, which includes borrowings under our U.S. Bank credit facility, were approximately $4,288,000. The proceeds from the U.S. Bank credit facility were primarily used to pay off the principal balance of existing debt. Proceeds from the issuance of common stock were approximately $391,000. Offsetting the cash provided by financing activities were principal payments on long-term debt of approximately $3,649,000 and payments of $418,000 of deferred costs associated with our public stock offering.

For the fiscal year ended June 30, 2009, cash provided by financing activities was approximately $790,000. Cash provided by financing activities was primarily from long-term borrowings of approximately $1,027,000 and proceeds from the issuance of common stock of approximately $364,000. Partially offsetting the cash provided by financing activities were principal payments on long-term debt of $641,000.

Adequacy of Capital Resources

For fiscal 2010 and 2009, we spent approximately $270,000 and $649,000 on property and equipment, respectively. We currently expect to finance equipment purchases with borrowings under our credit facility and cash flow from operations. We may need to incur additional debt if we have an unforeseen need for additional capital equipment or if our operating performance does not generate adequate cash flow.

For the twelve months ended June 30, 2010, we incurred and capitalized approximately $880,000 of legal defense costs associated with our trademark lawsuit. We reached a settlement in principle with respect to this lawsuit on September 16, 2010. We expect to continue to incur costs in connection with finalizing the settlement agreement. For additional information, see Part I, Item 3, Legal Proceedings.

In connection with the employment agreements we entered into with our Chief Executive Officer and Chief Financial Officer on January 1, 2010, we may be required to make cash payments to these officers if they resign following a change in control or are terminated at any time without cause. With respect to a resignation upon a change in control, the amount of the severance payment would be equal to two times the annual base salary then in effect. With respect to a termination without cause, the amount of the severance payment would be equal to the base salary of the executive then in effect. In each instance, the executive would also be entitled to a pro rata portion of any earned but unpaid incentive compensation at the time of termination, the severance would be payable in a lump sum within 60 days of the separation event, and the executive would, in order to receive the severance and continued benefits, be required to sign a release of claims against us, return all property owned by Electromed and agree not to disparage us.

The terms of the U.S. Bank credit facility require us to immediately prepay the outstanding loan amounts the the extent of net proceeds received from any equity offering. Management discussed this requirement with with U.S. Bank prior to closing the initial public offering. U.S. Bank agreed to waive this requirement in connection with the initial public offering and granted a formal waiver in September 2010, as discussed in Note 11 to the Consolidated Financial Statements, contained in Part II, Item 8 of this Report.

Based on our current operational performance, we believe our cash flow from operations, available cash and available borrowings under the existing credit facility will adequately provide our liquidity needs for, at a minimum, the next twelve months.

Certain Information Concerning Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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New Accounting Pronouncements

For recently issued accounting pronouncements, see Note 1 to the Consolidated Financial Statements, included in Part II, Item 8 of this Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Electromed, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of Electromed, Inc. and Subsidiary as of June 30, 2010 and 2009, and the related consolidated statements of income, stockholders equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Electromed, Inc. and Subsidiary as of June 30, 2010 and 2009, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Minneapolis, Minnesota
September 28, 2010

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Electromed, Inc. and Subsidiary
Consolidated Balance Sheets
June 30, 2010 and 2009

	June 30 2010	2009
Assets		
Current Assets		
Cash	$ 610,727	$ 361,916
Accounts receivable (net of allowances for doubtful accounts of $45,000)	6,577,002	6,348,146
Inventories	1,470,775	1,178,689
Prepaid expenses and other current assets	269,193	167,272
Deferred income taxes	514,000	357,000
Total current assets	9,441,697	8,413,023
Property and equipment, net	2,688,941	2,731,269
Finite-life intangible assets, net	1,055,776	228,783
Deferred common stock offering costs	828,034	-
Other assets	128,789	88,023
Total assets	$ 14,143,237	$ 11,461,098
Liabilities and Stockholders Equity		
Current Liabilities		
Revolving line of credit	$ 1,768,128	$ -
Current maturities of long-term debt	397,886	392,251
Accounts payable	1,239,827	426,320
Accrued compensation	665,083	541,125
Warranty reserve	363,277	292,254
Other accrued liabilities	60,308	111,879
Income taxes payable	7,789	334,031
Total current liabilities	4,502,298	2,097,860
Long-term debt, less current maturities	2,033,325	3,167,496
Deferred income taxes	145,000	137,000
Total liabilities	6,680,623	5,402,356
Commitments and Contingencies (Note 9)		
Stockholders Equity		
Electromed, Inc. stockholders equity:		
Common stock, $0.01 par value; authorized: 10,000,000 shares; issued and outstanding: 6,187,885 and 6,047,152 shares, respectively	61,879	60,472
Additional paid-in capital	6,685,362	6,201,636
Retained earnings (deficit)	797,873	(118,465)
Common stock subscriptions receivable for shares outstanding of 48,500 and 53,500 respectively	(82,500)	(91,500)
Total Electromed, Inc. stockholders equity	7,462,614	6,052,143
Noncontrolling interest	-	6,599
Total stockholders equity	7,462,614	6,058,742
Total liabilities and stockholders equity	$ 14,143,237	$ 11,461,098

See Notes to Consolidated Financial Statements.

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Electromed, Inc. and Subsidiary
Consolidated Statements of Income
Years Ended June 30, 2010 and 2009

	Years Ended June 30 2010	2009
Net revenues	$ 14,303,848	$ 12,998,627
Cost of revenues	3,707,509	3,340,041
Gross profit	10,596,339	9,658,586
Operating expenses		
Selling, general and administrative	8,199,386	6,845,106
Research and development	600,986	357,871
Total operating expenses	8,800,372	7,202,977
Operating income	1,795,967	2,455,609
Interest expense, net of interest income of $6,417 and $8,746 respectively	263,431	270,446
Net income (loss) before income taxes	1,532,536	2,185,163
Income tax expense	(599,000)	(830,000)
Net income	933,536	1,355,163
Less: Net income attributable to noncontrolling interest	(17,198)	(22,257)
Net income attributable to Electromed, Inc.	$ 916,338	$ 1,332,906
Earnings per share attributable to Electromed, Inc. common shareholders:		
Basic	$ 0.15	$ 0.22
Diluted	0.15	0.22
Weighted-average Electromed, Inc. common shares outstanding:		
Basic	6,081,030	5,987,383
Diluted	6,114,919	6,020,458

See Notes to Consolidated Financial Statements.

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Electromed, Inc. and Subsidiary
Consolidated Statements of Stockholders Equity
Years Ended June 30, 2010 and 2009

	Electromed, Inc.						
	Common Stock		Additional Paid-in Capital	Retained Earnings (Deficit)	Common Stock Subscriptions Receivable	Noncontrolling Interest	Total Stockholders Equity
	Shares	Amount					
Balance at June 30, 2008	5,880,911	$ 58,809	$ 5,540,922	$ (1,451,371)	$ (111,999)	$ 4,658	$ 4,041,019
Net income	-	-	-	1,332,906	-	22,257	1,355,163
Sale of common stock	58,572	586	214,414	-	-	-	215,000
Issuance of common stock for exercise of warrants	49,669	497	148,507	-	-	-	149,004
Issuance of common stock for warrants exercised with subscription notes	31,000	310	46,190	-	(46,500)	-	-
Issuance of common stock for acquisition of property and payment of services	30,000	300	104,700	-	-	-	105,000
Proceeds on subscription notes receivable	-	-	-	-	66,999	-	66,999
Repurchase of common stock	(3,000)	(30)	(6,330)	-	-	-	(6,360)
Distributions paid to holders of noncontrolling interest	-	-	-	-	-	(20,316)	(20,316)
Share-based compensation expense	-	-	153,233	-	-	-	153,233
Balance at June 30, 2009	6,047,152	60,472	6,201,636	(118,465)	(91,500)	6,599	6,058,742
Net income	-	-	-	916,338	-	17,198	933,536
Issuance of common stock upon exercise of warrants	135,733	1,357	389,475	-	-	-	390,832
Issuance of common stock for payment of services	5,000	50	22,450	-	-	-	22,500
Proceeds from subscription notes receivable	-	-	-	-	9,000	-	9,000
Distributions paid to holders of noncontrolling interest	-	-	-	-	-	(18,417)	(18,417)
Share-based compensation expense	-	-	168,895	-	-	-	168,895
Income tax benefit related to exercise of stock warrants	-	-	22,526	-	-	-	22,526
Purchase of noncontrolling interest in Electromed Financial, LLC	-	-	(119,620)	-	-	(5,380)	(125,000)
Balance at June 30, 2010	6,187,885	$ 61,879	$ 6,685,362	$ 797,873	$ (82,500)	$ -	$ 7,462,614

See Notes to Consolidated Financial Statements.

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Electromed, Inc. and Subsidiary
Consolidated Statements of Cash Flows
Years Ended June 30, 2010 and 2009

	Years Ended June 30, 2010	2009
Cash Flows From Operating Activities		
Net income	$ 933,536	$ 1,355,163
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation	298,928	302,162
Amortization of finite-life intangible assets	52,820	16,783
Amortization of debt issuance costs	53,404	9,638
Share-based compensation expense	168,895	153,233
Deferred income taxes	(149,000)	299,000
Loss on disposal of property and equipment	4,258	56,301
Issuance of common stock for payment of services	22,500	35,000
Changes in operating assets and liabilities:		
Accounts receivable	(228,856)	(2,418,665)
Inventories	(292,086)	(329,181)
Prepaid expenses and other assets	(111,345)	(66,562)
Accounts payable and accrued liabilities	(145,117)	(570,578)
Net cash provided by (used in) operating activities	607,937	(1,157,706)
Cash Flows From Investing Activities		
Expenditures for property and equipment	(269,616)	(648,716)
Purchase of noncontrolling interest in Electromed Financial, LLC	(125,000)	-
Expenditures for finite-life intangible assets	(514,505)	(61,908)
Net cash used in investing activities	(909,121)	(712,320)
Cash Flows From Financing Activities		
Net borrowings on revolving line of credit	1,768,128	-
Principal payments on long-term debt including capital lease obligations	(3,648,744)	(641,409)
Proceeds from long-term debt	2,520,000	1,027,399
Noncontrolling interest distributions paid	(18,417)	(20,316)
Payments of deferred financing fees	(75,780)	(1,696)
Proceeds from sales of common stock and warrant exercises	390,832	364,004
Proceeds on subscription notes receivable	9,000	66,999
Income tax benefit related to exercise of stock warrants	22,526	-
Expenditures for deferred offering costs	(417,550)	-
Repurchase of common stock	-	(6,360)
Net cash provided by financing activities	549,995	(790,317)
Net increase (decrease) in cash and cash equivalents	248,811	(1,079,709)
Cash		
Beginning of period	361,916	1,441,625
End of period	$ 610,727	$ 361,916

See Notes to Consolidated Financial Statements.

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Electromed, Inc. and Subsidiary

Consolidated Statements of Cash Flows (Continued)
Years Ended June 30, 2010 and 2009

	Years Ended June 30	
	2010	2009
Supplemental Disclosures of Cash Flow Information		
Cash paid for interest	$ 227,454	$ 266,265
Cash paid for income taxes	1,052,640	192,703
Supplemental Disclosures of Noncash Investing and Financing Activities		
Common stock issued for acquisition of property and equipment	$ -	$ 70,000
Reduction in basis of acquired building formerly under capital lease	93,172	-
Common stock issued for subscription notes	-	46,500
Accrued expenditures for finite-life intangible assets included in accounts payable	365,308	-
Deferred common stock offering costs included in accounts payable	410,484	-
Expenditures for property and equipment included in accounts payable	-	20,000
Property and equipment financed through capital leases	87,769	75,366

See Notes to Consolidated Financial Statements.

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Electromed, Inc. and Subsidiary
Notes to Consolidated Financial Statements

Note 1. Nature of Business and Summary of Significant Accounting Policies

Nature of business: Electromed, Inc. (the Company) develops, manufactures and markets innovative airway clearance products which apply High Frequency Chest Wall Oscillation (HFCWO) therapy in pulmonary care for patients of all ages. The Company markets its products in the United States to the home health care and institutional markets for use by patients in personal residences, hospitals and clinics. The Company also sells internationally both directly and through distributors. The Company had international sales of approximately $647,000 and $919,000 for the years ended June 30, 2010 and 2009 respectively. Since its inception, the Company has operated in a single industry segment: developing, manufacturing and marketing medical equipment. As a result, the information disclosed herein materially represents all of the financial information related to the Company s operating segment.

Principles of consolidation and related party transaction: The accompanying consolidated financial statements include the accounts of Electromed, Inc. and its subsidiary, Electromed Financial, LLC. Electromed Financial, LLC was established by the Company to assist in raising capital from outside investors. The Company owned 95 percent of Electromed Financial, LLC through March 2, 2010, at which time the Company acquired the remaining five percent of Electromed Financial, LLC from a director of the Company for $125,000. Income related to the noncontrolling interest in the subsidiary is reflected as noncontrolling interest on the consolidated financial statements. All significant intercompany accounts and transactions have been eliminated in consolidation.

A summary of the Company s significant accounting policies follows:

Use of estimates: Management uses estimates and assumptions in preparing the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could vary from the estimates that were used. The Company believes the critical accounting policies that require the most significant assumptions and judgments in the preparation of its consolidated financial statements include: revenue recognition and the estimation of selling price adjustments, allowance for doubtful accounts, inventory obsolescence, valuation allowance for deferred income tax assets and warranty liability.

Revenue recognition: The Company recognizes revenue when persuasive evidence of a sales arrangement exists, delivery of goods occurs through the transfer of title and risks and rewards of ownership, the selling price is fixed or determinable, and collectability is reasonably assured. Revenues are primarily recognized upon shipment.

Direct patient sales are recorded at amounts to be received from patients under reimbursement arrangements with third-party payers, including private insurers, prepaid health plans, Medicare and Medicaid. In addition, the Company records an estimate for selling price adjustments which often arise from changes in a patient s insurance coverage, changes in a patient s domicile, insurance company coverage limitations or patient death. Other than the installment sales as discussed below, the Company expects to receive payment on the vast majority of accounts receivables within one year and therefore has classified all accounts receivable as current. However, in some instances, payment for direct patient sales can be delayed or interrupted, resulting in a small portion of collections occurring later than one year.

Certain third-party reimbursement agencies pay the Company on a monthly installment basis, which can span over several years. Due to the length of time over which cash is collected and the inherent uncertainty of collectability with these installment sales, the Company cannot make a reasonable estimate of revenue at the time of sale and does not record accounts receivable or revenue at the time of product shipment. Under the installment method, the Company defers and amortizes the costs associated with the sale and, as each installment is received, that amount is recognized as revenue. Deferred costs associated with the sale are amortized to cost of revenue ratably over the estimated period in which collections are scheduled to occur.

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A summary of sales made under the installment method are as follows:

	Years Ended June 30	
	2010	2009
Revenue recognized under installment sales	$ 467,000	$ 299,000
Amortized cost of revenues recognized	72,000	51,000

Unrecognized installment method sales were as follows:

	Years Ended June 30	
	2010	2009
Estimated unrecognized sales, net of discounts	$ 708,000	$ 716,000
Unamortized costs of revenues included in prepaids and other current assets	111,000	94,000

Shipping and handling expense: Shipping and handling charges billed to customers are included as a cost in arriving at gross profit. Shipping and handling charges incurred by the Company are included in selling, general and administrative expenses and were $218,000 and $174,000 for the years ended June 30, 2010 and 2009 respectively.

Cash: The Company maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits. The Company has not experienced any losses in these accounts.

Accounts receivable: The Company s receivable balance is comprised of amounts due from individuals, institutions and distributors. Balances due from individuals are typically remitted to the Company by third-party reimbursement agencies such as Medicare, Medicaid and private insurance companies. Accounts receivable are carried at amounts estimated to be received from patients under reimbursement arrangements with third-party payers. Accounts receivable are also net of an allowance for doubtful accounts. Management determines the allowance for doubtful accounts by regularly evaluating individual customer receivables and considering a customer s financial condition and credit history. Receivable are written off when deemed uncollectible. Recoveries of receivables previously written off are recorded when received. The allowance for doubtful accounts was approximately $45,000 as of June 30, 2010 and 2009.

Inventories: Inventories, consisting of material, labor and manufacturing overhead are stated at the lower of cost (first-in, first-out method) or market. Work in process and finished goods are carried at standard cost, which approximates actual cost, and includes materials, labor and allocated overhead. Standard costs are reviewed at least quarterly by management, or more often in the event circumstances indicate a change in cost has occurred. The reserve for obsolescence is determined by analyzing the inventory on hand and comparing it to expected production requirements.

Property and equipment: Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Leasehold improvements and assets acquired under capital leases are depreciated over the shorter of their estimated useful lives or the remaining lease term. The Company retains ownership of demonstration equipment in the possession of both inside and outside sales representatives, who use the equipment in the sales process.

Finite-life intangible assets: Finite-life intangible assets include patents and trademarks. These intangible assets are being amortized on a straight-line basis over their estimated useful lives, as described in Note 4.

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Long-lived assets: Long-lived assets, such as property and equipment and finite-life intangible assets are evaluated for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. In evaluating recoverability, the following factors, among others, are considered: a significant change in the circumstances used to determine the amortization period, an adverse change in legal factors or in the business climate, a transition to a new product or service strategy, a significant change in customer base, and a realization of failed marketing efforts. The recoverability of an asset is measured by a comparison of the unamortized balance of the asset to future undiscounted cash flows.

If the Company believes the unamortized balance is unrecoverable, it would recognize an impairment charge necessary to reduce the unamortized balance to the estimated fair value of the asset. The amount of such impairment would be charged to operations in the current period. The Company has not identified any indicators of impairment associated with its long-lived assets.

Warranty liability: The Company provides a lifetime warranty on its products to the prescribed patient for sales within the United States and Canada, a five-year warranty on its products to the prescribed patient for sales within Greece, and a three-year warranty for all institutional sales and sales to individuals outside the United States and Canada. The Company estimates the costs that may be incurred under its warranty and records a liability in the amount of such costs at the time the product is sold. Factors that affect the Company s warranty liability include the number of units sold, historical and anticipated rates of warranty claims, and cost per claim. The Company periodically assesses the adequacy of its recorded warranty liability and adjusts the amounts as necessary.

Changes in the Company s warranty liability were approximately as follows:

	Years Ended June 30	
	2010	2009
Beginning warranty reserve	$ 292,000	$ 195,000
Accrual for products sold	146,000	162,000
Expenditures and costs incurred for warranty claims	(75,000)	(65,000)
Ending warranty reserve	$ 363,000	$ 292,000

Income taxes: Deferred taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

The Company recognizes tax liabilities when the Company believes that certain positions may not be fully sustained upon review by tax authorities. Benefits from tax positions are measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon settlement. The current portion of tax liabilities is included in other liabilities. To the extent that the final tax outcome of these matters is different than the amounts recorded, such differences impact income tax expense in the period in which such determination is made. Interest and penalties, if any, related to accrued liabilities for potential tax assessments are included in income tax expense.

Research and development: Research and development costs include costs of research activities as well as engineering and technical efforts required to develop new products or make improvement to existing products. Research and development costs are expensed as incurred.

Advertising costs: Advertising costs are charged to expense when incurred. Advertising, marketing and trade show costs for the years ended June 30, 2010 and 2009 were approximately $527,000 and $642,000 respectively.

Share-based payments: Share-based payment awards consist of warrants issued to employees for services, and to nonemployees in lieu of payment for products or services. Expense is estimated using the fair value of products or services rendered or the Black-Scholes pricing model at the date of grant and is recognized on a straight-line basis over the requisite service or vesting period of the award.

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Fair value of financial instruments: The carrying values of cash, accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these instruments. The carrying value of long-term debt is the remaining amount due to debtors under borrowing arrangements. To estimate the fair value of debt, the Company estimates the interest rate necessary to secure financing to replace its debt. At June 30, 2010, the fair value of long-term debt was not significantly different than its carrying value.

Basic and diluted earnings per share: Basic per share amounts are computed by dividing net income attributable to Electromed, Inc. by the weighted-average number of common shares outstanding. Diluted per share amounts assume the conversion, exercise or issuance of all potential common stock instruments unless their effect is anti-dilutive, thereby reducing the loss per share or increasing the income per share (see Note 7 for information on stock warrants).

Recently issued accounting pronouncements: In June 2009, the FASB issued revised guidance for the consolidation of variable interest entities. This amends the original guidance requiring an enterprise to perform an analysis to determine whether the enterprise s variable interest or interests give it a controlling financial interest in a variable interest entity (VIE). This analysis identifies the primary beneficiary of a VIE as the enterprise that has both (a) the power to direct the activities of a VIE that most significantly impact the entity s economic performance, and (b) the obligation to absorb losses of the entity that could potentially be significant to the VIE. Additionally, this new guidance requires an enterprise to assess whether it has an implicit financial responsibility to ensure that a VIE operates as designed when determining it has the power to direct the activities of the VIE that most significantly impact the entity s economic performance. This guidance is effective at the beginning of the Company s 2011 fiscal year. This guidance is not expected to have a material effect on the Company s consolidated financial statements.

Reclassifications: Certain items in the fiscal 2009 financial statements have been reclassified to be consistent with the classifications adopted for fiscal 2010. The fiscal 2009 reclassifications had no impact on previously reported net income and stockholders equity.

Note 2. Inventories

The components of inventory at June 30, 2010 and 2009 are approximately as follows:

	June 30 2010	2009
Parts inventory	$ 765,000	$ 759,000
Work in process	56,000	114,000
Finished goods	680,000	336,000
Less: Reserve for obsolescence	(30,000)	(30,000)
Total	$ 1,471,000	$ 1,179,000

Note 3. Property and Equipment

Property and equipment, including assets under capital leases, consisted of approximately the following:

	Estimated Useful Lives(Years)	**June 30**	
		2010	**2009**
Building and building improvements	15-39	$ 1,892,000	$ 1,920,000
Land	N/A	200,000	200,000
Land improvements	15	162,000	162,000
Equipment	3-7	921,000	755,000
Demonstration equipment	3	507,000	396,000
Vehicles	5	35,000	35,000
		3,717,000	3,468,000
Less: Accumulated depreciation		(1,028,000)	(737,000)
Total property and equipment		$ 2,689,000	$ 2,731,000

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Note 4. Finite-Life Intangible Assets

The carrying value of patents and trademarks includes the original cost of obtaining the patents, periodic renewal fees, and other costs associated with maintaining and defending patent and trademark rights. Patents and trademarks are amortized over their estimated useful lives, generally 15 and 12 years, respectively. Accumulated amortization was $114,000 and $61,000 at June 30, 2010 and 2009, respectively.

The activity and balances of finite-life intangible assets were approximately as follows:

	Years Ended June 30	
	2010	2009
Balance, beginning	$ 229,000	$ 184,000
Additions	880,000	62,000
Amortization expense	(53,000)	(17,000)
Balance, ending	$ 1,056,000	$ 229,000

Based on the carrying value at June 30, 2010, amortization expense is expected to be approximately $93,000 annually.

Additions during the year ended June 30, 2010 consisted primarily of legal defense costs associated with a trademark infringement lawsuit filed against the Company (see Note 9). Such defense costs are being capitalized by the Company and amortized over the remaining useful life of the trademark. In the event the Company is unsuccessful in defending this trademark, such capitalized legal defense costs will be immediately expensed. The future amortization amount is expected to change as the Company incurs additional costs associated with its patents and trademarks, including the trademark defense costs.

Note 5. Financing Arrangements

The Company entered into a $3,500,000 revolving line of credit on December 9, 2009, which expires on November 30, 2010, if not renewed. Advances are due at the expiration date and are secured by substantially all Company assets. The amount available for borrowing is limited to 60 percent of eligible accounts receivable less the outstanding balance on the Company s 4.28% term note due December 2012. Interest on advances accrues at LIBOR plus 2.75 percent and is payable monthly. As of June 30, 2010, there was approximately $1,768,000 outstanding on the line of credit and $883,000 available for future borrowing.[(a)]

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Long-term debt consists of approximately the following as of June 30, 2010 and 2009:

	June 30 2010	2009
Mortgage note payable with bank, due in monthly installments of $10,706, including interest at 5.79%, remaining due December 2014, secured by land and building[(a)]	$ 1,494,000	$ -
Term note payable with bank, due in monthly installments of $29,649, including interest at 4.28%, due December 2012, secured by substantially all assets[(a)]	815,000	-
Capital lease obligations, due in varying monthly installments, including interest ranging from 8.99% to 12.07%, to July 2013, secured by equipment	122,000	78,000
Capital lease obligation for building, implied interest of 11.92%, terminated with the purchase of the building	-	654,000
Notes payable with bank, interest ranging from 6.75% to 9.0%, paid in full in fiscal 2010	-	1,629,000
Construction and mortgage notes payable with bank, interest at 6.0%, paid in full prior to December 31, 2009	-	1,198,000
Total	2,431,000	3,559,000
Less: Current portion	398,000	392,000
Long-term debt	$ 2,033,000	$ 3,167,000

(a) These instruments have certain financial and nonfinancial covenants which, among others, require the Company to maintain a minimum fixed charge coverage ratio and a maximum cash flow leverage ratio, and restrict the payment of dividends. Under the terms of the credit facility, the Company is required to immediately pay to the bank any net proceeds raised from an equity offering. The bank has agreed to waive this requirement as it relates to the initial public offering as discussed in Note 11.

Approximate future maturities of long-term debt as of June 30, 2010 are as follows:

Year ending June 30:	
2011	$ 398,000
2012	429,000
2013	239,000
2014	50,000
2015	1,315,000
Total	$ 2,431,000

Capital leases and related party transaction: The Company has financed certain office equipment through capital leases. The Company also had a building capital lease with a director of the Company through December 2009, at which time the Company purchased the building for approximately $555,000 using the proceeds from a new mortgage note with a bank. The net carrying value of the capital lease obligation exceeded the purchase price by approximately $93,000 which was recognized as a reduction in the net book value of the acquired building, which had been capitalized at the inception of the lease.

At June 30, 2010 and 2009, carrying value of assets under these capital leases are approximately as follows:

	June 30 2010	2009
Building	$ -	$ 675,000
Fixtures and office equipment	181,000	96,000
Less: Accumulated depreciation	(38,000)	(67,000)
Total	$ 143,000	$ 704,000

Depreciation expense for these assets was $26,000 and $29,000 for the years ended June 30, 2010 and 2009 respectively.

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Approximate future minimum payments under capital leases as of June 30, 2010 are as follows:

Year ending June 30:	
2011	$ 71,000
2012	48,000
2013	18,000
Total	137,000
Less: Amount representing interest	(15,000)
Present value of future minimum lease payments (included in long term debt above)	$ 122,000

Note 6. Common Stock

Common stock issued for property and services: In fiscal 2009, the Company issued 20,000 and 10,000 shares for land improvements and services with estimated fair values of $70,000 and $35,000, respectively. During the year ended June 30, 2010, the Company issued 5,000 shares for services valued at $22,500.

Common stock subscription receivables: During fiscal 2008, the Company issued 47,333 shares of common stock to unrelated third parties upon the exercise of outstanding warrants. The Company agreed to accept subscription notes receivable from these individuals for a total of approximately $112,000. For the year ended June 30, 2009, cash collected on these notes was approximately $52,000.

During fiscal 2009, the Company issued 31,000 shares of common stock to an employee upon exercise of outstanding warrants. The Company agreed to accept a subscription note receivable from this individual for $46,500. For the year ended June 30, 2010 and 2009, cash collected on this note was approximately $9,000 and $15,000, respectively. The Company revalued the warrants upon issuance of this subscription note and recognized additional share-based expense of approximately $67,000 for the year ended June 30, 2009.

Sales of common stock: The Company from time to time has sold common stock to investors for cash. During the year ended June 30, 2009, the Company sold 48,572 shares at $3.50 per share and 10,000 shares at $4.50 per share, for total cash proceeds of approximately $215,000. All shares were sold to unrelated third-party investors.

Note 7. Share-Based Payments

Employee warrants: The Company grants stock warrants to employees as long-term incentive compensation. All warrants are granted at exercise prices equal to or greater than the estimated fair market value of the Company s common stock, based upon recent common stock sales transactions with independent third-party investors. Warrants generally expire four to ten years from the grant date and vest over a period of up to five years. Warrants have not been granted under a formal plan; however, the number of warrants eligible for issuance is limited to the number of authorized shares of the Company s common stock.

The Company recognizes compensation expense related to share-based payment transactions in the consolidated financial statements based on the estimated fair value of the award issued. The fair value of each warrant is estimated using the Black-Scholes pricing model at the time of award grant. The Company estimates the expected life of warrants based on the expected holding period by the warrant holder. The risk-free interest rate is based upon observed U.S. Treasury interest rates for the expected term of the warrants. The Company makes assumptions with respect to expected stock price volatility based upon the volatility of similar companies. Forfeitures are estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from initial estimates. Forfeitures are estimated based on the percentage of awards expected to vest, taking into consideration the seniority level of the award recipient.

Share-based compensation expense for the years ended June 30, 2010 and 2009 was approximately $169,000 and $153,000 respectively.

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The following weighted-average assumptions were used to estimate the fair value of warrants granted:

	Years Ended June 30	
	2010	2009
Risk-free interest rate	1.45%	3.24%
Expected life (years)	4 - 10	4 - 10
Expected volatility	46.0%	46.9%
Expected dividends	0%	0%

The following table presents employee warrant activity for the years ended June 30, 2010 and 2009:

	Number of Shares	Weighted - Average Grant Date Fair Value	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)
Warrants outstanding at June 30, 2008	272,000	$ 1.32	$ 2.64	1.14
Granted	307,800	2.13	3.55	-
Exercised	(31,000)	0.61	1.50	-
Canceled or forfeited	(40,000)	1.06	2.56	-
Warrants outstanding at June 30, 2009	508,800	1.87	3.27	6.03
Activity:				
Granted	25,000	1.68	4.50	-
Exercised	(117,000)	1.77	2.90	-
Canceled or forfeited	(25,000)	2.02	2.60	-
Warrants outstanding at June 30, 2010	391,800	1.87	3.47	6.74
Warrants exercisable at June 30, 2010	124,560	1.51	3.21	4.75

For the years ended June 30, 2010 and 2009 net cash proceeds from the exercise of employee warrants was approximately $339,000 and $47,000 respectively. The Company received an excess income tax benefit of approximately $23,000 in 2010 and no income tax benefit in 2009 from the exercise of employee warrants.

At June 30, 2010, the Company had approximately $450,000 of unrecognized stock-based compensation, which is expected to be recognized over a weighted-average period of 3.2 years. The aggregate intrinsic value of warrants outstanding was approximately $403,000, and the intrinsic value of warrants exercisable was approximately $161,000 at June 30, 2010.

Warrants issued to non-employees for services: In years prior to fiscal 2009, the Company issued warrants to non-employees for services in lieu of cash payments. At June 30, 2010, the Company had warrants outstanding and exercisable to purchase 20,000 shares of common stock at a weighted-average exercise price of $3.00 per share. These warrants expire at various dates through January 3, 2011.

All outstanding warrants issued for services were granted prior to the 2009 fiscal year. All services related to these warrants were completed prior to fiscal 2009. The Company has therefore recorded all share-based expense associated with these services in prior years. During the year ended June 30, 2010, a warrant to purchase 5,000 shares was exercised at an exercise price of $3.50 per share. There were no warrants forfeited during the year ended June 30, 2010. During the year ended June 30, 2009, there were 400,000 warrants forfeited. The warrants canceled during the year ended June 30, 2009 were forfeited as a result of a termination agreement with an independent sales representative (see Note 9).

Warrants issued with convertible debt: In years prior to fiscal 2009, the Company issued convertible notes payable to certain individuals. In conjunction with the issuance of these convertible notes, creditors also received warrants to purchase common stock for an exercise price of $3.00 per share. At June 30, 2010, the Company had approximately 83,000 warrants outstanding and exercisable at a weighted-average exercise price of $3.00 per share. Approximately 38,000 warrants expire in September 2012 and approximately 45,000 expire in September 2015. During the years ended June 30, 2010 and 2009, warrant holders exercised 13,733 and 49,669 warrants at a weighted-average exercise price of $2.50

and $3.00 respectively. There were no warrants forfeited and cancelled during the year ended June 30, 2010. During the year ended June 30, 2009, 62,338 warrants were forfeited and canceled.

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Note 8. Income Taxes

Components of the provision for (benefit from) income taxes for the years ended June 30, 2010 and 2009, are as follows:

	Years Ended June 30	
	2010	2009
Current	$ 748,000	$ 531,000
Deferred	(149,000)	299,000
Total	$ 599,000	$ 830,000

The total income tax expense differs from the expected tax expense, computed by applying the federal statutory rate to the Company s income before income taxes, as follows:

	Years Ended June 30	
	2010	2009
Tax expense at statutory federal rate	$ 515,000	$ 743,000
State income tax benefit, net of federal tax	55,000	75,000
Other permanent items	29,000	12,000
Income tax expense	$ 599,000	$ 830,000

The significant components of deferred income taxes are as follows:

	June 30	
	2010	2009
Deferred tax assets (liabilities):		
Revenue recognition and accounts receivable	$ 228,000	$ 221,000
Accrued liabilities	296,000	200,000
Net operating loss carryforwards	2,000	31,000
Property and equipment	(195,000)	(118,000)
Finite-life intangible assets	(60,000)	(52,000)
Investment in subsidiary	-	(80,000)
Warrants	110,000	82,000
Other	(12,000)	(64,000)
Net deferred tax assets	$ 369,000	$ 220,000

The components giving rise to the net deferred income tax assets described above have been included in the accompanying consolidated balance sheets as follows:

	June 30	
	2010	2009
Current assets	$ 514,000	$ 357,000
Long-term liabilities	(145,000)	(137,000)
Net deferred tax assets	$ 369,000	$ 220,000

The Company has state net operating loss carryforwards at June 30, 2010, of approximately $19,000 to reduce future income tax liabilities, which will begin to expire in 2024.

The Company has evaluated its exposure to unrecognized tax benefits as of June 30, 2010 and 2009, and has estimated that there are no unrecognized benefits which would be material to the consolidated financial statements. The Company s policy would be to recognize accrued interest and penalties related to unrecognized tax benefits as a component of income tax expense.

The Company is subject to U.S. federal income tax as well as income tax of multiple state jurisdictions. With limited exceptions, tax years prior to fiscal 2007 are no longer open to federal, state and local examination by taxing authorities.

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Note 9. Commitments and Contingencies

Settlement of sales representation agreement: In July 2008, the Company settled a lawsuit with an independent sales representative organization. The terms of the settlement required the Company pay all commissions upon cash collection for sales through July 31, 2008, in accordance with the original agreement. Approximately $28,000 and $71,000 of commissions related to this independent sales representative organization were accrued in the accompanying consolidated financial statements as of June 30, 2010 and 2009, respectively. The period for which commissions would otherwise be payable to the independent sales representative organization was reduced by three months from October 31, 2008, to July 31, 2008. As a condition of the settlement, the independent sales representative organization did not exercise and forfeited their warrants for 400,000 shares of Company common stock, which had been previously expensed. Additional conditions of the settlement included the cancellation of a $1,000,000 contingent payment clause upon a change in control of the Company and a requirement by the Company to repurchase 3,000 shares of its common stock held by the independent sales representative organization for $2.12 per share.

Litigation: Subsidiaries of Hill-Rom Holdings, Inc., (collectively, Hill-Rom) brought an action on August 21, 2009, against the Company alleging that the Company s use of the term SmartVest infringes on its alleged trademark The Vest. The Company answered the allegations and brought counter-claims against Hill-Rom alleging, among other things, defamation and libel. For the year period ended June 30, 2010, the Company incurred and capitalized costs of $880,000 in defending this trademark. Subsequent to June 30, 2010 and through July 31, 2010 the Company incurred and capitalized approximately $27,000 in defending this trademark.

In the addition to the trademark matter discussed above, the Company is occasionally involved in claims and disputes arising in the ordinary course of business. The Company insures its business risks where possible to mitigate the financial impact of individual claims, and establishes reserves for an estimate of any probable cost of settlement or other disposition. In the opinion of management, the ultimate disposition or resolution of these matters, if any, will not have a material adverse effect on the Company s financial position, results of operations, or liquidity.

401(k) profit sharing plan: The Company has an employee benefit plan under Section 401(k) of the Internal Revenue Code covering all employees who are 21 years of age or older and have 1,000 hours of service with the Company. The Company matches each employee s salary reduction contribution, not to exceed 4 percent of annual compensation. Total employer contributions to this plan for the years ended June 30, 2010 and 2009 were approximately $125,000 and $108,000.

Employment Agreements: Effective January 1, 2010, the Company entered into new employment agreements with its chief executive officer and chief financial officer. These agreements provide the officers, with among other things, one year s salary upon a separation of service without cause for termination. Also, in the event the employee resigns within six months of a change in control, the chief executive officer and chief financial officer are entitled to receive a severance equal to two year s base salary.

Note 10. Related Parties

The Company uses a related-party service provider, a director and minority shareholder of which was the original inventor of the Company s product, to perform certain outsourced research and development functions. The Company s chief executive officer is also the president, chief executive officer and chairman of the board of directors of the service provider and owns approximately 11% of that entity s outstanding common stock. In addition, two members of the Company s board of directors are directors and minority shareholders of the service provider. The Company has an agreement with the service provider which provides that the service provider will perform 80 hours per week of research and development work in exchange for a monthly fee, in the amount of $25,000 through June 2010 and $30,000 through December 2010. For the years ended June 30, 2010 and 2009, expenses for these services totaled approximately $280,000 and $115,000 respectively, and such expenses are included in research and development expense in the income statement.

Also see Notes 1 and 5 for additional related party transactions with Company directors.

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Note 11. Subsequent Events

On August 13, 2010, The Company completed an initial public stock offering (IPO) of 1,700,000 shares of common stock at an offering price of $4.00 per share. In addition, the Company received notice on September 23, 2010 that the underwriter in the IPO would acquire an additional 200,000 pursuant to exercise of a portion of its over-allotment option. After deducting the payment of underwriting discounts, commissions and offering costs, the net proceeds from the sale of shares in the IPO and pursuant to the over-allotment option will be approximately $5,990,000. In connection with the IPO and the exercise of the over-allotment option, the Company also issued to Feltl warrants to purchase up to 190,000 additional shares of the Company s common stock at a price of $4.80 per share.

The changes to the balance sheet adjusted for the IPO, over-allotment and subsequent $500,000 payment to the revolving line of credit are as follows:

	June 30, 2010	
	Audited	Proforma (Unaudited)
Assets	$ 14,143,237	$ 19,634,039
Liabilities	6,680,623	6,180,623
Stockholders equity	7,462,614	13,453,416

Under the terms of the Company s credit facility with U.S. Bank, the Company is required to immediately pay to the bank any net proceeds raised from an equity offering. The bank has agreed to waive this requirement as it relates to the initial public offering.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) or Rule 15d-15(e), as of the end of the period subject to this Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the periodic and current reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the periods specified by the Securities and Exchange Commission s rules and forms.

Management s Report on Internal Control over Financial Reporting and Auditor Attestation

This annual report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the Company s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes to Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of fiscal 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other information.

None.

Part III

Item 10. Directors, Executive Officers, and Corporate Governance.

Other than the information included in this Annual Report on Form 10-K under the caption Executive Officers of the Registrant, which is set forth at the end of Part I, the information required by Item 10 is incorporated herein by reference to the sections labeled Election of Directors, Corporate Governance, Compliance With Section 16(a) of the Exchange Act, and Security Ownership of Principal Shareholders, Directors, and Management in our definitive proxy statement for our Fiscal 2011 Annual Meeting of Shareholders.

Item 11. Executive Compensation.

The information required by Item 11 is incorporated herein by reference to the sections labeled Executive Compensation, Director Compensation, and Corporate Governance Personnel and Compensation Committee in our definitive proxy statement for our Fiscal 2011 Annual Meeting of Shareholders.

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

The beneficial ownership information required by Item 12 is incorporated herein by reference to the section labeled Security Ownership of Principal Shareholders, Directors, and Management in our definitive proxy statement for our Fiscal 2011 Annual Meeting of Shareholders.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information concerning our equity compensation plans as of June 30, 2010:

Plan Category	Number of securities to be issued upon exercise of outstanding warrants (a)	Weighted-average exercise price of outstanding warrants (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans not approved by security holders	411,800	$3.45 per share	N/A[1]
Total	411,800	$3.45 per share	N/A[1]

(1) Our Board has not presently authorized a pool of securities that would be available for future issuance pursuant to equity compensation arrangements. Other than as prohibited by any contractual restrictions to which we are subject, the Board could authorize future equity grants on a case-by-case basis as compensation to new employees, in an aggregate amount up to our then-remaining number of authorized shares. We currently have 10,000,000 authorized shares of common stock. We would be required by Nasdaq rules to obtain shareholder approval for most other forms of equity compensation arrangements.

Currently, we have no formal equity compensation plans in place. We have issued warrants for services in lieu of cash payments from time to time. The warrants issued pursuant to these arrangements may be exercised upon payment of the exercise price in cash and expire at various dates through November 2018. The warrants contain standard antidilution provisions. Please see Note 7 to the Consolidated Financial Statements, included in Part II, Item 8 of this Report.

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

The information required by Item 13 is incorporated herein by reference to the sections labeled Corporate Governance Independence and Certain Transactions and Business Relationships in our definitive proxy statement for our Fiscal 2011 Annual Meeting of Shareholders.

Item 14. Principal Accounting Fees and Services.

The information required by Item 14 is incorporated herein by reference to the sections labeled Ratification of the Appointment of McGladrey & Pullen, LLP as the Company s Independent Registered Public Accountant Firm Audit Fees in our definitive proxy statement for our Fiscal 2011 Annual Meeting of Shareholders.

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report.

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(1) Financial Statements. The following financial statements are included in Part II, Item 8 of this Report:

Report of McGladrey & Pullen, LLP on Consolidated Financial Statements and Financial Statement Schedule as of June 30, 2010 and June 30, 2009

Consolidated Balance Sheets as of June 30, 2010 and June 30, 2009

Consolidated Statements of Income for each of the two years in the period ended June 30, 2010

Consolidated Statements of Stockholders Equity for each of the two years in the period ended June 30, 2010

Consolidated Statements of Cash Flows for each of the two years in the period ended June 30, 2010

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules. The following consolidated financial statement schedule is included in Item 8: Not applicable.

(3) Exhibits. See Exhibit Index to Form 10-K immediately following the signature page of this Form 10-K

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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.

ELECTROMED, INC.

Date: September 28, 2010

/s/ Robert D. Hansen
Robert D. Hansen
Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Each person whose signature appears below constitutes and appoints Robert D. Hansen as the undersigned s true and lawful attorney-in fact and agent, with full power of substitution and resubstitution, for the undersigned and in the undersigned s name, place and stead, in any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granted unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Signature	*Title*	*Date*
/s/ Robert D. Hansen Robert D. Hansen	Co-Founder, Chairman and Chief Executive Officer (principal executive officer)	September 28, 2010
/s/ Terry M. Belford Terry M. Belford, CPA, CMA	Chief Financial Officer (principal financial officer and principal accounting officer)	September 28, 2010
/s/ Craig N. Hansen Craig N. Hansen	Co-Founder and Director	September 28, 2010
/s/ Dr. Noel D. Collis, MD Dr. Noel D. Collis, MD	Director	September 28, 2010
/s/ Thomas M. Hagedorn Thomas M. Hagedorn	Director	September 28, 2010
/s/ Dr. George H. Winn, DDS Dr. George H. Winn, DDS	Director	September 28, 2010

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EXHIBIT INDEX
ELECTROMED, INC.
FORM 10-K

Exhibit Number	Description
3.1	Articles of Incorporation of Electromed, Inc., as amended.[(a)]
3.2	Bylaws of Electromed, Inc.[(a)]
10.1	Credit Agreement, dated December 9, 2009, between Electromed, Inc. and U.S. Bank, N.A.[(a)]
10.2	$3,500,000 Revolving Note, dated December 9, 2009, payable to U.S. Bank, N.A.[(a)]
10.3	$1,520,000 Term Loan A, dated December 9, 2009, payable to U.S. Bank N.A.[(a)]
10.4	$1,000,000 Term Loan B, dated December 9, 2009, payable to U.S. Bank N.A.[(a)]
10.5	Security Agreement, dated December 9, 2009, between Electromed, Inc. and U.S. Bank N.A.[(a)]
10.6	Security Agreement, dated December 9, 2009, between Electromed Financial, LLC and U.S. Bank N.A.[(a)]
10.7	Pledge Agreement, dated December 9, 2009, between Electromed, Inc. and U.S. Bank N.A.[(a)]
10.8	Mortgage, Security Agreement, Assignment of Leases and Rents and Fixture Financing Statement, dated December 9, 2009, between Electromed, Inc. and U.S. Bank N.A.[(a)]
10.9	Guaranty, dated December 9, 2009, between Electromed Financial, LLC and U.S. Bank, N.A.[(a)]
10.10	Environmental and ADA Indemnification Agreement dated December 9, 2009, between Electromed, Inc. and U.S. Bank N.A.[(a)]

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10.11 Form of Assignment of Patent Application.[(b)]

10.12 Employment Agreement, dated January 1, 2010, between Electromed, Inc. and Robert D. Hansen.[(a)]**

10.13 Employment Agreement, dated January 1, 2010, between Electromed, Inc. and Terry Belford.[(a)]**

10.14 Non-Competition, Non-Solicitation, and Confidentiality Agreement dated January 1, 2010 between Electromed, Inc. and Robert D. Hansen.**[(a)]

10.15 Non-Competition, Non-Solicitation, and Confidentiality Agreement dated January 1, 2010, between Electromed, Inc. and Terry Belford.**[(a)]

10.16 Purchase Agreement, dated March 2, 2010, between Electromed, Inc. and Robert D. Hansen.[(a)]

10.17 Letter Agreement dated February 16, 2010, between Electromed, Inc. and Hansen Engine Technologies, Inc.[(c)]

10.18 Form of warrant issued to investors, incorporated herein by reference to the exhibit 4.2 in Amendment 2, filed with the Commission on July 7, 2010, to Registration Statement on Form S-1, Reg. No. 333-166470, filed with the Commission on May 3, 2010.

10.19 Form of warrant issued to employees and service providers, incorporated herein by reference to the exhibit 4.3 in Amendment 2, filed with the Commission on July 7, 2010, to Registration Statement on Form S-1, Reg. No. 333-166470, filed with the Commission on May 3, 2010.

10.20 Form of warrant issued in connection with 7% Senior Secured Convertible Notes, incorporated herein by reference to the exhibit 4.4 in Amendment 2, filed with the Commission on July 7, 2010, to Registration Statement on Form S-1, Reg. No. 333-166470, filed with the Commission on May 3, 2010.

10.21 Form of Underwriter s Warrant, incorporated herein by reference to the exhibit 4.5 in Amendment 2, filed with the Commission on July 7, 2010, to Registration Statement on Form S-1, Reg. No. 333-166470, filed with the Commission on May 3, 2010.

10.22 Letter Agreement, dated September 23, 2010, between Electromed, Inc. and U.S. Bank N.A.*

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21.1 Subsidiaries of Electromed, Inc.*

31.1 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*

31.2 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*

32.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*

32.2 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*

* Filed herewith

** Management compensatory contract or arrangement.

(a) Incorporated herein by reference to the cited exhibit in Registration Statement on Form S-1, Reg. No. 333-166470, filed with the Commission on May 3, 2010.

(b) Incorporated herein by reference to the cited exhibit in Amendment 1, filed with the Commission on June 17, 2010, to Registration Statement on Form S-1, Reg. No. 333-166470, filed with the Commission on May 3, 2010.

(c) Incorporated herein by reference to the cited exhibit in Amendment 2, filed with the Commission on July 7, 2010, to Registration Statement on Form S-1, Reg. No. 333-166470, filed with the Commission on May 3, 2010.