Electromed, Inc.
Form 10-K
September 25, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Fiscal Year Ended **June 30, 2018**

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Transition Period From _____ to _____.

Commission File number **001-34839**

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 56071

(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	**NYSE American**
(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 No

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

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

Indicate by check mark whether the registrant has submitted electronically 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 No

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.

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if smaller reporting company)	Smaller reporting company
	Emerging growth company

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of December 31, 2017 was approximately $41,152,000 based upon the closing price of the registrant’s common stock, as reported on the NYSE American, on such date.

There were 8,329,826 shares of the registrant’s common stock outstanding as of September 21, 2018.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant’s Fiscal 2019 Annual Meeting of Shareholders, to be filed within 120 days of June 30, 2018, are incorporated by reference into Part III of this Form 10-K.

Electromed, Inc.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this Annual Report on Form 10-K that are not statements of historical fact should be considered forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include, but are not limited to, statements regarding: our business strategy, including our intended level of investment in research and development and marketing activities; our expectations with respect to earnings, gross margins and sales growth, industry relationships, marketing strategies and international sales; estimated sizes of markets into which our products are or may be sold; our business strengths and competitive advantages; ability to grow additional sales or distribution channels; our intent to retain any earnings for use in operations rather than paying dividends; our expectation that our products will continue to qualify for reimbursement and payment under government and private insurance programs; our intellectual property plans and practices; the expected impact of applicable regulations on our business; our beliefs about our manufacturing processes; our expectations and beliefs with respect to our employees and our relationships with them; our belief that our current facilities are adequate to support our growth plans; our expectations with respect to ongoing compliance with the terms of our credit facility; our expectations regarding the ongoing availability of credit and our ability to renew our line of credit; the enhancements to our products and services; expected excise tax exemption for the SmartVest System; and our anticipated revenues, expenses, capital requirements and liquidity. Words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "goal," "intend," "may," "ongoing," "plan," "potential," "pr "target," "will," "would," and similar expressions, including the negative of these terms, are intended to identify forward-looking statements but are not the exclusive means of identifying such statements. Although we believe these forward-looking statements are reasonable, they involve risks and uncertainties that may cause actual results to differ materially from those projected by such statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements.

Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

the competitive nature of our market;

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

changes to health care laws;

changes affecting the medical device industry;

our ability to develop new sales channels for our product;

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

new drug or pharmaceutical discoveries;

general economic and business conditions;

our ability to renew our line of credit or obtain additional credit as necessary;

our ability to protect and expand our intellectual property portfolio; and

the risks associated with expansion into international markets.

This list of factors is not exhaustive, however, and these or other factors, many of which are outside of our control, could have a material adverse effect on us and our results of operations. Therefore, you should consider these risk factors with caution and form your own critical and independent conclusions about the likely effect of these risk factors on our future performance. Forward-looking statements speak only as of the date on which the statements are made, and we undertake no obligation to update any forward-looking statement for any reason, even if new information becomes available or other events occur in the future. You should carefully review the disclosures and the risk factors described in this and other documents we file from time to time with the Securities and Exchange Commission (the “SEC”), including our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements set forth herein.

PART I

Item 1. Business.

Overview

Electromed, Inc. ("we," "our," "us," "Electromed" or the "Company") develops, manufactures, markets and sells innovative products that provide airway clearance therapy, including the SmartVest® Airway Clearance System ("SmartVest System") and related products, to patients with compromised pulmonary function with a commitment to excellence and compassionate service. Our goal is to make High Frequency Chest Wall Oscillation ("HFCWO") treatments as effective, convenient, and comfortable as possible, so our patients, in their homes, will adhere to their prescribed treatment schedule, leading to improved airway clearance, enhanced respiratory function and reduced healthcare utilization. We employ a direct-to-patient and provider model, through which we obtain patient referrals from clinicians, manage insurance claims on behalf of our patients and their clinicians, deliver our solutions to patients and train them on proper use in their homes. This model allows us to directly approach patients and clinicians, whereby we disintermediate the traditional durable medical equipment ("DME") channel and capture both the manufacturer and distributor margins. Electromed was incorporated in Minnesota in 1992. Our common stock is listed on the NYSE American under the ticker symbol "ELMD."

The SmartVest System features a programmable air pulse generator, a therapy garment worn over the upper body and a connecting hose, which together provide safe, comfortable, and effective airway clearance therapy. The SmartVest System generates HFCWO, an airway clearance therapy. The garment repeatedly compresses and releases the upper body at frequencies from 5 to 20 cycles per second creating a "mini cough." Each compression (or oscillation) produces pulsations that thin and loosen secretions from the surfaces of the lung airways, propelling them toward the mouth where they can be removed by normal coughing or suction.

HFCWO facilitates airway clearance by loosening and mobilizing respiratory secretions in a patient's lungs. One factor of respiratory health is the ability to clear secretions from airways. Impaired airway clearance, when mucus cannot be expectorated, may result in labored breathing and/or inflammatory and immune systems boosting mucus production that invites bacteria trapped in stagnant secretions to cause infections. Studies show that HFCWO therapy is as effective an airway clearance method for patients who have compromised pulmonary function as traditional chest physical therapy ("CPT") 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 that HFCWO 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 and often result in costly hospital visits and repeated antibiotic use.

The SmartVest System is designed for patient comfort and ease of use which promotes compliance with prescribed treatment schedules, leading to improved airway clearance, enhanced respiratory function and a reduction in healthcare utilization. We offer a broad range of garments, referred to as vests and wraps, in sizes for children and adults that allow for tailored fit and function. User-friendly controls allow children and the elderly to administer their own daily therapy with minimal or no assistance. Our direct product support services provide patient and clinician education, training, and follow-up to ensure the product is integrated into each patient's daily treatment regimen. Additionally, our reimbursement and billing departments assure we are working on behalf of the patient by processing their physician paperwork, providing clinical support as needed and billing Medicare or the applicable insurance provider on their behalf. We believe that the advantages of the SmartVest System and the Company's customer services to the patient include:

improved quality of life;

reduction in healthcare utilization;

independence from a dedicated caregiver;

consistent treatments at home;

improved comfort during therapy;

portability; and

eligibility for reimbursement by private insurance, federal or state government programs or combinations of the foregoing.

Our Products

Since 2000, we have marketed the SmartVest System and its predecessor products to patients suffering from cystic fibrosis, bronchiectasis and repeated episodes of pneumonia. Additionally, we offer our products to a patient population that includes neuromuscular disorders such as cerebral palsy, muscular dystrophies, amyotrophic lateral sclerosis ("ALS"), the combination of emphysema and chronic bronchitis commonly known as chronic obstructive pulmonary disease ("COPD"), and patients with post-surgical complications or who are ventilator dependent or have other conditions involving excess secretion and impaired mucus transport.

Our products are primarily sold into the home health care market for patients with chronic lung issues, including bronchiectasis, cystic fibrosis and neuromuscular disease. We also sell our products in acute care settings (e.g., hospitals and clinics) when the patient is in a post-surgical or intensive care unit or was admitted for a lung infection brought on by compromised airway clearance. Accordingly, our sales points of contact include adult pulmonology clinics, cystic fibrosis centers, neuromuscular clinics, pulmonary rehabilitation centers, hospitals and home health care centers.

We have received clearance from the U.S. Food and Drug Administration ("FDA") to market the SmartVest System to promote airway clearance and improve bronchial drainage. In addition, Electromed is certified to apply the Conformité Européenne ("European Conformity" or "CE") marking for HFCWO device sales in all European Union countries and approved for HFCWO device sales in other, select international countries. The SmartVest System is available only with a physician's prescription.

As part of our growth strategies, we periodically evaluate opportunities involving products and services, especially those that may provide value to the respiratory homecare and institutional market.

The SmartVest System

The SmartVest System consists of an inflatable therapy garment, a programmable air pulse generator and a patented single-hose that delivers air pulses from the generator to the garment. The SmartVest System is currently available in two models – SV2100 and SQ®– both of which are sold into home care and institutional markets for use by patients and hospitals. Both models deliver the same clinically effective HFCWO therapy. Additionally, both systems are

designed for maximum comfort and lifestyle convenience, so patients can readily fit HFCWO therapy into their daily routines:

Patented single-hose design: When the SmartVest System is in use, a single-hose delivers oscillations to the SmartVest garment, which we believe provides therapy in a more comfortable and unobtrusive manner than a two-hose system. Oscillations are delivered evenly from the base of the SmartVest garment, extending the forces upward and inward in strong but smooth cycles surrounding the chest.

Open system design with active inflate – active deflate: The active inflate – active deflate mechanism of the SmartVest System provides patients a more comfortable treatment experience by working in unison with patients to allow them to take deep breaths and breathe more easily without feeling restricted.

Soft-fabric garment is lightweight and comfortable: The SmartVest garment is lightweight and designed to resemble an article of clothing. Quick fit Velcro®-like closures allow for a secure, comfortable fit without bulky straps and buckles. The simple design creates a broad size adjustment range to ensure a properly tailored fit. The SmartVest garment is available in a variety of colors and sizes to accommodate pediatric and adult patients.

Programmable generator with user-friendly device operation: The SmartVest System generator uses an internal programmable memory feature to manage air pulse frequency, air pulse pressure and treatment time to be set as prescribed by the patient's physician. The air pulse frequency can be adjusted from 5 to 20 cycles per second and the air pulse pressure can be adjusted from 10 to 100% of a maximal pressure range.

Patented Soft Start® and 360° garment oscillation coverage: Soft Start creates an upward flow of air that gently fills the garment while initiating the squeeze/release pulse, acclimating the patient to therapy and minimizing "vest creep." All SmartVest garments provide 360° oscillation coverage, which delivers simultaneous treatment to all lobes of the lungs.

The SmartVest SQL System

We designed the SmartVest SQL, our latest generation, with an array of features that make it easier to use and enable greater patient freedom as compared to the SmartVest SV2100. In addition to incorporating the unique benefits of the SV2100, the SmartVest SQL was designed to be significantly smaller, quieter, and lighter than its predecessor, and offers advanced generator programmability, including an enhanced pause feature with save, lock and restore functionality:

Smaller, quieter and lighter: The SmartVest SQL System is 25% smaller, 5db quieter and 30% lighter than the SmartVest SV2100. The SmartVest SQL is the lightest and overall quietest HFCWO generator on the market, weighing less than 16 pounds, making it easier for patients to use and integrate HFCWO therapy into their daily lives.

Programmable ramp: The SmartVest SQL integrates fully programmable and adjustable ramp, which allows HFCWO therapy to start at a low frequency and pressure, ramp up, and then reduce the frequency and pressure during treatment. This allows clinicians greater flexibility to program patient-specific HFCWO therapy protocols.

Enhanced programmability: The SmartVest SQL features new programmability options for saving, locking and restoring protocols, providing an extra layer of security. Further, an enhanced pause feature allows the physician to program dedicated time(s) for the patient to clear secretions.

SmartVest Connect

In June 2017, we launched the SmartVest SQL with SmartVest Connect™ wireless technology, a personalized HFCWO therapy management portal for patients with compromised pulmonary function. The SmartVest SQL with wireless technology features built-in cellular connectivity, offering healthcare teams and patients access to treatment information to better collaborate in making patient-centered care decisions. SmartVest Connect is available to pediatric and cystic fibrosis patients using a wirelessly enabled SmartVest SQL system. We expanded SmartVest Connect availability to targeted adult pulmonary clinics throughout fiscal 2018.

Performance insights: SmartVest Connect enables patients to track progress of their therapy plan and includes a real-time SmartVest Score and easy-to-read goal reports that provide an in-depth look at performance.

Treatment collaboration: Created to encourage patient engagement, SmartVest Connect provides feedback for patients to take an active role in their HFCWO therapy, fostering improved therapy adherence.

Engineered for simplicity: SmartVest SQL with SmartVest Connect is simple, intuitive, and designed to automatically update following completion of a therapy session.

Other Products

We market the Single Patient Use ("SPU") SmartVest® and SmartVest Wrap® to health care providers, particularly those working in intensive care units. Hospitals issue the SPU SmartVest or SmartVest Wrap to an individual patient for the duration of the patient's stay. Both SPU products facilitate continuity of care because they introduce the patient to our product line and may encourage use of the SmartVest System for home care, which can be provided to patients with a chronic condition upon discharge. Both SPU products also provide full coverage pulsation.

The Aerobika® Oscillating Positive Expiratory Pressure ("OPEP") device is sold in to the U.S. home care market through a distributor agreement with Monaghan Medical Corp. since early calendar year 2017. The Aerobika OPEP device is a drug-free, easy to use, hand-held device with a proprietary pressure-oscillation dynamic that provides intermittent resistance and creates positive pressure and oscillations simultaneously. The device opens weak or collapsed airways to mobilize and assist mucociliary clearance to the upper airways where it can be coughed out. After over a year of offering Aerobika® OPEP, we have determined that continuing to offer the product direct to patients is unlikely to serve a broader patient population as originally planned. We plan to discontinue distribution of the Aerobika OPEP device prior to December 1, 2018.

Our Market

We estimate the total served U.S. market for HFCWO in 2017 was approximately $150 million to $170 million. We believe our business model is supported by many market trends related to an aging population and growing awareness by physicians of diseases and conditions for which patients can benefit from using HFCWO therapy. Indications for when HFCWO should be prescribed are not specific to any one disease. A physician may elect to prescribe HFCWO when he or she believes the patient will benefit from improved airway clearance and external chest manipulation is the treatment of choice to enhance mucus transport and improve bronchial drainage.

The SmartVest System is prescribed for patients with bronchiectasis, ALS, cerebral palsy, cystic fibrosis, muscular dystrophy, quadriplegia and the combination of emphysema and chronic bronchitis commonly known as chronic obstructive pulmonary disease ("COPD"). The estimated patient populations in 2017 for diseases and conditions routinely prescribed HFCWO therapy are listed below.

Bronchiectasis: We believe that bronchiectasis, an irreversible lung condition where the airways become damaged and abnormally widened from recurring inflammation or infection, represents the fastest growing diagnostic category and greatest potential for HFCWO growth in the United States. Bronchiectasis is currently under recognized and underdiagnosed. Several recent studies have estimated prevalence of bronchiectasis, which we believe are helpful for estimating a range of the market size.

Seitz (2012) estimated that 190,000 unique cases of bronchiectasis were diagnosed in Medicare patients in 2007 and bronchiectasis prevalence increased 8.7% annually between 2000 and 2007[1]. Based on historic growth in prevalence and assuming a constant growth rate, the estimated number of bronchiectasis diagnoses in 2017 exceeded 440,000.

Martinez-Garcia (2013) indicated that prevalence of bronchiectasis is high in patients with moderate-to-severe COPD and has been associated with exacerbations and bacterial colonization. Ninety-nine patients in Global Initiative for Chronic Obstructive Lung Disease (GOLD) II, 85 in GOLD III, and 17 in GOLD IV stages were included in the study. Bronchiectasis was present in 115 patients (57.2%). Bronchiectasis was associated with an independent increased risk of all-cause mortality in patients with moderate-to-severe COPD.[2]

Chalmers (2017) found that prevalence of bronchiectasis in patients with COPD ranged from a low of 4% to as high as 69% with mean prevalence of 54% in a recent systematic literature review. In many studies in patients with COPD, the presence of bronchiectasis was associated with reduced lung function, greater sputum production, more frequent exacerbations and increased mortality versus those with COPD alone.[3]

Weycker (2017) projected approximately 4.2 million adults in the United States over 40 years may have bronchiectasis, suggesting there is a large pool of patients with undiagnosed disease.[4]

These clinical studies indicate a wide range of potential prevalence of bronchiectasis patients from a low of 440,000 to as high as 4.2 million patients in the United States. We also believe that it is difficult to estimate from these clinical studies which patients will need or benefit from HFCWO. A clinical study published in 2017 using data from the US bronchiectasis research registry indicated approximately 15% of the registered patients were prescribed HFCWO as part of their treatment plan.[5] Using that study data, we estimate that, within the diagnosed Medicare population of 440,000, approximately 15% or 66,000 have been prescribed HFCWO. We believe that bronchiectasis is underdiagnosed in the U.S. based on clinical study evidence. We also believe that HFCWO is under prescribed for bronchiectasis patients. By applying approximately 15% HFCWO penetration of diagnosed Medicare patients to the Weycker clinical study to the estimated 4.2 million prevalence of bronchiectasis in the U.S., we derived that the HFCWO opportunity may be 630,000 forecasted units. (See Figure 1)

Bronchiectasis is experiencing a surge in clinical interest and awareness, including the relationship to COPD, commonly referred to as bronchiectasis COPD overlap syndrome ("BCOS"). A recent paper that evaluated the U.S. Bronchiectasis Research Registry ("BRR") found that out of 1,826 patients with bronchiectasis enrolled between 2008 and 2014, 20% (n=350) also had COPD and 29% (n=515) also had asthma.[5] Other studies have found that the overlap between bronchiectasis and COPD is currently observed in 27% to 57% of patients with COPD. [6–8]

Estimated HFCWO Market Opportunity - Bronchiectasis Patients (U.S.) – Figure 1

[1]Seitz, A.E., et al. Trends in Bronchiectasis Among Medicare Beneficiaries in the United States, 2000 to 2007. *Chest.* 2012;142(2), 432–439.

[2]Martínez-García, M.A., et al. Prognostic Value of Bronchiectasis in Patients with Moderate-to-Severe Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med.* 2013;187(8):823–31.

[3]Chalmers J.D. and Sethi S. Raising awareness of bronchiectasis in primary care: overview of diagnosis and management strategies in adults. *NPJ Prim Care Respir Med*. 2017;27:18.

[4]Weycker D, Hansen G, Seifer F. Prevalence and incidence of noncystic fibrosis bronchiectasis among US adults in 2013. *Chronic Respiratory Disease.* 2017; 14(4):377-384.

[5]Aksamit T.R., et al. Bronchiectasis Research Registry C. Adult Patients With Bronchiectasis: A First Look at the US Bronchiectasis Research Registry. *Chest*. 2017;151:982-92

[6]Patel I.S., et al. Bronchiectasis, exacerbation indices, and inflammation in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*. 2004;170:400-7.

[7]O'Brien C, et al. Physiological and radiological characterisation of patients diagnosed with chronic obstructive pulmonary disease in primary care. *Thorax*. 2000;55:635-42.

[8]Bafadhel M, et al. The role of CT scanning in multidimensional phenotyping of COPD. *Chest*. 2011;140:634-42.

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Neuromuscular and neuromotor disorders: A range of neuromuscular and neuromotor disorders — including ALS, cerebral palsy, Duchenne muscular dystrophy, and quadriplegia — can cause respiratory muscle weakness and compromised airway clearance. Effective airway clearance therapy is a critical aspect of respiratory care for people with neuromuscular or neuromotor disorders who lack respiratory muscle strength. Not all people with neuromuscular or neuromotor disorders will require airway clearance therapy. We estimate the total number of people in the U.S. with a neuromuscular or neuromotor disorder that may benefit from airway clearance therapy is approximately 250,000.

Cystic Fibrosis: In the U.S., approximately 30,000 people are living with cystic fibrosis, and an estimated 1,000 new cases of cystic fibrosis are diagnosed each year.

Marketing, Sales and Distribution

Our sales and marketing efforts are focused on building market awareness and acceptance of our products and services with physicians, clinicians, patients, and third-party payers. Because the sale of the SmartVest System requires a physician's prescription, we market to physicians and health care providers as well as directly to patients. The vast majority of our revenue comes from domestic home care sales through a physician referral model. We have established our own domestic sales force, which we believe is able to provide superior education, support and training to our customers. Our direct U.S. sales force works with physicians and clinicians, primarily pulmonologists, in defined territories to help them understand our products and services and the value they provide to their respective patients. As of June 30, 2018, we had 50 field sales employees, including five regional sales managers, 42 clinical area managers ("CAMs") and three clinical educators. We also have developed a network of approximately 300 respiratory therapists and health care professionals across the U.S. to assist with in-home SmartVest patient training on a non-exclusive independent contractor basis. These independent contractors are credentialed by the National Board for Respiratory Care as either Certified Respiratory Therapists or Registered Respiratory Therapists.

Of the $28.2 million of our revenue derived from the U.S. in fiscal 2018, approximately 94% represented home care and 6% represented institutional sales. Due to readmission penalties associated with the Patient Protection and Affordable Care Act, as reconciled by the Health Care and Education Reconciliation Act of 2010 (collectively the "PPACA"), for certain diseases and conditions including COPD and pneumonia, we believe opportunities for further growth exist for HFCWO therapy because the device used by a patient in an institution may influence the choice of device prescribed at discharge. We expect to achieve future sales, earnings, and overall market share growth with increasing home care referrals by educating and building awareness of diseases and conditions that may benefit from HFCWO, like bronchiectasis, with physicians and patients and the value of SmartVest Airway Clearance System's differentiated features and benefits.

We generate sales leads through multiple channels that include visits to pulmonology clinics and medical centers, participation in medical conferences, maintenance of industry contacts in order to increase the visibility and acceptance of our products by physicians and health care professionals, participation with patient organizations such

as the Cystic Fibrosis Foundation, as well as through patients by word of mouth and traffic to our website. We are currently evaluating opportunities to offer the SmartVest System through selected Home Medical Equipment ("HME") distributors. The addition of a HME distribution network would expand our access to physicians and institutions in certain areas of the United States and would be expected to support our other growth strategies. In addition, we place advertisements in leading medical magazines and journals.

Additionally, because the availability of reimbursement is an important consideration for health care professionals and patients, we must also demonstrate the effectiveness of our products to public and private insurance providers. The availability of reimbursement exists primarily due to an established Healthcare Common Procedure Coding System ("HCPCS") code for HFCWO. A HCPCS code is assigned to services and products by the Centers for Medicare and Medicaid Services ("CMS"). Because our product has an assigned HCPCS code, a claim can be billed for reimbursement using that code.

International Marketing

Approximately 1.7% and 2.8% of our net revenues were from sales outside the U.S. in our fiscal years ended June 30, 2018 and 2017 ("fiscal 2018" and "fiscal 2017"), respectively. We sell our products outside the U.S. primarily through independent distributors specializing in respiratory products. Through June 30, 2018, the majority of our distributors operated in exclusive territories. Our principal distributors are located in Europe, Southeast Asia, South and Central America and the Arab states of the Persian Gulf. Units are sold at a fixed contract price with payments made directly from the distributor, rather than being tied to reimbursement rates of a patient's insurance provider as is the case for domestic sales. Our sales strategy outside the U.S. is to focus our corporate resources on maintaining our current distributors with less emphasis on contracting with new distributors.

Third-Party Reimbursement

In the U.S., individuals who use the SmartVest System generally will 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. Approximately half of our home care revenue is from commercial payers and one quarter is from each of the Medicare and Medicaid programs. Reimbursement for HFCWO therapy and the SmartVest System varies among public and private insurance providers.

A key strategy to grow sales is achieving world class customer service and support for our patients and clinicians. We do this with an established and effective reimbursement department working on behalf of the patient by processing physician paperwork, seeking insurance authorization and processing claims. 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 generally 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 payment amount we receive for any single referral may vary based on a number of factors, including Medicare and third-party reimbursement processes and policies. The patient retains the risk of reimbursement to the Company in the event of non-payment by third-party payers.

Our SmartVest System is reimbursed under HCPCS code E0483. Currently, the Medicare total allowable amount of reimbursement for this billing code is approximately $12,000. The allowed amount for state Medicaid programs range from approximately $8,000 to $12,000, which is similar to commercial payers. Actual reimbursement from third-party payers can vary and can be significantly less than the full allowable amount. Deductions from the allowable amount include co-payments, deductibles and/or maximums on durable medical equipment, decrease the reimbursement received from the third-party payer. Collecting a full allowable amount depends on our ability to obtain reimbursement from the patient's secondary and/or supplemental insurance if the patient has additional coverage, or our ability to collect amounts from individual patients.

Most patients are able to qualify for reimbursement and payment from Medicare, Medicaid, private insurance or combinations of the foregoing. We expect that subsequent generations of HFCWO products also will 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 marketing 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.

Research and Development