

**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, 2022**

or

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Transition Period From _____ to _____.

Commission File number **001-34839**

Electromed, Inc.

(Exact Name of Registrant as Specified in its Charter)

Minnesota
(State or other jurisdiction of
incorporation or organization)

41-1732920
(IRS Employer
Identification No.)

500 Sixth Avenue NW, New Prague, MN 56071
(Address of principal executive offices, including zip code)

(952) 758-9299

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	ELMD	NYSE American

Securities registered pursuant to Section 12(g) of the 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☐

Smaller reporting company ☒

Emerging growth company ☐

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

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

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, 2021 was approximately \$91,856,000 based upon the closing price of the registrant's common stock, as reported on the NYSE American, on such date.

There were 8,475,438 shares of the registrant's common stock outstanding as of August 23, 2022.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for the registrant's Fiscal 2023 Annual Meeting of Shareholders, to be filed within 120 days of June 30, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.



Electromed, Inc.
Index to Annual Report on Form 10-K

<u>PART I</u>	1
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	13
Item 1B. <u>Unresolved Staff Comments</u>	13
Item 2. <u>Properties</u>	13
Item 3. <u>Legal Proceedings</u>	13
Item 4. <u>Mine Safety Disclosures</u>	13
 <u>PART II</u>	 13
Item 5. <u>Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	13
Item 6. <u>[Reserved]</u>	14
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 8. <u>Financial Statements and Supplementary Data</u>	F-1
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	23
Item 9A. <u>Controls and Procedures</u>	23
Item 9B. <u>Other Information</u>	23
Item 9C. <u>Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</u>	24
 <u>PART III</u>	 24
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	24
Item 11. <u>Executive Compensation</u>	25
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	25
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	25
Item 14. <u>Principal Accountant Fees and Services</u>	25
 <u>PART IV</u>	 25
Item 15. <u>Exhibits and Financial Statement Schedules</u>	25
Item 16. <u>Form 10-K Summary</u>	27

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, 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: the expected impact of the COVID-19 pandemic on our business; 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; our ability to grow additional sales 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; 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,” “intend,” “may,” “ongoing,” “plan,” “potential,” “project,” “goal,” “target,” “should,” “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 following:

- the duration, extent and severity of the COVID-19 pandemic, including its effects on our business, operations and employees as well as its impact on our customers and distribution channels and on economies and markets more generally;
 - ability to obtain reimbursement from Medicare, Medicaid, or private insurance payers for our products including potential adverse impact with an expiration of the Centers for Medicare and Medicaid Services waiver for certain respiratory diseases;
 - component or raw material shortages, changes to lead times or significant price increases
 - adverse changes to state and federal health care regulations;
 - our ability to develop new sales channels for our products such as the home care distributor channel;
 - our ability to maintain regulatory compliance and to gain future regulatory approvals and clearances;
 - entry of new competitors including new drug or pharmaceutical discoveries;
 - adverse economic and business conditions or intense competition;
 - wage and component price inflation;
 - technical problems with our research and products;
 - changes affecting the medical device industry;
 - adverse international health care regulation impacting current international business;
 - our ability to renew our line of credit or obtain additional credit as necessary;
 - our ability to protect and expand our intellectual property portfolio;
 - the risks associated with cyberattacks, data breaches, computer viruses and other similar security threats; and
-

- the risks associated with our planned sales force expansion.

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, and expressly disclaim any such obligation, to update any forward-looking statement for any reason other than as required by law, 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”). 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 can breathe easier and live better with improved respiratory function and fewer exacerbations.

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 deliver the SmartVest System to patients, training 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. We also sell our products in the acute care setting for patients in a post-surgical or intensive care unit, or who were admitted for a lung infection brought on by compromised airway clearance. 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. 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.¹ 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 airway clearance 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 adherence to prescribed treatment schedules, leading to improved airway clearance, patient outcomes and quality of life, 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. User-friendly controls allow patients to administer their daily therapy with minimal or no assistance. Our direct product support services provide patient and clinician education, training, and follow-up to ensure that the product is integrated into each patient’s daily treatment regimen. Additionally, our reimbursement department assures we are working on behalf of the patient by processing their physician paperwork, providing clinical support and billing the applicable insurance provider. 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; and
- eligibility for reimbursement by private insurance, federal or state government programs or combinations of the foregoing.

¹Nicolini A, et al. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. *BMC Pulmonary Medicine*. 2013;13(21).

Our Products

Since 2000, we have marketed the SmartVest System and its predecessor products to patients suffering from bronchiectasis, cystic fibrosis, and neuromuscular conditions such as cerebral palsy and amyotrophic lateral sclerosis (“ALS”). Our products are sold into the home health care market and the acute care setting for patients in a post-surgical or intensive care unit, or who were 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 and hospitals.

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 member countries and approved for HFCWO device sales in other, select international countries. The SmartVest System is available only with a physician’s prescription.

The SmartVest System is currently available in one model – SQL[®] – which is sold into home care and hospital markets. We will continue to support and service earlier SmartVest models pursuant to the applicable product warranty.

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. To that end, we made meaningful progress in the development of our next generation SmartVest System during our fiscal year ended June 30, 2022 (“fiscal 2022”) and estimate launching such device and completing the corresponding FDA 510(k) clearance process in the first half of our fiscal year ending June 30, 2023 (“fiscal 2023”).

The SmartVest SQL System

The SmartVest SQL 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 SQL is designed for maximum comfort and lifestyle convenience, so patients can readily fit therapy into their daily routines. The SmartVest SQL was designed to be significantly smaller, quieter, and lighter than its predecessor, and offers features that make it easier to use and enable greater patient freedom.

- **Patented single-hose design:** 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 allowing 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 to accommodate pediatric and adult patients.
- **Patented Soft Start[®] and 360° garment oscillation coverage:** Soft Start gently fills the garment to acclimate the patient to therapy. All SmartVest garments provide 360° oscillation coverage, which delivers simultaneous treatment to all lobes of the lungs.
- **Smaller, quieter and lighter:** The SmartVest SQL System is 25% smaller, 5db quieter and 30% lighter than the prior SmartVest SV2100 System, which we previously discontinued on July 1, 2021. 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 generator with user-friendly device operation:** The SmartVest SQL features multiple operating modes, including ramp, and options for saving, locking and restoring protocols. Further, an enhanced pause feature allows the physician to program dedicated times 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. In March 2020, we launched the SmartVest Connect app for both the iOS and Android operating systems. The SmartVest Connect app securely connects to the SmartVest SQL System through Bluetooth[™] technology. This interface allows patients and healthcare teams to track therapy in real-time and collaborate on care decisions to improve therapy adherence and patient outcomes. SmartVest Connect is available to pediatric and cystic fibrosis patients, and targeted adult pulmonary clinics using a Bluetooth-enabled SmartVest SQL System.

Other Products

We market the Single Patient Use (“SPU”) SmartVest and SmartVest Wrap[®] to health care providers in the acute care setting. Hospitals issue the SPU SmartVest or SmartVest Wrap to an individual patient for managing airway clearance. Both SPU products provide full coverage oscillation and facilitate continuity of care because they introduce the patient to our product and may encourage use of the SmartVest System for home care, which can be provided to patients with a chronic condition upon discharge.

Our Market

We estimate the total served U.S. market for HFCWO has returned to pre-pandemic levels and is estimated at approximately \$220 million to \$240 million, with growth in HFCWO adoption at approximately 5% based on independent third-party market research. We believe the market for HFCWO is continuing to expand due to an aging population, higher incidence of chronic lung disease, growing awareness by physicians of diseases and conditions for which patients can benefit from using HFCWO therapy, and treatments moving to lower cost home care settings. Indications for when HFCWO may be prescribed are not specific to any one disease. A physician may elect to prescribe HFCWO when such individual 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 primarily prescribed for patients with bronchiectasis, cystic fibrosis, and neuromuscular conditions such as cerebral palsy and ALS. We believe that bronchiectasis represents the fastest growing diagnostic category and greatest potential for HFCWO growth in the United States exhibiting an 8.7% increase in patients diagnosed between 2000 and 2007⁹. Bronchiectasis is an irreversible, chronic lung condition characterized by enlarged and permanently damaged bronchi. The condition is associated with recurrent lower respiratory infections, inflammation, reduction in pulmonary function, impaired respiratory secretion clearance, increased hospitalizations and medication use, and increased morbidity and mortality.

We are driven to make life's important moments possible, one breath at a time, by leading the HFCWO therapy market in clinical evidence that supports the therapeutic imperative of clearing excess mucus from the lungs. Electromed continues to add to the body of evidence in support of HFCWO with multiple published clinical outcome studies demonstrating a significant improvement in quality of life and reduction in exacerbation rates, hospitalizations, emergency department visits, and antibiotic prescriptions in bronchiectasis patients using the SmartVest System. This includes the most recent clinical study, a 2022 publication in the American Journal of Respiratory and Critical Care Medicine reviewing outcomes among non-cystic fibrosis bronchiectasis patients with HFCWO Therapy.²⁻⁶ Generating additional clinical evidence to further support the SmartVest System as a preferred treatment for bronchiectasis patients will remain a focus for us in fiscal 2023, with two clinical studies in progress. The first such clinical study is a prospective, multi-center bronchiectasis outcomes study utilizing SmartVest therapy, and the second is a post surveillance study with chronic obstructive pulmonary disease (“COPD”) and bronchiectasis patients prescribed SmartVest utilizing quality of life questionnaires to measure outcomes prior to therapy and at two intervals following initiation of the therapy.

We believe that bronchiectasis is under recognized and underdiagnosed but is experiencing a surge in clinical interest and awareness, including the relationship to COPD, commonly referred to as bronchiectasis COPD overlap syndrome. The overlap of bronchiectasis and COPD increases exacerbations and hospitalizations, reduces pulmonary function, and increases mortality. Several recent studies have estimated prevalence of bronchiectasis, which we believe are helpful for estimating a range of the overall market size.

- Weycker (2017) projected 4.2 million adults in the United States over the age of 40 may have bronchiectasis, suggesting there is a large pool of patients with undiagnosed disease.⁷
- Henkle (2018) confirmed a high prevalence of bronchiectasis in the United States, identifying over 600,000 unique patients with at least one bronchiectasis claim (ICD-9 claims 494.0 or 494.1). The study also observed that patients with dual diagnosis of bronchiectasis and COPD were in poorer health, with more office visits, more inpatient admissions and more acute respiratory infections.⁸
- 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 2007.⁹ Based on historic growth in prevalence and assuming a constant growth rate, the estimated number of bronchiectasis diagnoses in Medicare patients in 2021 exceeded 608,000.
- Aksamit (2017) found 20% (n=350) of patients with bronchiectasis enrolled in the U.S. Bronchiectasis Research Registry between 2008 and 2014 also had COPD and 29% (n=515) also had asthma.⁷ Other studies have found that the overlap between bronchiectasis and COPD is observed in 27% to 57% of patients with COPD.¹⁰⁻¹³⁻⁸
- 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 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.¹⁴

These studies indicate a wide range of potential prevalence of bronchiectasis patients in the United States. We also believe that it is difficult to estimate from these studies which patients will need or benefit from HFCWO. Internal company estimates derived from 2020 analysis of the IQVIA PharMetrics Plus database, one of the largest US health plan databases of adjudicated integrated medical and pharmacy claims, indicate a 15% to 20% penetration of HFCWO within the diagnosed Bronchiectasis population¹⁵. By conservatively assessing the market size in relation to the clinical studies cited above, we calculate that current HFCWO adoption may account for only 90,000 patients of the 500 to 600 thousand currently diagnosed and treatable patients (see Figure 1 below). We believe that bronchiectasis is underdiagnosed in the U.S. based on clinical study and epidemiology evidence with an even greater number of patients that could potentially benefit from diagnosis and treatment. We believe that HFCWO is under prescribed for bronchiectasis patients resulting in a large, underpenetrated US market opportunity and growth potential for HFCWO therapy.

²Sievert C, et al. Using High Frequency Chest Wall Oscillation in a Bronchiectasis Patient Population: An Outcomes-Based Case Review. *Respiratory Therapy Journal*. 2016;11(4): 34–38.

³Sievert C, et al. Cost-Effective Analysis of Using High Frequency Chest Wall Oscillation (HFCWO) in Patients with Non-Cystic Fibrosis Bronchiectasis. *Respiratory Therapy Journal*. 2017;12(1): 45–49.

⁴Sievert C, et al. Incidence of Bronchiectasis-Related Exacerbation Rates After High Frequency Chest Wall Oscillation (HFCWO) Treatment — A Longitudinal Outcome-Based Study. *Respiratory Therapy Journal*. 2018;13(2): 38–41.

⁵Powney J, et al. Employment of an algorithm of care including chest physiotherapy results in reduced hospitalizations and stability of lung function in bronchiectasis. *BMC Pulmonary Medicine*. 2019;19(82).

⁶DeKoven M, Mandia K, DeFabis N, Chen J, Ruscio A. Patient Characteristics, Healthcare Resource Utilization And Outcomes Among Non-Cystic Fibrosis Bronchiectasis Patients With High Frequency Chest Wall Oscillation (HFCWO) Therapy. *American Journal of Respiratory and Critical Care Medicine*. 2022. Vol 205:A3090

⁷Weycker 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.

⁸Henkle E, et al. Characteristics and Health-care Utilization History of Patients with Bronchiectasis in US Medicare Enrollees With Prescription Drug Plans, 2006 to 2014. *Chest*. 2018;154(6), 1311–1320.

⁹Seitz A, et al. Trends in Bronchiectasis Among Medicare Beneficiaries in the United States, 2000 to 2007. *Chest*. 2012;142(2), 432–439.

¹⁰Aksamit T, et al. Bronchiectasis Research Registry C. Adult Patients With Bronchiectasis: A First Look at the US Bronchiectasis Research Registry. *Chest*. 2017;151:982-92.

¹¹Patel I.S., et al. Bronchiectasis, exacerbation indices, and inflammation in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med*. 2004;170:400-7.

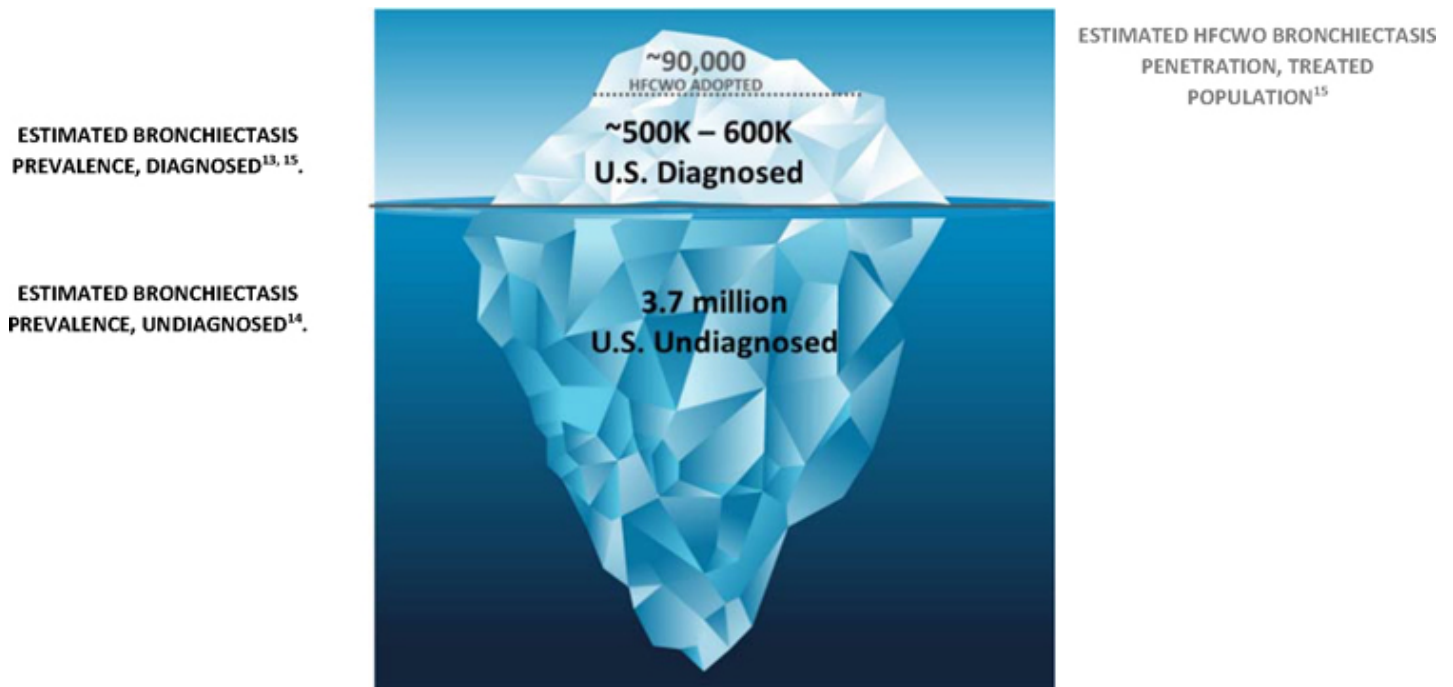
¹²O'Brien C, et al. Physiological and radiological characterization of patients diagnosed with chronic obstructive pulmonary disease in primary care. *Thorax*. 2000;55:635-42.

¹³Bafadhel M, et al. The role of CT scanning in multidimensional phenotyping of COPD. *Chest*. 2011;140:634-42.

¹⁴Chalmers J. 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.

¹⁵Internal company estimates derived from IQVIA 2018 PharMetrics Plus Database

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



The heightened awareness of bronchiectasis speaks to the growing body of clinical evidence supporting treatments to improve symptoms and manage disease progression.

- In 2019, an observational comparative retrospective cohort study published in *BMC Pulmonary Medicine* evaluated the efficacy of a treatment algorithm in 65 patients with radiographic and symptom confirmed bronchiectasis, centered on initiation of HFCWO therapy with the SmartVest System.⁵ Patients were treated per the algorithm if they reported greater than two exacerbations in the previous year and symptoms, including chronic cough, sputum production, or dyspnea. Results show that at one-year: exacerbations requiring hospitalization and antibiotic use were significantly reduced and mean forced expiratory volume remained stable post enrollment, suggesting early initiation of HFCWO therapy may slow the otherwise normal progression of the disease.
- In 2022, the American Journal of Respiratory and Crucial Care Medicine published the results of a third-party retrospective cohort analysis of 101 qualifying NCFBE patients who received HFCWO. Key findings revealed that patients who used HFCWO therapy experienced improved health outcomes, a reduction in healthcare resource utilization and reduction in medication usage.⁶

Marketing, Sales and Distribution

Our sales and marketing efforts are focused on driving adoption of our products and services with physicians, clinicians, patients, and third-party payers and building market awareness to the benefits of HFCWO for treatment of bronchiectasis. 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 majority of our revenue comes from domestic home care sales through a physician referral model. We have established our own domestic sales force and support network, 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, 2022, we had 52 field sales employees, including six regional sales managers, 43 clinical area managers (“CAMs”) and three clinical educators. We also have developed a network of approximately 250 respiratory therapists and health care professionals across the U.S. to assist with in-home SmartVest System 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 and provide national coverage to an internal team of Registered Respiratory Therapists dedicated to supporting SmartVest patients. Additionally, Electromed employs a team of reimbursement specialists dedicated to managing insurance and payer relations and supporting prescribers and patients in navigating financial considerations. The availability of reimbursement is an important consideration for health care professionals and patients. Because our product has an assigned Healthcare Common Procedure Coding System (“HCPCS”) code, a claim can be billed for reimbursement using that code. We must demonstrate the effectiveness of our products to public and private insurance providers. The availability of reimbursement exists primarily due to an established HCPCS code for HFCWO. A HCPCS code is assigned to services and products by the Centers for Medicare and Medicaid Services (“CMS”).

- Of the \$41.7 million of our revenue derived from the U.S. in fiscal 2022, approximately 91% represented home care and 4% represented hospital sales. We expect to achieve future sales, earnings, and overall market share growth through a continued focus on product innovation, differentiation and improved patient experiences and outcomes in the home care segment. We believe that our position in the market, direct sales team and a dedication to advancing education on HFCWO awareness positions us to drive market awareness and growth to the benefits of HFCWO in treatment of bronchiectasis. We believe that dedicated service to our providers and patients is a key component of achieving future sales. Providers seek companies that are easy to work with, are responsive and care for their patients as an extension of their practices.

We generate sales interest through multiple channels that include visits to pulmonology clinics and medical centers, participation in medical conferences, maintenance of industry contacts 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 a focus on increasing patients by word of mouth and traffic to our website and social media channels. We continue to evaluate opportunities to offer the SmartVest System through selected Home Medical Equipment (“HME”) distributors. We maintain agreements with three HME distributors, one national and two regional, to distribute and sell the SmartVest System in the United States home care market. We expect to continue our direct sales channel as our primary homecare revenue source.

International Marketing

Approximately 1.3% and 1.8% of our net revenues were from sales outside of the U.S. in our fiscal 2022 and our fiscal year ended June 30, 2021 (“fiscal 2021”), respectively. We sell our products outside of the U.S. primarily through independent distributors specializing in respiratory products. Through June 30, 2022, the majority of our distributors operated in exclusive territories. Our principal distributors are located in Europe, the Arab states of the Persian Gulf, Southeast Asia, South America and Central America. 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 of the U.S. is to maintain 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 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. Our home care revenue comes from reimbursement from commercial payers, Medicare, Medicaid, Veterans Affairs and direct patient payments. 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 and increasing the number of covered lives across a broad payer market. 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 one 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. The reimbursement department includes the payer relations function working directly with all payer types to increase the covered lives for the SmartVest System with national and regional private insurers and applicable state and federal government entities as well as to maintain all of the current licenses with state and federal government and payer contracts.

Our SmartVest System is reimbursed under HCPCS code E0483. Currently, the Medicare total allowable amount of reimbursement for this billing code is approximately \$13,000. The allowed amount for state Medicaid programs ranges from approximately \$8,000 to \$13,000, 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, such as 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 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.

In response to the COVID-19 pandemic and the U.S. federal government's declaration of a public health emergency in March 2020, CMS implemented a number of temporary rule changes and waivers to allow prescribers to best treat patients during the period of the public health emergency. These waivers are retroactively effective to March 1, 2020. Clinical indications and documentation typically required will not be enforced for respiratory related products including the SmartVest System (solely with respect to Medicare patients). The minimum documentation now requires a valid order and documentation of a respiratory-related diagnosis. Face-to-face and in-person requirements for respiratory devices are being waived while the waiver is in place. The CMS waiver was recently extended in conjunction with the extension of the federal public health emergency for an additional 90-day period beginning July 15, 2022.

Research and Development

Our research and development ("R&D") capabilities consist of full-time engineering staff and several consultants. We periodically engage consultants and contract engineering employees to supplement our development initiatives. Our team has a demonstrated record of developing new products that receive the appropriate product approvals and regulatory clearances around the world.

During fiscal 2022 and 2021, we incurred R&D expenses of approximately \$1,356,000 and \$1,722,000, or 3.3% and 4.8% of our net revenues, respectively. As a percentage of sales, we expect spending on R&D expenses to decrease significantly during fiscal 2023 as compared with fiscal 2022, as we conclude the design and testing of our next generation device in preparation for an anticipated product launch during the first half of fiscal 2023. Product enhancements were driven by voice of customer survey and in-person information focused on patient useability and device portability. We also estimate that the next generation product will be a lower cost of goods compared to the SmartVest SQL.

Intellectual Property

As of June 30, 2022, we held 13 United States and 43 foreign-issued patents covering the SmartVest System and its underlying technology and had 13 pending United States and foreign patent applications. These patents and patent applications offer coverage in the field of air pressure pulse delivery to a human in support of airway clearance.

We generally pursue patent protection for patentable subject matter in our proprietary devices in foreign countries that we have identified as key markets for our products. These markets include the European Union, Japan, and other countries.

We also have received 10 U.S. and 100 foreign trademark and service mark registrations.

Manufacturing

Our headquarters in New Prague, Minnesota includes a dedicated manufacturing and engineering facility of more than 14,000 square feet, and we are certified on an annual basis to be compliant with International Organization for Standardization (“ISO”) 13485 quality system standards. Our site has been audited regularly by the FDA and ISO, in accordance with their practices, and we maintain our operations in a manner consistent with their requirements for a medical device manufacturer. While components are outsourced to meet our detailed specifications, each SmartVest System is assembled, tested, and approved for final shipment at our manufacturing site in New Prague, consistent with FDA, Underwriters Laboratory, and ISO standards. Many of our strategic suppliers are located within 100 miles of our headquarters, which enables us to closely monitor our component supply chain. We maintain established inventory levels for critical components and finished goods to assure continuity of supply. During fiscal 2022 we experienced longer lead times for critical electronic components related to worldwide supply shortages due to COVID-19 and the related U.S. and global economic recovery. We did not experience any material disruptions to customer shipments in fiscal 2022.

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 each home care SmartVest System initially purchased and currently located in the U.S. and Canada, we provide a lifetime warranty to the individual patient for whom the SmartVest System is prescribed. For sales to institutions and HME distributors within the U.S., and for all international sales, except Canadian home care, we provide a three-year warranty.

Competition

The original HFCWO technology was licensed to American Biosystems, Inc. (now part of Hill-Rom Holdings, Inc.) (“Hillrom”), which, until the introduction of our original MedPulse Respiratory Vest System[®] in 2000, was the only manufacturer of a product with HFCWO technology cleared for market by the FDA (Hillrom’s The Vest[®] Airway Clearance System). Respiratory Technologies, Inc. (now RespirTech, part of Koninklijke Phillips N.V.) received FDA clearance to market their HFCWO product, the inCourage[®] Airway Clearance Therapy in 2005. Both Hillrom and RespirTech employ a direct-to-patient model, with RespirTech additionally offering its HFCWO device through selected DME distributors.

The AffloVest[®] from Tactile Systems Technology Inc. (“Tactile Medical”) also participates in the same market as our SmartVest System. Tactile Medical primarily sells its device through DME companies who distribute home care medical devices and supplies. Based on annual revenue, we estimate that Hillrom maintains the highest market share in HFCWO followed by RespirTech with Electromed in the third position.

Alternative products for administering pulmonary therapy include: Positive Expiratory Pressure, Intrapulmonary Percussive Ventilation, CPT and breathing techniques. 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.

Key drivers of HFCWO product sales continue to be clinical and cost-effective evidence, technology innovations including wireless connectivity, and HFCWO patient experience benefits such as size, weight of the generator, and product reputation. We believe we distinguish ourselves in these areas with competitive advantages over alternative treatments ultimately improving the patient comfort, ease of use, and the effectiveness of HFCWO treatment. Because HFCWO is not “technique dependent,” as compared to most other alternative pulmonary therapy products, therapy remains consistent and controlled for the duration of treatment.

Governmental Regulation

Medicare and Medicaid

Recent government and private sector initiatives in the U.S. and foreign countries aim at limiting 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. These initiatives are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical devices that result in better clinical outcomes. Government programs, including Medicare and Medicaid, have attempted to control costs by limiting the amount of reimbursement the program 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. Many private insurance programs look to Medicare as a guide in setting coverage policies and payment amounts. These initiatives have created an increasing level of price sensitivity among our customers.

Home Medical Equipment Licensing

Although we do not fall under competitive bidding for Medicare, we often must satisfy the same licensing requirements as other DME providers that qualify for competitive bidding. In response to out-of-state businesses winning the competitive bidding process, which had a significant impact on small local DME businesses, many states have enacted regulations that require a DME provider to have an in-state business presence, specifically through state HME licensing boards or through state Medicaid programs. In order to do business with any patients in the state or to be a provider for the state Medicaid program, a DME provider must have an in-state presence. In addition to Minnesota, the location of our corporate headquarters, we have a licensed in-state presence in three other states. We also maintain an in-state presence in California in order to meet their state Medicaid requirements. In-state presence requirements vary from state to state, but generally require a physical location that is staffed and open during regular business hours. We are licensed to do business in all states except for Alaska and Hawaii.

Product Regulations

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign regulatory 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, and compliance with these laws and regulations entails significant costs for us. Our regulatory and quality assurance departments provide detailed oversight in their areas of responsibility to support required clearances and approvals to market our products.

In addition to the clearances and approvals discussed below, we obtained ISO 13485 certification in January 2005 and receive annual certification of our compliance to the current ISO quality standards.

FDA Requirements

We have received clearance from the FDA to market our products, including the SmartVest System. We may be required to obtain additional FDA clearance before marketing a new or modified product in the U.S., either through the 510(k) clearance process or the more complex premarket approval process. The process may be time consuming and expensive, particularly if human clinical trials are required. Failure to obtain such clearances or approvals could adversely affect our ability to grow our business.

Continuing Product Regulation

In addition to its approval processes for new products, the FDA may require testing and post-market surveillance programs to monitor the safety and effectiveness of previously cleared products that have been commercialized and may prevent or limit further marketing of products based on the results of post-mark surveillance results. At any time after marketing clearance of a product, the FDA may conduct periodic inspections to determine compliance with both the FDA's Quality System Regulation ("QSR") requirements and current medical device reporting regulations. Product approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial market clearance. The failure to comply with regulatory standards or the discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances, seizures or recalls of products (with the attendant expenses), the banning of a particular device, an order to replace or refund the cost of any device previously manufactured or distributed, operating restrictions and criminal prosecution, as well as decreased sales as a result of negative publicity and product liability claims.

We must register annually with the FDA as a device manufacturer and, as a result, are subject to periodic FDA inspection for compliance with the FDA's QSR requirements that require us to adhere to certain extensive regulations. In addition, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. We also must maintain certain certifications to sell products internationally, and we undergo periodic inspections by notified bodies to obtain and maintain these certifications.

Advertising and marketing 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. Competitors and others also can initiate litigation relating to advertising and/or marketing claims. If the FDA were to determine our promotional or training materials constitute promotion of an unapproved or uncleared claim of use, it is possible we would need to modify our training or promotional materials or be subject to regulatory or enforcement actions that could result in civil fines or criminal penalties. Other federal, state or foreign enforcement authorities could also take similar action if they were to determine that our promotional or training materials constitute promotion of an unapproved use, which could result in significant fines or penalties.

European Union and Other Regions

European Union rules require that medical products receive the right to affix the CE mark, demonstrating adherence to quality standards and compliance with relevant European Union Medical Device Directives (“MDD”). Products that bear CE mark can be imported to, sold or distributed within the European Union. We obtained clearance to use the CE mark on our products in April 2005. Renewal of CE marking 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 marking in good standing since originally receiving it and most recently renewed it in January 2020. The renewal of our MDD certificate will allow us to continue to CE mark and sell our SmartVest SQL device, with no substantial changes, in the European Union until the certificate expires in May 2024. We are currently working on finalizing updates to the quality system to achieve full compliance with Regulation (EU) 2017/745 (EU MDR) which came into effect in May 2021. We also require all of our distributors in the European Union and other regions to comply with their home country regulations in our distributor agreements.

Federal Physician Payments Sunshine Act

The Federal Physician Payments Sunshine Act (Section 6002 of the PPACA) (the “Sunshine Act”) was adopted on February 1, 2013, to create transparency for the financial relationship between medical device companies and physicians and/or teaching hospitals (covered recipients). In January 2021, the Sunshine Act was expanded to cover payments made to these additional covered recipients, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives. The Sunshine Act requires all manufacturers of drugs and medical devices to annually report to CMS any payments or any other “transfers of value” made to any covered recipients, including but not limited to consulting fees, grants, clinical research support, royalties, honoraria, meals, and value of long-term use (over 90 days) of evaluation equipment. This information is then posted on a public website so that consumers can learn how much was paid to their physician by drug and medical device companies. The Sunshine Act requires ongoing data collection and annual management and reporting by us and imposes civil penalties for manufacturers that fail to report timely, accurately, or completely to CMS.

Fraud and Abuse Laws

Federal health care laws apply to the marketing of our products and when we or our customers submit claims for items or services that are reimbursed under Medicare, Medicaid or other federally funded health care programs. The principal applicable 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
- the Stark Law, which prohibits physicians from profiting (actually or potentially) from their own referrals.

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. Enforcement of all of these regulations has become increasingly stringent, particularly due to more prevalent use of the whistleblower provisions under the False Claims Act, which 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. 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 and disbarment from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

HIPAA, HITECH and Other Privacy Regulations

Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of such information. The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act (“HITECH”) set forth privacy and security standards that govern the use and disclosure of protected electronic health information by “covered entities,” which include healthcare providers, health plans and healthcare clearinghouses. 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. Failure to comply with HIPAA and HITECH or any state or foreign laws regarding personal data protection may result in significant fines or penalties and/or negative publicity. In addition to federal regulations issued under HIPAA and HITECH, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA and HITECH. 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.

The HIPAA and HITECH health care fraud and false statement statutes also prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private payers, and 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.

Environmental Laws

We are 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, sterilization, and disposal processes. We do not expect that compliance with environmental protection laws will have a material impact on our results of operations, financial position, or cash flows.

Cybersecurity and Data Privacy

Protecting the privacy of customer and personnel information is important to us, and we maintain security protocols and processes, including ongoing training and education for all personnel, designed to combat the risk of unauthorized access or inadvertent disclosure. Our business operations involve confidential information, including patient health information subject to regulation as discussed under “*HIPAA, HITECH and Other Privacy Regulations*” above. Our information technology infrastructure is designed to offer reliability, scalability, performance, security and privacy for our personnel, clients and third-party contractors.

We maintain comprehensive compliance and security programs designed to help safeguard and ensure the integrity of the confidential information we possess, which includes both organizational and technical control measures. We also have programs in place to monitor the safety of confidential information as well as plans for immediate, coordinated action in the event of a potential security incident. We routinely conduct employee trainings on important information security procedures and engage with independent third-party firms to test and measure compliance on these security measures. In addition, we have maintained appropriate cyber insurance policies that limit the financial risk of any potential incident. Our cyber insurance policies include dedicated support for remediating a specific cybersecurity or data privacy incident and limit the potential financial risk associated with an actual incident.

Even though we have implemented administrative, physical and technical safeguards designed to help protect the confidential data we possess and the integrity of our information systems and infrastructure, these safeguards may not be effective in preventing future cybersecurity incidents or data breaches.

Human Capital

We believe that our dedicated, talented employees are our most valuable resource and a key strength in accomplishing our collective mission and goals. As of June 30, 2022, we had 156 employees, an increase of 15.4% from fiscal 2021, who are located in 29 states throughout the United States. 18 of our employees were respiratory therapists licensed by appropriate state professional organizations. We also had approximately 250 respiratory therapists and health care professionals retained on a non-exclusive, independent contractor basis to provide training to our customers in the U.S. None of our employees are covered by a collective bargaining agreement. We believe our relations with our employees are good.

We are committed to attracting, retaining, and developing diverse and high-performing talent that includes a strong focus on performance and development, total rewards, diversity, inclusion and equity, and employee safety. These serve as the pillars to our human capital management framework.

We understand that our success and growth depend on attracting, retaining, and developing talent across all levels of the organization. Our recruitment strategies are continuously reviewed with leadership and partners to ensure our practices align with our mission, purpose, and values.

We believe in ensuring that employees understand our mission, purpose, and goals as well as their impact on our success. We use an annual performance review process to support development and performance discussions with employees. In addition, every employee is eligible to participate in our incentive plan, which allows for us to share the rewards of the company with the people who significantly contribute to our success.

To cultivate a learning culture that provides enhancement and growth for our people, we offer educational assistance, online training (220 courses completed during fiscal 2022), seminars, specific skill training, and participation in business and industry organizations. We are also committed to contributing our talents and resources to serve the communities in which we live and work through various charitable campaigns, employee programs and volunteerism. We believe that this commitment assists in our efforts to attract and retain employees.

We believe that sharing rewards is essential to increasing employee engagement and improving morale and creating a positive culture. We also offer our employees a competitive salary and benefits package and are committed to continuous review of these programs. These benefits include but are not limited to retirement savings, a variety of health insurance options and other benefits programs, including dental and vision, disability insurance, contributions to health savings accounts, paid maternity/paternity leave, and wellness resources. In addition, we offer opportunities for remote work and flexible schedules and location, depending on business needs and the specific role.

We are committed to ensuring a diverse workforce in a safe environment by maintaining compliance with applicable employment laws and governmental regulations. Treating employees with dignity and equality is of utmost importance in everything we do. We take pride in the fact that women represent 53% of our total managerial roles and comprise 57% of our executive leadership team. We pride ourselves on accepting, hearing, and celebrating multiple approaches and points of view and building on an inclusive and diverse culture.

Safety is a vital aspect to the success of our people and business. We are proud of our employees' collective commitment to secure and maintain safe work practices that have resulted in zero lost time injuries within our manufacturing operations. We also provide wellbeing services to support each employee's physical and mental health and will continue to emphasize the importance of the safety and health of our employees in all we do.

Available Information

Our Internet address is www.smartvest.com. We have made available on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports, as soon as reasonably practicable after we electronically file these materials with, or furnish them to, the SEC. Reports of beneficial ownership filed by our directors and executive officers pursuant to Section 16(a) of the Exchange Act are also available on our website. We are not including the information contained on our website as part of, or incorporating it by reference into, this Annual Report on Form 10-K. The SEC also maintains an Internet site that contains our reports, proxy and information statements, and other information we file or furnish with the SEC, available at www.sec.gov.

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 37,000 square feet, which are located on an approximately 2.3-acre parcel in New Prague, Minnesota. All of the Company's revenues, profits, and assets are associated with this facility. We believe that our facilities are satisfactory for our long-term growth plans.

Item 3. Legal Proceedings.

The disclosure regarding legal proceedings set forth in Note 11 to our Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K is incorporated herein by reference. Occasionally, we may be party to legal actions, proceedings, or claims in the ordinary course of business, including claims based on the assertions of patent and trademark infringement. Corresponding costs are accrued when it is probable 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.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market Information

Our common stock is listed on the NYSE American under the symbol "ELMD".

As of August 23, 2022, there were 59 registered holders of our common stock.

Dividends

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

Recent Sales of Unregistered Equity Securities

None.

Purchases of Equity Securities by the Company and Affiliated Purchasers

On May 26, 2021, our Board of Directors approved a stock repurchase authorization. Under the authorization, we were originally able to repurchase up to \$3.0 million of outstanding shares of our common stock through May 26, 2022. On May 26, 2022, our Board of Directors removed the date limitation. The shares of our common stock may be repurchased on the open market or in privately negotiated transactions subject to applicable securities laws and regulations. The following table sets forth information concerning purchases of shares of our common stock for the three months ended June 30, 2022:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plans or Programs
April 1 to April 30, 2022	1,253	\$ 12.53	1,253	\$ 898,000
May 1 to May 31, 2022	28,126	\$ 12.33	28,126	\$ 551,000
June 1 to June 30, 2022	10,799	\$ 11.48	10,799	\$ 427,000
Total	40,178	\$ 12.10	40,178	

Item 6. [Reserved].

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the accompanying notes included elsewhere in this Annual Report on Form 10-K. The forward-looking statements include statements that reflect management's good faith 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 Annual Report on Form 10-K.

Overview

Electromed develops and provides innovative airway clearance products applying HFCWO technologies in pulmonary care for patients of all ages.

We manufacture, market and sell products that provide HFCWO, including the SmartVest System that includes our newest generation SmartVest SQL® and previous generation SV2100 and related products, to patients with compromised pulmonary function. The SmartVest SQL is smaller, quieter and lighter than our previous product with enhanced programmability, ease of use. Our products are sold in both the home health care market and the institutional market for use by patients in hospitals, which we refer to as "institutional sales." The SmartVest SQL has been sold in the domestic home care market since 2014. In 2015, we launched the SmartVest SQL into institutional and certain international markets. In June 2017, we announced the launch of the SmartVest SQL with SmartVest Connect™ wireless technology, which allows data connection between physicians and patients to track therapy performance and collaborate in treatment decisions. SmartVest Connect is currently available to pediatric and cystic fibrosis patients and was made available to certain targeted adult pulmonary clinics starting in November 2017. 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, ALS, the combination of emphysema and chronic bronchitis commonly known as COPD, and patients with post-surgical complications or who are ventilator dependent or have other conditions involving excess secretion and impaired mucus transport.

The SmartVest System is often eligible for reimbursement from major private insurance providers, health maintenance organizations (“HMOs”), state Medicaid systems, and the federal Medicare system, which we believe is an important consideration for patients considering an HFCWO course of therapy. For domestic sales, the SmartVest System may be reimbursed under the Medicare-assigned billing code (E0483) for HFCWO 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 neuromuscular 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 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 channel and capture both the manufacturer and distributor margins. We have engaged a limited number of regional durable medical equipment distributors focused on respiratory therapies as an alternate sales channel. Revenue through this channel was 4% of our total revenues in fiscal 2022.

Our key growth strategies for fiscal 2023 are to: accelerate our revenue growth by taking market share and expanding the addressable population for the largest and fastest growing segments of the market: adult pulmonology/bronchiectasis. Actions to support accelerating our growth include the following:

- Expand our sales force in targeted geographies with high potential, adding an additional five territories and direct sales reps;
- Increase Electromed brand awareness through direct-to-consumer and physician marketing, and peer to peer education;
- Provide best-in-class customer care and support;
- Develop and promulgate the body of bronchiectasis clinical evidence to increase physician adoption of the SmartVest System for patients; and
- Introduce our innovative next generation device that appeals to patients.

Critical Accounting Estimates

During the preparation of our financial statements, we are required to make estimates, assumptions and judgment that affect reported amounts. Those estimates and assumptions affect our reported amounts of assets and liabilities, our disclosure of contingent assets and liabilities, and our reported revenues and expenses. We update these estimates, assumptions, and judgment as appropriate. Some of our accounting policies and estimates require us to exercise significant judgment in selecting the appropriate assumptions for calculating financial statements. Such judgments are subject to an inherent degree of uncertainty. Among other factors, these judgments are based upon our historical experience, known trends in our industry, terms of existing contracts and other information from outside sources, as appropriate. The following is a summary of our primary critical accounting policies and estimates. See also Note 1 to the Financial Statements, included in Part II, Item 8, of this Annual Report on Form 10-K.

Impacts of COVID-19 on Our Business and Operations

In March 2020, the World Health Organization designated COVID-19 as a global pandemic, and the U.S. Department of Health and Human Services designated COVID-19 as a public health emergency. The impact of the COVID-19 pandemic on our business remains uncertain, and its effects on our operational and financial performance will depend in part on future developments, which cannot be reasonably estimated at this time. Such future developments include, but are not limited to, the duration, scope and severity of the COVID-19 pandemic in geographic areas in which we operate or in which our patients live, actions taken to contain or mitigate its impact, the impact on governmental healthcare programs and budgets, the development and distribution of treatments or vaccines, and the resumption of widespread economic activity. Due to the inherent uncertainty of the unprecedented and evolving situation, we are unable to predict with confidence the likely impact of the COVID-19 pandemic on our future operations.

During fiscal 2022, we experienced a reduction in the number of clinics allowing face-to-face access by our sales team although not to the extent experienced in fiscal 2021 as the number of infections relating to the Omicron variant and related subvariants of COVID-19 increased throughout most regions of the United States, and hospitals implemented additional safety protocols. Our sales team continued to utilize a hybrid sales process of virtual and face-to-face clinician interaction with strict adherence to specific clinic and healthcare system safety protocols, which we believe allowed them to drive stronger referral growth compared to fiscal 2021. During the second half of fiscal 2022, we observed an improvement in clinic access and patient flow compared to earlier in the fiscal year, which we believe is likely a result of Omicron-related case reductions throughout most of the United States, contributing to a record high number of monthly referrals for our company.

We believe that the impact of the COVID-19 pandemic on our home care and institutional business will continue during at least the beginning of fiscal 2023. Our home care revenue for fiscal 2022 has increased as compared to fiscal 2021; however, if COVID-19 infection rates increase and federal, state and local restrictions on commerce, stay-at-home orders or other restrictions on businesses are reinstated, we believe that such measures could have a material adverse effect on our business.

We observed increased changes to our supply chain timelines and increased material and shipping costs during the second half of fiscal 2022, but we did not experience any disruptions that materially impacted product availability for our customers. We anticipate that increased material and shipping costs will continue during fiscal 2023 relating to supply chain availability and inflationary trends in electronic components but may extend to other components as well. In certain instances, we have purchased key electronic materials in advance to ensure adequate future supply and mitigate the risk of supply chain disruption. It is possible that the COVID-19 pandemic could have a greater adverse impact on our supply chain in the future, including impacts associated with preventative and precautionary measures taken by other businesses and applicable governments. A reduction or interruption in any of our manufacturing processes could have a material adverse effect on our business. Any significant increases to our raw material or shipping costs could reduce our gross margins.

We have also taken measures to ensure the safety of our employees and to comply with applicable governmental orders. We consider our business to be essential under applicable governmental orders, primarily due to our role in manufacturing and supplying needed medical devices to patients with respiratory-related issues and have therefore continued to operate during the government restrictions put in place in response to the pandemic.

In response to the COVID-19 pandemic and the U.S. federal government's declaration of a public health emergency, the CMS implemented a number of temporary rule changes and waivers to allow prescribers to best treat patients during the period of the public health emergency. These waivers became effective on March 1, 2020. Clinical indications and documentation typically required will not be enforced for respiratory-related products including the SmartVest System (solely with respect to Medicare patients). The minimum documentation now requires a valid order and documentation of a respiratory-related diagnosis. Face-to-face and in-person requirements for respiratory devices are being waived while the waiver is in place. The CMS waiver was recently extended in conjunction with the extension of the federal public health emergency for an additional 90-day period beginning July 15, 2022.

We did not receive any direct financial assistance from any government program during fiscal 2021 or fiscal 2022 in connection with COVID-19 relief measures.

Revenue Recognition

Revenue is measured based on consideration specified in the contract with a customer, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, including consideration paid or payable to customers and significant financing components. Revenue from all customers is recognized when a performance obligation is satisfied by transferring control of a distinct good or service to a customer.

Individual promised goods and services in a contract are considered a performance obligation and accounted for separately if the individual good or service is distinct (i.e., the customer can benefit from the good or service on its own or with other resources that are readily available to the customer and the good or service is separately identifiable from other promises in the arrangement). If an arrangement includes multiple performance obligations, the consideration is allocated between the performance obligations in proportion to their estimated standalone selling price, unless discounts or variable consideration is attributable to one or more but not all the performance obligations. Costs related to products delivered are recognized in the period incurred, unless criteria for capitalization of costs under Accounting Standards Codification ("ASC") 340-40, "Other Assets and Deferred Costs," or the requirements under other applicable accounting guidance are met.

The Company includes shipping and handling fees in net revenues. Shipping and handling costs associated with the shipment of the Company's SmartVest System after control has transferred to a customer are accounted for as a fulfillment cost and are included in cost of revenues.

We request that customers return previously sold units that are no longer in use to us 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 are certified to recondition and resell returned SmartVest System units. Returned units are typically reconditioned and resold and continue to be used for demonstration equipment and warranty replacement parts.

Inventory Valuation

Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Work in process and finished goods are carried at standard cost, which approximates actual cost, and includes materials, labor and allocated overhead. The reserve for obsolescence is determined by analyzing the inventory on hand and comparing it to expected future sales. Estimated inventory to be returned is based on how many devices that have shipped that are expected to be returned prior to completion of the insurance reimbursement process.

Warranty Reserve

The Company provides a lifetime warranty on its products to the prescribed patient for sales within the U.S. and a three-year warranty for all institutional sales and sales to individuals outside the U.S. 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 shipped. Factors that affect the Company's warranty reserve include the number of units shipped, historical and anticipated rates of warranty claims, the product's useful life and cost per claim. The Company periodically assesses the adequacy of its recorded warranty reserve and adjusts the amounts as necessary.

Share-Based Compensation

Share-based payment awards consist of options to purchase shares of our common stock issued to employees. Expense for share-based payment awards consist of options to purchase shares of our common stock issued to employees for services. Expense for options is estimated using the Black-Scholes pricing model at the date of grant and expense for restricted stock is determined by the closing price on the day the grant is made. Expense is recognized on a straight-line basis over the requisite service or vesting period of the award, or at the time services are provided for non-employee awards. In determining the fair value of options, we make various assumptions using the Black-Scholes pricing model, including expected risk-free interest rate, stock price volatility, and life. See Note 8 to the Financial Statements included in Part II, Item 8, of this Annual Report on Form 10-K for a description of these assumptions.

Results of Operations

Fiscal Year Ended June 30, 2022 Compared to Fiscal Year Ended June 30, 2021

Revenues

Revenue for the fiscal years ended June 30, 2022 and 2021 are summarized in the table below (dollar amounts in thousands).

	Fiscal Years Ended June 30,		Increase (Decrease)	
	2022	2021		
Home Care Revenue	\$ 38,004,000	\$ 32,986,000	\$ 5,018,000	15.2%
Institutional Revenue	1,660,000	1,549,000	111,000	7.2%
Home Care Distributor Revenue	1,474,000	563,000	911,000	161.8%
International Revenue	521,000	658,000	(137,000)	(20.8%)
Total Revenue	\$ 41,659,000	\$ 35,756,000	\$ 5,903,000	16.5%

Home Care Revenue. Home care revenue increased by \$5,018,000, or 15.2%, in fiscal 2022 compared to fiscal 2021. The revenue increase compared to fiscal 2021 was primarily due to increases in referrals and approvals. The increase in referrals was primarily due to an increase in direct sales representatives, increased sales representative productivity driven by increased clinic access and patient flow, our sales team refining their selling process and clinic targeting methodology, and benefits of the CMS waiver on the non-commercial Medicare portion of our home care revenue. Additionally, we also benefitted from a Medicare allowable rate increase that took effect on January 1, 2022. Annual Medicare rate increases for our device are linked closely to changes in the Urban Consumer Price Index.

The CMS waiver benefitted the non-commercial Medicare portion of our home care revenue by increasing the number of referrals and the approval percentage for previously non-covered diagnoses. We believe that our ongoing sales team execution, along with the expected return to pre-COVID-19 levels of patient face-to-face engagement with physicians and clinic access for our sales team, has the potential to mitigate the impact of a CMS waiver expiration, which is currently effective until October 2022.

Institutional Revenue. Institutional revenue increased by \$111,000, or 7.2%, in fiscal 2022 compared to fiscal 2021. Institutional revenue includes sales to group purchasing organizations, rental companies and other institutions. The revenue increase was due to increased capital purchases and stronger consumable volumes compared to fiscal 2021, as hospitals resumed utilization of HFCWO protocols after reducing utilization early in the COVID-19 pandemic.

Home Care Distributor Revenue. Home care distributor revenue increased by \$911,000, or 161.8%, in fiscal 2022 compared to fiscal 2021. The revenue increase in fiscal 2022 was due to increased demand from one of our primary home care distribution partners. We began selling to a limited number of home medical equipment distributors during our fiscal year ended June 30, 2020, who in turn sell our SmartVest System in the U.S. home care market.

International Revenue. International revenue decreased by \$137,000, or 20.8%, in fiscal 2022 compared to fiscal 2021. International revenue growth is not currently a primary focus for us, and our corporate resources are focused on supporting and maintaining our current distributors. International sales are affected by the timing of international distributor purchases that can cause significant fluctuations in reported revenue on a quarterly basis.

Gross Profit

Gross profit increased to \$31,442,000 in fiscal 2022, or 75.5% of net revenues, from \$27,305,000, or 76.4% of net revenues, in fiscal 2021. The increase in gross profit was primarily related to increases in domestic home care revenue including the Medicare allowable rate increase that took effect in January 2022. The decrease in gross profit as a percentage of net revenue was driven by higher raw material and shipping costs as well as patient training related expenses due to increase in face-to-face trainings.

We believe as we continue to grow revenue, we will be able to leverage manufacturing costs, although there may be fluctuations on a short-term basis related to increased material and shipping costs as well as average reimbursement based on the mix of referrals during any given period. Factors such as diagnoses that are not assured of reimbursement, insurance programs with lower allowable reimbursement amounts (for example, state Medicaid programs), whether an individual patient meets prerequisite medical criteria for reimbursement, and continuation of the Medicare waiver currently in place may have an effect on average reimbursement received on a short-term basis. We have a goal of improving our gross margin percentage over time due to lower product costs associated with our next generation product, supplier optimization, and gaining operating leverage on higher volumes.

Operating Expenses

Selling, General and Administrative Expenses. Selling, general and administrative (“SG&A”) expenses were \$27,114,000 in fiscal 2022, representing an increase of \$4,671,000 or 20.8% from \$22,443,000 in fiscal 2021.

SG&A payroll and compensation-related expenses increased by \$2,206,000, or 15.3%, to \$16,640,000 in fiscal 2022, compared to \$14,434,000 in fiscal 2021. The increase in the current year was primarily due to a higher average number of sales, sales support and marketing personnel, increased reimbursement personnel to process higher patient referrals, increased temporary resources to assist with systems infrastructure investments and increased incentive payments on higher home care revenue. We have also continued to provide regular merit-based increases for our employees and are regularly benchmarking our compensation ranges for new and existing employees to ensure we can hire and retain the talent needed to drive growth in our business. Field sales employees totaled 52, of which 43 were direct sales, as of June 30, 2022, compared to 46 as of June 30, 2021, of which 37 were direct sales.

Professional and legal fees increased by \$875,000, or 36.0%, to \$3,308,000 in fiscal 2022, compared to \$2,433,000 in fiscal 2021. Professional fees include services related to legal costs, shareowner services and reporting requirements, information technology technical support and consulting fees. The increase in the current year was primarily due to a shareholder activism matter, increased investment in our system infrastructure and increased clinical study costs. Our shareholder activism matter concluded with a cooperation agreement in September 2021. We continue to make key investments in systems infrastructure including implementing a new enterprise resource planning (“ERP”) system, enhancing our customer relationship management system and further optimizing of the revenue cycle management system that was implemented in June 2021. We expect these system infrastructure investments will result in more efficient and scalable operational processes and provide enhanced analytics to drive business performance. We also expect to continue investing in our on-going clinical studies in order to continue building the body of evidence around positive outcomes from bronchiectasis patients using HFCWO and SmartVest therapy.

Total discretionary marketing expenses decreased by \$238,000, or 22.4% to \$824,000 in fiscal 2022, compared to \$1,062,000 in fiscal 2021. The decrease in the current year was primarily due to a shift to more cost-effective direct-to-consumer marketing investments.

Travel, meals and entertainment expenses increased \$734,000, or 41.2%, to \$2,514,000 for fiscal 2022 compared to \$1,780,000 in fiscal 2021. The increase in the current year period was primarily due to our sales team resuming closer-to-normal levels of travel compared to the COVID-19 driven travel restrictions in the prior year and an increase in regional sales meetings that were cancelled in the prior year due to COVID-19. The Company also held an in-person national sales meeting in August 2021 whereas the national sales meeting was held virtually in fiscal 2021 due to COVID-19.

Recruiting fees increased by \$362,000 or 134.6% to \$631,000 for fiscal 2022 compared to \$269,000 in fiscal 2021. The increase in recruiting fees is primarily due to increased recruiting for senior leadership and direct sales representative positions.

Insurance expenses increased by \$229,000 or 20.6% to \$1,339,000 for fiscal 2022 compared to \$1,110,000 in fiscal 2021. The increase in the current year is primarily due to higher health insurance, director and officer insurance costs and cyber insurance costs.

Research and Development Expenses

R&D expenses decreased by \$366,000, or 21.3%, to \$1,356,000 in fiscal 2022 compared to \$1,722,000 in fiscal 2021. The decrease in the current year was primarily due to reduced professional consulting costs associated with our next generation platform development activities. R&D expenses were 3.3% of revenue in fiscal 2022 compared to 4.8% of revenue in fiscal 2021. We expect R&D spending to be between 2.0% and 3.0% of revenue during fiscal 2023, as we look to finalize our development and product testing work in preparation for an anticipated fiscal year 2023 next generation product launch.

Interest Income, net

Net interest income was approximately \$25,000 in fiscal 2022 compared to net interest income of \$39,000 in fiscal 2021. The decrease in the current year was primarily due to lower rates earned on our cash deposits and lower cash deposits in the bank compared to prior fiscal periods.

Income Tax Expense

Income tax expense in fiscal 2022 was 692,000, which includes a current tax expense of \$1,181,000 and a deferred benefit of \$489,000. Estimated income tax expenses include a discrete current tax benefit of approximately \$37,000 related to exercised fully vested stock options and a discrete current benefit of approximately \$21,000 related to the excess tax benefit of non-qualified stock options that were exercised during the period.

Income tax expense in fiscal 2021 was \$805,000, which included a current tax expense of \$1,099,000 and a deferred benefit of \$294,000. Estimated income tax expense included a discrete deferred tax expense of approximately \$81,000 related to unexercised fully vested stock options that expired and a discrete current tax benefit of approximately \$33,000 related to the excess tax benefit of non-qualified stock options that were exercised during the period.

The effective tax rates were 23.1% and 25.4% for fiscal 2022 and 2021, respectively. The effective tax rates differ from the statutory federal rate due to the effect of state income taxes, R&D tax credits, and other permanent items that are non-deductible for tax purposes relative to the amount of taxable income.

Net Income

Net income for fiscal 2022 was \$2,305,000, compared to net income of \$2,362,000 in fiscal 2021. The decrease in current year net income was primarily due to increased strategic investments in SG&A, shareholder activism costs and higher product costs partially offset by stronger home care and distributor revenue growth.

Liquidity and Capital Resources

Cash Flows and Sources of Liquidity

Cash Flows from Operating Activities

Net cash used in operating activities in fiscal 2022 was \$686,000. Cash flows from operating activities consisted of net income of \$2,305,000, non-cash expenses of approximately \$1,115,000, a \$2,170,000 increase in accounts payable and accrued liabilities and a decrease in contract assets of \$107,000. These cash flows from operating activities were offset by a \$4,020,000 increase in accounts receivable, an increase in inventory of \$1,072,000, and a \$1,322,000 increase in prepaid expenses. The increase in accounts receivable was primarily due to an increase in the Medicare portion of our home care business, which has a 13-month payment cycle. Three distinct items have negatively impacted our operating cash flow in fiscal 2022, including tax payments on higher-than-expected fiscal 2021 net income, increased payments to secure adequate supply of key raw material components, and a one-time payout of accrued vacation balances as part of an enhancement to our paid time off policy. Our cash receipt collection remains strong, with the three months ended June 30, 2022 period having the highest cash receipt collections in our company's history, building upon the prior record that was set in the previous quarter.

Cash Flows from Investing Activities

Net cash used in investing activities in fiscal 2022 was approximately \$1,525,000. Cash used in investing activities consisted of approximately \$1,425,000 in expenditures for property and equipment, approximately \$943,000 for software and \$482,000 for equipment, and \$100,000 in payments for patent and trademark costs.

Cash Flows from Financing Activities

Net cash used in financing activities in fiscal 2022 was approximately \$1,525,000, consisting of \$1,448,000 used for our share repurchase program and \$77,000 for taxes paid on net share settlements of stock option exercises.

Adequacy of Capital Resources

Our primary working capital requirements relate to adding employees to our sales force and support functions, continuing infrastructure investments, and supporting general corporate needs, including financing equipment purchases and other capital expenditures incurred in the ordinary course of business. Based on our current operational performance, we believe our working capital of approximately \$27,389,000 and available borrowings under our existing credit facility will provide adequate liquidity for fiscal 2023.

Effective December 17, 2021, we renewed our credit facility, which provides us with a revolving line of credit. Interest on borrowings on the line of credit accrues at the prime rate (4.75% as of June 30, 2022) less 1.0% and is payable monthly. There was no outstanding principal balance on the line of credit as of June 30, 2022 or June 30, 2021. The amount eligible for borrowing on the line of credit is limited to the lesser of \$2,500,000 or 57.0% of eligible accounts receivable, and the line of credit expires on December 18, 2023, if not renewed. As of June 30, 2022, the maximum \$2,500,000 was available under the line of credit. Payment obligations under the line of credit are secured by a security interest in substantially all of our tangible and intangible assets.

The documents governing our line of credit contain certain financial and nonfinancial covenants that include a minimum tangible net worth of not less than \$10,125,000 and restrictions on our ability to incur certain additional indebtedness or pay dividends.

Any failure to comply with these covenants in the future may result in an event of default, which if not cured or waived, could result in the lender accelerating the maturity of our indebtedness, preventing access to additional funds under the line of credit, requiring prepayment of outstanding indebtedness, or refusing to renew the line of credit. If the maturity of the indebtedness is accelerated or the line of credit is not renewed, sufficient cash resources to satisfy the debt obligations may not be available and we may not be able to continue operations as planned. If we are unable to repay such indebtedness, the lender could foreclose on these assets.

During fiscal 2022 and 2021, we spent approximately \$1,425,000 and \$287,000, respectively, on property and equipment. We currently expect to finance planned equipment purchases with cash flows from operations or borrowings under our credit facility. 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 flows.

While the impact of the COVID-19 pandemic and other factors such as inflation are difficult to predict, we believe our cash, cash equivalents and cash flows from operations will be sufficient to meet our working capital, capital expenditure, operational cash requirements for fiscal 2023.

Accounting Standards Recently Issued But Not Yet Adopted by the Company

See Note 1 of the Notes to our Financial Statements in this Annual Report on Form 10-K for information on new accounting standards adopted in fiscal 2022 or pending adoption.

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.

Index to Financial Statements

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets</u>	F-4
<u>Statements of Operations</u>	F-5
<u>Statements of Shareholders' Equity</u>	F-6
<u>Statements of Cash Flows</u>	F-7
<u>Notes to Financial Statements</u>	F-8

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Electromed, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Electromed, Inc. (the Company) as of June 30, 2022 and 2021, the related statements of operations, shareholders' equity and cash flows for the years then ended, and the related notes to the financial statements. In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Measurement of Customer Revenue Net of Adjustments

As discussed in Note 2 to the financial statements, revenues are recognized at a point in time when control passes to the customer upon product shipment or delivery. Net patient revenues (patient revenue less estimated adjustments) are recognized at the estimated net realizable amounts from third-party payers and customers in exchange for the product. The Company has agreements with third-party payers that provide for payments at amounts different from its established rates. Each quarter, the Company estimates its adjustments for each sale based on the terms of third-party payer contracts and historical collections experience, then applies an estimate for an adjustment reserve percentage to the gross accounts receivable balances.

We identified the measurement of the adjustment reserve related to customer revenue as a critical audit matter due to the audit effort, degree of auditor judgment, and subjectivity involved in evaluating the audit evidence related to management's estimate.

Our audit procedures related to the Company's measurement of the adjustment reserve included the following, among others.

- Selected a sample of product sales to inspect and compare to the underlying source documents and final cash collections to test the reasonableness of the contractual adjustment and collection percentage assumptions used in management's estimate.
- For a sample of product sales, we traced gross revenue and adjustments to net revenue recorded in the general ledger.
- Evaluated the reasonableness of management's estimate of contractual and collection reserves by:
 - Comparing the estimates of realization percentages to historical net collection percentages for portfolio groups.
 - Recalculating the contractual and collection reserve estimates and compared them to the general ledger.
 - Evaluating the quarterly trend analysis for portfolio groups for changes in historical realization percentages.

/s/ RSM US LLP

We have served as the Company's auditor since 2010.

Rochester, Minnesota
August 23, 2022

Electromed, Inc.
Balance Sheets
June 30, 2022 and 2021

	June 30,	
	2022	2021
Assets		
Current Assets		
Cash and cash equivalents	\$ 8,153,000	\$ 11,889,000
Accounts receivable (net of allowances for doubtful accounts of \$45,000)	21,052,000	17,032,000
Contract assets	286,000	393,000
Inventories	3,178,000	2,114,000
Prepaid expenses and other current assets	1,870,000	276,000
Total current assets	34,539,000	31,704,000
Property and equipment, net	4,568,000	3,605,000
Finite-life intangible assets, net	599,000	663,000
Other assets	120,000	88,000
Deferred income taxes	1,538,000	1,049,000
Total assets	\$ 41,364,000	\$ 37,109,000
Liabilities and Shareholders' Equity		
Current Liabilities		
Accounts payable	\$ 1,261,000	\$ 685,000
Accrued compensation	2,742,000	2,474,000
Income tax payable	51,000	288,000
Warranty reserve	1,256,000	940,000
Other accrued liabilities	1,840,000	252,000
Total current liabilities	7,150,000	4,639,000
Other long-term liabilities	41,000	54,000
Total liabilities	7,191,000	4,693,000
Commitments and Contingencies		
Shareholders' Equity		
Common stock, \$0.01 par value, 13,000,000 shares authorized; 8,475,438 and 8,533,209 issued and outstanding, as of June 30, 2022 and June 30, 2021, respectively	85,000	85,000
Additional paid-in capital	18,308,000	17,409,000
Retained earnings	15,780,000	14,922,000
Total shareholders' equity	34,173,000	32,416,000
Total liabilities and shareholders' equity	\$ 41,364,000	\$ 37,109,000

See Notes to Financial Statements.

Electromed, Inc.
Statements of Operations
Years Ended June 30, 2022 and 2021

	Years Ended June 30,	
	2022	2021
Net revenues	\$ 41,659,000	\$ 35,756,000
Cost of revenues	10,217,000	8,451,000
Gross profit	31,442,000	27,305,000
Operating expenses		
Selling, general and administrative	27,114,000	22,443,000
Research and development	1,356,000	1,722,000
Total operating expenses	28,470,000	24,165,000
Operating income	2,972,000	3,140,000
Interest income, net	25,000	27,000
Net income before income taxes	2,997,000	3,167,000
Income tax expense	692,000	805,000
Net income	\$ 2,305,000	\$ 2,362,000
Income per share:		
Basic	\$ 0.27	\$ 0.28
Diluted	\$ 0.26	\$ 0.27
Weighted-average common shares outstanding:		
Basic	8,471,320	8,566,224
Diluted	8,768,703	8,911,842

See Notes to Financial Statements.

Electromed, Inc.
Statements of Shareholders' Equity
Years Ended June 30, 2022 and 2021

	Common Stock		Additional Paid-in Capital	Retained Earnings	Total Shareholders' Equity
	Shares	Amount			
Balance as of June 30, 2020	8,567,834	\$ 86,000	\$ 16,480,000	\$ 13,684,000	\$ 30,250,000
Net income	—	—	—	2,362,000	2,362,000
Issuance of restricted stock	37,090	—	—	—	—
Issuance of common stock upon exercise of options	32,496	—	46,000	—	46,000
Taxes paid on stock option exercised on a net basis	—	—	(141,000)	—	(141,000)
Share-based compensation expense	—	—	1,024,000	—	1,024,000
Repurchase of common stock	(104,211)	(1,000)	—	(1,123,000)	(1,124,000)
Balance as of June 30, 2021	8,533,209	85,000	17,409,000	14,922,000	32,416,000
Net income	—	—	—	2,305,000	2,305,000
Issuance of restricted stock	49,400	1,000	—	—	1,000
Issuance of common stock upon exercise of options	13,245	—	—	—	—
Taxes paid on stock option exercised on a net basis	—	—	(77,000)	—	(77,000)
Share-based compensation expense	—	—	976,000	—	976,000
Repurchase of common stock	(120,416)	(1,000)	—	(1,447,000)	(1,448,000)
Balance as of June 30, 2022	8,475,438	\$ 85,000	\$ 18,308,000	\$ 15,780,000	\$ 34,173,000

See Notes to Financial Statements.

Electromed, Inc.
Statements of Cash Flows
Years Ended June 30, 2022 and 2021

	Years Ended June 30,	
	2022	2021
Cash Flows from Operating Activities		
Net income	\$ 2,305,000	\$ 2,362,000
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation	503,000	477,000
Amortization of finite-life intangible assets	125,000	133,000
Share-based compensation expense	976,000	1,024,000
Deferred income taxes	(489,000)	(294,000)
Changes in operating assets and liabilities:		
Accounts receivable	(4,020,000)	(4,091,000)
Contract assets	107,000	510,000
Inventories	(1,072,000)	971,000
Prepaid expenses and other current assets	(1,322,000)	151,000
Income tax payable	(237,000)	550,000
Accounts payable and accrued liabilities	2,170,000	214,000
Accrued compensation	268,000	1,070,000
Net cash (used in) provided by operating activities	(686,000)	3,077,000
Cash Flows from Investing Activities		
Expenditures for property and equipment	(1,425,000)	(287,000)
Expenditures for finite-life intangible assets	(100,000)	(161,000)
Net cash used in investing activities	(1,525,000)	(448,000)
Cash Flows from Financing Activities		
Issuance of common stock upon exercise of options	—	46,000
Taxes paid on stock options exercised on a net basis	(77,000)	(141,000)
Repurchase of common stock	(1,448,000)	(1,124,000)
Net cash used in financing activities	(1,525,000)	(1,219,000)
Net (decrease) increase in cash	(3,736,000)	1,410,000
Cash and cash equivalents		
Beginning of period	11,889,000	10,479,000
End of period	<u>\$ 8,153,000</u>	<u>\$ 11,889,000</u>
Supplemental Disclosures of Cash Flow Information		
Cash paid for income taxes	\$ 1,418,000	\$ 534,000
Supplemental Disclosures of Noncash Investing and Financing Activities		
Property and equipment acquisitions in accounts payable	\$ 44,000	\$ 10,000
Intangible asset acquisitions in accounts payable	\$ 3,000	\$ 42,000
Lease assets obtained in exchange for new operating lease liabilities	\$ 117,000	\$ 91,000

See Notes to Financial Statements.

Electromed, Inc.
Notes to 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 that apply High Frequency Chest Wall Oscillation (“HFCWO”) therapy in pulmonary care for patients of all ages. The Company markets its products in the U.S. 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. International sales were \$521,000 and \$658,000 for the fiscal years ended June 30, 2022 (“fiscal 2022”) and June 30, 2021 (“fiscal 2021”), respectively. Since its inception, the Company has operated in a single industry segment: developing, manufacturing and marketing medical equipment.

Impacts of COVID-19 on the Company’s business

The Company did not receive any direct financial assistance from any government program during fiscal 2021 or fiscal 2022 in connection with COVID-19 relief measures.

In response to the COVID-19 pandemic and the U.S. federal government’s declaration of a public health emergency, the Centers for Medicare and Medicaid Services (“CMS”) implemented a number of temporary rule changes and waivers to allow prescribers to best treat patients during the period of the public health emergency. These waivers were made retroactively effective to March 1, 2020 and were in place for the duration of fiscal 2021 and fiscal 2022. Clinical indications and documentation typically required were not enforced for respiratory related products including the Company’s SmartVest® Airway Clearance System (“SmartVest System”) (solely with respect to direct Medicare covered patients) applicable for the Company’s home care prescriptions. The minimum documentation now requires a valid order and documentation of a respiratory related diagnosis. Face-to-face and in-person requirements for respiratory devices are being waived while the waiver is in place. The CMS waiver was recently extended in conjunction with the extension of the federal public health emergency for an additional 90-day period beginning July 15, 2022. A temporary suspension of a 2% tax on Medicare payments was also initiated in May 2020 and was extended through December 2021.

The impact of the COVID-19 pandemic on the Company’s business remains uncertain and its effects on operational and financial performance will depend in part on future developments, which cannot be reasonably estimated at this time. Such future developments include, but are not limited to, the duration, scope and severity of the COVID-19 pandemic in geographic areas in which the Company operates or in which its patients live, actions taken to contain or mitigate its impact, the impact on governmental healthcare programs and budgets, the deployment of treatments or vaccines, and the resumption of widespread economic activity. Due to the inherent uncertainty of the unprecedented and evolving situation, the Company is unable to predict with confidence the likely impact of the COVID-19 pandemic on its future operations.

A summary of the Company’s significant accounting policies follows:

Use of estimates: Management uses estimates and assumptions in preparing the financial statements in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). 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 financial statements include revenue recognition and the related estimation of variable consideration, inventory valuation, share-based compensation and warranty reserve.

Revenue recognition: Revenue is measured based on consideration specified in the contract with a customer, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, including noncash consideration, consideration paid or payable to customers and significant financing components. Revenue from all customers is recognized when a performance obligation is satisfied by transferring control of a distinct good or service to a customer. See Note 2 for information on revenue.

Shipping and handling expense: Shipping and handling charges incurred by the Company are included in cost of revenues and were \$982,000 and \$530,000 for fiscal 2022 and 2021, respectively.

Cash and cash equivalents: Cash and cash equivalents consist of cash in bank deposits and money market funds with original maturities of three months or less at the time of purchase. The Company has not experienced any losses in these accounts.

Accounts receivable: The Company's accounts 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. Receivables are written off when deemed uncollectible. Recoveries of receivables previously written off are recorded when received. The allowance for doubtful accounts was \$45,000 as of June 30, 2022 and 2021.

Contract assets: Contract assets include amounts recognized as revenue that are estimates of variable consideration for Medicare appeals where the final determination of the insurance coverage amount is dependent on future approval of an appeal, or when the consideration due to the Company is dependent on a future event such as the patient meeting a deductible prior to the Company's claim being processed by the payer. Contract assets are classified as current as amounts will turn into accounts receivable and be collected during the Company's normal business operating cycle. Contract assets are reclassified to accounts receivable when the right to receive payment is unconditional.

Inventories: Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. 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 future sales. Estimated inventory to be returned is based on how many devices that have shipped that are expected to be returned prior to completion of the insurance reimbursement process.

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 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 amortized on a straight-line basis over their estimated useful lives, as described in Note 5.

Long-lived assets: Long-lived assets, primarily 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 or asset group 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 or asset group is measured by a comparison of the carrying value of the asset to future undiscounted cash flows.

If the Company believes the carrying value is unrecoverable, then it recognizes an impairment charge necessary to reduce the unamortized balance to the estimated fair value of the asset or asset group. The amount of such impairment is charged to operations in the current period.

Warranty liability: The Company provides a lifetime warranty on its products to the prescribed patient for sales within the U.S. and a three-year warranty for all institutional sales and sales to individuals outside the U.S. 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 shipped or delivered. Factors that affect the Company's warranty liability include the number of units shipped, historical and anticipated rates of warranty claims, the product's useful life, 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 as follows:

	Years Ended June 30,	
	2022	2021
Beginning warranty reserve	\$ 940,000	\$ 740,000
Accrual for products sold	494,000	354,000
Expenditures and costs incurred for warranty claims	(178,000)	(154,000)
Ending warranty reserve	\$ 1,256,000	\$ 940,000

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. The Company reverses a valuation allowance if it determines, based on the weight of all available evidence, including when cumulative losses become positive income, that it is more likely than not that some or all of the deferred tax assets will 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 50 percent likely of being realized upon settlement. 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 improvements 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 fiscal 2022 and 2021 were \$936,000 and \$1,062,000, respectively.

Share-based payments: Share-based payment awards consist of options to purchase shares of common stock and restricted shares of common stock issued to employees for services. Expense for options is estimated using the Black-Scholes pricing model at the date of grant and expense for restricted stock is determined by the closing price on the day the grant is made. Expense is recognized on a straight-line basis over the requisite service or vesting period of the award, or at the time services are provided for non-employee awards.

Fair value of financial instruments: The carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these instruments.

Net income per common share: Net income is presented on a per share basis for both basic and diluted common shares. Basic net income per common share is computed using the weighted-average number of common shares outstanding during the period, excluding any restricted stock awards which have not vested. The diluted net income per common share calculation includes outstanding restricted stock grants and assumes that all stock options were exercised and converted into shares of common stock at the beginning of the period unless their effect is anti-dilutive. Common stock equivalents included in the calculation of diluted earnings per share were 297,383 and 345,618 shares for fiscal 2022 and 2021, respectively. Common stock equivalents excluded from the calculation of diluted earnings per share because their impact was anti-dilutive were 113,646 and 48,617 shares for fiscal 2022 and 2021, respectively.

Recently Issued Accounting Standards

In June 2016, the Financial Accounting Board issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments -- Credit Losses: Measurement of Credit Losses on Financial Instruments, which was subsequently amended by ASU 2018-19, ASU 2019-04, 2019-05, 2019-10, 2019-11, and 2020-02. The standard introduces new accounting guidance for credit losses on financial instruments within its scope, including trade receivables. This new guidance adds an impairment model that is based on expected losses rather than incurred losses. It is effective for interim and annual reporting periods beginning after December 15, 2022, with early adoption permitted.

Note 2. Revenues

Revenue is measured based on consideration specified in the contract with a customer, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, including consideration paid or payable from customers and significant financing components. Revenue from all customers is recognized when a performance obligation is satisfied by transferring control of a distinct good or service to a customer, as further described below under *Performance obligations and transaction price*.

Individual promised goods and services in a contract are considered a performance obligation and accounted for separately if the individual good or service is distinct (i.e., the customer can benefit from the good or service on its own or with other resources that are readily available to the customer and the good or service is separately identifiable from other promises in the arrangement). If an arrangement includes multiple performance obligations, the consideration is allocated between the performance obligations in proportion to their estimated standalone selling price, unless discounts or variable consideration is attributable to one or more but not all the performance obligations. Costs related to products delivered are recognized in the period incurred, unless criteria for capitalization of costs under Accounting Standards Codification (“ASC”) 340-40, “Other Assets and Deferred Costs” (“ASC 340”), or other applicable guidance are met.

The Company includes shipping and handling fees in net revenues. Shipping and handling costs associated with the shipment of the Company’s SmartVest® Airway Clearance System (“SmartVest System”) after control has transferred to a customer are accounted for as a fulfillment cost and are included in cost of revenues in the Statements of Operations.

The timing of revenue recognition, billings and cash collections results in accounts receivable on the Balance Sheets as further described below under *Accounts receivable* and *Contract assets*.

Disaggregation of revenues. In the following table, revenue is disaggregated by market:

	Years Ended June 30,	
	2022	2021
Home care	\$ 38,004,000	\$ 32,986,000
Institutional	1,660,000	1,549,000
Home care distributor	1,474,000	563,000
International	521,000	658,000
Total	\$ 41,659,000	\$ 35,756,000

In the following table, home care revenue is disaggregated by payer type:

	Years Ended June 30,	
	2022	2021
Commercial	\$ 14,904,000	\$ 12,530,000
Medicare	21,144,000	19,044,000
Medicaid	1,045,000	846,000
Other	911,000	566,000
Total	\$ 38,004,000	\$ 32,986,000

Revenues in the Company's home care, home care distributor and international markets are recognized at a point in time when control passes to the customer upon product shipment or delivery. Revenues in the Company's institutional market include sales recognized at a point in time upon shipment or delivery as well as revenues recognized over time under operating leases.

Performance obligations and transaction price. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account under ASC 606, "Revenue From Contracts With Customers" ("ASC 606"). A contract's transaction price is allocated to each distinct performance obligation in proportion to the standalone selling price for each and recognized as revenue when, or as, the performance obligation is satisfied. The Company's performance obligations and the timing or method of revenue recognition in each of the Company's markets are discussed below:

Home care market. In the Company's home care market, its customers are patients who use the SmartVest System. The various models of the SmartVest System are comprised of three main components - a generator, a vest and a connecting hose - that are sold together as an integrated unit. Accordingly, in contracts within the home care market, the Company regards the SmartVest System to be a single performance obligation.

The Company makes available to its home care patients limited post-sale services that are not material in the context of the contracts, either individually or taken together, and therefore does not consider them to be performance obligations. The costs associated with the services are accrued and expensed when the related revenues are recognized. As such, transactions in the home care market consist of a single performance obligation: the SmartVest System.

Home care patients generally will rely on third-party payers, including commercial payers and governmental payers such as Medicare, Medicaid and the U.S. Department of Veterans Affairs to cover and reimburse all or part of the cost of the SmartVest System. The third-party payers' reimbursement programs fall into three types, distinguished by the differences in the timing of payments from the payer, consisting of either (i) outright sale, in which payment is received from the payer based on standard terms, (ii) capped installment sale, under which the SmartVest System is sold for a series of payments that are capped not to exceed a prescribed or negotiated amount over a period of time or (iii) installment sale, under which the SmartVest System is paid for over a period of several months as long as the patient continues to use the SmartVest System.

Regardless of the type of transaction, provided criteria for an enforceable contract are met, it is the Company's long-standing business practice to regard all home care agreements as transferring control to the patient upon shipment or delivery, in spite of possible payment cancellation under government or commercial programs where the payer is controlling the payment over specified time periods. For home care sales that feature installment payments, the ultimate amount of consideration received from Medicare, Medicaid or commercial payers can be significantly less than expected if the contract is terminated due to changes in the patient's status, including insurance coverage, hospitalization, death or otherwise becoming unable to use the SmartVest System. However, once delivered to a patient who needs the SmartVest System, the patient is under no obligation to return the SmartVest System should payments be terminated as a result of the described contingencies. As a result, the Company's product sales qualify for point in time revenue recognition. Control transfers to the patient, and revenue is recognized, upon shipment or delivery of the SmartVest System. At this point, physical possession and the significant risks and rewards of ownership are transferred to the patient and either a current or future right to payment is triggered, as further discussed under *Accounts receivable* and *Contract assets* below.

The Company's contractually stated transaction prices in the home care market are generally set by the terms of the contracts negotiated with insurance companies or by government programs. The transaction price for the Company's products may be further impacted by variable consideration. ASC 606 requires the Company to adjust the transaction price at contract inception and throughout the contract duration for the estimated value of payments to be received from insurance payers based on historical experience and other available information, subject to the constraint on estimates of variable consideration. Transactions requiring estimates of variable consideration primarily include (i) capped installment payments, which are subject to the third-party payer's termination due to changes in insurance coverage, death or the patient's discontinued use of the SmartVest System, (ii) contracts under appeal and (iii) patient responsibility amounts for deductibles, coinsurance, copays and other similar payments.

Although estimates may be made on a contract-by-contract basis, whenever possible, the Company uses all available information including historical collection patterns to estimate variable consideration for portfolios of contracts. The Company's estimates of variable consideration consist of amounts it may receive from insurance providers in excess of its initial revenue estimate due to patients meeting deductibles or coinsurance during the payment duration, changes to a patient's insurance status, changes in an insurance allowable, claims in appeals with Medicare and amounts received directly from patients for their allowable or coinsurance. The Company believes it has representative historical information to estimate the amount of variable consideration in relevant portfolios considering the significant experience it has with each portfolio and the similarity of patient accounts within a portfolio. The analysis includes steps to ensure that revenue recognized on a portfolio basis does not result in a material difference when compared with an individual contract approach. The Company also leverages its historical experience and all available relevant information for each portfolio of contracts to minimize the risk its estimates used to arrive at the transaction price will result in a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur.

For contracts in which the Company believes the criteria for reimbursement under government or commercial payer contracts have been met but for which coverage is unconfirmed or payments are under appeal, the Company has significant observable evidence of relatively consistent claims recovery experience over the prior three to five years. The Company believes the low volatility in historical claims approval rates for populations of patients whose demographics are similar to those of current patients provides reliable predictive value in arriving at estimates of variable consideration in such contracts. Similarly, historical payment trends for recovery of claims subject to payer installments and payments from patients have remained relatively consistent over the past five years. No significant changes in patient demographics or other relevant factors have occurred that would limit the predictive value of such payment trends in estimating variable consideration for current contracts. As a result, the Company believes its estimates of variable consideration are generally not subject to the risk of significant revenue reversal.

For each type of variable consideration discussed above, there are a large number of contracts with similar characteristics with a wide range of possible transaction prices. For that reason, the Company uses the probability-weighted expected value method provided under ASC 606 to estimate variable consideration.

The Company often receives payment from third-party payers for the SmartVest System sales over a period of time that may exceed one year. Despite these extended payment terms, no significant financing component is deemed to exist because the purpose of such terms is not to provide financing to the patient, the payer or the Company. Rather, the extended payment terms are mandated by the government or commercial insurance programs, the fundamental purpose of which is to avoid paying the full purchase price of equipment that may potentially be used by the patient for only a short period of time.

Home care distributors. Sales to distributors, who sell direct to patients, are made at fixed contract prices and may include tiered pricing structures or volume-based rebates which offer more favorable pricing once certain volumes are achieved per the negotiated contract. The distributor's purchases accumulate to give the distributor a right to a higher discount on purchases in excess of the specified level within the contract period. As a result, to the extent the Company expects the distributor to exceed the specified volume of purchases in the annual period, it recognizes revenue at a blended rate based on estimated total annual volume and sales revenue. This effectively defers a portion of the transaction price on initial purchases below the specified volumes for recognition when the higher discount is earned on purchases in excess of specified volumes. Transfer of control of the products occurs upon shipment or delivery to the distributor as applicable.

Institutional market. The Company’s institutional sales are made to hospitals and home health care centers, pulmonary rehabilitation centers and other clinics. Sales to these institutions are negotiated with the individual institution or with group purchasing organizations, with payments received directly from the institution. No insurance reimbursement is involved. Generators are either sold or leased to the institutions and associated hoses and wraps (used in institutional settings rather than vests) are sold separately. Accordingly, each product is distinct and considered a separate performance obligation in sales to institutional customers. The agreements with institutions fall into two main types, distinguished by differences in the timing of transfer of control and timing of payments:

- Outright sale – Under these transactions, the Company sells its products for a prescribed or negotiated price. Transfer of control of the product, and associated revenue recognition, occurs at the time of shipment and payment is made within normal credit terms, usually within 30 days.
- Wrap usage agreements – Under these transactions, the Company provides a generator device at no cost to the hospital in return for a fixed annual commitment to purchase consumable wraps. These agreements are cancellable upon at least sixty days prior written notice by either party. If cancelled, the generator is returned to the Company, where it can be refurbished and used again at a later date. Revenue for the consumable wraps is recognized when control transfers to the customer.

International market. Sales to international markets are made directly to a number of independent distributors at fixed contract prices that are not subject to further adjustments for variable consideration. Transfer of control of the products occurs upon shipment or delivery to the distributor as applicable.

Product warranty. The Company offers warranties on its products. These warranties are assurance type warranties not sold on a standalone basis or are otherwise considered immaterial in the context of the contract, and therefore are not considered distinct performance obligations under ASC 606. The Company estimates the costs that may be incurred under its warranties and records a liability in the amount of such costs at the time the product is sold.

Accounts receivable. The Company’s accounts 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. Receivables are written off when deemed uncollectible.

Contract assets. Contract assets include amounts recognized as revenue that are estimates of variable consideration for Medicare appeals where the final determination of the insurance coverage amount is dependent on future approval of an appeal, or when the consideration due to the Company is dependent on a future event such as the patient meeting a deductible prior to the Company’s claim being processed by the payer. Contract assets are classified as current as amounts is expected to turn into accounts receivable and be collected during the Company’s normal business operating cycle. Contract assets are reclassified to accounts receivable when the right to receive payment is unconditional.

Contract balances. The following table provides information about accounts receivable and contracts assets from contracts with customers:

	June 30,	
	2022	2021
Receivables, included in “Accounts receivable, net of allowance for doubtful accounts”	\$ 21,052,000	\$ 17,032,000
Contract Assets	\$ 286,000	\$ 393,000

Significant changes in contract assets during the period are as follows:

	Year Ended June 30, 2022	Year Ended June 30, 2021
	Increase (decrease)	Increase (decrease)
Contract assets, beginning	\$ 393,000	\$ 903,000
Reclassification of contract assets to accounts receivable	(833,000)	(1,551,000)
Contract assets recognized	784,000	1,060,000
Increase (decrease) as a result of changes in the estimate of amounts to be realized from payers, excluding amounts transferred to receivables during the period	(58,000)	(19,000)
Contract assets, ending	\$ 286,000	\$ 393,000

Note 3. Inventories

The components of inventory were as follows:

	June 30,	
	2022	2021
Parts inventory	\$ 2,672,000	\$ 1,779,000
Work in process	100,000	23,000
Finished goods	469,000	445,000
Estimated inventory to be returned	228,000	167,000
Less: Reserve for obsolescence	(291,000)	(300,000)
Total	\$ 3,178,000	\$ 2,114,000

Note 4. Property and Equipment

Property and equipment were as follows:

	Estimated Useful Lives (Years)	June 30,	
		2022	2021
Building and building improvements	15-39	\$ 3,420,000	\$ 3,446,000
Land	N/A	200,000	200,000
Land improvements	15	162,000	166,000
Equipment	3-10	2,752,000	3,467,000
Demonstration and rental equipment	3	1,036,000	1,060,000
Construction in progress	N/A	957,000	26,000
		8,527,000	8,365,000
Less: Accumulated depreciation		(3,959,000)	(4,760,000)
Net property and equipment		\$ 4,568,000	\$ 3,605,000

Note 5. 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 \$433,000 and \$1,248,000 as of June 30, 2022 and 2021, respectively.

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

	Years Ended June 30,	
	2022	2021
Balance, beginning	\$ 663,000	\$ 598,000
Additions	61,000	198,000
Amortization expense	(125,000)	(133,000)
Balance, ending	<u>\$ 599,000</u>	<u>\$ 663,000</u>

Based on the carrying value as of June 30, 2022, future amortization is expected to be as follows:

Fiscal years ending June 30:

2023	\$ 46,000
2024	42,000
2025	40,000
2026	39,000
2027	38,000
Thereafter	394,000
Total	<u>\$ 599,000</u>

Note 6. Financing Arrangements

The Company has a credit facility that provides for a revolving line of credit and a term loan. Effective December 17, 2021, the Company renewed its \$2,500,000 revolving line of credit. There was no outstanding principal balance on the line of credit as of June 30, 2022 or June 30, 2021. Interest on borrowings under the line of credit, if any, accrues at the prime rate (4.75% as of June 30, 2022) less 1.0% and is payable monthly. The amount eligible for borrowing on the line of credit is limited to the lesser of \$2,500,000 or 57.0% of eligible accounts receivable and the line of credit expires on December 18, 2023, if not renewed before such date. At June 30, 2022, the maximum \$2,500,000 was eligible for borrowing. Payment obligations under the line of credit, if any, are secured by a security interest in substantially all of the tangible and intangible assets of the Company.

The documents governing the line of credit contain certain financial and nonfinancial covenants that include a minimum tangible net worth covenant of not less than \$10,125,000 and restrictions on the Company's ability to incur certain additional indebtedness or pay dividends.

Note 7. Common Stock

Authorized shares: The Company's Articles of Incorporation, as amended, have established 15,000,000 authorized shares of capital stock consisting of 13,000,000 shares of common stock, par value \$0.01 per share, and 2,000,000 shares of undesignated stock.

On May 26, 2021 the Company's Board of Directors (the "Board") approved a stock repurchase authorization. Under the authorization, the Company was originally able to repurchase up to \$3.0 million of shares of common stock through May 26, 2022. On May 26, 2022, our Board of Directors removed the date limitation. As of June 30, 2022, a total of 120,416 shares have been repurchased and retired under this authorization for a total cost of \$1,448,000, or \$12.02 per share. Repurchased shares have been retired and constitute authorized but unissued shares.

Note 8. Share-Based Compensation

Share-based compensation expense for fiscal 2022 and 2021 was \$976,000 and \$1,024,000, respectively, related to employee stock options and restricted stock awards. This expense is included in selling, general and administrative expense in the Statements of Operations. As of June 30, 2022, the Company had \$460,000 of unrecognized compensation expense related to non-vested equity awards, which is expected to be recognized over a weighted-average period of 1.5 to 2.0 years related to restricted stock awards and employee stock options, respectively.

Employee options: The Company has historically granted stock options to employees as long-term incentive compensation. Options expire ten years from the grant date and vest over a period of three years. In November 2017, the Company's shareholders approved the 2017 Omnibus Incentive Plan (the "2017 Plan") which supersedes the 2014 Equity Incentive Plan (the "2014 Plan"). The 2017 Plan allows the Board to grant stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards, as well as cash incentive awards to all employees, non-employee directors, and advisors or consultants of the Company. The vesting schedule and term for each award are determined by the Board upon each grant. Upon vesting, and the Company's determination that any necessary conditions precedent to the exercise of shares (such as satisfaction of tax withholding and compliance with applicable legal requirements) have been satisfied, shares purchased are delivered to the participant in a manner prescribed or permitted by the Board. The maximum number of shares of common stock available for issuance under the 2017 Plan is 900,000. There were 248,500 options granted under the 2014 Plan and prior plans outstanding as of June 30, 2022. There were 253,584 options issued under the 2017 Plan outstanding and 370,789 shares available for grant under the 2017 Plan as of June 30, 2022.

The Company recognizes compensation expense related to share-based payment transactions in the financial statements based on the estimated fair value of the award issued. The fair value of each option is estimated using the Black-Scholes pricing model at the time of award grant. The Company estimates the expected life of options based on the expected holding period by the option holder. The risk-free interest rate is based upon observed U.S. Treasury interest rates for the expected term of the options. The Company makes assumptions with respect to expected stock price volatility based upon the historical volatility of its stock price. Forfeitures are accounted for as they occur.

The following assumptions were used to estimate the fair value of options granted:

	Years Ended June 30,	
	2022	2021
Risk-free interest rate	0.89-2.52 %	0.31-0.59 %
Expected term (years)	6	6
Expected volatility	55-64 %	283-335 %

During the year ended June 30, 2022, the Company had a change in estimate related to its expected volatility used to estimate the fair value of options granted. The change had no impact on the Financial Statements. The following table presents employee stock option activity for fiscal 2022 and 2021:

	Number of Shares	Weighted-Average Grant Date Fair Value	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)
Options outstanding as of June 30, 2020	590,780	\$ 3.96	\$ 4.34	6.87
Granted	61,017	\$ 14.13	\$ 14.14	—
Exercised	(71,150)	\$ 4.78	\$ 5.09	—
Canceled or forfeited	(112,598)	\$ 6.24	\$ 6.50	—
Options outstanding as of June 30, 2021	468,049	\$ 4.61	\$ 4.98	5.82
Options exercisable as of June 30, 2021	442,437	\$ 4.16	\$ 4.54	5.64
Granted	81,901	\$ 6.63	\$ 11.52	—
Exercised	(32,000)	\$ 3.70	\$ 5.44	—
Canceled or forfeited	(15,866)	\$ 6.63	\$ 11.30	—
Options outstanding as of June 30, 2022	502,084	\$ 3.71	\$ 5.82	5.35
Options exercisable as of June 30, 2022	429,888	\$ 3.16	\$ 4.77	4.76

The intrinsic value of a stock option is the amount by which the fair value of the underlying stock exceeds its exercise price. At June 30, 2022, the weighted average remaining contractual term for all outstanding stock options was 5.4 years and their aggregate intrinsic value was \$2,244,000. Outstanding at June 30, 2022 were 502,084 stock options issued to employees, of which 429,888 were vested and exercisable and had an aggregate intrinsic value of \$2,244,000.

Restricted stock: The 2017 Plan permits the Personnel and Compensation Committee of the Board to grant other stock-based awards, including shares of restricted stock. The Company makes restricted stock grants to key employees and non-employee directors that vest over six months to three years following the applicable grant date.

The Company issued restricted stock awards to employees totaling 31,400 and 30,756 during fiscal 2022 and 2021, respectively, with a vesting term of one to three years and a fair value of \$11.48 and \$14.68 per share, respectively. During fiscal 2022 and 2021, the Company issued restricted stock awards to directors totaling 18,000 each year, with a vesting term of six months and a fair value of \$12.09 and \$9.94 per share for fiscal 2022 and 2021, respectively. Restricted stock transactions during the years ended June 30, 2022 and 2021 are summarized as follows:

	Shares of Restricted Stock	Weighted-Average Grant Date Fair Value per Share
Outstanding as of June 30, 2020	22,499	\$ 6.19
Granted	48,756	\$ 12.93
Vested	(40,752)	\$ 9.47
Outstanding as of June 30, 2021	30,503	\$ 12.57
Granted	49,400	\$ 11.70
Vested	(45,219)	\$ 11.61
Outstanding as of June 30, 2022	34,684	\$ 12.59

Note 9. Income Taxes

Components of the provision for income taxes were as follows:

	Years Ended June 30,	
	2022	2021
Current:		
Current Federal	\$ 891,000	\$ 861,000
Current State	290,000	238,000
Total Current	1,181,000	1,099,000
Deferred:		
Deferred Federal	(348,000)	(204,000)
Deferred State	(141,000)	(90,000)
Total Deferred	(489,000)	(294,000)
Total Income Tax Expense	\$ 692,000	\$ 805,000

The total income tax expense differed from the expected tax expense, computed by applying the federal statutory rate to the Company's pretax income, as follows:

	Years Ended June 30,	
	2022	2021
Tax expense at statutory federal rate	\$ 629,000	\$ 665,000
State income tax expense, net of federal tax effect	105,000	110,000
Change in valuation allowance on deferred tax assets	27,000	34,000
Other permanent items	(69,000)	(4,000)
Income tax expense	\$ 692,000	\$ 805,000

The effective tax rates for fiscal 2022 and 2021 were 23.1% and 25.4%, respectively.

The significant components of deferred income taxes were as follows:

	June 30,	
	2022	2021
Deferred tax assets (liabilities):		
Revenue recognition and accounts receivable reserves	\$ 917,000	\$ 655,000
Accrued liabilities	325,000	297,000
Property and equipment	(246,000)	(218,000)
Finite-life intangible assets	(41,000)	(15,000)
Stock options	532,000	414,000
Tax credits	152,000	125,000
Accounting method change	—	(140,000)
Valuation allowance on deferred taxes	(152,000)	(125,000)
Other	51,000	56,000
Net deferred tax assets	<u>\$ 1,538,000</u>	<u>\$ 1,049,000</u>

The Company has state tax credits of \$152,000, net of federal taxes, which if unused, will begin to expire in calendar year 2026. The Company has taken a full valuation allowance against these credits which relate to research and development tax credits in Minnesota, a state in which the Company has a low state apportionment factor.

The Company applies the accounting standard for uncertain tax positions pursuant to which a more-likely-than-not threshold is utilized to determine the recognition and derecognition of uncertain tax positions. Once the more-likely-than-not threshold is met, the amount of benefit to be recognized is the largest amount of tax benefit that is greater than 50 percent likely of being ultimately realized upon settlement. It further requires that a change in judgment related to the expected ultimate resolution of uncertain tax positions be recognized in earnings in the period of such a change. The Company does not have any uncertain tax positions as of June 30, 2022 and June 30, 2021.

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 the Company's fiscal year ended June 30, 2019 are no longer open to federal, state and local examination by taxing authorities. The Company's examination by the Internal Revenue Service (the "IRS") for the fiscal year ended June 30, 2020 is complete and the IRS has no findings. The Company is not under any current income tax examinations by any other state or local taxing authority. If any issues addressed in the Company's tax audits are resolved in a manner not consistent with management's expectations, the Company could be required to adjust its provision for income taxes in the period such resolution occurs.

Note 10. Leases

The Company has leases for office and warehouse space and office equipment that require monthly payments. These leases have payments ranging from \$200 to \$4,700 per month which expire through December 2025 and are recognized on a straight-line basis over the life of the lease. All leases are classified as operating leases which do not include renewal options. The Company currently does not have any short-term or variable lease costs. The Company elected the practical expedient to calculate the present value of the fixed payments without having to perform an allocation to lease and non-lease components.

The Company has recognized right of use assets associated with its operating leases of \$120,000 and \$88,000 as of June 30, 2022 and June 30, 2021, respectively, which is included in other assets on the Company's balance sheet. Operating lease liabilities were \$120,000 and \$87,000 as of June 30, 2022 and June 30, 2021, respectively, which are included in other accrued liabilities and other long-term liabilities on the Company's balance sheet.

As of June 30, 2022, the Company has a weighted-average lease term of 1.1 years for its operating leases, which have a weighted-average discount rate of 4.0%. Operating lease payments of \$94,000 are included in operating cash flows in fiscal 2022.

Maturities of lease liabilities, which are included in other accrued liabilities and other long-term liabilities on the Balance Sheet, are as follows:

Schedule of maturities of lease liabilities

Fiscal years ending June 30:

2023	\$	81,000
2024		17,000
2025		17,000
2026		9,000
Total lease payments		124,000
Less: Interest		(4,000)
Present value of lease liabilities	\$	120,000

Note 11. Commitments and Contingencies

Litigation: The Company is occasionally involved in claims and disputes arising in the ordinary course of business. The Company insures certain 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.

On September 8, 2021 a state court putative class action lawsuit was filed in Minnesota against the Company asserting injury resulting from the previously announced data breach that impacted the Company's customer protected health information and employee personal information and seeking compensatory damages, equitable relief, and attorneys' fees and costs. On October 6, 2021, the proceeding was removed to the District of Minnesota. The Company believes the plaintiff was not injured as a result of the data privacy incident, and, as a result, the claims are without merit. Accordingly, on November 11, 2021, the Company moved to dismiss the complaint in its entirety. Prior to the hearing on the motion to dismiss, the parties agreed in principal to settle the case. The parties are continuing to negotiate the settlement agreement and expect to submit a motion to settle the class action in the near future. If the parties are unable to agree to the settlement terms or, if the Court does not grant the motion for settlement, the Company will continue to vigorously defend the lawsuit; however, at this time, the Company is unable to determine the ultimate outcome or potential exposure to loss, if any.

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 at least 1,000 hours of service with the Company. The Company matches each employee's salary reduction contribution, not to exceed four percent of annual compensation. Total employer contributions to this plan for fiscal 2022 and 2021 were \$461,000 and \$399,000, respectively.

Employment Agreements: The Company has entered into formal employment agreements with its President and Chief Executive Officer, its Interim Chief Financial Officer, and its Chief Commercial Officer, as amended from time to time. These agreements provide these officers with, among other things, twelve to eighteen months of base salary upon a termination without "Cause" or in the event the employee resigns for "Good Reason" or within twelve months of a "Change in Control," as such terms are defined in the respective employment agreements.

Note 12. Related Parties

The Company uses a parts supplier whose founder and president was a director of the Company through November 12, 2021. The Company made payments to the supplier of \$360,000 and \$1,000 during fiscal year 2022 and 2021, respectively. Amounts due to the supplier at June 30, 2022 were \$160,000, which were included in accounts payable on the Balance Sheets. There was no amount due to the supplier at June 30, 2021.

Note 13. Subsequent Events

The Company evaluates, as of each reporting period, events or transactions that occur after the balance sheet date through the date the financial statements are issued for either disclosure or adjustment to the Company's financial results. Except as described below, there have been no events subsequent to June 30, 2022 which would require recognition in the Financial Statements or Notes to the Financial Statements.

Michael J. MacCourt, the Company's former Chief Financial Officer, Treasurer and Secretary, ceased to serve in those positions effective July 1, 2022 at which time the Company terminated its formal employment agreement with Mr. MacCourt.

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

None.

Item 9A. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act, as of the end of the period subject to this Annual Report on Form 10-K. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Internal control over financial reporting refers to the process designed by, or under the supervision of, our President and Chief Executive Officer and our Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting cannot provide absolute assurance of preventing and detecting misstatements on a timely basis. It is possible to design into the process safeguards to reduce, though not eliminate, the risk that misstatements are not prevented or detected on a timely basis. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company.

Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in the report entitled Internal Control-Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on this assessment, management has concluded that, as of June 30, 2022, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the SEC that exempt smaller reporting companies from the auditor attestation requirement.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of fiscal 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Certain information required by Part III is incorporated by reference from our definitive Proxy Statement for the Fiscal 2023 Annual Meeting of Shareholders (the “Proxy Statement”). Except for those portions specifically incorporated in this Annual Report on Form 10-K by reference to the Proxy Statement, no other portions of the Proxy Statement are deemed to be filed as part of this Annual Report on Form 10-K.

Item 10. Directors, Executive Officers and Corporate Governance.

Information about our Executive Officers

The following sets forth certain information about our current executive officers:

Kathleen S. Skarvan, age 66, joined Electromed in December 2012 as Chief Executive Officer, became a director in November 2013 and was appointed to the additional position of President in August 2015. Ms. Skarvan served as Vice President of Operations at OEM Fabricators from November 2011 until October 2012. Prior to her position with OEM Fabricators, Ms. Skarvan served in various roles at Hutchinson Technology Incorporated, most recently as the President of the Disk Drive Components Division from April 2007 until March 2011. As President of the Disk Drive Components Division, Ms. Skarvan managed a public company division with annual revenues in excess of \$300 million. Ms. Skarvan also served as a Senior Vice President of Hutchinson Technology Incorporated from December 2010 to March 2011, and as Vice President of Sales & Marketing of the Disk Drive Components Division from October 2003 until April 2007. She has served on the Board of Trustees of the St. Cloud State University Foundation since June 2015. Ms. Skarvan has a bachelor’s degree from St. Cloud State University.

Michelle C. Wirtz, age 39, joined Electromed in December 2021 as the Company’s Corporate Controller and has served as Electromed’s Interim Chief Financial Officer, Treasurer and Secretary, since June 1, 2022. Prior to joining Electromed, she served as Corporate Controller at Icaro, Inc. from June 2018 to December 2021. She was a senior consultant at Salo LLC from 2016 to June 2018. She began her career in accounting, serving in various roles focused on the life sciences industry at McGladrey & Pullen LLP (now RSM US LLP) and Ernst & Young Global Limited. Ms. Wirtz graduated from North Dakota State University with a degree in Accounting and holds an active Certified Public Accountant (CPA) license in the State of Minnesota.

Christopher G. Holland, age 53, joined Electromed in February 2022 as the Company’s Chief Commercial Officer. Prior to joining Electromed, Mr. Holland was the Vice President of Commercialization at Prosomnus Sleep Technologies, Inc., a Medical Device manufacturer of a mandibular advancement device for sleep apnea where he led new product introduction and revenue-growth initiatives across the enterprise, from August 2021 to February 2022. Prior to his time at Prosomnus, from 2008 to 2020, Mr. Holland served in various positions at Nonin Medical, Inc., a producer of noninvasive pulse oximeters, regional oximeters, and capnographs, including most recently as Executive Vice President, Sales & Global Development from January 2019 to July 2020, and as Chief Commercial Officer and Senior Vice President Global Sales, Marketing, Business Development from 2015 to July 2020. Earlier in his career, Holland held various leadership roles at Cisco Systems and PriceWaterhouseCoopers. Mr. Holland graduated from Minnesota State University with a degree in Computer Science/Math (minor) and obtained a Master in Business Administration (MBA) with Distinction from Jack Welch Management Institute – Strayer University.

Code of Ethics

Our Board annually reviews and approves revisions to our Code of Ethics and Business Conduct (the “Code of Ethics”) that applies to all employees, directors, and officers, including the Chief Executive Officer and the Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer). The Code of Ethics was updated in May 2020 and is available in the “Investor Relations” section of our website at www.smartvest.com. We intend to disclose on our website any amendment to or waiver from any provision of the Code of Ethics that applies to our Chief Executive Officer or our Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), and that relates to any element of the Code of Ethics identified in Item 406(b) of Regulation S-K, as promulgated by the SEC. Such disclosure will be provided promptly following the date of the amendment or waiver.

The additional information required by this item is incorporated herein by reference to the sections labeled “Election of Directors,” “Corporate Governance,” “and “Security Ownership Certain Beneficial Owners and Management” and, if any, under “Delinquent Section 16(a) Reports” in the Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated herein by reference to the sections labeled “Executive Compensation,” “Director Compensation,” and “Corporate Governance – Personnel and Compensation Committee” in the Proxy Statement.

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

The information required by this item relating to the security ownership of certain holders is incorporated herein by reference to the sections labeled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the sections labeled “Corporate Governance–Independence” and “Related Person Transaction Approval Policy” in the Proxy Statement.

Item 14. Principal Accountant Fees and Services.

Our independent registered public accounting firm is RSM US LLP, Rochester, MN, Auditor firm ID: 49.

The information required by this item is incorporated herein by reference to the section labeled “Ratification of the Appointment of the Company's Independent Registered Public Accounting Firm - Audit Fees” in the Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this report.

(1) Financial Statements. The following financial statements are included in Part II, Item 8 of this Annual Report on Form 10-K:

- Report of Independent Registered Public Accounting Firm
- Balance Sheets as of June 30, 2022 and 2021
- Statements of Operations for the years ended June 30, 2022 and 2021
- Statements of Shareholders' Equity for the years ended June 30, 2022 and 2021
- Statements of Cash Flows for the years ended June 30, 2022 and 2021
- Notes to Financial Statements

(2) Financial Statement Schedules. No financial statement schedule is required to be included in this Annual Report on Form 10-K.

Exhibit Number	Description	Method of Filing
<u>3.1</u>	<u>Composite Articles of Incorporation, as amended through November 8, 2010 (incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K for the fiscal year ended June 30, 2015)</u>	Incorporated by Reference
<u>3.2</u>	<u>Amended and Restated Bylaws, effective September 29, 2020 (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed September 29, 2020)</u>	Incorporated by Reference
<u>4.1</u>	<u>Description of Securities (incorporated by reference to Exhibit 4.1 to Annual Report on Form 10-K for the fiscal year ended June 30, 2019)</u>	Incorporated by Reference
<u>10.1</u>	<u>Electromed, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed November 15, 2011)*</u>	Incorporated by Reference
<u>10.2</u>	<u>Form of Stock Option Award Agreement under the Electromed, Inc. 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q for the quarter ended December 31, 2011)*</u>	Incorporated by Reference
<u>10.3</u>	<u>Electromed, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed November 25, 2014)*</u>	Incorporated by Reference
<u>10.4</u>	<u>Form of Incentive Stock Option Agreement under the Electromed, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed November 25, 2014)*</u>	Incorporated by Reference
<u>10.5</u>	<u>Form of Nonqualified Stock Option Agreement under the Electromed, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed November 25, 2014)*</u>	Incorporated by Reference
<u>10.6</u>	<u>Form of Restricted Stock Agreement under the Electromed, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed November 25, 2014)*</u>	Incorporated by Reference
<u>10.7</u>	<u>Electromed, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 99.1 to Registration Statement on Form S-8 filed December 4, 2017)*</u>	Incorporated by Reference
<u>10.8</u>	<u>Form of Restricted Award Agreement under the 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.11 to Annual Report on Form 10-K for the fiscal year ended June 30, 2018)*</u>	Incorporated by Reference
<u>10.9</u>	<u>Form of Non-Qualified Option Agreement under the 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for the quarter ended March 31, 2019)*</u>	Incorporated by Reference
<u>10.10</u>	<u>Form of Restricted Stock Agreement (Non-Employee Directors) under the 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.13 to Annual Report on Form 10-K for the fiscal year ended June 30, 2018)*</u>	Incorporated by Reference
<u>10.11</u>	<u>Non-Competition, Non-Solicitation and Confidentiality Agreement with Kathleen S. Skarvan dated effective December 1, 2012 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed December 3, 2012)*</u>	Incorporated by Reference
<u>10.12</u>	<u>Non-Competition, Non-Solicitation and Confidentiality Agreement with Michelle C. Wirtz dated effective December 20, 2021*</u>	Filed electronically
<u>10.13</u>	<u>Non-Competition, Non-Solicitation and Confidentiality Agreement with Christopher G. Holland dated effective February 16, 2022*</u>	Filed electronically
<u>10.14</u>	<u>Amended and Restated Employment Agreement with Kathleen S. Skarvan dated as of December 2, 2019 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed December 6, 2019)*</u>	Incorporated by Reference
<u>10.15</u>	<u>Employment Agreement with Michelle C. Wirtz dated February 21, 2022 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed June 7, 2022)*</u>	Incorporated by Reference

Exhibit Number	Description	Method of Filing
<u>10.16</u>	<u>Amendment to Employment Agreement with Michelle C. Wirtz, dated June 1, 2022 (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed June 7, 2022)*</u>	Incorporated by Reference
<u>10.17</u>	<u>Employment Agreement with Christopher G. Holland dated February 16, 2022 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 10, 2022)*</u>	Incorporated by Reference
<u>10.18</u>	<u>Business Loan Agreement with Choice Financial Group, dated December 18, 2019 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed December 17, 2019)</u>	Incorporated by Reference
<u>10.19</u>	<u>Rider to Business Loan Agreement (Asset Based) with Choice Financial Group, dated December 18, 2019 (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed December 17, 2019)</u>	Incorporated by Reference
<u>10.20</u>	<u>Rider to Business Loan Agreement (Asset Based) with Choice Financial Group, dated December 16, 2020 (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed December 17, 2020)</u>	Incorporated by Reference
<u>10.21</u>	<u>Rider to Business Loan Agreement (Asset Based) with Choice Financial Group, Dated December 17, 2021 (incorporated by reference to Exhibit 10. 1 to Current Report on 8-K filed December 17, 2021)</u>	Incorporated by Reference
<u>10.22</u>	<u>Cooperation Agreement, dated July 25, 2022, by and among Electromed, Inc. and Summers Value Partners LLC and certain of its affiliates signatory thereto (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed July 25, 2022)</u>	Incorporated by Reference
<u>10.23</u>	<u>Description of Fiscal Year 2022 Officer Bonus Plan (incorporated by reference to Exhibit 10.17 to Annual Report on Form 10-K for the fiscal year ended June 30, 2021)*</u>	Incorporated by Reference
<u>10.24</u>	<u>Description of Fiscal Year 2023 Officer Bonus Plan*</u>	Filed Electronically
<u>23.1</u>	<u>Consent of Independent Registered Public Accounting Firm</u>	Filed Electronically
<u>24.1</u>	<u>Powers of Attorney</u>	Filed Electronically
<u>31.1</u>	<u>Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	Filed Electronically
<u>31.2</u>	<u>Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	Filed Electronically
<u>32.1</u>	<u>Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	Furnished Electronically
<u>32.2</u>	<u>Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	Furnished Electronically
101.CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed Electronically
101.DEF	XBRL Taxonomy Extension Definition Linkbase	Filed Electronically
101.INS	XBRL Instance Document	Filed Electronically
101.LAB	XBRL Taxonomy Extension Label Linkbase	Filed Electronically
101.PRE	XBRL Taxonomy Extension Presentation Linkbase	Filed Electronically
101.SCH	XBRL Taxonomy Extension Schema	Filed Electronically
104	Cover Page Interactive Data File (embedded within the inline XBRL Document)	Filed electronically

* Management compensatory contract or arrangement.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

ELECTROMED, INC.

Date: August 23, 2022

By /s/ Kathleen S. Skarvan
Kathleen S. Skarvan
President 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.

Signature	Title	Date
<u>/s/ Kathleen S. Skarvan</u> Kathleen S. Skarvan	President, Chief Executive Officer and Director (principal executive officer)	August 23, 2022
<u>/s/ Michelle C. Wirtz</u> Michelle C. Wirtz	Interim Chief Financial Officer (principal financial and accounting officer)	August 23, 2022
<u>*</u> Lee A. Jones	Chairman and Director	August 23, 2022
<u>*</u> Stan K. Erickson	Director	August 23, 2022
<u>*</u> Gregory J. Fluet	Director	August 23, 2022
<u>*</u> Joseph L. Galatowitsch	Director	August 23, 2022
<u>*</u> Andrea M. Walsh	Director	August 23, 2022
<u>*</u> Kathleen A. Tune	Director	August 23, 2022
<u>*</u> Andrew J. Summers	Director	August 23, 2022

* The undersigned, by signing her name hereto, does hereby sign this document on behalf of each of the above-named directors of the registrant pursuant to powers of attorney duly executed by such persons.

By /s/ Kathleen S. Skarvan
Kathleen S. Skarvan
Attorney-in-Fact