

ALLIED HEALTHCARE PRODUCTS INC
Form 10-K
September 28, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 June 30, 2017

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 0-19266

ALLIED HEALTHCARE PRODUCTS, INC.

[Exact name of registrant as specified in its charter]

DELAWARE

(State or other jurisdiction of
Incorporation or organization)

25-1370721

(I.R.S. employer identification no.)

1720 Sublette Avenue
St. Louis, Missouri

63110

(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code (314) 771-2400

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$.01	The NASDAQ Stock Market LLC

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 whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.
Yes No

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

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes. No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

Emerging growth company

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

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

As of December 31, 2016, the last business day of the registrant's most recently completed second fiscal quarter; the aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$4,453,744. All executive officers and directors of the registrant and all persons filing a Schedule 13D with the Securities and Exchange Commission in respect to registrant's common stock have been deemed, solely for the purpose of the foregoing calculation, to be "affiliates" of the registrant.

As of September 1, 2017, there were 4,013,537 shares of common stock, \$0.01 par value (the "Common Stock"), outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement to be filed within 120 days after June 30, 2017 (portion) (Part III)

ALLIED HEALTHCARE PRODUCTS, INC.

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“SAFE HARBOR” STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION

REFORM ACT OF 1995

Statements contained in this Report, which are not historical facts or information, are “forward-looking statements.” Words such as “believe,” “expect,” “intend,” “will,” “should,” and other expressions that indicate future events and trends identify such forward-looking statements. These forward-looking statements involve risks and uncertainties, which could cause the outcome and future results of operations and financial condition to be materially different than stated or anticipated based on the forward-looking statements. Such risks and uncertainties include both general economic risks and uncertainties, risks and uncertainties affecting the demand for and economic factors affecting the delivery of health care services, impacts of the U.S. Affordable Care Act and specific matters which relate directly to the Company’s operations and properties as discussed in Items 1, 1A, 3 and 7 of this Report. The Company cautions that any forward-looking statements contained in this report reflect only the belief of the Company or its management at the time the statement was made. Although the Company believes such forward-looking statements are based upon reasonable assumptions, such assumptions may ultimately prove inaccurate or incomplete. The Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement was made. Readers should carefully review all disclosures we file from time to time with the Securities and Exchange Commission which are available on our website at www.alliedhpi.com under “Financial/SEC Filings.”

PART I

Item 1. Business

General

Allied Healthcare Products, Inc. (“Allied”, the “Company”, “we”, or “us”) manufactures a variety of respiratory products used in the health care industry in a wide range of hospital and alternate site settings, including sub-acute care facilities, home health care and emergency medical care. The Company’s product lines include respiratory care products, medical gas equipment and emergency medical products.

The Company’s products are marketed under well-recognized and respected brand names to hospitals, hospital equipment dealers, hospital construction contractors, home health care dealers, emergency medical products dealers and others. Allied’s product lines include:

Respiratory Care Products

respiratory care/anesthesia products

- home respiratory care products

Medical Gas Equipment

- medical gas system construction products
- medical gas system regulation devices
- disposable oxygen and specialty gas cylinders
- portable suction equipment

Emergency Medical Products

- respiratory/resuscitation products
- trauma and patient handling products

The Company's principal executive offices are located at 1720 Sublette Avenue, St. Louis, Missouri 63110, and its telephone number is (314) 771-2400.

Markets and Products

In fiscal 2017, respiratory care products, medical gas equipment and emergency medical products represented approximately 27%, 53% and 20%, respectively, of the Company's net sales. In comparison, in fiscal 2016, respiratory care products, medical gas equipment and emergency medical products represented approximately 25%, 55%, and 20%, respectively, of the Company's net sales. The Company operates in a single industry segment and its principal products are described in the following table:

Product	Description	Principal Brand Names	Primary Users
<i>Respiratory Care Products</i>			
Respiratory Care/Anesthesia Products	Large volume compressors; ventilator calibrators; humidifiers and mist tents; and carbon dioxide absorbent	Timeter®; Carbolime®; Litholyme®	Hospitals and sub-acute facilities
Home Respiratory Care Products	O2 cylinders; pressure regulators; nebulizers; portable large volume compressors; portable suction equipment and disposable respiratory products	Timeter®; B&F®; Schuco®	Patients at home
<i>Medical Gas Equipment</i>			
Construction Products	In-wall medical gas system components; central station pumps and compressors and headwalls	Chemetron®; Oxequip®	Hospitals and sub-acute facilities
Regulation Devices	Flowmeters; vacuum regulators; pressure regulators and related products	Chemetron®; Oxequip®; Timeter®	Hospitals and sub-acute facilities
Disposable Cylinders	Disposable oxygen and gas cylinders	Lif-O-Gen®	First aid providers and specialty gas distributors
Suction Equipment	Portable suction equipment and disposable suction canisters	Gomco®; Allied; Schuco	Hospitals, sub-acute facilities and homecare products
<i>Emergency Medical Products</i>			
Respiratory/Resuscitation	Demand resuscitation valves; bag mask resuscitators; emergency transport ventilators, oxygen regulators, SurgeX - surge suppressing post valve, mass casualty ventilation line, and the AHP300 Ventilator	LSP; Omni-Tech®; Allied	Emergency service providers
Trauma and Patient Handling Products	Spine immobilization products; pneumatic anti-shock garments, trauma burn kits and Xtra backboards	LSP	Emergency service providers

Respiratory Care Products

Market. Respiratory care products are used in the treatment of acute and chronic respiratory disorders such as asthma, emphysema, bronchitis and pneumonia. Respiratory care products are used in both hospitals and alternate care settings. Sales of respiratory care products are made through distribution channels focusing on hospitals and other sub-acute facilities. Sales of home respiratory care products are made through durable medical equipment dealers through telemarketing, and by contract sales with national chains.

Respiratory Care/Anesthesia Products. The Company manufactures and sells a broad range of products for use in respiratory care and anesthesia delivery, including carbon dioxide absorbents. These products include large volume air compressors, calibration equipment, humidifiers, croup tents, equipment dryers and a complete line of respiratory disposable products such as oxygen tubing, facemasks, cannulas and ventilator circuits.

Home Respiratory Care Products. Allied's broad line of home respiratory care products include aluminum oxygen cylinders, oxygen regulators, pneumatic nebulizers, portable suction equipment and a full line of respiratory disposable products.

Medical Gas Equipment

Market. The market for medical gas equipment consists of hospitals, alternate care settings and surgery centers. The medical gas equipment group is broken down into three separate categories: construction products, regulation devices and suction equipment, and disposable cylinders.

Construction Products. Allied's medical gas system construction products consist of in-wall medical system components, central station pumps and compressors, and headwalls. These products are typically installed during construction or renovation of a health care facility and are built in as an integral part of the facility's physical plant. Typically, the contractor for the facility's construction or renovation purchases medical gas system components from manufacturers and ensures that the design specifications of the health care facility are met.

Allied's in-wall components, including outlets, manifolds, alarms, ceiling columns and zone valves, serve a fundamental role in medical gas delivery systems.

Central station pumps and compressors are individually engineered systems consisting of compressors, reservoirs, valves and controls designed to drive a hospital's medical gas and suction systems. Each system is designed specifically for a given hospital or facility, which purchases pumps and compressors from suppliers. The Company's sales of pumps and compressors are driven, in large part, by its share of the in-wall components market.

The Company's construction products are sold primarily to hospitals, alternate care settings and hospital construction contractors. The Company believes that these products are installed in more than three thousand hospitals in the United States. The Company believes that most hospitals and sub-acute care facility construction spending is for expansion or renovation of existing facilities. Many hospital systems and individual hospitals undertake major renovations to upgrade their operations to improve the quality of care they provide, reduce costs and attract patients and personnel.

Regulation Devices and Suction Equipment. The Company's medical gas system regulation products include flowmeters, vacuum regulators and pressure regulators, as well as related adapters, fittings and hoses which measure,

regulate, monitor and help transfer medical gases from walled piping or equipment to patients in hospital rooms, operating theaters or intensive care areas.

Portable suction equipment is typically used when in-wall suction is not available or when medical protocol specifically requires portable suction. The Company also manufactures disposable suction canisters, which are clear containers used to collect the fluids suctioned by in-wall or portable suction systems. The containers have volume calibrations, which allow the medical practitioner to measure the volume of fluids suctioned.

The market for regulation devices and suction equipment includes hospital and sub-acute care facilities. Sales of these products are made through the same distribution channel as our respiratory care products. The Company believes that it holds a significant share of the U.S. market in both regulation devices and suction equipment.

Disposable Cylinders. Disposable oxygen cylinders are designed to provide oxygen for short periods of time in emergency situations. Since they are not subjected to the same pressurization as standard containers, they are much lighter and less expensive than standard gas cylinders. The Company markets filled disposable oxygen cylinders through industrial safety distributors and similar customers, principally to first aid providers, restaurants, industrial plants and other customers that require oxygen for infrequent emergencies.

Emergency Medical Products

Market. Emergency medical products are used in the treatment of trauma-induced injuries. The Company's emergency medical products provide patient resuscitation or ventilation during cardiopulmonary resuscitation or respiratory distress as well as immobilization and treatment for burns. The Company expects that additional countries will develop trauma care systems in the future, although no assurance can be given that such systems will develop or that they will have a favorable impact on the Company. Sales of emergency medical products are made through specialized emergency medical products distributors to ambulance companies, fire departments and emergency medical systems volunteer organizations.

The emergency medical products are broken down into two categories: respiratory/resuscitator products and trauma patient handling products.

Respiratory/Resuscitation Products. The Company's respiratory/resuscitation products include demand resuscitation valves, portable resuscitation systems, bag masks and related products, emergency transport ventilators, precision oxygen regulators, minilators, multilators and humidifiers.

Demand resuscitation valves are designed to provide 100% oxygen to breathing or non-breathing patients. In an emergency situation, they can be used with a mask or tracheotomy tubes and operate from a standard regulated oxygen system. The Company's portable resuscitation systems provide fast, simple and effective means of ventilating a non-breathing patient during cardiopulmonary resuscitation and 100% oxygen to breathing patients on demand with minimal inspiratory effort. The Company also markets a full line of disposable and reusable bag mask resuscitators, which are available in a variety of adult and child-size configurations. Disposable mouth-to-mask resuscitation systems have the added advantage of reducing the risk of transmission of communicable diseases.

The Company's autovent transport ventilator can meet a variety of needs in different applications ranging from typical emergency medical situations to more sophisticated air and ground transport. Each autovent is accompanied by a patient valve, which provides effective ventilation during cardiopulmonary resuscitation or respiratory distress. When administration of oxygen is required at the scene of a disaster, in military field hospitals or in a multiple-victim incident, Allied's minilators and multilators are capable of providing oxygen to one or a large number of patients.

The Company's transport and mass casualty ventilation line has been designed to meet the unique ventilation demands that affect everyday inter-hospital and intra-hospital transport scenarios, and amplify exponentially during a mass casualty event or pandemic. Our ventilators for transport and mass casualty are rugged, easy to operate, and capable of providing reliable ventilation even in unpredictable environments and conditions. Additionally, they are affordable

to purchase and require little periodic maintenance, minimizing the cost of ownership over time.

To complement the family of respiratory/resuscitation products, the Company offers a full line of oxygen product accessories. This line of accessory products includes reusable aspirators, tru-fit masks, disposable cuffed masks and related accessories.

Trauma and Patient Handling Products. The Company's trauma and patient handling products include spine immobilization products, pneumatic anti-shock garments and trauma burn kits. Spine immobilization products include a backboard that is designed for safe immobilization of injury victims and provides a durable and cost effective means of emergency patient transportation and extrication. The infant/pediatric immobilization board is durable and scaled for children. The half back extractor/rescue vest is useful for both suspected cervical/spinal injuries and for mountain and air rescues. The Company's pneumatic anti-shock garments are used to treat victims experiencing hypovolemic shock. Allied's trauma burn kits contain a comprehensive line of products for the treatment of trauma and burns.

Sales and Marketing

Allied sells its products primarily to hospitals, hospital equipment dealers, hospital construction contractors, home health care dealers, emergency medical products dealers and others. The Company maintains a sales force of 17 sales professionals, all of whom are full-time employees of the Company.

The sales force includes seven domestic hospital, homecare and emergency specialists, five domestic construction specialists, and three international sales representatives. A total of two sales managers lead the sales groups. A product manager is responsible for the marketing activities of our product lines.

The domestic hospital specialists are responsible for sales of all Allied products with the exception of construction products within their territory. Sales of hospital products are accomplished through respiratory care/anesthesia distributors for the regulation devices, suction equipment, respiratory care/anesthesia products and disposable cylinders. The domestic construction specialists are responsible for sales of all Allied construction products within their territory. Emergency products are principally sold to ambulance companies, fire departments and emergency medical systems volunteer organizations through specialized emergency medical products distributors.

Construction products are sold direct to hospital construction contractors and through distributors.

The Company's international specialists sell all Allied products within their territory. Allied's net sales to foreign markets totaled 22% of total net sales in fiscal 2017, 24% in 2016 and 23% in 2015. International sales are made through a network of dealers, agents and U.S. exporters who distribute the Company's products throughout the world. Allied has market presence in Canada, Mexico, Central and South America, Europe, the Middle East and the Far East.

Manufacturing

Allied's manufacturing processes include fabrication, electro-mechanical assembly operations, plastics manufacturing, and chemical processing with automated packaging. A significant part of Allied's manufacturing operations involves electro-mechanical assembly of proprietary products and the Company is vertically integrated in most elements of metal machining and fabrication. Most of Allied's hourly employees are involved in machining, metal fabrication, plastics manufacturing and product assembly.

Allied manufactures small metal components from bar stock in a machine shop, which includes automatic screw machines, horizontal lathes and drill presses and computer controlled machining centers. The Company makes larger metal components from sheet metal using computerized punch presses, brake presses and shears. In its plastics manufacturing processes, the Company utilizes both extrusion and injection molding. In its chemical process, the Company utilizes mixing, drying, and sizing equipment. The Company believes that its production facilities and equipment are in good condition and sufficient to meet planned increases in volume over the next few years and that the conditions in local labor markets should permit the implementation of additional shifts and days operated.

Research and Development

Allied Healthcare Products' research and development group is responsible for the development of new products. This group is staffed with mechanical and electrical engineers.

During fiscal year 2017 the research and development group continued to provide post-launch support of the AHP300 and AHP300P ventilators.

The group is actively working on other products that were not released during the fiscal year 2017.

Government Regulation

The Company's products and its manufacturing activities are subject to extensive and rigorous government regulation by federal and state authorities in the United States and other countries. In the United States, medical devices for human use are subject to comprehensive review by the United States Food and Drug Administration (the "FDA"). The Federal Food, Drug, and Cosmetic Act ("FDC Act"), and other federal statutes and regulations, govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, advertising and promotion of such products. Noncompliance with applicable requirements can result in warning letters, fines, recall or seizure of products, injunction, refusal to permit products to be imported into or exported out of the United States, refusal of the government to clear or approve marketing applications or to allow the Company to enter into government supply contracts, or withdrawal of previously approved marketing applications and criminal prosecution.

The Company is required to file a premarket notification in the form of a premarket approval ("PMA") with the FDA before it begins marketing a new medical device that offers new technology that is currently not on the market. The Company also must file a premarket notification in the form of a 510(k) with the FDA before it begins marketing a new medical device that utilizes existing technology for devices that are currently on the market. The 510(k) submission process is also required when the Company makes a change or modifies an existing device in a manner that could significantly affect the device's safety or effectiveness.

Compliance with the regulatory approval process in order to market a new or modified medical device can be uncertain, lengthy and, in some cases, expensive. There can be no assurance that necessary regulatory approvals will be obtained on a timely basis, or at all. Delays in receipt or failure to receive such approvals, the loss of previously received approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company manufactures and distributes a broad spectrum of respiratory therapy equipment, emergency medical equipment and medical gas equipment. To date, all of the Company's FDA clearances have been obtained through the 510(k) clearance process. These determinations are very fact specific and the FDA has stated that, initially, the manufacturer is best qualified to make these determinations, which should be based on adequate supporting data and documentation. The FDA however, may disagree with a manufacturer's determination not to file a 510(k) and require the submission of a new 510(k) notification for the changed or modified device. Where the FDA believes that the change or modification raises significant new questions of safety or effectiveness, the agency may require a manufacturer to cease distribution of the device pending clearance of a new 510(k) notification. Certain of the Company's medical devices have been changed or modified subsequent to 510(k) marketing clearance of the original device by the FDA. Certain of the Company's medical devices, which were first marketed prior to May 28, 1976, and therefore, grandfathered and exempt from the 510(k) notification process, also have been subsequently changed or modified. The Company believes that these changes or modifications do not significantly affect the devices' safety or effectiveness, or make a major change or modification in the devices' intended uses and, accordingly, submission of new 510(k) notification to the FDA is not required. There can be no assurance, however, that the FDA would agree

with the Company's determinations.

In addition, commercial distribution in certain foreign countries is subject to additional regulatory requirements and receipt of approvals that vary widely from country to country. The Company believes it is in compliance with regulatory requirements of the countries in which it sells its products.

The Medical Device Reporting regulation requires that the Company provide information to the FDA on deaths or serious injuries alleged to have been associated with the use of its devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The Medical Device Tracking regulation requires the Company to adopt a method of device tracking of certain devices, such as ventilators, which are life-supporting or life-sustaining devices used outside of a device user facility, some of which are permanently implantable devices. The regulation requires that the method adopted by the Company will ensure that the tracked device can be traced from the device manufacturer to the person for whom the device is indicated (i.e., the patient). In addition, the FDA prohibits a company from promoting an approved device for unapproved applications and reviews a company's labeling for accuracy. Labeling and promotional activities also are in certain instances, subject to scrutiny by the Federal Trade Commission.

The Company's medical device manufacturing facilities are registered with the FDA, and have received ISO 9001 certification under the Medical Device Directive (MDD - European) for certain products in 1998, and ISO 13485 certification in 2002. The Company's St. Louis facility is ISO 9001:2008 certified and ISO13485:2003 certified. The Company's Stuyvesant Falls facility is ISO13485:2003 certified. The Company is subject to audit by the FDA, International Organization for Standardization ("ISO"), and European auditors for compliance with the Good Manufacturing Practices ("GMP"), the ISO, CMDCAS, and MDD regulations for medical devices. These regulations require the Company to manufacture its products and maintain its products and documentation in a prescribed manner with respect to design, manufacturing, testing and control activities. The Company also is subject to the registration and inspection requirements of state regulatory agencies.

There can be no assurance that any required FDA or other governmental approval will be granted, or, if granted, will not be withdrawn. Governmental regulation may prevent or substantially delay the marketing of the Company's proposed products and cause the Company to undertake costly procedures. In addition, the extent of potentially adverse government regulation that might arise from future administrative action or legislation cannot be predicted. Any failure to obtain, and maintain, such approvals could adversely affect the Company's ability to market its products or proposed products.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Medical products shipped to the European Community generally require CE certification. The letters "CE" are an abbreviation of Conformité Européenne, French for European conformity. Whether or not FDA approval has been obtained, approval of a device by a comparable regulatory authority of a foreign country generally must be obtained prior to the commencement of marketing in those countries. The time required to obtain such approvals may be longer or shorter than that required for FDA approval. In addition, FDA approval may be required under certain circumstances to export certain medical devices.

The Company is also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protections, fire hazard control and disposal of hazardous or potentially hazardous substances.

Patents, Trademarks and Proprietary Technology

The company owns and maintains domestic and foreign patents on several products it believes are useful to the business and provided the Company with an advantage over its competitors. During fiscal 2017 the company received a total of 6 U.S. and foreign patents for the AHP300 ventilator. The company continues to seek U.S. and foreign patents on the EPV200 and AHP300 ventilators.

Patents which will expire in the period of 2017 to 2034 in the aggregate are believed to be of material importance in the operation of Allied's business. Allied believes no single patent, except that related to Litholyme®, is material in relation to Allied's future business as a whole. Although the expiration of an individual patent may lead to increased competition, other factors such as a competitor's need to obtain regulatory approvals prior to marketing a competitive product and the nature of the market, may allow Allied to continue to have commercial advantages after the expiration of the patent.

The company owns and maintains U.S. trademarks for Allied Healthcare Products Inc., Chemetron®, Gomco®, Oxequip®, Lif-O-Gen®, Life Support Products®, Timeter®, Vacutron® and Schuco®, its principle trademarks. Registrations for these trademarks are also owned and maintained in countries where such products are sold and such registrations are considered necessary to preserve the Company's proprietary rights therein.

Environmental and Safety Regulation

The Company is subject to federal, state and local environmental laws and regulations that impose limitations on the discharge of pollutants into the environment and establish standards for the treatment, storage and disposal of toxic and hazardous wastes. The Company is also subject to the Federal Occupational Safety and Health Act and similar state statutes. From time to time, the Company has been involved in environmental proceedings involving cleanup of hazardous waste. There are no such material proceedings currently pending. Costs of compliance with environmental, health and safety requirements have not been material to the Company. The Company believes it is in material compliance with all applicable environmental laws and regulations.

Competition

The Company has different competitors within each of its product lines. Many of the Company's principal competitors are larger than the Company and have greater financial and other resources. The Company competes primarily on the basis of price, quality and service. The Company believes that it is well positioned with respect to product cost, brand recognition, product reliability, and customer service to compete effectively in each of its markets.

Employees

At June 30, 2017, the Company had approximately 218 full-time employees. Approximately 130 employees in the Company's principal manufacturing facility located in St. Louis, Missouri, are covered by a collective bargaining agreement that will expire on May 31, 2018.

Executive Officers of the Registrant

This section provides information regarding the executive officers of the Company who are appointed by and serve at the pleasure of the Board of Directors:

Name	Age	Position
Earl R. Refsland	74	Director, President and Chief Executive Officer (1)
Andrew D. Riley	41	Vice President of Operations (2)
Daniel C. Dunn	57	Vice President of Finance, Chief Financial Officer, Secretary & Treasurer (3)

(1) Mr. Refsland has been Director, President and Chief Executive Officer of the Company since September, 1999.

Mr. Riley has been Vice President — Operations since July, 2014. He previously held the position of Director of (2) Operations and Plant Manager from January 2012 to July 2014. Prior to that time, Mr. Riley held multiple leadership positions at Owens Corning from 2005 to 2012.

Mr. Dunn has been Vice President — Finance, Chief Financial Officer, Secretary and Treasurer since July, 2001. He (3) previously held the position of Director of Finance at MetalTek International from 1998 to 2001. Prior to that time, Mr. Dunn held the position of Corporate Controller at Allied Healthcare Products, Inc. from 1994 to 1998.

Item 1A. Risk Factors

The Company's business, operations and financial condition are subject to various risks and uncertainties. You should carefully consider the risks and uncertainties described below, together with all of the other information in this annual report on Form 10-K and in the Company's other filings with the Securities and Exchange Commission ("SEC") before making any investment decision with respect to the Company's securities. The risks and uncertainties described below may not be the only ones the Company faces. Additional risks and uncertainties not presently known by the Company or that the Company currently deems immaterial may also affect the Company's business. If any of these known or unknown risks or uncertainties actually occur or develop, the Company's business, financial condition, and results of operations could change.

We participate in a highly competitive environment.

The medical device industry is characterized by rapid technological change, changing customer needs and frequent new product introductions. Our products may be rendered obsolete as a result of future innovations. We face intense competition from other manufacturers. Some of our competitors may be larger than we are and may have greater financial, technical, research, marketing, sales, distribution and other resources than we do. We believe that price competition will continue among products developed in our markets. Our competitors may develop or market technologies and products that are more effective or commercially attractive than any we are developing or marketing. Our competitors may succeed in obtaining regulatory approval and introducing or commercializing products before we do. Such developments could have a significant negative effect on our business, financial condition and results of operations. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

Decreased availability or increased costs of raw materials could increase our costs of producing our products.

We purchase raw materials, fabricated components and services from a variety of suppliers. Raw materials such as brass, plastics, and calcium hydroxide are considered key raw materials. We believe that our relationships with our suppliers are satisfactory and that alternative sources of supply are readily available. From time to time, however, the prices and availability of these raw materials fluctuate due to global market demands, which could impair the company's ability to procure necessary materials, or increase the cost of such materials. Inflationary and other increases in costs of these raw materials have occurred in the past and may recur from time to time. In addition, freight costs associated with shipping and receiving product and sales are impacted by fluctuations in the cost of oil and gas. A reduction in the supply or increase in the cost of those raw materials could impact our ability to manufacture our products and could increase the cost of production.

Changes in third party reimbursement could negatively impact our revenues and profitability.

The cost of a majority of medical care in the United States is funded by the U.S. Government through the Medicare and Medicaid programs and by private insurance programs, such as corporate health insurance plans. Although we do not receive payments for our products directly from these programs, home respiratory care providers and durable medical equipment suppliers, who are the primary customers for several of our products, depend heavily on payments from Medicare, Medicaid and private insurers as a major source of revenues. In addition, sales of certain of our products are affected by the extent of hospital and health care facility construction and renovation at any given time. The federal government indirectly funds a significant percentage of such construction and renovation costs through Medicare and Medicaid reimbursements. In recent years, governmentally imposed limits on reimbursement to hospitals and other health care providers have impacted spending for services, consumables and capital goods. A material decrease from current reimbursement levels or a material change in the method or basis of reimbursing health care providers is likely to adversely affect future sales of our products.

Our success depends upon the development of new products and product enhancements, which entails considerable time and expense.

We place a high priority on the development of new products to add to our product portfolio and on the development of enhancements to our existing products. Product development involves substantial expense and we cannot be certain that a completed product will generate sufficient revenue for our business to justify the resources that we devote to research and development related to such product. The time and expense required to develop new products and product enhancements is difficult to predict and we cannot assure you that we will succeed in developing, introducing and marketing new products and product enhancements. Our inability to successfully develop and introduce new or enhanced products on a timely basis or at all, or to achieve market acceptance of such products, could materially impair our business.

We are dependent on adequate protection of our patent and proprietary rights.

We rely on patents, trade secrets, trademarks, copyrights, know-how, license agreements and contractual provisions to establish and protect our intellectual property rights. However, these legal means afford us only limited protection and may not adequately protect our rights or remedies to gain or keep any advantages we may have over our competitors. We cannot assure you that others may not independently develop the same or similar technologies or otherwise obtain access to our technology and trade secrets. Our competitors, many of which have substantial resources and may make substantial investments in competing technologies, may apply for and obtain patents that will prevent, limit, or interfere with our ability to manufacture or market our products. Further, while we do not believe that any of our products or processes interfere with the rights of others, third parties may nonetheless assert patent infringement claims against us in the future.

Costly litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how we own, to defend us against claimed infringement of the rights of others or to determine the ownership, scope, or validity of our proprietary rights and the rights of others. Any claims of infringement against us may involve significant liabilities to third parties, could require us to seek licenses from third parties, and could prevent or delay us from manufacturing, selling, or using our products. The occurrence of such litigation or the effect of an adverse determination in any of this type of litigation could have a material adverse effect on our business, financial condition and results of operations.

Our business of manufacturing, marketing, and selling of medical devices involves the risk of liability claims and such claims could seriously harm our business, particularly if our insurance coverage is inadequate.

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Like other participants in the medical device market, we are from time to time involved in lawsuits, claims and proceedings alleging product liability and related claims such as negligence. If any current or future product liability claims become substantial, our reputation could be damaged significantly, thereby harming our business. We may be required to pay substantial damage awards as a result of any successful product liability claims. Any product liability claim against us, whether with or without merit, could result in costly litigation, and divert the time, attention, and resources of our management.

As a result of our exposure to product liability claims, we currently carry product liability insurance covering our products with policy limits per occurrence and in the aggregate that we have deemed to be sufficient. Our insurance may not cover certain product liability claims or our liability for any claims may exceed our coverage limits. Therefore, we cannot predict whether this insurance is sufficient, or if not, whether we will be able to obtain sufficient insurance to cover the risks associated with our business or whether such insurance will be available at premiums that are commercially reasonable. In addition, these insurance policies must be renewed annually. Although we have been able to obtain liability insurance, such insurance may not be available in the future on acceptable terms, if at all. A successful claim against us or settlement by us with respect to uninsured liabilities or in excess of our insurance coverage, or our inability to maintain insurance in the future, or any claim that results in significant costs to or adverse publicity against us, could have a material adverse effect on our business, financial condition and results of operations.

We are subject to substantial domestic and international government regulation, including regulatory quality standards applicable to our manufacturing and quality processes. Failure by us to comply with these standards could have an adverse effect on our business, financial condition or results of operations.

The FDA regulates the approval, manufacturing, and sales and marketing of many of our products in the U.S. Significant government regulation also exists in Canada, Japan, Europe, and other countries in which we conduct business. As a device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation ("QSR") requirements, which require manufacturers

of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. 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. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Failure to comply with current governmental regulations and quality assurance guidelines could lead to temporary manufacturing shutdowns, product recalls or related field actions, product shortages or delays in product manufacturing. Efficacy or safety concerns, an increase in trends of adverse events in the marketplace, and/or manufacturing quality issues with respect to our products could lead to product recalls or related field actions, withdrawals, and/or declining sales.

Our products may be subject to product recalls even after receiving FDA clearance or approval, which would harm our reputation and our business.

The FDA and similar governmental authorities in other countries in which our products are sold, have the authority to request and, in some cases, require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects. Any recall of product would divert managerial and financial resources, may harm our reputation with our customers and could damage our business.

We are exposed to certain credit risks, resulting primarily from customer sales.

Substantially all of our receivables are due from homecare providers, distributors, hospitals, and contractors. Our customers are located throughout the U.S. and around the world. We record an estimated allowance for uncollectible amounts based primarily on our evaluation of the payment pattern, financial condition, cash flows, and credit history of our customers, as well as current industry and economic conditions. Our inability to collect on our trade accounts receivable could substantially reduce our income and have a material adverse effect on our financial condition and results of operations.

Our common stock is thinly traded and its market price may fluctuate widely.

Our common stock is listed on the NASDAQ Capital Market but is thinly traded. As a result, stockholders may not be able to sell shares of common stock on short notice. Additionally, the market price of our common stock could be subject to significant fluctuations in response to quarter-to-quarter variation in our operating results, announcements of new products or services by us or our competitors, and other events or factors. For example, a shortfall in net sales or net income, or an increase in losses could have an immediate and significant adverse effect on the market price and volume fluctuations that have particularly affected the market prices of many micro and small capitalization companies and that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations, as well as general economic and market conditions, may adversely affect the market price for our common stock.

If a natural or man-made disaster strikes our manufacturing facilities, we may be unable to manufacture certain products for a substantial amount of time and our revenue could decline.

We have two manufacturing operations. In the event that one of these facilities were severely damaged or destroyed as a result of a natural or man-made disaster we would be forced to relocate production to other facilities and/or rely on third-party manufacturers. Such an event could have a material adverse effect on our business, results of operations and financial condition. Although we have insurance for damage to our property and the interruption of our business, this insurance may not be sufficient in scope or amount to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

If we are unable to hire or retain key employees, it could have a negative impact on our business.

Our failure to attract and retain skilled personnel could hinder the management of our business, our research and development, our sales and marketing efforts, and our manufacturing capabilities. However, there is no assurance that we will continue to be able to hire or retain key employees. We compete to hire new employees, and then must train them and develop their skills and competencies. Our operating results could be adversely affected by increased costs due to increased competition for employees, higher employee turnover or increased employee benefit costs. Any unplanned turnover could deplete our institutional knowledge base and erode our competitive advantage.

The U.S. healthcare environment is changing in many ways, some of which may not be favorable to us, as a result of federal healthcare legislation enacted in 2010.

Our products and services are primarily intended to function within the current structure of the healthcare industry in the United States. In recent years, the healthcare industry has undergone significant changes designed to control costs. The use of managed care has increased; Medicare and Medicaid reimbursement levels have declined; distributors, manufacturers, healthcare providers have consolidated; and large, sophisticated purchasing groups have become more prevalent.

In March 2010, Congress approved, and the President signed into law, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (collectively the "Healthcare Reform Acts"). Among other things, the Healthcare Reform Acts seek to expand health insurance coverage to approximately 32 million uninsured Americans. Many of the significant changes in the Healthcare Reform Acts did not take effect until 2014, including a requirement that most Americans carry health insurance. The Healthcare Reform Acts contain many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid. Beginning in 2013, each medical device manufacturer must now pay a tax in an amount equal to 2.3% of the price for which the manufacturer sells its medical devices, as discussed in "Item 7- Management's Discussion and Analysis of Financial Condition and Results of Operations" below. We manufacture and sell devices that are subject to this tax. On December 18, 2015, The Consolidated Appropriations Act, 2016 was signed into law. This Act included a moratorium on the medical device tax during the period beginning on January 1, 2016, and ending on December 31, 2017. If the moratorium expires as scheduled, our costs will increase as a result of this tax.

We also could be adversely affected by, among other things, changes in the delivery or pricing of or reimbursement for medical devices.

Other provisions of this law as currently enacted, including an independent payment advisory board and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered, and may adversely affect our business and results of operations. Further, we cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation in the U.S. or internationally. However, any changes that lower reimbursements for our products, reduce medical procedure volumes or increase cost containment pressures on us or other participants in the healthcare industry could adversely affect our business and results of operations.

Regulations related to conflict minerals could adversely impact our business.

The Dodd-Frank Wall Street Reform and Consumer Protection Act contains provisions to improve transparency and accountability concerning the supply of certain minerals, known as conflict minerals, originating from the Democratic Republic of Congo (DRC) and adjoining countries. As a result, in August 2012 the SEC adopted annual disclosure and reporting requirements for those companies who use conflict minerals mined from the DRC and adjoining countries in their products. These new requirements required due diligence efforts beginning in fiscal 2014, with initial disclosure requirements which began in May 2014. There were and continue to be costs associated with complying with these disclosure requirements, including for diligence to determine the sources of conflict minerals used in our products and other potential changes to products, processes or sources of supply as a consequence of such verification activities. The implementation of these rules could adversely affect the sourcing, supply and pricing of materials used in our products. The limited information provided by the suppliers in response to the survey in some cases did not identify the facilities used to process or the country of origin of the necessary conflict minerals in its products. As there may be only a limited number of suppliers offering “conflict free” conflict minerals, we cannot be sure that we will be able to obtain necessary conflict minerals from such suppliers in sufficient quantities or at competitive prices. Also, we may face reputational challenges if we determine that certain of our products contain minerals not determined to be conflict free or if we are unable to sufficiently verify the origins for all conflict minerals used in our products through the procedures we may implement.

We have a history of net losses in fiscal 2015, 2016 and 2017 and we may not be able to return to profitability in the future, which may cause the market price of our common stock to decline.

We have a history of net losses. We reported a net loss of \$1.8 million in fiscal 2015, a net loss of \$2.3 million in fiscal 2016 and a net loss of \$2.1 million in fiscal 2017. We will need to generate and sustain increased sales levels in the future to become consistently profitable, and, even if we do, we may not be able to maintain or increase our level of profitability. We intend to improve our sales execution both domestically and internationally and also expand markets for our new ventilator products and our new carbon dioxide absorbent, Litholyme®. However, there is no guarantee that we will be successful in our efforts. We may also incur losses in the future for a number of reasons, including the other risks described in this Form 10-K, and unforeseen expenses, difficulties, complications and delays and other unknown events. If we are unable to achieve and sustain profitability, the market price of our common stock may significantly decrease.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

The Company's headquarters are located in St. Louis, Missouri and the Company maintains manufacturing facilities in Missouri and New York. Set forth below is certain information with respect to the Company's manufacturing facilities at June 30, 2017.

Location	Square Footage (Approximate)	Owned/Leased	Activities/Products
St. Louis, Missouri	242,000	Owned	Headquarters; medical gas equipment; respiratory care products; emergency medical products
Stuyvesant Falls, New York	30,000	Owned	Carbon dioxide absorbent

In addition, the Company owns a 16.8-acre parcel of undeveloped land in Stuyvesant Falls, New York.

Item 3. *Legal*