

ALLIED HEALTHCARE PRODUCTS INC
Form 10-K
September 25, 2009

**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, 2009**

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

25-1370721

(State or Other Jurisdiction of
Incorporation or Organization)

(I.R.S. Employer
Identification No.)

1720 Sublette Avenue
St. Louis, Missouri
(Address of Principal Executive Offices)

63110
(Zip Code)

Registrant's Telephone Number, Including Area Code (314) 771-2400

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

Title of Each Class	Name of Each Exchange on Which Registered
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

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, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12 b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

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, 2008, 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 \$14,298,175.

As of September 19, 2009, there were 8,091,886 shares of common stock, \$0.01 par value (the Common Stock), outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement to be dated October 9, 2009 (portion) (Part III)

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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, and specific matters which relate directly to the Company's operations and properties as discussed in Items 1, 1A, 3 and 7 in 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.

PART I

Item 1. Business

General

Allied Healthcare Products, Inc. (Allied or the Company) 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 believes that it maintains significant market shares in selected product lines.

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

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

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In fiscal 2009, respiratory care products, medical gas equipment and emergency medical products represented approximately 24%, 57% and 19%, respectively, of the Company's net sales. In comparison, in fiscal 2008, 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
Respiratory Care Products			
Respiratory Care/ Anesthesia Products	Large volume compressors; ventilator calibrators; humidifiers and mist tents; and CO2 absorbent	Timeter	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
Medical Gas Equipment			
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
Emergency Medical Products			
Respiratory/Resuscitation	Demand resuscitation valves; bag mask resuscitators; emergency transport ventilators, oxygen regulators, SurgeX surge suppressing post valve, and mass casualty ventilation line	LSP; Omni-Tech	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.

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Respiratory Care/Anesthesia Products. The Company manufactures and sells a broad range of products for use in respiratory care and anesthesia delivery. 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. Home respiratory care products represent one of Allied's potential growth areas. Allied's broad line of home respiratory care products include aluminum oxygen cylinders, oxygen regulators, pneumatic nebulizers, portable suction equipment and the 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 it holds a major share of the U.S. market for its construction products, that these products are installed in more than three thousand hospitals in the United States and that its installed base of equipment in this market will continue to generate follow-on sales. 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. The Company's leadership position in the in-wall components market provides a competitive advantage in marketing medical gas system regulation devices that are compatible with those components.

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.

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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 has seen growth in the trauma care venue for health care services, as the trend continues toward providing health care outside the traditional hospital setting. The Company also expects that other 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 mass casualty ventilation line has been designed to meet the unique ventilation demands that can occur during a mass casualty event or pandemic. The mass casualty products are lightweight, robust, and easy to operate.

Designed for surge capacity, these products are capable of providing reliable ventilation even in unpredictable environments and conditions, and require minimal periodic maintenance.

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.

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Sales and Marketing

Allied sells its products primarily to respiratory care/anesthesia product distributors, hospital construction contractors, emergency medical equipment dealers and directly to hospitals. The Company maintains a sales force of 34 sales professionals, all of whom are full-time employees of the Company.

The sales force includes 10 domestic hospital specialists, 10 domestic construction specialists, 4 emergency specialists and 6 international sales representatives. A total of four sales managers lead each of the sales groups. Two product managers are 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. The domestic construction specialists are responsible for sales of all Allied construction products within their territory. Sales of products are accomplished through respiratory care/anesthesia distributors for the regulation devices, suction equipment, respiratory care/anesthesia products and disposable cylinders. The homecare products are sold primarily through our own in house telemarketing. Construction products are sold direct to hospital construction contractors and through distributors.

Emergency medical specialists are responsible for sales of respiratory/resuscitation products, trauma and patient handling products. These products are principally sold to ambulance companies, fire departments and emergency medical systems volunteer organizations through specialized emergency medical products distributors.

The international specialists sell all Allied products within their territory. Allied's net sales to foreign markets totaled 19% of the Company's net sales in fiscal 2009, compared to 19% in fiscal 2008, and 18% in fiscal 2007. 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 and plastics manufacturing. 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. 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's research and development department group is responsible for the development of new products. This group is staffed with mechanical and electrical engineers.

During fiscal year 2008 the Autovent 4000 family of ventilators were released for production. These ventilators add models with new features to the existing Autovent line.

During fiscal year 2009 the research and development group has completed the design and released to production the EPV100 ventilator, MCV100 Mass Casualty Ventilator, MCV200 Mass Casualty Ventilator, and EPV200 ventilator.

This line of ventilators has been designed to meet the needs of the mass casualty and pandemic markets.

As part of the agreement relating to the withdrawal of the Baralyme® product in August 2004, Abbott Laboratories agreed to pay to Allied up to \$2,150,000 in product development costs to pursue development of a new carbon dioxide absorption product for use in connection with inhalation anesthetics that does not contain potassium hydroxide and does not produce a significant exothermic reaction with currently available

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inhalation agents. Allied has pursued development of a new carbon dioxide absorption product. As of June 30, 2009 the Company had been reimbursed \$2,150,000 by Abbott. More detailed information concerning this agreement is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

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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. The Company's St. Louis facility is ISO 9000 certified. The Company is subject to audit by the FDA, ISO, and European auditors for compliance with the Good Manufacturing Practices (GMP), the ISO 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 patents on several products it believes is useful to the business and provides the company with an advantage over its competitors. During fiscal 2009 the company continued to pursue patents on the construction alarm, Resuscitimer, Mask Restraint system and the EPV100 ventilator.

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 principal 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 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 clean up 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.

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Competition

The Company has different competitors within each of its product lines. Many of the Company's principal competitors are larger than Allied and the Company believes that most of these competitors 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, 2009, the Company had approximately 350 full-time employees. Approximately 226 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, 2012.

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	66	Director, President and Chief Executive Officer ⁽¹⁾
Eldon P. Rosentrater	55	