ALLIED HEALTHCARE PRODUCTS INC
Form 10-K
September 28, 2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year June 30, 2007

or

o **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. o No. þ

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

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. þ No. o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. þ

Indicate by check mark whether the registrant is large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12 b-2 of the Exchange Act. (Check one):
Large accelerated filer o Accelerated filer o Non-accelerated filer þ

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

As of December 31, 2006, 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 $23,853,382.

As of September 28, 2007, there were 7,883,577 shares of common stock, $0.01 par value (the Common Stock), outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement to be dated October 8, 2007 (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, 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

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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Markets and Products

In fiscal 2007, respiratory care products, medical gas equipment and emergency medical products represented approximately 25%, 58% and 17%, respectively, of the Company s net sales. In fiscal 2006, respiratory care products, medical gas equipment and emergency medical products represented approximately 25%, 57%, and 18%, 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 CO_2 absorbent	Timeter	Hospitals and sub-acute facilities
Home Respiratory Care Products	O_2 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 and SurgeX surge suppressing post valve	LSP; Omni-Tech LSP	Emergency service providers

Trauma and Patient Handling Products	Spine immobilization products; pneumatic anti-shock garments, trauma burn kits and Xtra backboards	Emergency service providers

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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. 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.

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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 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.

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 36 sales professionals, all of whom are full-time employees of the Company.

The sales force includes 11 domestic hospital specialists, 11 domestic construction specialists, 3 emergency specialists and 5 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 18% of the Company s net sales in fiscal 2007, 18% of the Company s net sales in fiscal 2006, and 17% of the Company s net sales in fiscal 2005. 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 2007 the research and development group completed the design and released to manufacturing the ResusciTimer. This is an accessory for a bag mask resuscitator that will help EMS personnel use the bag mask per the American Heart Association guidelines.

The research and development group has also completed the design and received FDA approval for new models of the Autovent family of pneumatically powered ventilators. These ventilators will be released for sale in the first quarter of fiscal year 2008.

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

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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 inhalation agents. It is Allied s intention to pursue development of a new carbon dioxide absorption product. As of June 30, 2007 the Company had spent $854,000 to pursue development of a new carbon dioxide absorbent. As of June 30, 2007 the Company had been reimbursed $720,000 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

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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 for the St. Louis facility and certification per the Medical Device Directive (MDD European) for certain products in 1998. As such, the Company will be audited 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, or delay in obtaining, such approvals could adversely affect the Company s ability to market its 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 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 has also received ISO 13485 Certification for medical device manufacturers in 2002.

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 2007 the company was granted two additional US patents on the SurgeX post valve for oxygen cylinders. The SurgeX opens slowly to prevent the fire hazards that are associated with opening conventional post valves quickly. The company continues to pursue patents on the Construction alarm, ResusciTimer and the ventilator products under development.

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.

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.

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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	64	Director, President and Chief Executive Officer(1)
Richard A. Setzer	51	Vice President of Sales & Marketing(2)
Eldon P. Rosentrater	53	Vice President of Administration & Corporate Planning(3)
Robert B. Harris	50	Vice President of Operations(4)
Daniel C. Dunn	48	Vice President of Finance, Chief Financial Officer, Secretary & Treasurer(5)

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

(2) Mr. Setzer has been Vice President Sales and Marketing of the Company since November 1, 2005. He previously held the position of Global Integration Manager for the Health Imaging Division of Eastman Kodak from 2003 to 2005. Prior to that time, Mr. Setzer held the position of Vice President of Sales at Fuji Medical Systems USA from 2002 to 2003.

(3) Mr. Rosentrater has been Vice President-Administration/Corporate Planning of the Company since March, 2003. He previously held the position of Vice President Operations from October 1999 to 2003. Prior to that time, Mr. Rosentrater held the positions of Assistant to the President from 1998 to 1999; Director of Information Technologies from 1995 to 1998; Director of Business Development from 1993 to 1995 and Group Product Manager from 1989 to 1993.

(4) Mr. Harris has been Vice President Operations since July, 2006. He previously held the positions for Command Medical Products, Inc. of Vice President Operations from January 2002 to January 2006 and Director of Operations from October 1999 to December 2001. Prior to that time, Mr. Harris held the position of Plant Manager for Sherwood Medical, a subsidiary of Tyco Healthcare from 1997 to 1999.

(5) Mr. Dunn has been Vice President Finance, Chief Financial Officer, Secretary and Treasurer since July, 2001. He 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.

Employees

At June 30, 2007, the Company had approximately 384 full-time employees. Approximately 255 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, 2009.

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.

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 SEC, before making any investment

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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.

The Company participates 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 the company s costs of producing its products.

The company purchases raw materials, fabricated components and services from a variety of suppliers. Raw materials such as brass and plastics are considered key raw materials. The Company believes that its relationships with its 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 the company s ability to manufacture its products and could increase the cost of production.

Changes in third party reimbursement could negatively impact the Company s 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 the Company does not receive payments for its products directly from these programs, home respiratory care providers and durable medical equipment suppliers, who are the primary customers for several of the Company s products, depend heavily on payments from Medicare, Medicaid and private insurers as a major source of revenues. In addition, sales of certain of the Company s 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 the Company s 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

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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 claim of infringement against us may involve significant liabilities to third parties, could require us to seek licenses from third parties, and could prevent us from manufacturing, selling, or using our products. The occurrence of this 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 the manufacturing, marketing, and sale 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.

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The Company is subject to substantial domestic and international government regulation, including regulatory quality standards applicable to its manufacturing and quality processes. Failure by the Company to comply with these standards could have an adverse effect on the Company s business, financial condition or results of operations.

The FDA regulates the approval, manufacturing, and sales and marketing of many of the Company s products in the U.S. Significant government regulation also exists in Canada, Japan, Europe, and other countries in which the Company conducts business. As a device manufacturer, the Company is required to register with the FDA and is 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 the Company 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, the Company is required to maintain certain ISO certifications in order to sell its 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 the Company s 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, harm our reputation with our customers and damage our business.

The Company is exposed to certain credit risks, resulting primarily from customer sales.

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

The market price of our common stock may fluctuate widely.

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.

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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.

The Company has one principal manufacturing operation. In the event that this facility, located in St. Louis, Missouri, were severely damaged or destroyed as a result of a natural or man-made disaster, the Company 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 the Company s 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.

Requirements associated with the evaluation of internal controls required by Section 404 of the Sarbanes-Oxley Act of 2002 have required and will require significant company resources and management attention.

Although we believe that we