

ANGEION CORP/MN
Form 10-K
January 26, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
for the fiscal year ended October 31, 2008.
OR
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from _____ to _____.

Commission File Number 001-13543

ANGEION CORPORATION

(Exact name of registrant as specified in its charter)

Minnesota
(State or other jurisdiction of
incorporation or organization)
41-1579150
(IRS Employer
Identification No.)
350 Oak Grove Parkway, Saint Paul, Minnesota 55127-8599
(Address of principal executive offices)

Registrant's telephone number, including area code: **(651) 484-4874**

Securities registered pursuant to Section 12(b) of the
Act: **Common Stock, \$0.10 Par Value**

Securities registered pursuant to Section 12(g) of the
Act: **None**

Name of Exchange on Which Registered: **NASDAQ**

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act:
Yes No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Edgar Filing: ANGEION CORP/MN - Form 10-K

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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act:

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer Smaller Reporting Company

The aggregate value of the Company's Common Stock held by non-affiliates of the Company was approximately \$29,501,000 as of the last day of the Company's most recently completed second fiscal quarter, when the last reported sales price was \$7.24 per share.

As of January 8, 2009, the Company had outstanding 4,120,411 shares of Common Stock, \$0.10 par value.

TABLE OF CONTENTS

PART I

<u>Item 1.</u>	<u>Business</u>	3
<u>Item 1A.</u>	<u>Risk Factors</u>	12
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	15
<u>Item 2.</u>	<u>Properties</u>	15
<u>Item 3.</u>	<u>Legal Proceedings</u>	16
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	16

PART II

<u>Item 5.</u>	<u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	17
<u>Item 6.</u>	<u>Selected Financial Data</u>	18
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	27
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	28
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	52
<u>Item 9A.</u>	<u>Controls and Procedures</u>	52
<u>Item 9B.</u>	<u>Other Information</u>	52

PART III

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	53
<u>Item 11.</u>	<u>Executive Compensation</u>	55
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	60
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	61
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	61

PART IV

<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	63
-----------------	---	----

SIGNATURES

65

PART I

Item 1. Business.

Unless the context requires otherwise, references in this Form 10-K to Angeion or the Company means Angeion Corporation, while references to Medical Graphics refer to Medical Graphics Corporation, a wholly owned subsidiary of Angeion. Angeion and Medical Graphics are collectively referred to as the Company.

Overview

The Company is a medical device manufacturer with revenues of \$30.0 million for the year ended October 31, 2008. Domestic product sales and service revenue accounted for 79.4% of fiscal 2008 revenue while international product sales accounted for the remaining 20.6%. The Company, through its Medical Graphics Corporation subsidiary, designs and markets non-invasive cardio-respiratory diagnostic systems that are sold under the MedGraphics and New Leaf brand and trade names. These cardio-respiratory diagnostic systems have a wide range of applications in healthcare, wellness and health and fitness. Revenue consists of equipment and supply sales as well as service revenue. Equipment and supply sales reflect sales of non-invasive cardio-respiratory diagnostic equipment and aftermarket sales of peripherals and supplies. Service revenue consists of revenue from extended service contracts, non-warranty service visits and additional training.

(a) General Development of Business.

Angeion Corporation was incorporated in Minnesota during May 1986 for the purpose of developing, manufacturing and selling medical products. In July 1988, Angeion merged with Verde Ventures Incorporated, a public company organized in March 1987 that had no operations at the time of the merger and the surviving legal entity changed its name to Angeion Corporation.

During the period from 1990 through March 2000, Angeion was engaged in the development and sale, directly and through joint ventures, of implantable cardioverter defibrillator (ICD) systems. ICDs are designed to treat abnormally rapid heartbeats in the ventricular (or lower) chambers of the heart, a condition known as ventricular tachycardia (VT), and a severe form of VT known as ventricular fibrillation (VF), that if not terminated will lead to sudden cardiac death. ICDs are electronic devices that are implanted within the body and are connected to the heart with defibrillator leads. These devices monitor the patient's heartbeat and, in the event of VT or VF, deliver an electrical shock to return the heartbeat to normal rhythm. During 1999 and 2000, the Company completed two restructurings, granted a series of non-exclusive licenses to its ICD technology and discontinued its ICD operations.

In December 1999, Angeion acquired Medical Graphics Corporation.

On June 17, 2002, Angeion filed a voluntary petition for reorganization under Chapter 11 of the federal bankruptcy laws (Chapter 11 or Bankruptcy Case) in the United States Bankruptcy Court for the District of Minnesota and in the process converted \$20.0 million of Convertible Notes into 95% of the Company's common stock. Angeion emerged from Bankruptcy in October 2002.

(b) Financial Information about Industry Segments.

The Company is a medical device manufacturer that designs and markets non-invasive cardiorespiratory diagnostic systems. All of the Company's cardiorespiratory diagnostic products are similar because they have a common functional testing platform—the measurement of air flow and

respiratory pressures and, in most cases, the analysis of inhaled and exhaled gases such as oxygen and carbon dioxide. Consequently, the Company operates in a single industry segment: the research, development, manufacture and marketing of non-invasive cardiorespiratory diagnostic systems.

(c) Narrative Description of Business.

General

Through its Medical Graphics Corporation subsidiary, Angeion designs and markets non-invasive cardiorespiratory diagnostic systems that are sold under both the MedGraphics and New Leaf brand and trade names. These cardiorespiratory diagnostic systems have a wide range of applications in healthcare, wellness, and health and fitness.

Healthcare professionals use these cardiorespiratory diagnostic systems to diagnose shortness of breath and lung diseases such as asthma, emphysema, or Chronic Obstructive Pulmonary Disease (COPD), and manage related treatment. Through breath-by-breath analysis, some of the Company's cardiorespiratory diagnostic systems measure fitness or conditioning levels to help physicians diagnose heart diseases such as heart failure and coronary disease. The Company also sells its cardiorespiratory diagnostic systems and services to clinical research customers for use in conducting safety and efficacy clinical trial studies both in the United States and internationally. Other health professionals use cardiorespiratory diagnostic systems to measure calorie consumption and to prescribe safe and effective exercise in rehabilitation, weight management, general fitness, and athletic performance. All of these applications are accomplished by measuring air flow and the concentrations of inhaled and exhaled gases such as oxygen and carbon dioxide while a person is at rest, or exercising on a bike or treadmill. Professionals use this same assessment of gases and air flow to determine nutritional requirements of critically-ill patients in a hospital or to design a weight loss program for members in a health club wishing to assess the number of calories they should consume and burn daily.

Primary MedGraphics brand products include pulmonary function (PFT) and cardiopulmonary gas exchange (GX) testing systems. All MedGraphics systems are designed to be simple and easy-to-use while at the same time provide the flexibility to address the specific needs of hospitals, clinics and physician offices. MedGraphics products, except for certain OEM products, are generally sold with a personal computer, full color monitor, printer and other peripherals.

The Company also sells one of its cardiorespiratory diagnostic systems together with other consumable products under the New Leaf brand to consumers through health and fitness clubs, personal training studios, weight loss centers and other retail outlets. These fitness products provide the consumer with a personalized exercise plan based on an assessment of the individual's level of fitness and metabolism. The assessment is performed at a health club or personal training studio equipped with one of the Company's VQassessment systems. Through the New Leaf assessment, an individual's metabolism is measured and correlated to the heart rate while exercising. The participating consumer must purchase an assessment package containing the single user materials required for the VO₂ assessment and, optionally, a heart rate monitor and watch to help the user exercise at the correct intensity level to achieve the desired results for weight loss, general fitness improvement or athletic performance.

Pulmonary Function Systems

Health care professionals use assessment of pulmonary function to diagnose lung diseases such as COPD, asthma and emphysema, and manage treatment of their patients. Pulmonary function applications include screening asthma patients, pre-operative and post-operative assessment of heart and lung surgery patients, evaluating lung damage from occupational exposures and documenting responses to therapy.

Edgar Filing: ANGEION CORP/MN - Form 10-K

These pulmonary function systems fall into three major product categories: Spirometry, Complete Pulmonary Function and Body Plethysmography. These products are sold under the MedGraphics name.

Spirometry. Spirometry provides measurements of airflow, lung volume and elastic/mechanical properties. The CPF-S/D USB spirometer is comprised of a flow measurement module and a personal computer (PC). The spirometer can serve as a platform that can be upgraded to either a complete pulmonary function or cardiopulmonary exercise system.

Complete Pulmonary Function Systems. The Ultima/PF Series is MedGraphics complete pulmonary function system. The Ultima/PF is available as a desktop or cart-mounted module that performs rapid, non-invasive assessment of an individual s lung volumes, respiratory pressures and gas diffusion in addition to spirometry measurements.

Body Plethysmograph Systems. The Platinum Elite Series comprises MedGraphics body plethysmograph system. A body plethysmograph is an enclosed metal and clear acrylic chamber that offers the most sensitive method for measuring chest wall movement. The patient sits inside the chamber and undergoes diagnostic pulmonary function tests. MedGraphics medical design Platinum Elite Series minimizes patient anxiety and discomfort while maximizing accuracy. The system s design optimizes patient comfort with a clear-view acrylic enclosure and allows testing of a broad population including pediatric patients and individuals in wheelchairs.

The Platinum Elite Series is available in two configurations:

Platinum Elite DL. The Platinum Elite DL performs spirometry, measures the total volume of air in the lung and resistance to airflow in the airways of the person s lungs. It also performs the diffusion test in the same manner as the Ultima/PF.

Platinum Elite DX. The Platinum Elite DX performs all the same tests as a Platinum Elite DL, and adds an additional lung volume measurement.

All MedGraphics pulmonary function products use the patented preVerifTM pneumotach, a disposable/cleanable mouthpiece/flow measurement device that eliminates concern over the transmission of infectious diseases. The preVent pneumotach gives all MedGraphics products the capability to perform spirometry testing to measure the flow rates, volumes (capacities) and mechanical properties of the lung. MedGraphics pulmonary function products use a patented expert system, Pulmonary Consult, to assist physicians in the interpretation of test results.

Applications include evaluating the effect of medication, monitoring patients with chronic disease, diagnosing lung diseases (i.e. COPD, asthma and emphysema), managing treatment, assessing the surgical risk of lung transplant and lung reduction candidates and evaluating the impact of diseases such as neuromuscular disease on breathing.

MedGraphics pulmonary function products ease of use, infection control features, compact, lightweight design and mobility option attract a wide variety of customers, including pulmonary laboratories in hospitals, clinics, physician offices, occupational medicine clinics, asthma/allergy practices, and clinical research centers worldwide.

Cardiopulmonary Exercise Testing Systems

MedGraphics cardiopulmonary exercise (CPX) testing systems measure functional capacity, fitness or conditioning levels as well as help physicians diagnose heart and lung diseases. This is

Edgar Filing: ANGEION CORP/MN - Form 10-K

accomplished by measuring the volume and concentrations of oxygen and carbon dioxide as they enter and leave the lungs while a person exercises on a machine such as a bike or treadmill.

The Ultima/CPX systems measure each breath using a patented breath-by-breath methodology and the same patented preVent pneumotach as the pulmonary function systems. MedGraphics cardiopulmonary exercise systems include a patented oxygen analyzer and a carbon dioxide analyzer as well as patented gas sampling and data reporting, including an evaluation of the information obtained from cardiopulmonary exercise assessments.

MedGraphics systems can also perform measurements of individuals at rest to determine nutritional requirements of critically-ill patients or individuals wishing to assess the number of calories burned per day, which is termed energy expenditure. This measurement is known as a metabolic assessment and is marketed by Medical Graphics as the Ultima/CCM option. Configurations using both the CPX and CCM applications are marked as an Ultima/MAX system.

The Ultima Series is sold in the following different configurations:

Ultima/CPX/D. This is a basic exercise testing system that measures an individual's fitness level while exercising and measures the ability to perform work (functional capacity) or activities of daily living. The Ultima/CPX/D can also be used in conjunction with other manufacturers stand-alone ECG systems. The electrocardiogram, which measures heart functions, is generally referred to as an ECG.

Ultima/CCM/D. This basic metabolic assessment system measures the nutritional requirements of a patient at rest.

Ultima/CardiO₂. This configuration adds an integrated 12-lead electrocardiogram stress option.

VO2000. The VO2000 is a portable/ambulatory version that can transmit data via telemetry. In addition to uses for exercise and nutritional requirements, these portable and wearable products include assessment of work capacity in occupational medicine and physical therapy as well as field training of amateur and elite athletes during participation in their actual events. The VO2000 technology platform, reconfigured as a VO2PAS, is a key component of the Company's New Leaf Active Metabolic Training™ System health and fitness product.

Applications for the Ultima and VO2000 exercise and metabolic systems include distinguishing between cardiovascular and pulmonary disease, screening for early signs of cardiac and pulmonary dysfunction, establishing exercise prescriptions and training programs and evaluating the efficacy of prescribed therapy. Customers include hospital cardiopulmonary laboratories, cardiology and pulmonary office-based clinics, critical care units, cardiac rehabilitation units, weight loss clinics, human performance laboratories and health clubs.

Cycle Ergometers and Treadmills

The Company offers several models of cycle ergometers providing healthcare professionals and patients a tool for more successful outcomes in clinical rehabilitation and athletic training. A cycle ergometer is a specially-designed stationary exercise bicycle that can operate at a broad spectrum of resistance levels while a treadmill is a motorized walking/running surface that can operate at different inclines to produce a range of work levels. Medical Graphics has cycle ergometers and treadmills that are used in diagnostic, rehabilitation, training and sports medicine applications. The ergometers and treadmills are used and controlled by the Company's cardiopulmonary exercise testing systems.

Competition

The industry for companies selling cardiopulmonary diagnostic systems is competitive. There are a number of companies that currently offer, or are in the process of developing, products that compete with products offered by Medical Graphics. The Company's competitors include both large and small medical companies, some of which have greater financial and technical resources and broader product lines. Cardinal Health, Inc, Cosmed and nSpire Health are the principal competitors for the Company's MedGraphics branded products. The Company believes that the primary competitive factors in its markets are product features, customer service, price, quality, product performance, market reputation, breadth of product offerings and effectiveness of sales and marketing efforts. The Company believes its MedGraphics brand product quality, product performance, market reputation and customer service are true differentiators that will contribute to future growth.

The Company's New Leaf branded products for the health and fitness market have a few competitors, which include metabolic measurement systems (Korr Medical and Cosmed), nutrition education and lifestyle enhancement software (e-Diets) and weight loss programs (Jenny Craig and Weight Watchers). The Company believes that its proprietary technology, expert-designed exercise programs and its training and education service provide a notable and unique advantage in the weight loss, general fitness and athletic performance markets.

The Company believes competition based on price will continue to be an important factor in customer purchasing patterns as a result of healthcare cost containment pressures in the health care industry. Price competition may exert downward pressure on prices the Company is able to charge for its products. There can be no assurance that it will be able to offset any downward price pressure through corresponding cost reductions. Any failure to offset this pressure could have an adverse effect on the Company's business, results of operations or financial condition.

Any product developed by the Company that gains regulatory approval will have to compete for market acceptance and market share. The timing of market introduction of competitive products could adversely affect the competitiveness of Medical Graphics' products. Accordingly, the relative speeds with which the Company can develop products, complete clinical testing and the regulatory approval process and supply commercial quantities of the product to the market are important competitive factors. The Company expects that competition will also be based on many factors, including device size and weight, longevity, ease of programmability, ability to provide diagnostic capability, product reliability, physician familiarity with the device, patent protection, sales and marketing capability, third-party reimbursement policies, reputation and price. The Company has protected its products with various patents when possible.

Manufacturing

Medical Graphics currently designs and assembles all major analyzer components of its cardiopulmonary diagnostic systems including a waveform analyzer, flow board, gas sample lines, gas chromatograph, nitrogen analyzer, CO₂ analyzer and oxygen analyzer. Company-designed sheet metal, electrical components, printed circuit boards and some measurement devices are purchased from outside vendors and are tested, assembled and packaged by Medical Graphics personnel into fully integrated systems. Medical Graphics also acquires general-purpose computers, monitors and printers from a variety of sources and integrates its proprietary software modules into these systems. Medical Graphics acquires its cycle ergometers and treadmills from third parties.

Medical Graphics Quality Management System is certified to the requirements of ISO 13485:2003, Canadian Medical Device Regulations Part 1, and European Union Medical Device

Edgar Filing: ANGEION CORP/MN - Form 10-K

Directive Annex II regarding the Development and Production of Cardio Respiratory devices. See Regulation by Foreign Governments below for additional discussion of the Company's ISO 13485:2003 certification.

Marketing and Distribution

Medical Graphics markets its products in the United States through two direct sales forces that sell into hospitals, university-based medical centers, medical clinics, physician offices, health and fitness clubs, weight loss clinics and personal training studios. The Company markets its products to a wide range of customers that utilize its non-invasive capabilities across a broad healthcare market continuum.

On the healthcare end of the continuum, the MedGraphics branded products are sold to hospitals, physician offices, clinics, pulmonary physicians, cardiologists, critical care physicians, rehabilitation professionals and physical therapy professionals. The Company also supplies medical equipment and support for clinical research trials. During 2008, the Company concluded its relationship with its largest clinical research customer.

On the fitness end of the continuum, the New Leaf branded products are sold to health and fitness clubs, corporations, weight loss centers, training studios, personal trainers and coaches. Each salesperson is responsible for a specific geographic area and is compensated with a base salary, expense reimbursement and a territory sales goal commission plan.

Outside the United States, Medical Graphics markets its products through a network of independent distributors. During fiscal 2008, Medical Graphics used approximately 58 distributors to sell its products into 60 countries. These distributors typically carry a select inventory of MedGraphics products and sell those products in specific geographic areas, generally on an exclusive basis. International revenues accounted for 20.6% and 24.8% of total revenue for the years ended October 31, 2008 and 2007, respectively. All of Medical Graphics' international sales are made on a United States dollar-denominated basis to distributors.

International sales involve certain risks not ordinarily associated with domestic business including fluctuations in the purchasing power of local currencies, reliance on distributors and country-specific policies and procedures. The Company does not have direct exposure to currency exchange rates as all sales are dollar-denominated.

Medical Graphics executes multiple sales and marketing strategies both domestically and internationally. The Company's most successful sales and marketing tactics include product demonstrations that emphasize technological capabilities, breadth of services and unmatched customer service. In addition to onsite product demonstrations, the Company annually attends and hosts booth displays at various industry-specific conventions around the world. At these conventions, potential customers/clients have the ability to see and experience the unique features the products offer. Through these global conventions, the Company gains exposure to pulmonologists, respiratory therapists, allergy physicians, exercise physiologists, sports medicine professionals, personal trainers and exercise enthusiasts. Other marketing initiatives include educational seminars, print advertisements, direct mail campaigns and e-marketing campaigns through the (www.medgraphics.com) web site for MedGraphics branded products and (www.newleaffitness.com) for New Leaf branded products.

Research and Development

In 2008, Medical Graphics continued to develop new products and implemented product improvements designed to enhance product reliability and improve margins. The Company's research

Edgar Filing: ANGEION CORP/MN - Form 10-K

and development initiatives are targeted for hospitals, clinics, physician's offices and the health and fitness club markets. An integral component of the Company's future growth strategies includes developing and introducing additional new products.

Research and development expenses were \$2.4 million and \$2.8 million for the years ended October 31, 2008 and 2007, respectively.

Intellectual Property

Patents and trademarks are critical in the medical device industry. The Company believes strongly in protecting its intellectual property and has a long history of obtaining patents, when available, in connection with its research and product development programs. The Company also relies upon trade secrets and proprietary know-how.

The Company relies on a combination of patent, trademark and trade secret laws to establish proprietary rights in its products. Medical Graphics currently owns 25 United States patents and is actively developing and obtaining additional patents. These patents cover the various aspects of Medical Graphics' core technologies, including gas analysis, pressure and flow measurement, breath-by-breath assessment of gas exchange data analysis and expert system software. The Company employs various Medical Graphics' patents in its New Leaf business model. In addition, Medical Graphics has a number of foreign patents with respect to technologies covered by its United States patents.

Foreign patents generally expire 20 years after the date of original application, but vary from country to country. Medical Graphics intends to aggressively enforce its intellectual property rights and has successfully done so in the past. There can be no assurance, however, that these patents, or any patents that may be issued as a result of existing or future applications, will offer any degree of protection from competitors.

United States patents filed on or after June 8, 1995 have a term of 20 years from the date on which the application for the patent was filed. Domestic patents in force on June 8, 1995 and patents issued on applications filed prior to June 8, 1995 automatically have a term that is the greater of the 20 years from the date of filing or 17 years from the patent grant.

Medical Graphics also owns registered trademarks and has applied for other trademarks in the U.S. and certain foreign countries. Medical Graphics owns and actively enforces an array of related copyrights and trademarks. These include but are not limited to: MedGraphics, preVent Pneumotach, BreathPath, BreezeSuite, CPX/D, CCM/D, CardiO2, CPX/Express, CCM/Express, Ultima/PF, Ultima/CPX, Ultima/CCM, Ultima/PFX, 1085/DX, Elite/Dx, Elite/DL, PF/Dx, Platinum Elite/Dx, Platinum Elite/DL, CPF-S/D, Pulmonary Consult, Exercise Consult, KnowledgeNet and various logos.

Similarly, Medical Graphics owns registered New Leaf trademarks and copyrights and has applied for others including, but not limited to: New Leaf, ExerSmart, ExerScript, PDC Personal Digital Coach, PAS Personal Assessment System, New Leaf Active Metabolic Training, EneySmart and various logos.

Although patent and intellectual property disputes in the medical device area have often been settled through licensing agreements or similar arrangements, costs associated with these arrangements may be substantial, and there can be no assurance that necessary licenses would be available to the Company on satisfactory terms, if at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent the Company from

manufacturing and selling its products, which would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company seeks to protect its trade secrets and proprietary know-how, in part, through confidentiality agreements, non-compete agreements and assignment of invention provisions in agreements with employees, consultants and other parties, as well as through contractual exclusivity with certain suppliers. There can be no assurance, however, that these agreements will not be breached, that the Company would have adequate remedies for any breach, or that the Company's trade secrets will not otherwise become known to or independently developed by competitors.

The Company conducts ongoing evaluations of potential infringement of any proprietary rights of third parties by the products the Company intends to market. Regardless of the Company's efforts to evaluate the potential infringement of any proprietary rights of third parties, however, there can be no assurance that such infringements do not exist or may not arise in the future. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Litigation, which could result in substantial cost to and diversion of effort by the Company, may be necessary to enforce patents issued to or licensed by the Company, to protect trade secrets or know-how owned by the Company, to defend the Company against claimed infringement of the rights of others, and to determine the scope and validity of the proprietary rights of others. Adverse determinations in litigation could subject the Company to significant liabilities to third parties or could require the Company to seek licenses from third parties.

Government Regulation

Most of the products manufactured by the Company are devices as defined in the Federal Food, Drug and Cosmetic Act (the Act) and are subject to the regulatory authority of the Food and Drug Administration (FDA), which regulates the manufacture, distribution, related record keeping, labeling and advertising of such devices. The FDA classified medical devices in commercial distribution into one of three classes, Class I, II or III, following the enactment of the Medical Device Amendments to the Act in May 1976 (the Amendments). These classifications are based on the controls necessary to reasonably ensure the safety and efficacy of medical devices. The Company's New Leaf health and fitness products are not classified as medical devices as defined in the Act.

Many Class I devices have been exempted from pre-market notification requirements by the FDA. The same types of controls the FDA has used on devices since the passage of the Act in 1938 can adequately regulate these products. These general controls include provisions related to labeling, producer registration, defect notification, records and reports and good manufacturing practices. The more comprehensive Quality System Regulation (QSR) has replaced the good manufacturing practice regulation. As noted below, QSRs include implementation of quality assurance programs, written manufacturing specifications and processing procedures, written distribution procedures and record keeping requirements.

Class II devices are products for which the general controls of Class I devices are deemed not sufficient to assure the safety and effectiveness of the device and thus require special controls. Special controls for Class II devices include performance standards, post-market surveillance, patient registries and the use of FDA guidelines. Standards may include both design and performance requirements. Class III devices have the most restrictive controls and require pre-market approval by the FDA. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices. All of MedGraphics' branded products are Class II devices.

Edgar Filing: ANGEION CORP/MN - Form 10-K

If the Company does not comply with applicable regulatory requirements, including marketing products only for approved uses, it could be subject to fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval for products, withdrawal of approvals and criminal prosecution. In addition, changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of the Company's products or result in increased regulatory costs. Furthermore, once clearance or approval is granted, subsequent modifications to the approved product or manufacturing process may require a new round of clearances or approvals that could require substantial additional clinical data and FDA review.

Class II Requirements

Section 510(k) of the Act requires individuals or companies manufacturing medical devices intended for use with humans to file a notice with the FDA at least 90 days before introducing a product not exempted from notification requirements into the marketplace. The notice (a 510(k) Notification) must state the class in which the device is classified and the action taken to comply with performance standards or pre-market approval that may be needed if the device is a Class II or Class III device, respectively. Under Section 510(k), a medical device can be marketed if the FDA determines that the device is substantially equivalent to similar devices marketed prior to May 28, 1976. In the past, Medical Graphics has filed notifications with the FDA of its intent to market its systems pursuant to Section 510(k) of the Amendments, the FDA subsequently cleared these systems for commercial sale and Medical Graphics is now marketing the devices under Section 510(k). The action of the FDA does not, however, constitute FDA approval of Medical Graphics' products or pass upon their safety and effectiveness.

In addition to the requirements described above, the Act requires that all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices that they distribute commercially. The Act also requires that all manufacturers of medical devices comply with labeling requirements and manufacture devices in accordance with QSRs, which require that companies manufacture their products and maintain their documents in a prescribed manner with respect to manufacturing, testing and quality control. In addition, these manufacturers are subject to inspection on a routine basis for compliance with the QSRs. The FDA's Medical Device Reporting regulation requires that companies provide information to the FDA on death or serious injuries alleged to have been associated with the use of their products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA further requires that certain medical devices not cleared with the FDA for marketing in the United States meet specific requirements before they are exported. The FDA has authority to inspect the Company's facilities to ensure compliance with the Act and regulations thereunder. Failure to comply with these regulations could have a material adverse effect on the Company's business, financial condition and results of operations. Medical Graphics is registered as a manufacturer with the FDA and successfully passed its most recent FDA audit in September 2004.

Regulation by Foreign Governments

The Company's products are also subject to regulation similar to that of the FDA in various foreign countries. ISO 13485:2003 certification indicates that a company's development and manufacturing processes comply with standards for quality assurance and manufacturing process control. ISO 13485:2003 certification evidences compliance with the requirements that enable a company to affix the CE Mark to its products. The CE Mark denotes conformity with European standards for safety and allows certified devices to be placed on the market in all European Union (EU) countries. Since June 1998, medical devices cannot be sold in EU countries unless they display the CE Mark. Medical Graphics received ISO 13485:2003 certification for its development and manufacturing processes in 1998.

Edgar Filing: ANGEION CORP/MN - Form 10-K

and has passed annual surveillance and recertification audits since 1998. Medical Graphics has achieved CE certification for its primary cardiopulmonary testing products. There can be no assurance, however, that Medical Graphics will be able to obtain regulatory approvals or clearances for its products in foreign countries. In addition to compliance with ISO 13485:2003 certification, the Company's products also meet Part I of the Medical Device Requirements for Canada and the Medical Device Directive 93/42/EEC Annex II.

Employees

As of January 15, 2009, the Company had 121 full-time and 4 part-time employees. No employees are represented by a collective bargaining agreement and the Company has not experienced any work stoppage. Management believes that relations with its employees are good.

Cautionary Note Regarding Forward-looking Statements

The discussions in this Form 10-K in Business and Management's Discussion and Analysis of Financial Condition and Results of Operations contain forward-looking statements about Angeion's future financial results and business prospects that by their nature involve substantial risks and uncertainties. You can identify these statements by the use of words such as anticipate, believe, estimate, expect, project, intend, plan, will, target, and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or business plans or prospects. Our actual results may differ materially depending on a variety of factors including: (1) national and worldwide economic and capital markets conditions; (2) cost-containment efforts in the hospital, clinics, and office markets, (3) our ability to successfully operate our business including our ability to develop, improve, and update our cardiorespiratory diagnostic products and successfully sell these products under the MedGraphics and New Leaf brand names into existing and new markets, (4) our ability to maintain our cost structure at a level that is appropriate to our near to mid-term revenue expectations that will enable us to increase revenues and profitability as opportunities develop, (5) our ability to achieve constant margins for our products and consistent and predictable operating expenses in light of variable revenues from our clinical research customers, (6) our ability to effectively manufacture and ship products in required quantities to meet customer demands, (7) our ability to expand our international revenue through our distribution partners and our Milan, Italy representative branch office; (8) our ability to successfully defend ourselves from product liability claims related to our cardiorespiratory diagnostic products and claims associated with our prior cardiac stimulation products, (9) our ability to defend our intellectual property, (10) our ability to develop and maintain an effective system of internal controls and procedures and disclosure controls and procedures, and (11) our dependence on third-party vendors. These and other factors are summarized below in this Form 10-K under Risk Factors.

Item 1A. Risk Factors.

The Company incurred a net loss in fiscal 2008 and will need to reduce operating costs to achieve profitability in fiscal 2009 at lower revenues levels than in 2008 and 2007.

The Company incurred a net loss of \$686,000 in fiscal 2008 as its revenues decreased from \$38.6 million in fiscal 2007 to \$30.0 million in fiscal 2008. A significant reason for the decrease is the reduction in clinical research revenue due to the conclusion of the relationship with the Company's largest clinical research customer, which the Company is working to backfill. Although it achieved profitability in the second half of fiscal 2008, the Company believes that in fiscal 2009, it must establish a

cost structure, through operating efficiencies or headcount reductions, that enables it to operate profitably at a lower level of revenues than it achieved in 2007.

The Company's results are affected by the effects of, and changes in, worldwide economic and capital markets conditions.

The Company derived 20.6% and 24.8% revenues in 2008 and 2007, respectively, from outside the United States. The Company's business may be adversely affected by factors in the United States and other countries that are beyond its control, such as downturns in economic activity in a specific country or region, labor conditions in a specific country or region.

The Company's success will depend on its ability to sell its Med Graphics cardiorespiratory products into its core hospital, clinics and physician office market.

The Company sells its MedGraphics brand cardiorespiratory diagnostic systems and services to hospitals, clinics and physician offices. As a result of the disruptive and uncertain economic conditions that emerged in the second half of calendar 2008 and the cost containment measures initiated by these customers, the Company believes that it will encounter a challenging environment for the sale of its MedGraphics products in 2009.

The Company's success will also depend on its ability to sell its cardiorespiratory products to clinical research customers for use in conducting safety and efficacy clinical trial studies.

Sales of MedGraphics cardiorespiratory diagnostic systems and services to one large clinical research customer used in conducting safety and efficacy clinical trials both in the United States and internationally decreased from 17.3% of revenues in fiscal 2007 to 4.1% of revenues in fiscal 2008. Although the Company has focused efforts on obtaining significant future revenue from clinical research studies, there can be no assurance that it will be able to do so.

The Company's future growth is dependent on the timing and market acceptance of its New Leaf product offerings.

The Company is focusing a portion of its resources on the weight loss, general fitness, clinical research and disease prevention markets that are a logical extension of its core cardiorespiratory systems technology. The Company's principal products is its New Leaf Active Metabolic Training system. It also has new cardiorespiratory diagnostic products planned for introduction both domestically and internationally. The Company's future success will be dependent, in part, upon the successful introduction of these products and services into the weight loss, general fitness, clinical research and disease prevention markets. Also, since these products are sold mostly to consumers, sales may be adversely affected by a downturn in the economic environment. In developing these new products, it will incur additional research and development and marketing expenses.

If the Company is unable to regain profitability in 2009, its liquidity may be adversely affected.

Although it was profitable in fiscal 2006 and 2007, the Company was unprofitable in fiscal 2004, 2005 and 2008 and had an accumulated deficit of \$4.1 million as of October 31, 2008. While the Company believes that its existing cash balance of \$9.0 million at October 31, 2008 will be adequate to support operations for the next fiscal year or more, the Company must ultimately regain profitability or obtain additional financing to be able to meet its future cash flow requirements, and there can be no assurance that it will be able to do so.

The financial soundness of the Company's vendors could affect its business and results of operations.

The Company relies on third party vendors for certain components used in the Company's products. A number of significant components, such as capacitors, batteries and integrated circuits, are purchased from sole source suppliers. Although the Company attempts to maintain sufficient quantities of inventory of these components to minimize production delays or interruptions, there can be no assurance that the Company will find suitable alternatives at reasonable prices, if at all, or that any alternatives will remain available to the Company. The Company's inability to obtain acceptable components in a timely manner or find and maintain suitable replacement suppliers for components would have a material adverse effect on the Company, including its ability to manufacture its products. As a result of the disruptions in the financial markets and other macro-economic challenges currently affecting the economy of the United States and other parts of the world, the Company's vendors may experience cash flow concerns. As a result, vendors may increase their prices, reduce their output or change terms of sales. Any demands by vendors for different payment terms may adversely affect the Company's earnings and cash flow.

Technology in the medical device industry changes rapidly

Rapid technological change, changing customer needs and frequent new product introductions are all characteristics of the medical device industry. We face intense competition from other device manufacturers that may have access to greater resources. Our products may be rendered obsolete as a result of future innovations. Our competitors may succeed in obtaining regulatory approval and introducing products before we do. Such developments could have a significant negative impact on our business and results of operations.

The Company's future operations are dependent upon variables outside of its control.

Successful implementation of the Company's business plan is dependent on the interaction of many variables, including the effects of changing industry conditions and new competition. While the Company believes that its business plan reflects reasonable judgments in assessing those risks, there can be no assurance that influences not foreseen by the Company will not adversely affect its ability to execute its business plan strategies. While the Company believes that its business plan projections are in line with achievable performance levels, there can be no assurance that the Company will be able to obtain, and sustain, projected sales revenue.

Protection of Intellectual Property is critical to the Company business.

Patents and trademarks are critical in the medical device industry. The Company believes strongly in protecting its intellectual property and has a long history of obtaining patents, when available, in connection with its research and product development programs. The Company owns a number of United States and foreign patents. The Company also owns certain registered trademarks, and has applied for other trademarks in the United States and certain foreign countries. There can be no assurance that patents and trademarks will be granted in the future, or that any patents and trademarks that the Company now holds or may be granted, or under which it has held license rights, will be valid or otherwise be of value to the Company. Even if the Company's patents and trademarks are valid, others may be able to introduce non-infringing products that are competitive with those of the Company. Competitors of the Company may also hold or be granted patents that are not licensed to the Company.

Although patent and intellectual property disputes in the medical device area have often been settled through licensing agreements or similar arrangements, costs associated with such arrangements

may be substantial, and there can be no assurance that necessary licenses would be available to the Company on satisfactory terms or at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent the Company from manufacturing and selling its products, which would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company seeks to protect its trade secrets and proprietary know-how, in part, through confidentiality agreements, non-compete agreements and assignment of invention provisions in agreements with employees, consultants and other parties, as well as through contractual exclusivity with certain suppliers. There can be no assurance, however, that these agreements will not be breached, that the Company would have adequate remedies for any breach, or that the Company's trade secrets will not otherwise become known to or independently developed by competitors.

The Company is dependent upon its Senior Management and Other Key Personnel.

The Company's success depends largely on effective leadership from its senior management and other key personnel. Moreover, competition for qualified personnel with sufficient and relevant experience in the medical device industry is intense. Accordingly, the loss of the services of such individuals, or the inability to hire additional key individuals as required, could have a material adverse effect on the Company, including its current and future product development efforts.

Anti-Takeover Provisions in Minnesota law may make a hostile takeover of the Company's business more difficult.

The Company is governed by the provisions of Sections 302A.671 and 302A.673 of the Minnesota Business Corporation Act. These anti-takeover provisions could potentially operate to deny shareholders the receipt of a premium on their common stock and may also have a depressive effect on the market price of the Company's common stock. Section 302A.671 generally provides that the shares of a corporation acquired in a control share acquisition have no voting rights unless voting rights are approved by the shareholders in a prescribed manner. A control share acquisition is generally defined as an acquisition of beneficial ownership of shares that would, when added to all other shares beneficially owned by the acquiring person, entitle the acquiring person to have voting power of 20% or more in the election of directors. Section 302A.673 prohibits a public corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales and other transactions. An interested shareholder is a person who is the beneficial owner of 10% or more of the corporation's voting stock. Reference is made to the detailed terms of Sections 302A.671 and 302A.673 of the Minnesota Business Corporation Act. The Company has also entered into agreements with certain executive officers that provide for certain benefits upon a change of control. These agreements would make any sale of the Company more expensive to a third party.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company currently leases a 52,254 square foot building for its office, assembly and warehouse facilities located in suburban Saint Paul, Minnesota. The building is also the location of the Company's Medical Graphics subsidiary. The building lease for the Company's present office and

Edgar Filing: ANGEION CORP/MN - Form 10-K

manufacturing space, by its terms, will expire in June 2009. On December 21, 2008, the Company signed a one year lease extension through June 30, 2010, with similar terms to the previous lease. This extension includes a renewal option giving the Company the right to extend the agreement for an additional four years effective July 1, 2010 and commencing June 30, 2014. The Company also leases 1,390 square feet of office space in Milan, Italy with the lease agreement expiring in December 2012. Annual rental costs of both facilities will be approximately \$339,000 in fiscal year 2009. Rent expense for the Company's facilities was \$317,000 and \$307,000 for the years ended October 31, 2008 and 2007, respectively.

Item 3. Legal Proceedings.

The Company is subject to certain claims and lawsuits that have been filed in the ordinary course of business. From time to time, the Company brings suit against others to enforce patent rights or to collect debts in the ordinary course of business. Management believes that the settlement of all litigation would not have a material effect on the results of operations or liquidity of the Company.

Item 4. Submission of Matters to a Vote of Security Holders.

Not Applicable.

PART II

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

The Company's common stock is traded on the Nasdaq Capital Market under the symbol ANGN. The following table sets forth high and low sales prices as reported by the Nasdaq Capital Market for each quarter of FY 2008 and 2007.

Angeion Common Stock Prices			
Fiscal Years		High	Low
2008			
Fourth Quarter		\$ 5.72	\$ 2.80
Third Quarter		7.17	4.77
Second Quarter		8.83	6.51
First Quarter		9.77	5.95
2007			
Fourth Quarter		\$ 8.50	\$ 5.62
Third Quarter		13.83	7.78
Second Quarter		17.87	12.90
First Quarter		18.50	10.00

As of January 15, 2009, approximately 309 shareholders of record held the Company's common stock. In addition, nominees for approximately 4,285 shareholders held shares in street name.

Dividends

The Company has not paid any dividends on its common stock. The Company currently intends to retain any earnings for use in its operations and does not anticipate paying any cash dividends in the future.

Equity Compensation Plan Information

Under the Angeion Corporation 2002 Stock Option Plan (the 2002 Plan), the Company had reserved 800,000 shares of its common stock for issuance upon exercise of stock options. As of October 31, 2008, options for 800,000 shares had been granted, 426,850 shares had been issued upon exercise of options, 950 were forfeited and options to purchase 372,200 shares remained outstanding. In connection with the adoption of the 2007 Stock Incentive Plan described below, the 2002 Plan was amended to provide that no new options could be granted under the 2002 Plan.

At a Special Meeting of Shareholders held on August 22, 2007, the shareholders approved the Angeion Corporation 2007 Stock Incentive Plan (the 2007 Plan) and reserved 250,000 shares of its common stock for issuance under the 2007 Plan. At the 2008 Annual Meeting of Shareholders held on May 20, 2008, the shareholders approved an amendment to the 2007 Plan that increased the authorized shares of common stock for issuance by 300,000 to a total of 550,000 shares. As of October 31, 2008, stock options for 358,753 shares were outstanding, 74,667 shares were outstanding under restricted stock awards and 116,580 shares were available for future grant.

The following table provides information as of October 31, 2008 with respect to the shares of the Company's common stock that may be issued under its 2002 Plan and 2007 Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)
Equity compensation plans approved by security holders	730,953	\$ 5.96	116,580
Equity compensation plans not approved by security holders			
Total	730,953		116,580

Item 6. Selected Financial Data

In the table below, we have presented certain selected financial data as of and for each of the years in the five-year period ended October 31, 2008. The financial data has been derived from our audited consolidated financial statements. This data should be read in conjunction with Item 7, Management's Discussion and Analysis and Item 8, Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Edgar Filing: ANGEION CORP/MN - Form 10-K

(In thousands, except per share data)

	Years Ended October 31,				
	2008	2007	2006	2005	2004
Statement of Operations Data:					
Revenue	\$ 30,011	\$ 38,580	\$ 33,651	\$ 23,774	\$ 20,688
Cost of revenue	14,557	19,106	17,016	12,023	10,952
Gross margin	15,454	19,474	16,635	11,751	9,736
Operating expense:					
Selling and marketing	8,646	10,107	8,148	7,192	6,131
General and administrative	4,390	4,220	3,209	2,402	2,399
Research and development	2,437	2,820	2,367	2,061	1,672
Amortization of intangibles	728	733	812	811	951
Total operating expense	16,201	17,880	14,536	12,466	11,153
Operating income (loss)	(747)	1,594	2,099	(715)	(1,417)
Interest income	163	182	81	34	18
Income (loss) before taxes	(584)	1,776	2,180	(681)	(1,399)
Provision for taxes	102	719	914	9	