

ANGEION CORP/MN
Form 10KSB
January 31, 2005

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20509

FORM 10-KSB

- ý **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended October 31, 2004.**
- 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 NO. **001-13543**

ANGEION CORPORATION

(Name of Small Business Issuer in its charter)

Minnesota
(State or other jurisdiction of
incorporation or organization)

41-1579150
(I.R.S. Employer
Identification No.)

350 Oak Grove Parkway, Saint Paul, Minnesota 55127-8599
(Address of principal executive offices)

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

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, \$0.10 Par Value
Warrants for Common Stock Purchase Rights

Check whether the issuer filed all reports required to be filed by Section 12, 13 or 15(d) of the Exchange Act of 1934 after distribution of securities under a plan confirmed by a court:

Yes ☒ No ☐

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 ☐

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. ☒

The issuer's revenues for the year ended October 31, 2004 were \$20,688,000.

The aggregate market value of the issuer's common stock held by non-affiliates of the issuer as of January 14, 2005 was approximately \$5,934,000, based upon the closing sale price for the issuer's common stock on that date as reported by the Nasdaq SmallCap Market.

Edgar Filing: ANGEION CORP/MN - Form 10KSB

There were 3,606,038 shares of the issuer's Common Stock, \$0.10 par value per share, outstanding as of January 14, 2005.

Documents Incorporated By Reference: None.

PART I

Item 1. Description of Business.

Unless the context requires otherwise, references in this Form 10-KSB to Angeion or the Company means Angeion Corporation, while references to Medical Graphics or MedGraphics refers to Medical Graphics Corporation, a wholly owned subsidiary of Angeion. Angeion acquired Medical Graphics in December 1999. For periods after December 21, 1999 Angeion and Medical Graphics are collectively referred to as the Company.

In November 2002, Angeion changed its fiscal year from December 31 to October 31. The consolidated financial statements in this Form 10-KSB cover the years ended October 31, 2004 and 2003. Unless the context otherwise provides, all reference to years cover those fiscal periods.

(a) General Development of Business.

Events Prior to 2000

Angeion Corporation was incorporated in Minnesota during May 1986 for the purpose of developing, manufacturing and selling medical products. The Company initially used its engineering and manufacturing technologies to custom design and manufacture products to customers specifications, while it devoted its research and development capabilities to designing proprietary 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. Verde Ventures Incorporated, the surviving legal entity, changed its name to Angeion Corporation and continued the business of the pre-merger Angeion Corporation.

In August 1990, the Company established a subsidiary to assume responsibility for the intensified research efforts on the development of a laser catheter ablation system, and in October 1990, the Company acquired a company engaged in the development of an automatic implantable cardioverter defibrillator (ICD) system. Subsequent to this acquisition, Angeion designed, developed, manufactured and marketed products, including ICDs that treat irregular heartbeats (arrhythmias). 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 the period from 1990 through March 2000, Angeion was engaged in the development, design and manufacture of ICDs. 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, the Company acquired Medical Graphics Corporation.

Subsequent Developments.

Edgar Filing: ANGEION CORP/MN - Form 10KSB

In March 2000, Angeion announced that it had largely completed its assimilation of the Medical Graphics business and intended to focus its future efforts primarily on the markets served by and business operations of Medical Graphics and the acquisition and development of future businesses that contributed to shareholder value. Angeion entered into separate license agreements with Medtronic, Inc. and Sanofi-Synthélabo under which it granted each company non-exclusive licenses for its ICD technology.

On March 15, 2000, the Company, through Medical Graphics, acquired the operating assets of AeroSport, Inc., a privately held Ann Arbor, Michigan corporation, and obtained an exclusive worldwide license to AeroSport's patented technology. AeroSport was a leading global supplier of gas exchange metabolic analyzers for the health, fitness, and research and education markets. The acquisition of the assets included the purchase of inventory, fixed assets and intellectual property for \$468,000. In addition, Medical Graphics entered into an exclusive worldwide license agreement for AeroSport's patented technology for royalty payments of 5% of net sales of products covered by those patents up to a maximum of \$850,000, with a \$700,000 minimum over seven years required to retain those rights.

During the summer of 2001, the Company introduced the New Leaf brand as the umbrella brand name for its planned family of health and fitness products to be marketed to consumers through health and fitness clubs, cardiac rehabilitation centers, weight loss centers and other retail outlets. At that time, the Company introduced the first product to carry the New Leaf brand, the New Leaf Personal Exercise System. The product provides 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 fitness center equipped with one of the Company's VQassessment systems.

On June 17, 2002, Angeion Corporation 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 under case number 02-32260. The Joint Modified Plan of Reorganization (Plan) was filed jointly with the holders of the Company's 7-1/2% Senior Convertible Notes (Notes) due April 2003. During the bankruptcy period, the Company continued to operate as debtor in possession.

On September 19, 2002, the Company entered into a Settlement and License Agreement (Settlement Agreement) with Biotronik, Inc. (Biotronik) under which the Company granted to Biotronik a perpetual, non-exclusive license to use the Company's cardiac stimulation technology. In return, Biotronik agreed to pay the Company \$4,000,000 in cash. As a result, the Company recorded license revenue of \$2,900,000 relating to the Settlement Agreement, which is net of the related transaction expenses of \$1,100,000.

On October 24, 2002, the Bankruptcy Court entered an order confirming the Company's Plan. The Plan became effective on October 25, 2002, the first business day after the date of confirmation. Upon the effectiveness of the Plan, Messrs. Arnold A. Angeloni, John C. Penn, Richard E. Jahnke and Jeffrey T. Schmitz constituted the Board of Directors of the Company.

By approving the Plan on October 24, 2002, the Bankruptcy Court also approved the Company's Amended and Restated Articles of Incorporation (the Articles of Incorporation) and Amended and Restated Bylaws (the Bylaws). The Articles of Incorporation grant the Creditors Committee, formed under that Plan of Reorganization (the Creditors Committee) the right to designate four (4) directors at any time. This right terminates on the earlier of: (i) January 1, 2006 or (ii) the date on which the former holders of the Company's 7 1/2% Senior Convertible Notes due April 2003 collectively own less than forty percent (40%) of the outstanding shares of common stock. Until this right is terminated, there will be at least one (1) director serving as a Designee of the Creditors Committee. The unanimous vote of the Designee(s) of the Creditors Committee is required for the Board of Directors to approve (a) a merger of the Company with or into another entity or (b) a sale of all or substantially all of the assets of the Company. The current designee of the Creditors Committee is Jeffrey T. Schmitz.

Under the Bylaws, for a period of three years after the end of the fiscal year in which the Plan was confirmed or until November 1, 2005, no purchase of the Company's common stock may be made by any beneficial owner of 5% or greater of the Company's common stock (or any person who would

become a 5% or greater owner as a result of the purchase), unless the transfer is approved in advance by the Company's Board of Directors. Further, each person that was a beneficial owner of 5% or greater of the Company's common stock immediately following confirmation of the Plan was prohibited from transferring more than 60% of the holder's common stock during the two year period after confirmation, unless the transfer was approved in advance by the Board of Directors. This limitation of transferability expired October 31, 2004.

Under the Plan, all of the Company's Old Common Stock and all existing options and warrants to purchase the Company's Old Common Stock were canceled. To effectuate the Plan, the Company issued a total of 3,594,433 shares of its common stock (i) upon conversion of the Notes and (ii) in replacement of the Old Common Stock (the Replacement Common Stock).

Under the Plan, each holder of the Company's Notes and each holder of certain other unsecured claims received the holder's pro rata share of 95% of the Replacement Common Stock. Each holder of the Company's Old Common Stock received a pro rata share of 5% of the Replacement Common Stock and one common stock purchase warrant for each share of Replacement Common Stock (the New Warrants). For each 20 shares of common stock owned prior to the Plan confirmation date, shareholders received one Share of Replacement Common Stock and one New Warrant to purchase one share of Replacement Common Stock at \$7.79 per share. The New Warrants expire on October 31, 2007 and are subject to redemption by the Company for \$.01 per Warrant at any time after January 1, 2004, if the closing price of the common stock exceeds \$9.73 (subject to adjustment) for ten consecutive trading days after January 1, 2004.

The Company also reserved 600,000 shares of its Replacement Common Stock for issuance upon exercise of stock options to be issued to employees pursuant to the Angeion Corporation 2002 Stock Option Plan.

The effective date of the Company's emergence from bankruptcy was October 25, 2002. For accounting purposes, the Company adopted fresh-start reporting principles in accordance with SOP 90-7 as of October 31, 2002. In accordance with fresh-start reporting, all assets and liabilities were recorded at their respective fair values. An independent third-party appraiser determined the fair values of substantially all of the Company's tangible and intangible assets.

Notice for Indemnification.

As previously reported, ELA Medical advised Angeion in a letter dated June 6, 2002 that some of the ICD's formerly manufactured by Angeion were experiencing premature battery depletion. Following the June 6, 2002 letter, Angeion advised the attending physicians of the patients with these ICD's of the problems and provided a recommended procedure to determine what action is required. The text of these letters was reviewed and orally approved by the FDA during a site visit at Angeion. ELA Medical thereafter distributed both letters to physicians who subsequently reported that the devices in question had been implanted in 385 patients, excluding the 14 explantations previously reported in the June 6, 2002 letter. On July 31, 2002, the FDA issued a Field Corrective Action Report providing that the Angeion Lyra Model 2020, 2021, and 2022 ICD's be replaced (Field Corrective Action # Z-1152-2/Z-1154-2) because the devices could stop providing therapy due to premature battery depletion.

ELA Medical subsequently provided notice on June 18, 2003 for indemnification by Angeion for replacement of the ICD's pursuant to Supply Agreements under which Angeion had manufactured and sold the ICDs to ELA Medical and to a Joint Venture of which ELA Medical was a member. Angeion advised its insurance carriers of the ELA Medical claim. This claim and the related insurance coverage are currently in litigation as discussed under 2004 Developments.

2004 Developments.

On September 13, 2004, the basic insurer providing discontinued operations product liability coverage, Medmarc Casualty Insurance Company, advised Angeion that Medmarc was denying insurance coverage to Angeion for the claim by ELA Medical, Inc. In addition, on September 13, 2004, Medmarc commenced a declaratory judgment action against Angeion and ELA Medical in United States District Court for the District of Minnesota seeking a declaratory judgment that Medmarc's interpretation of the policy is correct. In the lawsuit, ELA Medical has entered a cross-claim against Angeion for the costs and expenses it incurred in connection with the recall in the equivalent amount of \$1,665,068.

Angeion has denied liability to ELA Medical and has counterclaimed against Medmarc and is seeking a declaratory judgment that Medmarc is liable (i) to Angeion for any amount that it is required to pay to ELA Medical, and (ii) for any fees and expenses that Angeion has incurred in connection with defense of the cross-claim by ELA Medical and the declaratory action by Medmarc. Angeion vigorously intends to pursue its available defenses against ELA Medical and it asserts that Medmarc is required to provide Angeion coverage with respect to these matters.

The lawsuit is just beginning and is currently only in the discovery stage. The Company expects that any trial in this matter will not occur until the spring of 2006.

See Note 13, Discontinued Operations, Notes to Consolidated Financial Statements in this Form 10-KSB for further discussion of this matter.

(b) Financial Information about Industry Segments.

The Company operates in a single industry segment: the research, development, manufacture and marketing of medical devices and fitness related products, including non-invasive cardiorespiratory diagnostic systems.

(c) Narrative Description of Business.

General

Angeion, through its Medical Graphics Corporation subsidiary, designs non-invasive cardiorespiratory diagnostic systems under the MedGraphics trade name that assist health care professionals in the prevention, early detection and cost-effective treatment of heart and lung disease. Primary MedGraphics products include pulmonary function and cardiopulmonary exercise (CPX) testing systems. MedGraphics cardiorespiratory systems operate with its proprietary BreezeSuite Windows NT/2000/XP compatible software, which is 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. This software provides a common platform for all MedGraphics cardiorespiratory products. All MedGraphics products, except for certain OEM products, are sold with a personal computer, full color monitor, printer and other peripherals.

Edgar Filing: ANGEION CORP/MN - Form 10KSB

The Company also sells health and fitness 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. The participating consumer must purchase a kit 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.

Pulmonary Function Systems. Health care professionals use assessment of pulmonary function to diagnose lung diseases, such as 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.

These pulmonary function systems fall into three major product categories: Spirometry, Complete Pulmonary Function and Body Plethysmography.

All MedGraphics pulmonary function products use the preVent™ pneumotach, a patented disposable mouthpiece/flow measurement device that eliminates concern over the transmission of infectious diseases. The preVent gives all MedGraphics products the capability to perform spirometry, a test that measures 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. Additionally, the Profiler and Ultima PF hardware module are designed for use as a component of the Elite Body Plethysmography system to maximize manufacturing economies of scale.

Spirometry. The new CPF-S/D USB spirometer is comprised of a flow measurement module and a personal computer (PC). The CPF-S/D can serve as a platform that can be upgraded to either a complete pulmonary function or cardiopulmonary exercise system.

Complete Pulmonary Function Systems. The Profiler and Ultima PF Series comprise MedGraphics Complete Pulmonary Function system. The Profiler and Ultima PF are desktop or cart-mounted modules that perform non-invasive assessment of an individual's volumes (capacities), pressures, gas diffusion and mechanical properties in the lung. The Profiler Series and Ultima PF use a patented patient circuit to enhance infection control.

Capabilities available with the Profiler Series and Ultima Series systems include:

Profiler DL. The Profiler DL performs spirometry and also measures how efficiently the lungs can transfer oxygen into the bloodstream. The Profiler DL measures this lung function by using a gas chromatograph that measures gas concentrations before the patient inhales a test gas mixture and after the patient breathes the gas out. This is referred to as diffusion or diffusing capacity testing.

Profiler DX. The Profiler DX has all the abilities of the Profiler DL, plus the additional ability to measure the total volume of air in the lungs. This is done with a patented gas analyzer that measures the amount of nitrogen in a person's breath.

Ultima PF. The Ultima PF performs the same tests as the Profiler DX but uses a different methodology for assessing lung volumes. The Ultima Series also incorporates a sleeker design that has a smaller footprint and less weight to facilitate mobility.

The Profiler and Ultima Series systems' compact design and mobility option attract a wide variety of customers, including pulmonary laboratories in hospitals, clinics, physician offices, occupational medicine clinics, asthma centers and clinical research centers.

Body Plethysmograph Systems. The 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.

Elite D. The Elite D performs spirometry, measures the total volume of air in the lungs and the resistance to airflow in the airways of a person's lungs.

Elite DL. The Elite DL performs the same tests as the Elite D, and performs the diffusion test in the same manner as the Profiler DL.

Elite DX. The Elite DX performs all the tests as an Elite DL, and adds the lung volume test from the Profiler DX.

The Elite Series systems applications include diagnosing lung diseases (i.e. 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. 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.

Cardiopulmonary Exercise Testing Systems. MedGraphics' cardiopulmonary exercise (CPX) testing systems measure fitness or conditioning levels as well as help physicians diagnose heart and lung diseases. This is accomplished by measuring the concentrations of oxygen and carbon dioxide as they enter and leave the lungs and assessing how they change as a person exercises on a bike or treadmill. The gas concentrations of a person at rest can also be measured to determine nutritional requirements of critically ill patients or individuals wishing to assess the number of calories burned per day, which is termed metabolic rate. This measurement is known as metabolic assessment and is marked by Medical Graphics as the CCM option. Configurations using both the CPX and CCM applications are marked as a MAX system. The CPX systems measure each breath using a patented breath-by-breath methodology. These CPX systems use the same patented preVent pneumotach as the pulmonary function systems. Medical Graphics' cardiopulmonary exercise systems also include a patented oxygen analyzer and a carbon dioxide analyzer. Medical Graphics holds several patents relating to gas sampling and data reporting, including two expert system software packages for evaluating the information obtained from cardiopulmonary exercise assessments.

The CPX and Ultima Series are sold in several different configurations:

CPX/D. The basic exercise testing system is a CPX/D, which measures an individual's fitness level while exercising and ability to perform work (functional capacity) or activities of daily living (ADL).

CCM/D. The basic metabolic assessment system is a CCM/D that measures the nutritional requirements of a patient at rest.

CPX/MAX/D. A CPX/MAX/D is a CPX/D with the metabolic assessment option added.

The CPX/D, CCM/D, and CPX/MAX/D systems all use the same base hardware platform and are differentiated primarily by software.

CardiO₂. A CardiO₂ is a CPX/D with an integrated 12-lead electrocardiogram stress option added. The electrocardiogram, which measures heart functions, is generally referred to as an ECG.

CardiO₂/MAX/D. A CardiO₂/MAX/D is a CPX/D with an integrated 12-lead ECG and the metabolic assessment option.

VO 2000. The VO 2000 is a portable/ambulatory version that is about twice the size of a typical portable CD player and can transmit data via telemetry. In addition to all of the uses for CPX, applications for 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 VO 2000 is a key component of the Company's New Leaf Personal Exercise System health and fitness product.

The CPX/D can also be used in conjunction with other manufacturers' stand-alone ECG systems.

Ultima CPX. This is the basic model that performs cardiopulmonary exercise testing like the CPX/D and incorporates the sleeker, lighter weight Ultima design.

Applications for the cardiopulmonary 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, human performance laboratories and health clubs.

Cycle Ergometers and Treadmills. MedGraphics 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. MedGraphics 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 MedGraphics cardiopulmonary exercise testing systems.

Competition

Edgar Filing: ANGEION CORP/MN - Form 10KSB

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. Medical Graphics' competitors include large medical companies, some of which have greater financial and technical resources and broader product lines. Viasys Healthcare, Inc. and Ferraris Medical, Inc represent the principal competitors for Medical Graphics' current products. The Company believes that the principal competitive factors in its markets are product features, price, quality, customer service, performance, market reputation, breadth of product offerings and effectiveness of sales and marketing efforts.

Competition based on price is expected to continue as an important factor in customer purchasing patterns as a result of cost containment pressures on, and consolidation in, the health care industry. This competition has exerted, and is likely to continue to 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 such downward price pressure through corresponding cost reductions. Any failure to offset this pressure could have an adverse effect on our 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's New Leaf products for the health and fitness market combine components that individually have numerous competitors including from metabolic measurement systems (HealtheTech), heart rate monitors (Polar), nutrition education and lifestyle enhancement software (e-Diets), and weight loss programs (Jenny Craig, Weight Watchers). The Company believes that its integration of these components together with its proprietary exercise programming into a weight loss program for the consumer has been accomplished in a unique manner. The Company has protected this product with various patents and is presently unaware of any other system that competes directly.

Manufacturing

Edgar Filing: ANGEION CORP/MN - Form 10KSB

Medical Graphics currently manufactures and assembles all major analyzer components of its pulmonary systems including a waveform analyzer, flow board, gas sample lines, gas chromatograph, nitrogen analyzer and oxygen analyzer. Sheet metal, electrical components 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 transducer modules into these systems. Medical Graphics acquires its cycle ergometers and treadmills from third parties. Although some of Medical Graphics' components are purchased from only one or a limited number of suppliers, Medical Graphics believes that if it were unable to obtain components from these suppliers, it would be able to obtain comparable components from other sources without significant additional expense or interruption of business.

Medical Graphics is ISO 13485 certified for its development and manufacturing processes. See [Regulation by Foreign Governments](#) for additional discussion of the Company's ISO 13485 certification.

Marketing and Distribution

Edgar Filing: ANGEION CORP/MN - Form 10KSB

Medical Graphics markets its products in the United States through a direct sales force that targets customers located in hospitals, university-based medical centers, clinics and physician offices of heart and lung specialists. Each salesperson is responsible for a specific geographic area and sells Medical Graphics' complete product line to all customers, from hospitals to physician offices within that area. The Company markets its New Leaf personal exercise product through a separate direct sales force that targets customers located in fitness clubs, weight loss centers and cardiac rehabilitation clinics. Medical Graphics salespersons are compensated with a base salary, expense reimbursement and a revenue-based commission.

Medical Graphics markets its products outside the United States through independent distributors. During 2004, Medical Graphics used approximately 55 distributors to sell its products into 64 countries. These distributors typically carry a limited inventory of MedGraphics products and sell these products in

specific geographic areas, generally on an exclusive basis. International sales accounted for 17.2% and 15.9% of total sales for the years ended October 31, 2004 and 2003, respectively. All of Medical Graphics' international sales are made on a United States dollar-denominated basis to distributors.

Sales into foreign countries involve certain risks not ordinarily associated with domestic business including fluctuations in exchange rates even when product sales are denominated in dollars, reliance on distributors and fluctuations in sales resulting from changes in local economies.

Medical Graphics believes that demonstration of its products' capabilities to potential customers is one of the most significant factors in achieving sales. Consequently, the main thrust of domestic and international promotional efforts is product demonstrations at trade shows and customer facilities. Other promotional efforts include educational seminars, print advertisements, direct mail campaigns and marketing through the (www.medgraphics.com) web site for cardiorespiratory diagnostic products and (www.newleaffitness.com) for New Leaf health and fitness products.

Research and Development

Edgar Filing: ANGEION CORP/MN - Form 10KSB

During 2003, the Company introduced two new Windows based BreezeSuite software products. In addition, Medical Graphics is continuing to add product improvements designed to enhance product reliability and improve margins as well as to migrate to newer operating platforms such as Windows XP and newer development tools such as .Net. Medical Graphics is also developing new products targeted for new growth markets, including products that will be marketed under the New Leaf brand. The Company believes ongoing research and development efforts have been and will remain important to its continuing success. Research and development expenses were \$1,672,000 and \$1,538,000 for the years ended October 31, 2004 and 2003, respectively.

Intellectual Property

Edgar Filing: ANGEION CORP/MN - Form 10KSB

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.

Angeion owns over 100 patents related to ICD technology while its Medical Graphics subsidiary relies on a combination of patent, trademark and trade secret laws to establish proprietary rights in its products. Medical Graphics currently owns 24 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. Also, the New Leaf business employs various Medical Graphics patents in its 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 application, 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 year term from the date of filing above or 17 years from the patent grant.

Both Angeion and Medical Graphics also own registered trademarks and have 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, 1085/DX, Elite/Dx, Elite/DL, PF/Dx, Profiler/Dx, Profiler/DL, CPF-S/D, Pulmonary Consult, Exercise Consult, KnowledgeNet and various Logos.

Similarly, New Leaf trademarks and copyrights include but are not limited to: New Leaf, ExerSmart, ExerScript, PDC Personal Digital Coach, PAS Personal Assessment System, 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 such 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 will 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.

Angeion has also entered into a number of license agreements over the past several years under which it has licensed its ICD technology to third parties. Angeion intends to continue to protect its intellectual technology and if appropriate to seek license agreements from third parties that utilize the Company's technology.

The Company has also entered into a Technology License Agreement under which it obtained a license related to the design and manufacture of talking heart rate monitors. This license represents the technology for the Company's New Leaf Personal Digital Coach.

Government Regulation

Edgar Filing: ANGEION CORP/MN - Form 10KSB

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. Following the enactment of the Medical Device Amendments to the Act in May 1976 (the Amendments), the FDA classified medical devices in commercial distribution into one of three classes, Class I, II or III. 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 Medical Graphics products are Class II devices. Angeion's ICD products were classified as Class III devices.

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

Edgar Filing: ANGEION CORP/MN - Form 10KSB

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. QSRs 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. Medical Graphics is registered as a manufacturer with the FDA and successfully passed an FDA audit in 2004.

The Company is subject to certain FDA regulations governing manufacturing practices, labels, packaging, defective products and complaints about its products. 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. Further, the FDA regulates the export of medical devices that have not been approved or cleared for marketing in the United States.

Regulation by Foreign Governments

Edgar Filing: ANGEION CORP/MN - Form 10KSB

The Company's products are also subject to regulation similar to that of the FDA in various foreign countries. ISO 13485 certification indicates that a company's development and manufacturing processes comply with standards for quality assurance and manufacturing process control. ISO 13485 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 certification for its development and manufacturing processes in 1998 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. Compliance with ISO 13485 certification also enables the Company's products to meet the Medical Device Requirements for Canada.

Employees

Edgar Filing: ANGEION CORP/MN - Form 10KSB

As of October 31, 2004, the Company had 117 full-time and 5 part-time employees, including 32 in sales and marketing, 29 in customer support, education and field service, 34 in engineering, materials and manufacturing, 11 in research, development and regulatory, and 16 engaged in finance and administration. 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

Edgar Filing: ANGEION CORP/MN - Form 10KSB

This Annual Report on Form 10-KSB contains certain forward-looking statements. For this purpose, any statements contained in this Form 10-KSB that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as may, will,

expect, believe, anticipate, estimate or continue or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties. The Company's actual results could differ materially from those anticipated in such forward-looking statements as a result of certain factors, including those set forth in the following risk factors and elsewhere in this Annual Report on Form 10-KSB. These forward-looking statements are made as of the date of this Annual Report on Form 10-KSB and the Company assumes no obligation to update such forward-looking statements, or to update the reasons why actual results could differ materially from those anticipated in such forward-looking statements.

Certain Risk Factors

History of Recent Losses. During the years ended October 31, 2004 and 2003, the Company incurred losses of \$2,300,000 and \$2,784,000, respectively. While the Company believes that its existing cash is adequate to support operations for the next 18 to 24 months or more, the Company must ultimately achieve profitability or obtain additional financing to be able to meet its future cash flow requirements, and there can be no assurance that it will do so.

Product Liability and Potential Insufficiency of Product Liability Insurance. The testing, manufacturing, marketing and sale of medical devices involve risk of liability claims and product recalls. ICD products that the Company sold in the past are highly complex and were used in medical procedures and in situations where there is a potential risk of serious injury, adverse side effects or death. As a result, the Company currently carries product liability insurance covering its products with policy limits per occurrence and in the aggregate which the Company has deemed to be sufficient. The Company cannot predict, however, whether this insurance is sufficient, or if not, whether the Company will be able to obtain sufficient insurance, to cover the risks associated with the Company's business or whether such insurance will be available at premiums that are commercially reasonable. Although the Company has discontinued its ICD business, a successful claim against or settlement by the Company in excess of its insurance coverage or the Company's inability to maintain insurance in the future could have a material adverse effect on the Company's business, results of operations, liquidity and financial condition.

The Company has received a claim for indemnification from ELA Medical, Inc. for expenses incurred by ELA Medical in connection with ICDs formerly manufactured by the Company. Although the Company believes its product liability insurance covers the potential liability associated with the ELA Medical claim, subject to applicable self-retention, there can be no assurance that the Company will not be subject to other claims in the future. During the years ended October 31, 2004 and 2003, the Company recorded losses in discontinued operations of \$901,000 and \$235,000, respectively, to reflect an impairment of the ICD patents, its liability for expenses associated with a claim by ELA Medical for reimbursement of costs related to ICDs formerly manufactured by the Company that were experiencing premature battery depletion and related matters. These losses are net of probable insurance recoveries and include other expenses associated with the claim. See Note 13, Discontinued Operations, in Notes to Consolidated Financial Statements and Item 3, Legal Proceedings in this Form 10-KSB.

Success of Business Plan. Successful implementation of the Company's business plan through its Medical Graphics subsidiary operating entity is dependent on the interaction of many variables, including the effects of changing industry conditions, competition and the Company's ability to successfully market and sell its new products. 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 would not adversely affect its ability to execute the 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, the projected sales volume increases.

Dependence upon New Products. The Company has previously announced that it intended to focus a significant portion of its resources on the weight loss, cardiac rehabilitation and disease prevention markets that are a logical extension of its core cardiorespiratory systems business. The Company's future success will be dependent, in part, upon its ability to successfully identify and introduce new products and services into the weight loss, cardiac rehabilitation and disease prevention markets. In developing new products, it will incur additional research and development and marketing expenses. The Company's success will also depend upon cost effective development of new products for its cardiorespiratory markets. There can be no assurance that revenues, if any, from new products will be sufficient to recoup the Company's expenses in developing and marketing any new product. Moreover, there is no assurance that the Company can manufacture these new Medical Graphics and New Leaf products at a cost, or sell these products at a price, that will result in an acceptable rate of return for the Company. Market acceptance of these new products may be slow or customers may not accept the new products at all. If the Company cannot successfully develop and market new products, its financial performance and results of operations will be adversely affected.

Need for Market Acceptance. Market acceptance of the Company's products will depend, in part, on the capabilities and operating features of its products compared to competing products, the Company's ability to convince the medical community of the clinical efficacy of its products, the timeliness of its product introductions compared to competing products and its ability to manufacture quality products profitably and in sufficient quantities. Failure of the Company's products to gain market acceptance would have a material adverse effect on the Company's business, financial condition and results of operations. Furthermore, even if there is growth in the markets for the Company's products, there can be no assurance that the Company will participate in such growth.

Importance of Intellectual Property Protection. Patents and trademarks are critical in the medical device industry, and 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.

Nasdaq SmallCap Market. Angeion's common stock is traded on the Nasdaq SmallCap Market. Under the rules for continued inclusion on the Nasdaq SmallCap Market, the Company must maintain a minimum bid price of \$1.00 for its common stock and must maintain a minimum of \$1.0 million in market value of its publicly held shares. Although the Company has been in compliance with the Nasdaq minimum bid requirements since December 2002, the Company can give no assurance that it will be able to meet the requirements for continued listing on the Nasdaq SmallCap Market in the future.

Dependence on Senior Management and Other Key Personnel. The Company's success depends largely on 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.

Dependence on Third Party Vendors. 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. Medical Graphics acquires its cycle ergometers and treadmills from third parties. Although the Company attempts to maintain sufficient quantities of inventory of such 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 such 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.

Effect of Certain Anti-Takeover Provisions. 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.

Under the Bylaws, for a period of three years after the end of the fiscal year in which the Reorganization Plan is confirmed or until November 1, 2005, no purchase of the Company's common stock may be made by any beneficial owner of 5% or greater of the Company's common stock (or any person who would become a 5% or greater owner as a result of the purchase), unless the transfer is approved in advance by the Company's Board of Directors.

The Company has also entered into agreements with certain executive officers that provide for certain benefits upon a change of control.

Item 2. Description of Property.

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 manufacturing space expires in June 2009. Annual rental costs will be approximately \$286,000 in fiscal year 2005. Rent expense was \$301,000 and \$297,000 for the years ended October 31, 2004 and 2003, 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. Apart from the litigation discussed below, management believes that the settlement of all litigation would not have a material effect on the financial position of the Company.

In June 2002, ELA Medical, a former partner of Angeion in a joint venture that manufactured and distributed ICDs, advised Angeion that some of the ICDs formerly manufactured by Angeion were experiencing premature battery depletion and that 14 had been explanted. In accordance with FDA procedures, Angeion instituted a field corrective action on certain of the ICDs.

In June 2003, ELA Medical sought reimbursement from Angeion for the cost of explanting and replacing the ICDs. Angeion advised its insurance carrier of the ELA Medical claim and sought coverage of the claim.

On September 13, 2004, the basic insurer, Medmarc Casualty Insurance Company, advised Angeion that Medmarc was denying insurance coverage to Angeion for the claim by ELA Medical, Inc. In addition, on September 13, 2004, Medmarc commenced a declaratory judgment action against Angeion and ELA Medical in United States District Court for the District of Minnesota seeking a declaratory judgment that Medmarc's interpretation of the policy is correct. In the lawsuit, ELA Medical has entered a cross-claim against Angeion for the costs and expenses it incurred in connection with the recall in the equivalent amount of \$1,665,068.

Angeion has denied liability to ELA Medical and has counterclaimed against Medmarc and is seeking a declaratory judgment that Medmarc is liable (i) to Angeion for any amount that it is required to pay to ELA Medical, and (ii) for any fees and expenses that Angeion has incurred in connection with defense of the cross-claim by ELA Medical and the declaratory action by Medmarc. Angeion vigorously intends to pursue its available defenses against ELA Medical and it asserts that Medmarc is required to provide Angeion coverage with respect to these matters.

The lawsuit is just beginning and is currently only in the discovery stage. The Company expects that any trial in this matter will not occur until the spring of 2006.

The Company believes that although it may have some liability to ELA Medical, for several reasons, it is not liable to ELA Medical for the entire amount alleged. The Company further believes that a certain portion of the amount expended by ELA Medical may not be covered by insurance. The Company currently believes that the amount of its potential liability to ELA Medical, including associated expenses, ranges from \$1,092,000 to \$2,198,000 and has recorded a liability of \$1,092,000 at October 31, 2004. Based on the relevant facts, the Company also believes it is probable that at least \$700,000 of any claims ultimately paid to ELA Medical are recoverable under existing insurance policies. Accordingly,

the Company recorded an additional loss of \$901,000 during FY 2004 to reflect its liability associated with this claim, an impairment of the ICD patents and other related matters. This loss is net of probable insurance recoveries and includes other expenses associated with the claim.

The ultimate amount of both the liability due to ELA Medical and the amount recoverable from the insurance carriers is subject to future development and additional information. The amounts currently estimated for the claim and associated expenses as well as the probable insurance recovery are based on data provided by ELA Medical for explantations that occurred through March 31, 2004 and other information related to the cause of the battery depletion. Since 167 devices remain implanted in patients at March 31, 2004, the amount of the claim may increase. While it is not possible to predict the ultimate amount of the claim or the associated expenses, the Company believes that if the amount of the claim increases, the amount recoverable from the insurance company would also increase. In addition, the Company's liability insurance coverage for claims associated with its ICD products expires on July 11, 2005.

The Company may incur additional expenses, which could be substantial, in connection with any purchase of insurance coverage beyond July 11, 2005.

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 Small Business Issuer Purchases of Equity Securities.**

The Company's common stock is traded on the Nasdaq SmallCap Market under the symbol ANG.N. The prices below are the high and low sales prices as reported by the Nasdaq SmallCap Market for each quarter of FY 2004 and 2003

Angeion Common Stock Prices

Fiscal Years	High	Low
2004		
Fourth quarter	\$ 1.70	\$ 1.18
Third quarter	1.95	1.06
Second quarter	2.98	1.71
First quarter	3.40	1.42
2003		
Fourth quarter	2.45	1.25
Third quarter	2.49	0.65
Second quarter	1.45	0.65
First quarter	5.00	0.25

As of December 2004, approximately 640 persons held the Company's common stock of record. In addition, nominees for approximately 5,000 shareholders held a number of 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

Edgar Filing: ANGEION CORP/MN - Form 10KSB

The following table provides information as of October 31, 2004 with respect to the shares of the Company's common stock that may be issued under its equity compensation plan. The Company has one equity compensation plan, its 2002 Stock Option Plan.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	482,800	\$ 5.78	117,200

Recent Sales of Unregistered Securities

The Company had no unregistered sales of equity securities during the quarter ended October 31, 2004.

Small Business Issuer Purchases of Equity Securities

The Company did not purchase any equity securities during the quarter ended October 31, 2004.

Item 6. Management's Discussion and Analysis or Plan of Operation.

Overview

The Company, through its Medical Graphics Corporation subsidiary, designs non-invasive diagnostic systems under the MedGraphics trade name that assist health care professionals in the prevention, early detection and cost-effective treatment of heart and lung disease. It also markets a version of some of these products under the New Leaf® brand to health and fitness clubs and personal trainers to assist them in developing exercise programs to help their clients meet their personal goals. Revenues consist of equipment and supply sales and service revenues. Equipment and supply sales reflect sales of Medical Graphics non-invasive cardiorespiratory diagnostic equipment, sales of New Leaf health and fitness products, and aftermarket sales of peripherals and supplies. Service revenues reflect contract revenues from extended service contracts, non-warranty service visits and training. Total revenue was \$20.7 million and \$18.7 million for the years ended October 31, 2004 and 2003, respectively.

The Company's primary objectives for 2004 included improvement of sales and margins from cardiorespiratory diagnostic products, and increasing the number of fitness clubs and training studios offering the New Leaf products to their clients as well as increasing client participation at those locations. In addition, the Company continued with the programs commenced in 2003 to strengthen both its MedGraphics brand and New Leaf brand product offerings.

The year 2004 was another positive year for the Company's cardiorespiratory products in both the United States and international markets. Demand from domestic customers got off to a slow start in the first quarter of 2004 but finished the year with three consecutive quarters of strong demand. Our customers' interest in replacing their older pulmonary function systems with new equipment together with introduction of the new CPX Ultima during the second quarter of 2004 gave rise to that demand. Sales of the Company's New Leaf products also significantly contributed to domestic growth during 2004.

Internationally, distributor order rates varied from quarter to quarter but were relatively strong throughout the year. In Europe, distributor orders increased as a result of improved focus on our distributor network and the weakened U.S. Dollar compared to the Euro. Orders from Latin American distributors increased as a result of improving economies in Venezuela and Brazil.

During 2003 the Company commenced development of several new products intended for potential growth opportunities identified within both our domestic and international cardiorespiratory markets. The first of those new products, the CPX Ultima, was introduced during the second quarter of 2004. We are on schedule to begin selling four additional new products during 2005. The Company will be announcing these new products to its customers as they are introduced.

Significant progress was made with the sales of New Leaf fitness products during 2004 as those sales contributed to domestic growth for the year. However, we continue to modify and improve not only

the products being offered but also our promotional programs to introduce the New Leaf products. Last year we reported that throughout 2003, the New Leaf program contended with both the availability and quality of the personal digital coach product as the vendor that supplied that product struggled to implement effective manufacturing quality control procedures. We attempted to remedy that problem by entering into a Technology License Agreement in September 2003 under which the Company assumed the responsibility for all manufacturing of that product. The Company continues to address those quality problems. In the meantime, alternative devices have been identified and are now being offered to our New Leaf customers.

In June 2002, ELA Medical, a former partner of Angeion in a joint venture that manufactured and distributed ICDs, advised Angeion that some of the ICDs formerly manufactured by Angeion were experiencing premature battery depletion and that 14 had been explanted. In accordance with FDA procedures, Angeion instituted a field corrective action on certain of the ICDs. In June 2003, ELA Medical sought reimbursement from Angeion for the cost of explanting and replacing the ICDs. Angeion advised its insurance carrier of the ELA Medical claim and sought coverage of the claim. The insurance company, Medmarc Casualty Insurance Company, initially advised the Company that there was coverage, at least in part, and even reserved \$1.0 million for that coverage. In September 2004, Medmarc advised the Company that it was denying coverage and commenced an action against the Company seeking a declaratory judgment that Medmarc's interpretation of the policy was correct. The Company vigorously intends to pursue its available defenses against ELA Medical and has asserted that Medmarc is required to provide Angeion coverage with respect to these matters. The lawsuit is just beginning and is currently only in the discovery stage. The Company expects that any trial in this matter will not occur until the spring of 2006. See Note 13, Discontinued Operations, Notes to Consolidated Financial Statements in this Form 10-KSB and Item 3, Legal Proceedings for further discussion of this matter.

All intangible asset fair values were determined at October 31, 2002 by an independent third-party appraiser under SOP 90-7. See Note 2, Summary of Significant Accounting Policies, *Basis of Presentation*. A portion of intangible assets is related to the value of patents associated with the Company's business of manufacturing and selling implantable cardioverter defibrillators (ICDs), which was discontinued in 2000.

During the period from 1999 through mid 2002, the Company licensed the ICD patents realizing \$53 million in cash and stock-based proceeds. The following schedule lists these transactions in chronological order.

Year	Amount (in thousands)
April 1999	\$ 35,000
March 2000	9,000
March 2000	5,000
September 2002	4,000

Subsequent to these transactions, an independent appraiser determined that the fair value of the ICD patents was \$450,000 at October 31, 2002. The most significant piece of information available to the independent appraiser at the time was the recent historical licensing revenue associated with the ICD patents.

Although the Company continues to explore the sale or licensing of the ICD patents, it has determined that the ICD patents have become impaired at October 31, 2004 because the Company does

not currently have an identifiable source of revenue or a bona fide agreement to provide a source of revenue for these patents to support their current value. Absent a revenue source, the patents were determined impaired and \$243,000 was charged to discontinued operations for the year ended October 31, 2004.

Despite this impairment, the Company believes the ICD patents continue to have value and remains committed to delivering that value on behalf of its shareholders. To that end, the Company continues to explore the sale or further licensing of the ICD patents.

The following paragraphs discuss the Company's performance for the year ended October 31, 2004 compared to 2003.

Results of Operations

Edgar Filing: ANGEION CORP/MN - Form 10KSB

The following table summarizes selected financial data relating to the operations of the Company. Data for the years ended October 31, 2004 and 2003 are derived from the audited financial statements of the Company.

(000 s omitted)	Year Ended October 31,	
	2004	2003
Revenue	\$ 20,688	18,712
Gross margin	9,736	8,110
Gross margin percentage	47.1%	43.3%
Operating expenses:		
Selling and marketing	6,131	5,581
General and administrative	2,399	2,722
Research and development	1,672	1,538
Amortization of intangibles	951	847
	11,153	10,688
Operating loss	(1,417)	(2,578)
Interest income	18	29
Loss before taxes	(1,399)	(2,549)
Tax benefit		
Loss from continuing operations	(1,399)	(2,549)
Loss from discontinued operations	(901)	(235)
Net loss	\$ (2,300)	(2,784)

Year Ended October 31, 2004 Compared to 2003

Revenues. Total revenue increased by 10.6% to \$20.7 million for the year ended October 31, 2004 from \$18.7 million for the year ended October 31, 2003. Domestic product revenue increased by 10.1% to \$14.0 million in 2004 compared to \$12.7 million in 2003. Internationally, product revenue

increased 19.5% to \$3.6 million in 2004 from \$3.0 million in 2003. Service revenue increased 3.7% to \$3.1 million in 2004 compared to \$3.0 million in 2003.

The increase in domestic product revenue for the year reflects increased customer demand for both cardiorespiratory product systems and New Leaf products. Customer orders for cardiorespiratory product systems have been strong for the last three quarters with no near term signs suggesting that order rates will decline. Revenue from the Company's new CPX Ultima products, first shipped during the second quarter, contributed to the increase for the year.

International product revenue finished 19.5% ahead of the prior year due to increased demand from both Latin American and European customers. Latin America business has improved due to improving economies and in Europe the weakened U.S. Dollar compared to the Euro has contributed to an improved business climate. Equipment orders from customers throughout the rest of the world modestly increased over 2003. While introduction of the new CPX Ultima products contributed to the international revenue increase, new products are subject to regulatory approval before they can be sold in certain countries.

Service revenue for 2004 increased over the prior year due to the Company's focus on increasing the number of non-warranty service visits.

Gross Margin. Gross margin percentage increased to 47.1% of revenue for the year ended October 31, 2004 compared to 43.3% for 2003. The impact of the 2002 fresh-start accounting adjustments resulted in a decrease in gross margin of \$283,000 or 1.5% for the year ended October 31, 2003. Without those adjustments, the underlying gross margin rate would have been 44.8% for 2003. Consequently, the underlying improvement of gross margins from 44.8% in 2003 compared to the 47.1% in 2004 is due to improved manufacturing efficiencies due to higher throughput.

Selling and Marketing. Total selling and marketing expenses increased 9.9% to \$6.1 million for the year ended October 31, 2004 compared to \$5.6 million in 2003. The increase resulted primarily from increased marketing expenses associated with the Company's New Leaf health and fitness products. In addition, the expenses associated with the Company's attendance at trade shows have increased over the prior year.

General and Administrative. General and administrative expenses decreased 11.9% to \$2.4 million in 2004 compared to \$2.7 million in 2003. The decrease in general and administrative expenses was due to decreased personnel expenses, a lower provision for doubtful accounts and reduced insurance expenses.

Research and Development. Research and development expenses increased 8.7% to \$1.7 million in 2004 from \$1.5 million in 2003. The Company's research and development costs are focused on developing additional cardiorespiratory diagnostic products. The increase in research and development expenses for the year reflects the incremental costs of developing those new products. The first of these products, the CPX Ultima, was shipped to customers during the second quarter of 2004. Additional new products are scheduled for release throughout 2005 with the next product planned for release during the second quarter of 2005.

Amortization of Intangibles. Amortization of intangibles increased to \$951,000 for the year ended October 31, 2004 compared to \$847,000 for the same period in 2003. The increase in amortization is due to the acquisition of a Technology License Agreement under which the Company obtained a license related to the design and manufacture of talking heart rate monitors. In addition, the Company

revised the amortized life of its ICD patents from 10 to 3 years effective for the fourth quarter of fiscal 2003.

Interest Income. Interest income decreased to \$18,000 in 2004 from \$29,000 in 2003. The decrease in interest income reflects an decrease in excess cash balances available for short-term investment.

Loss From Discontinued Operations. During the years ended October 31, 2004 and 2003, the Company recorded losses of \$901,000 and \$235,000, respectively, in connection with its discontinued operations, including an impairment of its ICD patents, its liability to ELA Medical for expenses associated with a claim for reimbursement of costs related to ICD s formerly manufactured by the Company that were experiencing premature battery depletion and other related matters. These losses are net of probable insurance recoveries and include other expenses associated with the claim. For additional details, see Note 13, Discontinued Operations, Notes to Consolidated Financial Statements in this Form 10-QSB.

Liquidity and Capital Resources

Edgar Filing: ANGEION CORP/MN - Form 10KSB

The Company has financed its liquidity needs over the last several years through revenue generated by the operations of its wholly owned subsidiary, Medical Graphics Corporation, through revenue from license agreements for patented ICD technology and through the use of cash balances.

The Company had cash of \$2.4 million and working capital of \$5.3 million as of October 31, 2004. During the year ended October 31, 2004, the Company used \$467,000 in cash from continuing operations, primarily as a result of its net loss of \$2.3 million, which was offset by \$1.5 million of depreciation and amortization. Cash was generated by an increase of \$499,000 in accounts payable. The Company used cash for increases of \$728,000 and \$173,000 in accounts receivable and inventories, respectively, as well as a decrease of \$105,000 in accrued employee compensation. The changes in receivables, inventories and accounts payable all reflect a need to support higher levels of revenue. In addition, the Company used \$501,000 in cash for discontinued operations, which included legal fees and the purchase of additional product liability insurance for its discontinued ICD products.

During the year ended October 31, 2004, the Company used \$240,000 in cash for the purchase of property and equipment.

The Company has no material commitments for capital expenditures for fiscal year 2005.

With respect to the ELA Medical claim associated with the discontinued ICD products, the Company vigorously intends to pursue its available defenses against ELA Medical and asserts that Medmarc is required to provide insurance coverage with respect to these matters. The lawsuit is just beginning and is currently only in the discovery stage. The Company expects that any trial in this matter will not occur until the spring of 2006. The ultimate amount of both the liability due to ELA Medical and the amount recoverable from the insurance carriers is subject to future development and additional information. It is always possible that the Company will not prevail in this effort and the resulting expenses could be substantial. Furthermore, the Company's liability insurance coverage for claims associated with its ICD products expires on July 11, 2005. The Company may incur additional expenses, which could be substantial, in connection with any purchase of insurance coverage beyond July 11, 2005. For additional details, see Note 13, Discontinued Operations, Notes to Consolidated Financial Statements in this Form 10-KSB.

The Company expects that its operating results will be cash flow positive for fiscal 2005. Subject to the ELA claim discussed above, the Company believes that its liquidity and capital resource needs for

fiscal year 2005 will be met through its current cash and cash equivalents, cash flows from operations and working capital.

Other Commitments

Edgar Filing: ANGEION CORP/MN - Form 10KSB

The Company has made various financial commitments in the ordinary course of conducting its business operations. Although these commitments are more fully discussed in the Notes to Consolidated Financial Statements, we are summarizing all of our significant commitments in the following table:

Contractual Obligations	Total	Payments due by period (in thousands)			More than 5 years
		Less than 1 year	1-3 years	3-5 years	
Operating lease obligations	\$				