MGC DIAGNOSTICS Corp
Form 10-K
January 30, 2017

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, 2016.
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

MGC DIAGNOSTICS 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 Capital Market
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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

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

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

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

The aggregate value of the Company's Common Stock held by non-affiliates of the Company was approximately $23,639,000 as of April 30, 2016, the last day of the Company's most recently completed second fiscal quarter, when the last reported sales price was $5.41 per share.

As of January 25, 2017, the Company had outstanding 4,387,643 shares of Common Stock, $0.10 par value.

Documents Incorporated by Reference: Portions of the Company's Proxy Statement for its Annual Meeting of Shareholders to be held on March 22, 2017 are incorporated by reference into Part III of this Form 10-K.

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PART I

Item 1. Business.

Unless the context requires otherwise, references in this Form 10-K to “MGC” or “MGC Diagnostics” mean MGC Diagnostics Corporation, while references to “Medical Graphics” refer to Medical Graphics Corporation, a wholly-owned subsidiary of MGC Diagnostics Corporation and references to “Medisoft” refer to Medisoft SA, a wholly-owned subsidiary of MGC Diagnostics Corporation, and its subsidiaries. MGC Diagnostics, Medical Graphics and Medisoft are collectively referred to as the “Company.”

Overview

MGC Diagnostics Corporation (the “Company”) is a global medical technology company dedicated to cardiorespiratory health solutions. The Company designs, markets and sells non-invasive cardiorespiratory diagnostic products through its Medical Graphics Corporation subsidiary under the MGC Diagnostics brand and trade name and through its Medisoft subsidiary under the Medisoft brand and trade name. MGC acquired Medisoft on August 1, 2014. The Company’s product portfolio provides solutions for disease detection, integrated care, and wellness across the cardiorespiratory healthcare spectrum. The Company sells its products internationally through distributors and in the United States through a direct sales force targeting specialists located in hospitals, university-based medical centers, medical clinics, physician offices, pharmaceutical companies, medical device manufacturers, and clinical research organizations (“CROs”). The Company’s cardiorespiratory diagnostic products measure flow and respiratory pressures and, in most cases analyze the inhaled and exhaled gases such as oxygen and carbon dioxide. The Company operates in a single industry segment: the research, development, manufacture and marketing of non-invasive cardiorespiratory diagnostic products.

The Company had revenues of $40.0 million and operating loss of $2.6 million for the year ended October 31, 2016. The operating loss included several significant items, including:

(i) charges of $3.3 million and $0.3 for impairment of goodwill and certain intangible assets, respectively, recorded upon the acquisition of Medisoft in fiscal 2014;

(ii) $1.0 million of combined charges for legal settlement costs and obsolete inventory related to the Company's 2014 strategic initiative to enter the sleep diagnostics market; and

(iii) $0.7 million of charges for impairment of excess inventory related to the Company's strategic initiatives to distribute the Resmon PRO FOT device.

Domestic product sales and service revenue accounted for 77% of fiscal 2016 revenue and international product sales accounted for the remaining 23%. Revenue consists of equipment, supply and accessory sales as well as service revenue. Equipment, supply and accessory sales reflect sales of non-invasive cardiorespiratory diagnostic equipment and aftermarket sales of peripherals, software, supplies and additional training. Service revenue consists of revenues from extended service contracts and non-warranty services.

General

MGC Diagnostics designs and markets non-invasive cardiorespiratory diagnostic products that have a wide range of applications within cardiorespiratory healthcare.

Healthcare professionals use cardiorespiratory diagnostic products to assess the cause and degree of severity for shortness of breath and lung diseases such as asthma, emphysema and bronchitis (each are forms of Chronic Obstructive Pulmonary Disease or “COPD”), and to manage related treatment. Through breath-by-breath analysis, some of the Company’s cardiorespiratory diagnostic products measure the level of disability and functional capacity to help physicians diagnose and treat heart diseases such as heart failure and coronary disease. The Company also sells its cardiorespiratory diagnostic products and services to clinical research customers for use in drug and device clinical trials both in the United States and internationally. Other health professionals use the Company’s cardiorespiratory diagnostic products to measure calorie consumption and to prescribe safe and effective exercise in rehabilitation, obesity management, general fitness, and athletic performance. These applications operate 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. This assessment of gases and air flow can also be used to determine nutritional requirements of critically ill patients in a hospital intensive care unit (“ICU”) and cardiac catheterization laboratory.

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Primary products for each of Medical Graphics and Medisoft include pulmonary function ("PFT") and gas exchange ("GX") testing products, as discussed below in "Pulmonary Function Products" and "Gas Exchange Testing Products." All MGC Diagnostics products are designed to be simple and easy to use while providing the flexibility to address specific needs of hospitals, clinics and physician offices. MGC Diagnostics' products, except for some original equipment manufacturer ("OEM") components, are generally sold with a personal computer, color monitor, printer and other peripherals. These products increasingly include networked and internet technologies that offer remote processing applications and communications.

Seasonality

The Company experiences some seasonality in its revenues, with the fourth quarter of its fiscal year traditionally being its strongest quarter. The Company experiences variability in the other three quarters due to a number of factors, including customer budget cycles, product introductions, Company sales incentive programs, general economic conditions and the timing of customer orders. See "Management's Discussion and Analysis of Financial Condition and Results of Operations-Seasonality."

Pulmonary Function Products

Pulmonary function testing (PFT) equipment and techniques have come into widespread use and standardization over the past 30 years. Advances in computer technology and miniaturization have aided in the development of devices that have become portable and user-friendly through sophisticated software.

Health care professionals use diagnostic pulmonary function assessment to diagnose lung diseases such as asthma or COPD; the majority of assessments are performed for diagnostic purposes or to monitor patient response to therapy. Pulmonary function testing is an important tool in the management of respiratory diseases including asthma, chronic bronchitis, cystic fibrosis, emphysema, and restrictive pulmonary disease, among others. The majority of pulmonary function assessments are performed on patients with suspected pulmonary disease; however, there are non-pulmonary applications for cardiology, chemotherapy and neuromuscular analysis. Pulmonary function applications range from (i) basic lung function screening, to (ii) pre-operative surgical evaluations and post-operative assessment of heart and lung transplant patients, to (iii) disability assessment from occupational exposures, and to (iv) documenting responses to a variety of therapies.

These pulmonary function products fall into four major product categories: (i) Spirometry, (ii) Complete Pulmonary Function, (iii) Body Plethysmography and (iv) Specialty Products.

Spirometry. Spirometry is a relatively simple, painless, and inexpensive method of assessing pulmonary function. In this procedure, the patient breathes into a spirometer, an instrument that measures and records (i) the volume of exhaled or "expired" air and (ii) the airflow rate for a specific time period. Spirometry provides measurement, lung capacity and mechanical properties of airflow. Due to the simplicity of testing and the availability of portable equipment, spirometry is widely used in both inpatient and outpatient settings. MGC Diagnostics markets the **Medical Graphics CPF S/D USB™** and the **Medisoft Micro 5000** and **Micro 6000** spirometers. The spirometer is a product platform that can be upgraded to complete a pulmonary function or cardiopulmonary exercise system.

Complete Pulmonary Function. Pulmonary function testing equipment measures and analyzes breathing to evaluate the condition of the heart, lungs, and metabolism. The technique is used to diagnose and manage numerous pulmonary conditions. Although diagnostic spirometry is adequate for basic pulmonary function screening, complete pulmonary function analysis is required to diagnose the specific cause of lung disease. MGC Diagnostics markets **Medical Graphics Ultima PF Series™**, **Medisoft SpiroAir** and **Medisoft HypAir** as complete pulmonary function systems. These complete pulmonary function systems, available as a desktop or cart-mounted configuration, perform spirometry, non-invasive measurement of an individual's total lung capacity, respiratory mechanics and diffusing capacity, and the oxygen transfer across the lungs into and out of the bloodstream. In fiscal 2016, the Company received Federal Drug Administration approval for the **Resmon PRO FOT** (Forced Oscillation Technique) device, adding to this range of equipment.

Body Plethysmograph. Body plethysmographs consist of an airtight, transparent patient cabin, an adjustable support arm, pressure transducers for measuring mouth and cabin pressure and a computer. Many devices also incorporate diffusing capacity and lung volume by nitrogen washout, which enhances the scope of use. The patient sits inside the enclosure and undergoes diagnostic pulmonary function tests. MGC Diagnostics markets the **Medical Graphics Platinum Elite** and the **Medisoft BodyBox Series**, each of which are designed to minimize patient anxiety and discomfort while maximizing accuracy. These systems' designs optimize patient comfort within a clear-view acrylic enclosure and allow testing of a broad population, including pediatric patients and individuals in wheelchairs.

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The Medical Graphics Platinum Elite is available in two primary configurations:

- Platinum Elite DL. The **Platinum Elite DL™** body plethysmograph 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 described below.

- Platinum Elite DX. The **Platinum Elite DX™** body plethysmograph performs all the same tests as a Platinum Elite DL, and also performs the nitrogen washout test.

The Medisoft BodyBox Series is available in three primary configurations:

- BodyBox Standard, XL and Pediatric Models. The **Medisoft BodyBox** models differ primarily in physical size designed to accommodate specific needs of specialized healthcare professionals performing testing in diverse settings.

- The **Medisoft BodyBox** testing options are highly configurable allowing the modular addition of multiple diffusion configuration options, nitrogen washout and lung mechanic options.

Specialty Products. Specialty diagnostic pulmonary function testing products include the measurement of exhaled biomarkers and complex cardiorespiratory neuro-mechanics. MGC Diagnostics markets the Medisoft **FeNO**, **FeNO+** and **HypAir Muscle Study Systems** using licensed technologies.

- Medisoft FeNO and FeNO+. Patients with allergic airway inflammation generally have higher than normal levels of nitric oxide (NO) in their exhaled breath. By measuring the concentration of NO in an exhaled breath (fractional exhaled nitric oxide or FeNO), clinicians can evaluate allergic airway inflammation in patients with underlying asthma. The **Medisoft FeNO** and **FeNO+ Nasal** devices are specifically designed for use in specialty laboratories by healthcare professionals in the evaluation of airway inflammation.

- Medisoft HypAir Muscle Study. Patients with complex neuromuscular disease may be evaluated by studying muscle and neural drive stimuli to breathing. The **Medisoft HypAir Muscle Study** system measures the work of breathing though a series of pressure sensors and external neural stimulators.

In fiscal 2012, the Company introduced modified versions of the Ultima PF, Platinum Elite DL and Platinum Elite DX, each of which includes real time diffusion ("RTD") technology and has now discontinued the production of its historical Gas Chromatography.

All MGC Diagnostics' Medical Graphics pulmonary function products use the proprietary preVent® flow sensor, a disposable/cleanable flow sensor that eliminates concern over the transmission of infectious diseases. The preVent flow sensor gives all Medical Graphics products the capability to perform spirometry testing to measure the flow rates, capacities and mechanical properties of the lung. Medical Graphics pulmonary function products use a proprietary "expert system," Pulmonary ConsultTM, to aid physicians in the interpretation of test results.

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MGC Diagnostics pulmonary function products include applications that:

enable the early detection of lung disease;
evaluate the effect of medication;
monitor patients with chronic disease;
diagnose lung diseases (i.e. asthma, emphysema and bronchitis/COPD);
manage treatment;
assess the surgical risk of lung transplant and lung reduction candidates; and
evaluate the impact of diseases such as neuromuscular disease on breathing.

MGC Diagnostics' pulmonary function products' ease of use, infection control features, compact, lightweight design, connectivity and mobility options 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.

Gas Exchange Testing Products

MGC Diagnostics' cardiopulmonary exercise ("CPX" or "CPET") testing products measure functional capacity, fitness or conditioning levels, evaluate prognostic criteria for surgical procedures as well as help physicians diagnose heart and lung diseases. Cardiopulmonary exercise testing provides objective, reliable, and quantitative assessment of the cardiovascular and respiratory responses to varying external workloads. These products operate by measuring the volume of air and concentrations of oxygen and carbon dioxide as they enter and leave the lungs while an individual exercises on a machine such as a bike or treadmill. These tests may be augmented by various types of monitoring, including electrocardiogram ("ECG"), blood pressure, and pulse oximetry.

Cardiopulmonary exercise testing is useful (i) to differentiate between cardiac and pulmonary problems, (ii) to diagnose exercise-induced asthma, (iii) to assess preoperative risk, (iv) to determine disability and response to therapeutic interventions, (v) to determine the functional status in heart failure, and (vi) to develop exercise programs.

MGC Diagnostics products 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 the Company as the indirect calorimetry option for many of its gas exchange products. Configurations combining the cardiopulmonary exercise testing, energy expenditure and pulmonary function applications are marketed under both MGC Diagnostics' Medical Graphics and Medisoft products.

The Medical Graphics Ultima Series is sold in the following different configurations:

The ***Ultima CPX metabolic stress testing system*** is a basic exercise testing system that measures an individual's fitness level while exercising and measures an individual's ability to perform work (functional capacity) or activities of daily living. The Ultima CPX can also be used in conjunction with other manufacturers' stand-alone ECG products that measure heart functions.

The ***Ultima CardiO$_2$ gas exchange analysis system*** configuration adds an integrated 12-lead electrocardiogram stress option to the Ultima CPX.

The ***CCM Express indirect calorimeter*** is a portable, self-contained metabolic assessment system that measures the nutritional requirements of a patient at rest and during mechanical ventilation in the critical care unit.

The **Face Tent Fan** is an option for the above systems and offered where open-circuit indirect calorimetry is a desired testing methodology.

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MGC Diagnostics' Medisoft Ergocard Series is sold in the following configurations:

The ***Ergocard Clinical*** is a basic exercise testing system that measures an individual's fitness level while exercising and measures an individual's ability to perform work (functional capacity) or activities of daily living. The Ergocard Clinical can also be used in conjunction with other manufacturers' stand-alone ECG products that measure heart functions.

The ***Ergocard Professional gas exchange analysis system*** configuration adds an integrated 12-lead electrocardiogram stress option to the Ergocard Clinical.

The ***Ergocard ECG*** is a compact lightweight PC electrocardiograph that measures resting and exercise ECG and provides automated arrhythmia detection.

Applications for MGC Diagnostics' Medical Graphics Ultima CPX, and CCM Express and Medisoft Ergocard Professional, Ergocard Clinical and Ergocard ECG exercise and metabolic products include:

screening for early signs of cardiac and pulmonary dysfunction through differential diagnosis (distinguishing between cardiovascular and pulmonary disease),

evaluating the efficacy of prescribed therapy, and

determining appropriate nutritional support requirements.

Customers currently include hospital pulmonary and stress testing laboratories, cardiology and pulmonary office-based clinics, critical care units, cardiac rehabilitation units and weight management clinics.

Cycle Ergometers and Treadmills

The Company offers several models of exercise devices that provide healthcare professionals and patients a tool for improved diagnosis and more successful outcomes in clinical rehabilitation. 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. These ergometers and treadmills can be used and controlled by the Company's cardiopulmonary exercise testing products.

Through MGC Diagnostics' Medical Graphics business, the Company sells non-proprietary cycle ergometers and treadmills manufactured by best-in-class industry partners used in diagnostic, rehabilitation and sports medicine applications. Through MGC Diagnostics' Medisoft business, the Company manufactures and sells three models of treadmills – the Clinical 870A, Sport 870S and Athlete 870C.

Electronic Medical Records Interfaces

Both Medical Graphics and Medisoft sell HL7 interface technology software, installation and support for data communication interfaces to achieve interoperability between the Company's products and the electronic medical records systems used in hospital and clinical settings. Electronic medical record systems are designed to facilitate more complete, rapid transmission of patient and test results between the patient care management systems and equipment. These patient information management systems are intended to improve quality of care and reduce operating costs through improved accuracy, timeliness and efficiency of records management.

Competition

The industry for companies selling cardiorespiratory diagnostic products is mature and competitive. There are a number of companies that currently offer, or are in the process of developing, products that compete with products offered by MGC Diagnostics. The Company's competitors include both large and small medical companies, some of which have greater financial and technical resources and broader product lines. Vyaire (a successor to the former CareFusion Respiratory Solutions entity), nSpire Health, Cosmed, Ganshorn, ndd and Morgan Scientific are the Company's principal competitors. Morgan Scientific markets select Medisoft hardware within the United States. 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 that its product quality, product performance, market reputation and customer service are true differentiators that will contribute to future growth.

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The Company believes price competition will continue to be an important factor in customer purchasing patterns as a result of healthcare cost containment pressures in both the domestic and international health care industry. Domestically, a number of industry participants and associations increasingly rely on group purchasing organizations ("GPOs") in the effort to contain healthcare costs. The Company became a qualified provider for several of the larger domestic GPOs to ensure the Company's continued access to its market and to efficiently increase its sales to the expanded numbers of companies using these buying groups. Our relationship with these GPOs is continuing and can provide MGC with additional exposure to customers whose relationships with the GPO precluded past relationships with them. As the numbers of purchasers aligning with these GPOs have increased, the percentage of Company revenues attributable to GPO sales has increased as well.

Any product developed by the Company that gains regulatory approval must compete for market acceptance and market share. The timing of market introduction of competitive products could adversely affect the competitiveness of the Company's 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 and trademarks when possible.

Manufacturing

MGC's Medical Graphics subsidiary currently designs and assembles all major sensor components of its cardiopulmonary diagnostic products including its data acquisition systems, flow measurement sensors, gas sample lines, gas chromatograph, nitrogen, carbon dioxide, oxygen and other gas analyzers. The Company purchases Medical Graphics-designed sheet metal, electrical components, printed circuit boards and some measurement devices from outside vendors and these components are tested, assembled and packaged by Medical Graphics personnel into fully integrated systems.

MGC's Medisoft subsidiary currently designs, fabricates and assembles most major sensor components of its cardiopulmonary diagnostic products including its data acquisition systems, flow measurement sensors, gas sample lines, nitrogen, carbon dioxide, oxygen and other gas analyzers. Medisoft designs and fabricates sheet metal, electrical components, and printed circuit boards at its Belgium facility. Medisoft purchases some measurement devices from outside vendors; Medisoft personnel then test, assemble and package these components into fully integrated systems.

The Company also acquires general-purpose computers, monitors and printers from a variety of sources and integrates its proprietary software modules into these products. Medical Graphics acquires its cycle ergometers and treadmills from third parties, while Medisoft manufactures its treadmills and acquires ergometers from third parties.

The Company's Quality Management System is certified to the requirements of ISO 13485:2003, Canadian Medical Device Regulations Part 1, and European Union Medical Device Directive Annex II regarding the Development and Production of Cardiorespiratory devices. See "Foreign Government Regulation." below for additional discussion of the Company's ISO 13485:2003 certification.

Marketing and Distribution

MGC Diagnostics' Medical Graphics subsidiary markets its products in the United States through its direct sales force that sells into hospitals, university-based medical centers, medical clinics, physician offices, pharmaceutical companies, medical device manufacturers and clinical research organizations. Medical Graphics markets its products to a wide range of customers that use its products and services across a broad market continuum. Each Medical Graphics domestic salesperson is responsible for a specific geographic area and is compensated with a base salary, expense reimbursement and a sales commission plan.

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Outside the United States, Medical Graphics markets its products through a network of independent distributors. During fiscal 2016, Medical Graphics used 57 distributors to sell its products into approximately 49 countries. These distributors typically carry a select inventory of Medical Graphics products and sell those products in specific geographic areas, generally on an exclusive basis. International revenues accounted for 12.8% and 17.7% of total Medical Graphics revenue for the years ended October 31, 2016 and 2015, respectively. All of Medical Graphics' international sales are made on a United States dollar-denominated basis to distributors.

MGC Diagnostics' Medisoft subsidiary markets its products in France, Belgium, the United Kingdom and Italy through its direct sales force that sells into hospitals, university-based medical centers, medical clinics, physician offices, pharmaceutical companies, medical device manufacturers and clinical research organizations. Medisoft markets its products to a wide range of customers that use its products and services across a broad market continuum.

Outside the direct markets of France and Belgium, Medisoft markets its products through a network of independent distributors. During fiscal 2016, Medisoft used approximately 20 distributors to sell its products into approximately 61 countries. These distributors typically carry a select inventory of Medisoft products and sell those products in specific geographic areas, generally on an exclusive basis. Revenues outside of Belgium accounted for 88.9% of total Medisoft revenue for fiscal 2016. All of Medisoft's international sales are made on a Euro-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. Medical Graphics sells all its products on a dollar-denominated basis while Medisoft sells all its products on a Euro-dominated basis. As a result, although neither subsidiary has direct exposure to currency exchange rates risk, changes in exchange rates affect the relative competitiveness of the Company's products and services in various markets.

MGC Diagnostics 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 and advantages, breadth of services and unmatched customer support. In addition to on-site product demonstrations, the Company annually attends and hosts booth displays at various industry-specific meetings and trade shows around the world. At these events, potential customers/clients have the ability to see and experience the unique features our products offer. Through these global events, the Company gains exposure to pulmonologists, cardiologists, respiratory therapists, allergy physicians, exercise physiologists, sports medicine professionals, personal trainers and exercise enthusiasts.

Other Company marketing initiatives include educational seminars, print advertisements, direct mail, telemarketing and e-marketing campaigns through its websites www.mgcdiagnostics.com and www.medisoft.be. Group Purchasing Organizations ("GPOs") have become increasingly present in our market as hospitals work to streamline their supply chain. Vendors can become accredited by the GPOs, which can facilitate the selling process. The Company has a relationship with all major GPOs, including Amerinet, HealthTrust, Premier Purchasing, Vizient, and the Government

Services Administration (“GSA”). Sales associated with GPO relationships were $20.5 million and $16.1 million in fiscal 2016 and 2015, respectively.

Research and Development

In fiscal 2016, MGC Diagnostics continued to develop new products and implemented product improvements designed to enhance product reliability and improve margins. The Company’s research and development initiatives are targeted for hospitals, clinics and physician’s offices. An integral component of the Company’s future growth strategy is the development and introduction of additional new products and complementary software.

Research and development expenses were $2.7 million and $2.9 million for the years ended October 31, 2016 and 2015, respectively. Fiscal 2016 and 2015 expenditures included costs of the Company’s initiative to migrate its products’ operating software to a next-generation platform that includes added functionality and flexibility, providing the foundation for a future product pipeline of new integrated patient care and potential consumer health and disease management programs.

In addition to research and development amounts expensed, the Company’s fiscal 2016 and 2015 internal investments included costs that were capitalized and will be amortized as the Company completes its software development and puts the products into service. See Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations-Research and Development.

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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. The Company's Medical Graphics subsidiary currently holds six United States patents (with various expirations between 2026 and 2031), with one patent pending and a number of foreign patents with respect to technologies covered by its United States patents. These patents collectively cover the various aspects of MGC Diagnostics' core technologies, ranging from gas analysis, pressure and flow measurement to methods of analyzing cardiorespiratory data and expert system software. The Company's Medisoft subsidiary currently has two patents pending covering diagnostic technologies used in its products. United States patents filed on or after June 8, 1995 have a term of 20 years from the date on which the patent application was filed.

Foreign patents generally expire 20 years after the date of original application, but vary from country to country. MGC Diagnostics intends to aggressively enforce its intellectual property rights and has successfully done so in the past. We cannot ensure, 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.

MGC Diagnostics' Medical Graphics subsidiary also owns registered trademarks and has applied for other trademarks in the U.S. and certain foreign countries. MGC Diagnostics owns and actively enforces an array of related copyrights and trademarks. These include: BreezeConnect™ HL7 interface technology, BreezeSuite WebReview™ physician review software, Platinum Elite™ body plethysmograph, RTD™ real-time diffusion, Ultima™ CardiO2® gas exchange analysis system, Ultima CPX™ metabolic stress testing system and Ultima PF™ pulmonary function system, as well as various logos.

Although patent and intellectual property disputes in the medical device industry have often been settled through licensing agreements or similar arrangements, costs associated with these arrangements may be substantial and we cannot ensure 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 operation.

The Company seeks to protect its trade secrets and proprietary intellectual property, including 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. We cannot ensure, 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, we cannot ensure 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.

United States Government Regulations.

Most of the products manufactured by the MGC Diagnostics' Medical Graphics subsidiary 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 these devices. The FDA classifies 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.

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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 ensure 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 MGC Diagnostics’ Medical Graphics products are Class II 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.

As Class II devices, the Company’s domestic sales of its registered devices became taxable when the Health Care and Education Reconciliation Act of 2010 (in conjunction with the Patient Protection and Affordable Care Act, Public Law 111-152) added section 4191, Medical Devices for sales subsequent to December 31, 2012. This excise tax is levied at a rate of 2.3% of the relevant sales price of the products. Effective January 1, 2016, and ending on December 31, 2017, The Consolidated Appropriations Act, 2016, signed into law on December 18, 2015, included a two-year moratorium on the medical device excise tax. Currently legislation is being drafted in both the House of Representatives and Senate to permanently repeal the tax, which if passed is expected to be signed into law by the new administration.

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 ("510(k) Notification") with the FDA at least 90 days before introducing a product not exempted from notification requirements into the marketplace. The 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 products pursuant to Section