

HAEMONETICS CORP
Form 10-K
May 25, 2007

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 March 31, 2007.

Commission file number 1-10730

HAEMONETICS CORPORATION

(Exact name of registrant as specified in its charter)

Massachusetts
(State of Incorporation)
400 Wood Road
Braintree, Massachusetts
(Address of principal executive offices)

04-2882273
(I.R.S. Employer Identification No.)
02184-9114
(Zip Code)

Registrant's telephone number, including area code: **(781) 848-7100**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Common stock, \$.01 par value

**Name of each exchange
on which registered**
New York Stock Exchange

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

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 whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark 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. ☒

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

Large accelerated filer ☒ x

Accelerated filer ☐ o

Non-accelerated filer ☐ o

Indicate by check mark whether the registrant is a shell Company. Yes ☐ o No ☒ x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (assuming for these purposes that all executive officers and Directors are affiliates of the Registrant) as of September 30, 2006, the last business day of the registrant's most recently completed second fiscal quarter was \$1,178,635,000 (based on the closing sale price of the Registrant's Common Stock on that date as reported on the New York Stock Exchange).

The number of shares of the registrant's common stock, \$.01 par value, outstanding as of April 30, 2007 was 26,543,692

Documents Incorporated By Reference

Portions of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held on August 1, 2007, are incorporated by reference in Part III.

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Item 1. Business

(A) General History of the Business

Our Company was founded in 1971 and became publicly owned for the first time in 1979. In 1983, American Hospital Supply Corporation (AHS) acquired us. When Baxter Travenol Laboratories, Inc. (Baxter) acquired AHS in 1985, Baxter divested the Haemonetics business to address antitrust concerns related to the AHS acquisition. As a result, in December 1985, a group of investors that included E. I. du Pont de Nemours and Company (Du Pont) and present and former Haemonetics employees purchased us. We were incorporated in Massachusetts in 1985. In May 1991, we completed an Initial Public Offering.

We are a pioneer and a market leader in developing and manufacturing blood processing technology. Our systems help ensure a safe and adequate blood supply and assist blood banks and hospitals in their efforts to operate efficiently and in compliance with regulatory requirements. To that end, throughout our history, we have been engaged in manufacturing automated systems and single use consumables used in blood donation, blood processing, and surgical salvage of blood. More recently, we also develop associated data management technology.

We developed our first automated blood processing system in 1971. Our direct customers are blood and plasma collectors, hospitals and hospital service providers.

In fiscal year 2004, we reorganized into two global product families that address our ultimate customer (that is, our customers' customer): blood donors and surgical patients. Also in fiscal year 2004 we embarked upon two strategies: 1) leveraging the core business to improve profitability and 2) expanding the business through internal R&D, marketing partnerships, and acquisitions. As a result of the second strategy, we have broadened our core product portfolio to include complementary products used by our blood collection and hospital customers. As a result, we have added a third global product family, software and services, to our business.

Within our product families we offer:

Donor Products

- 1) Plasma systems: Our PCS® brand systems automate the collection of plasma from donors who are often paid a fee for their donation. The collected plasma is then generally processed into therapeutic pharmaceuticals.
- 2) Blood bank systems:
 - a) Our MCS® brand system automates the collection of platelets from volunteer donors. The systems enable the donation of a larger volume of the donor's platelets, which are then generally given to cancer patients and others with bleeding disorders.
 - b) Our ACP® brand systems automate the process used to freeze, thaw and wash red blood cells. The ACP systems can also be used to wash other cellular parts from red blood cells units before transfusion.
 - c) We also contract manufacture sterile intravenous solutions for pharmaceutical customers. These solutions include generic and custom drug products.
- 3) Red cell systems: Other MCS and Cymbal systems automate the collection of red cells from volunteer donors. These systems maximize the volume of red cells that can be collected from one blood donation, thus helping to alleviate blood shortages. The highest sales volume product in the red cell product line is our double red cell collection technology which allows for two units of red cells to be collected from one donor. Specialty protocols enabling the simultaneous collection of a unit of red

cells and a unit of plasma or a unit of red cells and a unit of platelets are also available in various parts of the world.

Patient Products

- 1) **Blood salvage:** Our surgical blood salvage systems allow surgeons to collect the blood lost by a patient during or after surgery, clean that blood, and have it available to transfuse back to the patient if needed. In this way, a surgical patient can receive transfusions of the safest blood possible, his or her own. Our surgical blood salvage systems include:
 - a) Our Cell Saver® brand systems for higher blood loss surgeries and trauma:
 - b) Our OrthoPAT® brand systems for lower, slower blood loss procedures, typically orthopedic surgeries; and
 - c) Our cardioPAT® brand system for blood loss during and after beating heart surgeries or for blood loss after various coronary artery bypass graft (CABG) surgeries. The cardioPAT is our newest blood salvage system launched late in fiscal 2006.
- 2) **Surgical suction:** Our SmartSuction family of products, the SmartSuction HARMONY® and SmartSuction SOLO®, clear blood and debris from the surgical field. The systems can be used in conjunction with surgical blood salvage or stand-alone in surgery. These products were launched in late fiscal 2006 and mid fiscal 2007.

Software and Services

At this time, our software and services principally provides support to our Donor Division customers. Our goal in expanding the business is to add complementary products and services for our Patient Division customers.

- 1) **Software:** Through our 5D® Information Management (5D®) and Information Data Management (IDM®), we provide data management systems and technical support to blood donor recruitment and to promote efficient and compliant operations of blood and plasma collection centers.
- 2) **Services:** Through our services group, we offer business solutions to support blood collectors' process excellence, donor recruitment, and business design efforts. For example, we provide six sigma and lean manufacturing consulting services to blood banks. We also offer equipment repairs services under preventive maintenance contracts or emergency service visits, training programs and spare part sales.

Our principal operations are in the United States, Europe, Japan and other parts of Asia. Our products are marketed in more than 50 countries around the world via a direct sales force as well as independent distributors and agents.

In fiscal year 2007, we remained focused on increasing sales of our red cell collection technology and our software offerings. We also focused on retaining business in our U.S. orthopedic market, having transitioned from a distribution relationship to a direct sales business late in fiscal 2006. We were successful at retaining a majority of the U.S. business and revenues benefited in the year from the positive pricing impact of the change. Additionally, we executed to our plan to supply plasma collection systems to support rapid growth in the U.S. plasma collections market. We placed approximately 900 additional plasma collection systems in the U.S. Finally, we focused resources on seven products launched over the course of fiscal 2006 and fiscal 2007.

(B) Financial Information about Industry Segments

Although we address our customer constituents through three global product families (Donor, Patient and Software/Services), we manage our business as one operating segment: automated blood processing systems. Our chief operating decision maker uses consolidated financial results to make operating and strategic decisions. Manufacturing processes, as well as the regulatory environment in which we operate, are largely the same for all product lines.

The financial information required for the business segment is included herein in Note 16 of the financial statements, entitled SEGMENT, GEOGRAPHIC AND CUSTOMER INFORMATION.

(C) Narrative Description of the Business

(i) Products and Services

We develop and market a variety of automated systems for blood donors and surgical patients worldwide that collect and process blood. We also market data management systems to promote efficient and compliant operations of blood and plasma collection agencies.

All of our blood systems involve the extracorporeal processing of human blood, which is made up of components including red blood cells, plasma, platelets, and white blood cells. Doctors today generally treat patients with a transfusion of only the blood component needed, rather than with whole blood. The different components have different clinical applications. For example, plasma derived products treat a variety of illnesses and hereditary disorders such as hemophilia; red cells treat trauma patients or patients undergoing major surgeries involving high blood loss such as open heart surgery or organ transplant; and platelets treat cancer patients undergoing chemotherapy.

With our automated blood collection systems, a blood donation can be targeted to the specific blood component needed by a blood collector. More of that blood component can be collected during any one donation event because the blood components not targeted are returned to the donor through a sterile, closed-circuit disposable set used for the blood donation procedure. (See Plasma, Blood Bank and Red Cell product lines referred to in General History of the Business.)

With our automated blood processing systems, blood collectors and hospitals can freeze and thaw red cells so that they can maintain a frozen blood reserve. Blood reserves are often maintained to enable the blood provider to respond adequately to large-scale emergencies where many people require blood transfusions or to treat patients who require transfusions of very rare blood types. Our blood processing systems can also remove plasma from red cells for patients who need specially treated blood. (See ACP product referred to in General History of the Business.)

Our surgical blood salvage systems can collect blood lost by a surgical patient during or after the surgery, clean it, and make it available for transfusion back to the patient. These systems ensure that elective surgery will not be cancelled due to lack of available blood, and that a patient receives the safest blood possible his or her own. (See Cell Saver, OrthoPAT, and cardioPAT product lines referred to in General History of the Business.)

Our surgical suction systems can clear the surgical field of blood and debris to support a safe and effective operating environment. (See SmartSuction product referred to in General History of the Business.)

In every one of our major product offerings: plasma collection, platelet collection, red cell collection, cell processing and surgical cell salvage, we invented the technology that first created the market. We continue to innovate our product offerings with next generation technologies.

DONOR FAMILY OF PRODUCTS

The Plasma Collection Market for Fractionation

Automated plasma collection technology allows for the safe and efficient collection of plasma from donors who are usually paid a fee for their blood donation. There are approximately 15 million liters of plasma collected worldwide annually. The plasma collected is further processed (fractionated) by pharmaceutical companies into therapeutic and diagnostic products that aid in the treatment of: immune diseases, inherited coagulation disorders (e.g., hemophilia) and blood volume loss (e.g. from trauma). The collected plasma is also used in the manufacture of vaccines and blood testing and quality control reagents. Our role in the plasma industry is limited to the supply of plasma collection and data management systems to plasma collectors, many of whom also process the plasma which they collect. Our business does not include the actual collection, fractionation, or distribution of plasma-derived pharmaceuticals.

Haemonetics Automated Plasma Collection Systems (reported as plasma product line)

Until automated plasma collection technology was pioneered and introduced by our Company in the 1980s, plasma for fractionation was collected manually. Manual collection was time-consuming, labor-intensive, produced relatively poor yields, and posed risk to donors. Currently the vast majority of plasma collections worldwide are performed using automated collection technology because it is safe and cost-effective. We market our PCS2 automated plasma collection systems to commercial plasma collectors as well as not-for-profit blood banks and government affiliated plasma collectors worldwide.

We offer one stop shopping to our plasma collection customers, enabling them to source from us the full range of products necessary for their plasma collection operations. To that end, in addition to providing plasma collection equipment and disposables, we offer plasma collection containers and intravenous solutions necessary for plasma collection and storage, as well as data management technology through our 5D subsidiary to automate plasma collectors operations.

The Blood Collection Market for Transfusion

There are millions of blood donations throughout the world every year to obtain blood products for transfusion to surgical, trauma, or chronically ill patients. In the U.S. alone approximately 15 million units of blood are collected each year.

Patients requiring blood are rarely transfused with whole blood. Instead, a patient typically receives only the blood component necessary to treat their clinical condition: red cells to surgical or trauma patients, platelets to surgical or cancer patients, and plasma to surgical patients.

Worldwide demand for blood continues to rise as the population ages and more patients have need for and access to medical therapies that require blood transfusions. At the same time, tighter donor eligibility requirements to improve blood safety have decreased the number of donors willing or able to donate blood. Thus, this worldwide market is growing modestly in the low single digits.

Most donations worldwide are non-automated procedures (also referred to as manual or whole blood donations). In a manual donation, a person donates about a pint of whole blood, bleeding by gravity directly into a blood collection bag. After the donation, a laboratory worker manually processes the blood and separates it into its constituent parts: red cells, platelets and plasma. One pint of whole blood contains one transfusable dose of red cells, one-half to one transfusable dose of plasma, and one-fifth to one-eighth transfusable dose of platelets.

We do not sell whole blood collection disposables for the large, non-automated part of the blood collection market for transfusions. Others supply this market with whole blood collection supplies such as needles, plastic blood bags, solutions and tubing.

In contrast to manual collections, automated procedures eliminate the need to manually separate whole blood at a remote laboratory. Instead, the blood separation process is automated and occurs real-time while a person is donating blood. In this separation method, only the specific blood component targeted is collected, and the remaining components are returned to the blood donor. Among other things, automated blood collection allows significantly more of the targeted blood component to be collected during a donation event.

Today in the U.S., automated collection systems are used annually to collect more than 550,000 red cell units and about 1.5 million platelet units (called single donor platelets.) One donation from a single donor can produce enough platelets for a transfusable dose as compared to a pooled platelet that combines platelet fractions from 5-8 different whole blood donors.

Our products address the small part of the blood collection market that uses automation to enhance blood collection safety and efficiency, as well as regulatory compliance.

Haemonetics Automated Red Cell Collection Systems (reported as red cell product line)

Automated red cell collection, a technology we created, allows for the safe, efficient collection of more red cells from a single blood donor than from manual, whole blood collections. Most red cells are derived from manual collection of whole blood, after which the components are separated. This manual procedure involves time-consuming, error-prone secondary handling and processing in a laboratory that tax a blood collector's limited resources. Red cell shortages are a common problem plaguing many healthcare systems worldwide, particularly the U.S.

Our MCS brand systems help blood collectors address their operational challenges. The system automates the blood separation function, eliminating the need for laboratory processing and enables the collection of two transfusable doses of red cells from a single donor thus alleviating blood shortages. We call this our two unit protocol or double red cell collection.

In addition to the two unit protocol, blood collectors can use the MCS brand system to collect either one unit of red cells and a jumbo (double) unit of plasma or one unit of red cells and one unit of platelets from a single donor or they may leukoreduce the two unit red cell collections. Leukoreduction is the removal of potentially harmful white blood cells from the blood to prevent or mitigate adverse reactions by the patient receiving a blood transfusion. Leukoreduction has been adopted in many countries worldwide, and an estimated 80% of all red cells in the U.S. are now leukoreduced.

During fiscal year 2007, blood shortages continued and blood banks continued their adoption of double red cell collection. Currently approximately 7% of red cells collected in the U.S. are collected on our technology.

The Cymbal brand red cell collection system is an automated device to collect and process two units of red cells from donors. Cymbal is a second generation red cell collection system which is smaller, lighter and more portable than our current red cell collection technology. This mobility, including battery power, allows our customers to more easily use the device on mobile blood drives. We received CE marking in February 2006 and received FDA clearance on the device in February 2007. The system is now for sale in Europe and the U.S.

Haemonetics Automated Platelet Collection Systems (reported as blood bank product line)

Automated platelet collection systems collect one or more therapeutic doses of platelets during a single donation by a volunteer blood donor. Platelets derived from non-automated donations of whole blood (also called manual collections) must be pooled together with platelets from 4 to 7 other manual donations to make a single therapeutically useful dose because platelets are only a very small portion of whole blood volume. We invented the automation of platelet collection, resulting in improved platelet yields and improved patient safety.

Platelet therapy is frequently used to alleviate the effects of bone marrow suppression, a condition in which bone marrow is unable to produce a sufficient quantity of platelets. Bone marrow suppression is most commonly a side effect of chemotherapy. Doctors who prescribe platelet therapy increasingly turn to single donor platelet products (i.e., enough platelets collected from one donor, during an automated collection, to constitute a transfusable dose) to minimize a patient's exposure to multiple donors and possible blood-borne diseases.

Haemonetics Intravenous Solutions (reported as blood bank product line)

During an automated blood donation, intravenous solutions and other solutions are used. We manufacture solutions in our facility in Union, South Carolina. This facility also contract manufactures certain other solutions.

Automated Blood Cell Processing Systems (reported as blood bank product line)

Our cell processing business is based on technology that enables users to add and remove solutions or other substances to and from blood components. We have several technologies that support this business.

The most significant technology allows the freezing and thawing of blood to enable blood banks to better manage their red cell inventory. Although it has been possible for many years to freeze red cells for up to ten years, the freezing and thawing processes took place in a manual, open-circuit system, which exposed red cells to the potential for bacterial contamination. Once the cells were thawed, they had to be transfused within 24 hours or discarded. The Company's ACP215 automated cell processing system extends thawed cells' shelf life to 14 days by performing the freezing and thawing processes in an automated, closed-circuit system. We also invented the technology that allows freezing and thawing of red cells

PATIENT FAMILY OF PRODUCTS

The Autotransfusion Market

Surgical blood salvage, also known as autotransfusion, involves the collection of a patient's own blood during and after surgery, for reinfusion to that patient. In surgical blood salvage, blood is suctioned from a wound site, collected in a centrifuge, and cleaned and filtered to remove unwanted substances from the recovered blood. The blood is transferred to a collection bag and made available for transfusion back to the patient. This process occurs in a sterile, closed-circuit consumable set which sits inside our device. We market our surgical blood salvage products to hospital-based medical specialists, primarily cardiovascular, orthopedic, and trauma surgeons or to surgical suite service providers.

Loss of blood is common in open heart, trauma, transplant, vascular, and orthopedic procedures, and the need for transfusion of oxygen-carrying red cells to make up for lost blood volume is routine. Prior to the introduction of our technology, patients were transfused exclusively with blood from volunteer donors. Donor blood carries various potential risks including (i) risk of transfusion with the wrong blood type (the most common cause of transfusion-related death), (ii) risk of transfusion reactions including death, but more commonly chills, fevers or other side effects that can prolong a patient's recovery, and (iii) risk of transfusion of blood with a blood-borne disease or infectious agent.

As a result of numerous blood safety initiatives, today's blood transfusions are extremely safe, especially in developed and resourced health care systems. However, transfusions are not risk free. Surgical blood salvage reduces or eliminates a patient's dependence on blood donated from others and ensures that the patient receives the safest blood possible—his or her own.

Surgical blood salvage is also a cost effective alternative to transfusing donor blood. Blood shortages have also reinforced the benefits of surgical blood salvage. As hospitals are forced to consider canceling

elective surgeries due to unavailability of blood, they can turn to surgical blood salvage as a means of conserving their blood supply for other patients.

Haemonetics Surgical Product Line

The Cell Saver brand system is a surgical blood salvage system targeted to procedures that involve rapid, high volume blood loss such as cardiovascular surgeries. The new cardioPAT system is a surgical blood salvage system targeted to open heart surgeries when there is less blood loss and the blood loss continues post surgery.

Also included in our surgical product line is the SmartSuction family of products. In fiscal 2005, we purchased a line of surgical products from Harvest Technologies Corporation. Leveraging our core competency in manufacturing process control, we reworked these products to our quality specifications. The product line was launched in calendar 2006 and is an advanced suction system for removal of blood and debris from the surgical field. The systems can be used in conjunction with surgical blood salvage or stand-alone.

Haemonetics OrthoPAT Product Line

The OrthoPAT system is targeted to orthopedic procedures that involve slower, lower volume blood loss that often occurs well after surgery.

SOFTWARE/SERVICES

Data management is supplied through our subsidiaries, 5D and IDM, leading providers of information management products and services for blood collectors, plasma collectors and plasma fractionators. Our software and services offerings promote quality, compliance, and operational efficiency in blood and plasma collection.

(ii) Revenue Detail

We discuss our revenues using the following categories:

- Disposables (the consumables used in blood collection, processing, and salvaging and fees for the use of our equipment)
- Equipment (the sale of devices)
- Software and Service (including 5D and IDM software systems and service contracts)

In fiscal year 2007, sales of disposable products accounted for approximately 87.6% of net revenues. Sales of our disposable products were 7.2% higher in 2007 than in 2006 and grew at a compound average annual growth rate of 7.19% for the four years ended March 31, 2007. The unfavorable effects of foreign exchange contributed 0.4% decrease in net sales during fiscal year 2007 with the remaining 7.6% increase resulting from increases in disposable revenues across our plasma, red cell, blood bank and OrthoPAT product lines due to unit increases and pricing improvement.

Sales of equipment accounted for approximately 4.9% of net revenues in fiscal year 2007 and approximately 6.1% in fiscal year 2006. The decrease in equipment revenue during fiscal year 2007 is attributable to inequitable comparisons as fiscal 2006 equipment sales were very strong. Equipment sales are opportunistic and fluctuate on an annual basis.

Software and Service revenues accounted for approximately 7.5% and 6.4% of net revenues in fiscal year 2007 and 2006, respectively. The increase during fiscal year 2007 was largely due to software revenue growth from 5D. The increases in 5D sales were principally the result of a software support contract for a branch of the United States military and due to our acquisition of the assets of IDM.

(iii) Marketing/Sales/Distribution

We market and sell our products to commercial plasma collection centers, blood systems and independent blood banks, hospitals and hospital service providers, and national health organizations through our own direct sales force (including full-time sales representatives and clinical specialists) as well as independent distributors. Sales representatives target the primary decision-makers within each of those organizations.

In fiscal year 2007, for the seventh consecutive year, we received the Omega NorthFace ScoreBoard Award for exemplary service to customers. This award is presented to the highest-ranked organizations based on customer ratings of performance against customer expectations in areas such as phone support, on-site operations, technical services, and training.

(iv) United States

In fiscal year 2007, approximately 43% of consolidated net sales were generated in the U.S. where we use a direct sales force to sell our products.

(v) Outside the United States

In fiscal year 2007, approximately 57% of consolidated net revenues were generated through sales to non-U.S. customers. Our direct sales force in Europe and Asia includes full-time sales representatives and clinical specialists based in the United Kingdom, Germany, France, Sweden, the Netherlands, Italy, Austria, Hong Kong, Canada, Japan, Switzerland, Czech Republic, China, Taiwan, and Belgium. We also use various distributors to market our products in South America, the Middle East, and parts of Europe and the Far East.

(vi) Research and Development

We operate research and development (R&D) centers in Switzerland, Japan, and the United States, so that protocol variations are incorporated to closely match local customer requirements. In addition to the above R&D facilities, our 5D subsidiary maintains development operations in Edmonton, Alberta, Canada and our Arryx subsidiary maintains research laboratories in Chicago, Illinois.

Customer collaboration is also an important part of our technical strength and competitive advantage. These collaboration customers and transfusion experts provide us with ideas for new products and applications, enhanced protocols, and potential test sites as well as objective evaluations and expert opinions regarding technical and performance issues.

The development of extracorporeal blood processing systems has required us to maintain technical expertise in various engineering disciplines, including mechanical, electrical, software, biomedical, and materials. Innovations resulting from these various engineering efforts enable us to develop systems that are faster, smaller, and more user-friendly, or that incorporate additional features important to our customer base.

To further strengthen our research competency, in fiscal 2007 we acquired Arryx, Inc., a privately held nano-technology Company, for \$23.2 million in cash. Haemonetics and Arryx had been collaborating since October 2004 in developing and commercializing proprietary blood separation and processing technologies. Arryx's technology uses light to form optical traps to move and manipulate small objects. Using laser beams and holograms, the systems can independently and in parallel hold, move, separate, and otherwise manipulate hundreds of microscopic and nanoscopic objects. Arryx's first product, the BioRyx 200® system, is used to handle cells and other objects in a laboratory environment. The acquisition is a key component of our strategy to strengthen and diversify our internal research initiatives and expand the business into new, adjacent markets.

Our expenditures for R&D were \$23.9 million for fiscal year 2007 (5.3% of sales), exclusive of the Arrayx In-process Research and Development costs (see Footnote #3 Acquisition), \$26.5 million for fiscal year 2006 (6.3% of sales) and \$20.0 million for fiscal year 2005 (5.2% of sales). All R&D costs are expensed as incurred. We expect to continue to invest resources in R&D.

In fiscal year 2007, R&D resources were allocated to completing work on the Cymbal , a next generation, surgical blood salvage device, a blood collection software system (eLynx), and a next generation Donor apheresis platform, as well as several projects to enhance our current product portfolio. We also allocated resources to our Arrayx subsidiary for on-going research into nanotechnology applications in the blood processing field.

(vii) Manufacturing

Our principal manufacturing operations (equipment, disposables, and solutions) are located in Braintree, Massachusetts; Leetsdale, Pennsylvania; Union, South Carolina; and Bothwell, Scotland.

In general, our production activities occur in a controlled setting or clean room environment. Each step of the manufacturing and assembly process is quality checked, qualified, and validated. Critical process steps and materials are documented to ensure that every unit is produced consistently and meets performance requirements.

Some component manufacturing is performed by outside contractors according to our specifications. We maintain important relationships with two Japanese manufacturers that provide finished consumables in Singapore, Japan, and Thailand. Certain parts and components are purchased from various single sources. If necessary, we believe that, in most cases, alternative sources of supply could be identified and developed within a relatively short period of time. Nevertheless, an interruption in supply could temporarily interfere with production schedules and affect our operations. All of our equipment and disposable manufacturing sites are certified to the ISO 13485 standard and to the Medical Device Directive allowing placement of the CE mark of conformity.

Each blood processing machine is designed in-house and assembled from components that are either manufactured by us or by others to our specifications. The completed instruments are programmed, calibrated, and tested to ensure compliance with our engineering and quality assurance specifications. Inspection checks are conducted throughout the manufacturing process to verify proper assembly and functionality. When mechanical and electronic components are sourced from outside vendors, those vendors must meet detailed qualification and process control requirements. During fiscal 2007, we manufactured approximately 90% of our equipment. The remainder was manufactured for us by outside contractors.

We have established a Customer Oriented Redesign for Excellence (CORE) program, which is based on the tenets of Total Quality of Management (TQM) and using Six Sigma Statistic methods. This program s goals include: 1) improving customer satisfaction through top quality and on-time deliveries, 2) lowering production costs, and 3) optimizing inventories.

(vii) Intellectual Property

We hold patents in the United States and many international jurisdictions on some of our machines, processes, disposables and related technologies. These patents cover certain elements of our systems, including protocols employed in our equipment and certain aspects of our processing chambers and disposables. Our patents may cover current products, products in markets we plan to enter, or products in markets we plan to license, or the patents may be defensive in that they are directed to technologies not yet embodied in our current products. We also license patent rights from third parties that cover technologies that we use or plan to use in our business. We consider our patent rights to be important to our business. To maintain our competitive position, we rely on the technical expertise and know-how of our personnel and on our patent rights. We pursue an active and formal program of invention disclosure and patent application in both the United States and international jurisdictions. We own various trademarks that have been registered in the United States and certain other countries.

Our policy is to obtain patent and trademark rights in the U.S. and foreign countries where such rights are available and we believe it is commercially advantageous to do so. However, the standards for international protection of intellectual property vary widely. We cannot assure that pending patent and trademark applications will result in issued patents and trademarks, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that our patents will not be found to be invalid.

(viii) Competition

We created our technologies and have established a record of innovation and market leadership in each of the areas in which we compete. Although we compete directly with others, no one company competes with us across our full line of products.

To remain competitive, we must continue to develop and acquire cost-effective new products, technologies and services. We believe that our ability to maintain a competitive advantage will continue to depend on a combination of factors, including factors within our control (reputation, regulatory approvals, patents, unpatented proprietary know-how in several technological areas, product quality, safety and cost effectiveness and continual and rigorous documentation of clinical performance) as well as factors outside of our control (regulatory standards, medical standards and the practice of medicine).

In the automated plasma collection markets, we compete with Fenwal, Inc. on the basis of quality, ease of use, services and technical features of systems, and on the long-term cost-effectiveness of equipment and disposables. (Fenwal, Inc. is an independent Company founded in March 2007 when Texas Pacific Group and Maverick Capital, Ltd. acquired the Transfusion Therapies division of Baxter Healthcare Group.) Baxter had previously pursued a strategy of developing plasma collection sites and acquiring collection centers, which altered the competitive landscape and affected our past sales. In October 2003, Baxter acquired our largest U.S. plasma customer, Alpha Therapeutic Corporation (Alpha). Upon Baxter's announcement of its acquisition of Alpha's business, Baxter closed 38 of 41 of the former Alpha centers and sold the remaining three centers. These center closures significantly and negatively affected our plasma sales in fiscal 2005. (See Legal Proceedings section for more information.)

In the automated platelet collection business, competition is based on continual performance improvement, as measured by the time and efficiency of platelet collection and the quality of the platelets collected. Our product quality is exceptional, as evidenced by approximately 70% market share in Japan, where quality is the leading purchasing consideration. Our major competitors in automated platelet collection are Gambro BCT and Fenwal (formerly Baxter's Transfusion Therapies division). Each of these companies has taken a different technological approach in designing their systems for automated platelet collection. In the platelet collection market, we also compete with whole blood collections from which pooled platelets are derived.

In the cell processing market, competition is based on level of automation, labor-intensiveness, and system type (open versus closed). Open systems may be weaker in GMP compliance. Moreover, blood processed through open systems has a 24 hour shelf life. We have an open system cell processor as well as a closed system cell processor which gives blood processed through it a 14 day shelf life. We compete with Gambro BCT's open systems.

Our automated red cell collection systems were pioneered in the late 1990s. We preceded one competitor, Gambro BCT, to market by two years, and the other competitor, Fenwal (formerly Baxter's Transfusion Therapies division), to market by six years. However, it is important to note that less than 1% of the forty million red cells collected worldwide and only about 9% of the fifteen million red cells collected in the U.S. annually are collected via automation today by these three companies combined. So, we more often compete with traditional (manual/whole blood) methods of deriving red cells by collecting and separating a pint of whole blood on the basis of total cost, process control, product quality, and inventory management.

In the high blood loss surgical blood salvage market, competition is based on reliability, ease of use, service, support, and price. Each manufacturer's technology is similar, and we compete principally with Medtronic, Fresenius, and Sorin Biomedica. Our newly introduced cardioPAT system is the only washed surgical blood salvage device that is available when blood loss continues post operatively.

In the orthopedic surgical blood salvage market we compete against non-automated processing systems whose end product is an unwashed red blood cell unit for transfusion to the patient. The OrthoPAT system is the only system that washes the blood and is designed specifically for use in orthopedic surgeries where a patient often bleeds more slowly, bleeds less, and bleeds well after surgery.

Our technical staff is highly skilled, but many competitors have substantially greater financial resources and larger technical staffs at their disposal. There can be no assurance that competitors will not direct substantial efforts and resources toward the development and marketing of products competitive with those of Haemonetics.

(ix) Seasonality

Net revenues have historically been higher in the second half of our fiscal year, reflecting principally the seasonal buying patterns of our customers. This has proven true in four of our last five fiscal years with the exception of fiscal year 2003 where the second half of our fiscal year had slightly lower revenues due principally to market conditions in plasma.

(x) Government Regulation

The products we manufacture and market are subject to regulation by the Center of Biologics Evaluation and Research (CBER) and the Center of Devices and Radiological Health (CDRH) of the United States Food and Drug Administration (FDA), and other non-United States regulatory bodies.

All medical devices introduced to the United States market since 1976 are required by the FDA, as a condition of marketing, to secure either a 510(k) pre-market notification clearance or an approved Pre-market Approval Application (PMA). In the United States, software used to automate blood center operations and blood collections and to track those components through the system are considered by FDA to be medical devices, subject to 510(k) pre-market notification. Intravenous (IV) solutions marketed by us for use with our automated systems (blood anticoagulants and solutions for storage of red blood cells) require us to obtain from CBER an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). A 510(k) pre-market clearance indicates FDA's agreement with an applicant's determination that the product for which clearance is sought is substantially equivalent to another legally marketed medical device. The process of obtaining a 510(k) clearance may take up to 24 months and involves the submission of clinical data and supporting information. The process of

obtaining NDA approval for solutions is likely to take much longer than 510(k) approvals because the FDA review process is more complicated.

We maintain customer complaint files, record all lot numbers of disposable products, and conduct periodic audits to assure compliance with FDA regulations. We place special emphasis on customer training and advise all customers that blood processing procedures should be undertaken only by qualified personnel.

We are also subject to regulation in the countries outside the United States in which we market our products. Many of the regulations applicable to our products in such countries are similar to those of the FDA. However, the national health or social security organizations of certain countries require our products to be registered by those countries before they can be marketed in those countries. We have complied with these regulations and have obtained such registrations.

Federal, state and foreign regulations regarding the manufacture and sale of products such as ours are subject to change. We cannot predict what impact, if any, such changes might have on our business.

(xi) Environmental Matters

We do not anticipate that compliance with international, federal and local environmental protection laws presently in effect will have a material adverse impact upon our business or will require any material capital expenditures. We continue to monitor changes in US and International environmental regulations that may have a significant impact on the business. Action plans are developed to mitigate identified risks.

(xii) Employees

As of March 31, 2007, we employed the full-time equivalent of 1,826 persons assigned to the following functional areas: manufacturing, 932; sales and marketing, 245; general and administrative, 361; research and development, 83; and quality control and field service, 205. We consider our employee relations to be satisfactory.

(xiii) Availability of Reports and Other Information

All of our corporate governance materials, including the Principles of Corporate Governance, the Business Conduct Policy and the charters of the Audit, Compensation, and Nominating and Governance Committees are published on the Investor Relations section of our website at http://www.haemonetics.com/site/content/investor/corp_gov.asp. Such information is also available in print to any shareholder who requests it. All requests should be directed to our Company's Secretary. On this web site the public can also access, free of charge, our annual, quarterly and current reports and other documents filed or furnished to the Securities and Exchange Commission as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

(D) Financial Information about Foreign and Domestic Operations and Export Sales

The financial information required by this item is included herein in Note 16 of the financial statements, entitled *Segment, Geographic and Customer Information*. Sales to the Japanese Red Cross accounted for 15.8% of net revenues in fiscal year 2007. No other customer accounted for more than 10% of our net revenues. For more information concerning significant customers, see subheading of Note 2 of the financial statements, entitled, *Concentration of Credit Risk and Significant Customers*.

Cautionary Statement

Statements contained in this report, as well as oral statements we make which are prefaced with the words may, will, expect, anticipate, continue, estimate, project, intend, designed, and similar expressions, are intended to identify forward looking statements regarding events, conditions, and

financial trends that may affect our future plans of operations, business strategy, results of operations, and financial position. These statements are based on our current expectations and estimates as to prospective events and circumstances about which we can give no firm assurance. Further, any forward-looking statement speaks only as of the date on which such statement is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made. As it is not possible to predict every new factor that may emerge, forward-looking statements should not be relied upon as a prediction of our actual future financial condition or results. These forward-looking statements, like any forward-looking statements, involve risks and uncertainties that could cause actual results to differ materially from those projected or anticipated. Such risks and uncertainties include technological advances in the medical field and our standards for transfusion medicine and our ability to successfully implement products that incorporate such advances and standards, product demand and market acceptance of our products, regulatory uncertainties, the effect of economic and political conditions, the impact of competitive products and pricing, the impact of industry consolidation, foreign currency exchange rates, changes in customers' ordering patterns, the effect of industry consolidation as seen in the Plasma market, the effect of communicable diseases and the effect of uncertainties in markets outside the US (including Europe and Asia) in which we operate. The foregoing list should not be construed as exhaustive.

Item 1A. Risk Factors

Set forth below are the risks that we believe are material to our investors. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page 44.

Our inability to successfully expand the business, through internal research and development, marketing partnerships and acquisitions, could have a material adverse effect on our business. Promising partnerships and acquisitions may not be completed for reasons such as competition among prospective partners or buyers, our inability to reach satisfactory terms, or the need for regulatory approvals. Any acquisition that we complete may be dilutive to earnings and require that we invest significant resources. We may not be able to integrate any acquired businesses successfully into our existing business, make such businesses profitable, or realize anticipated market growth or cost savings.

If we are unable to successfully keep pace with technological advances in the medical field and the standards for transfusion medicine, our business, financial condition and results of operation could be adversely affected. The success of our products will depend upon our ability to anticipate and meet the needs of the medical field, particularly those who practice transfusion medicine. Additionally, we must be able to manufacture the products in a cost effective manner, with high quality and obtain permission to market and sell the products from various regulatory authorities.

As a medical device manufacturer we are subject to a number of existing laws and regulations, non-compliance with those laws or regulations could adversely affect our financial condition and results of operations. The manufacture, distribution and marketing of our products are subject to regulation by the FDA and other non-United States regulatory bodies. Some regulatory authorities outside the United States may have a bias in favor of locally produced goods that could delay or prevent our achieving regulatory approval to market our products in such geographies. We must obtain specific regulatory clearance prior to selling any new product or service, and our operations are also subject to continuous review and monitoring by the FDA and other regulatory authorities. The process of obtaining approval to market and distribute our products is costly and time-consuming. Export of US technology or goods manufactured in the United States to some jurisdictions requires special US export authorization that may be influenced by factors, including political dynamics, outside our control. Changes in privacy regulations and other developments in human subjects' clinical trials could make it more difficult and more expensive to conduct clinical trials necessary for product approval. Regulations about the use of certain materials in

the manufacture of health care products could also require us to identify alternate material(s), which may be at higher costs. The number of eligible blood donors is influenced by government regulations (including travel restrictions, health history, etc.) and other economic and sociological factors. Changes in donation related regulations coul