CARDIOGENESIS CORP /CA
Form 10-K
April 16, 2002

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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 December 31, 2001

Commission file number: 0-28288

CardioGenesis Corporation

(formerly known as Eclipse Surgical Technologies, Inc.)
(Exact name of Registrant as specified in its charter)

California	**77-0223740**
(State of incorporation)	*(I.R.S. Employer Identification Number)*

26632 Towne Center Drive
Suite 320
Foothill Ranch, California 92610
(Address of principal executive officers)

(714) 649-5000

(Registrant s telephone number, including area code)

Title of Each Class	**Name of Exchange on Which Registered**
Common Stock, no par value	Nasdaq National Market

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

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately $32,343,786 as of March 29, 2002, based upon the closing sale price reported for that date on the Nasdaq National Market. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

Indicate the number of shares outstanding of each of the issuer s classes of common stock outstanding as of the last practicable date.

36,506,723 shares
As of March 29, 2002

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PART I

Item 1. *Business.*

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. The statements contained herein that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including without limitation statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this document or incorporated by reference herein are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth in Item 7 and elsewhere.

General

CardioGenesis Corporation, formerly known as Eclipse Surgical Technologies, Inc., incorporated in California in 1989, designs, develops, manufactures and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization (TMR) and percutaneous transluminal myocardial revascularization (PMR). TMR and PMR are recent laser-based heart treatments in which channels are made in the heart muscle. It is believed these procedures encourage new vessel formation, or angiogenesis. TMR is performed by a cardiac surgeon through a small incision in the chest under general anesthesia. PMR is performed by a cardiologist in a catheter based procedure which utilizes local anesthesia. Clinical studies have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with TMR or PMR plus medications, when compared with patients who received medications alone.

We received CE Mark approval for our TMR system in May 1997 and our PMR systems in April 1998. On February 11, 1999, we received final approval from the FDA for our TMR products for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to other medical treatments and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization. Effective July 1, 1999, the Health Care Financial Administration began to provide Medicare coverage for TMR. Hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures.

We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre Market Approval application in December of 1999 along with subsequent amendments. As discussed below under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from that agency.

On March 17, 1999, we merged with the former CardioGenesis Corporation. Under the terms of the combination, each share of the former CardioGenesis common stock was converted into 0.8 of a share of our common stock, and the former CardioGenesis has become a wholly owned subsidiary of ours. As a result of the transaction, our outstanding shares increased by approximately 9.9 million shares. The transaction was structured to qualify as a tax-free reorganization and has been accounted for as a pooling of interests. Accordingly, the accompanying financial statements have been restated as if the combined entity existed for the 1999 period prior to the merger.

Background

Cardiovascular disease is the leading cause of death and disability in the U.S. according to the American Heart Association. Coronary artery disease is the principal form of cardiovascular disease and is characterized by a progressive narrowing of the coronary arteries which supply blood to the heart. This narrowing process is usually due to atherosclerosis, which is the buildup of fatty deposits, or plaque, on the inner lining of the arteries. Coronary artery disease reduces the available supply of oxygenated blood to the heart muscle,

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potentially resulting in severe chest pain known as angina, as well as damage to the heart. Typically, the condition worsens over time and often leads to heart attack and/or death.

Based on standards promulgated by the Canadian Heart Association, angina is typically classified into four classes, ranging from Class 1, in which angina pain results only from strenuous exertion, to the most severe class, Class 4, in which the patient is unable to conduct any physical activity without angina and angina may be present even at rest. The American Heart Association estimates that more than six million Americans experience angina symptoms.

The primary therapeutic options for treatment of coronary artery disease are drug therapy, balloon angioplasty also known as percutaneous transluminal coronary angioplasty or (PTCA), other interventional techniques which augment or replace PTCA such as stent placement and atherectomy, and coronary artery bypass grafting or (CABG). The objective of each of these approaches is to increase blood flow through the coronary arteries to the heart.

Drug therapy may be effective for mild cases of coronary artery disease and angina either through medical effects on the arteries that improve blood flow without reducing the plaque or by decreasing the rate of formation of additional plaque (e.g., by reducing blood levels of cholesterol). Because of the progressive nature of the disease, however, many patients with angina ultimately undergo either PTCA or CABG.

PTCA is a less-invasive alternative to CABG introduced in the early 1980s in which a balloon-tipped catheter is inserted into an artery, typically near the groin, and guided to the areas of blockage in the coronary arteries. The balloon is then inflated and deflated at each blockage site, thereby rupturing the blockage and stretching the vessel. Although the procedure is usually successful in widening the blocked channel, the artery often re-narrows within six months of the procedure, a process called restenosis, often necessitating a repeat procedure. A variety of techniques for use in conjunction with PTCA have been developed in an attempt to reduce the frequency of restenosis, including stent placement and atherectomy. Stents are small metal frames delivered to the area of blockage using a balloon catheter and deployed or expanded within the coronary artery. The stent is a permanent implant intended to keep the channel open. Atherectomy is a means of using mechanical, laser or other techniques at the tip of a catheter to cut or grind away plaque.

CABG is an open chest procedure developed in the 1960s in which conduit vessels are taken from elsewhere in the body and grafted to the blocked coronary arteries so that blood can bypass the blockage. CABG typically requires the use of a heart-lung bypass machine to render the heart inactive (to allow the surgeon to operate on a still, relatively bloodless heart) and involves prolonged hospitalization and patient recovery periods. Accordingly, it is generally reserved for patients with severe cases of coronary artery disease or those who have previously failed to receive adequate relief of their symptoms from PTCA or related techniques. Most bypass grafts fail within one to fifteen years following the procedure. Repeating the surgery (re-do bypass surgery) is possible, but is made more difficult because of scar tissue and adhesions that typically form as a result of the first operation. Moreover, for many patients CABG is inadvisable for various reasons, such as the severity of the patient s overall condition, the extent of coronary artery disease or the small size of the blocked arteries.

When these treatment options are exhausted, the patient is left with no viable surgical or interventional alternative other than, in limited cases, heart transplantation. Without a viable surgical alternative, the patient is generally managed with drug therapy, often with significant lifestyle limitations. TMR, which bears the CE Marking and has received FDA approval, and PMR, which bears the CE Marking and for which we are continuing to pursue FDA approval for use in the U.S., offer potential relief to a large population of patients with severe cardiovascular disease.

The TMR and PMR Procedures

TMR, or transmyocardial revascularization, is a surgical procedure performed on the beating or non-beating heart, in which a laser device is used to create pathways through the myocardium directly into the heart chamber. The pathways are intended to supply blood to ischemic, or oxygen-deprived regions of the myocardium and reduce angina in the patient. TMR can be performed using open chest surgery or minimally

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invasive surgery through a small incision between the ribs. TMR offers end-stage cardiac patients who have regions of ischemia not amenable to PTCA or CABG a means to alleviate their symptoms and improve their quality of life. We have received FDA approval for U.S. commercial distribution of our TMR laser system for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

PMR, or percutaneous transluminal myocardial revascularization, is an interventional procedure performed by a cardiologist. PMR is based upon the same principles as TMR, but the procedure is much less invasive. The patient is under local anesthesia and is treated through a catheter inserted in the femoral artery at the top of the leg. A laser transmitting catheter is threaded up into the heart chamber, where channels are created in the inner portion of the myocardium (i.e. heart muscle). We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre Market Approval application in December of 1999 along with subsequent amendments. As discussed below under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from that agency.

Business Strategy

Our objective is to become a recognized leader in the field of myocardial revascularization, with TMR and PMR established as well-known and acceptable therapies. Our strategies to achieve this goal are as follows:

Expand Market for our Products. We are seeking to expand market awareness of our products among opinion leaders in the cardiovascular field, the referring physician community and the targeted patient population. In connection with the FDA approved TMR product, we have prioritized our efforts in the U.S. on the top 600 hospitals that perform the greatest number of cardiovascular procedures. We also sell our products in Europe and to the rest of the world through our direct international sales organization along with several distributors and agents. In addition, we have developed a comprehensive training program to assist physicians in acquiring the expertise necessary to utilize our TMR or PMR products and procedures.

Demonstrate Clinical Utility of PMR. We are seeking to demonstrate the clinical safety and effectiveness of PMR. We have completed a pivotal clinical trial regarding PMR, and the study results were submitted to the FDA in a Pre Market Approval Supplemental application in December of 1999. As discussed below under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from the agency.

Leverage Proprietary Technology. We believe that our significant expertise in laser and catheter-based systems for cardiovascular disease and the proprietary technologies we have developed are important factors in our efforts to demonstrate the safety and effectiveness of our TMR and PMR procedures. We are seeking to develop additional proprietary technologies for TMR, PMR and related procedures. We have over 80 foreign and U.S. patents or allowed patent applications and more than 150 U.S. and foreign patent applications pending relating to various aspects of TMR, PMR and other cardiovascular therapies.

Products and Technology

The Company s TMR System

The Company s TMR system consists of our TMR 2000 laser console and a line of fiber-optic, laser-based surgical tools. Each surgical tool utilizes an optical fiber assembly to deliver laser energy from the source laser base unit to the distal tip of the surgical handpiece or PMR catheter. The compact base unit occupies a

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small amount of operating room floor space, operates on a standard 208 or 220-volt power supply, and is light enough to move within the operating room or among operating rooms in order to use operating room space efficiently. Moreover, the flexible fiberoptic assembly used to deliver the laser energy to the patient enables ready access to the patient and to various sites within the heart.

Our TMR system and related surgical procedures are designed to be used without the requirement of the external systems utilized with certain competitive TMR systems. For example, our TMR 2000 system does not require electrocardiogram synchronization, which monitors the electrical output of the heart and times the use of the laser to minimize electrical disruption of the heart, or transesophageal echocardiography, which tests each application of the laser to the myocardium during the TMR procedure to determine if the pathway has penetrated through the myocardium into the heart chamber.

Our Holmium Laser. Our TMR 2000 laser base unit generates laser light of a 2.1 micron wavelength by photoelectric excitation of a solid state holmium crystal. The holmium laser, because it uses a solid state crystal as its source, is compact, reliable and requires minimal maintenance.

SoloGrip. The single use SoloGrip handpiece system contains multiple, fine fiber-optic strands in a one millimeter diameter bundle. The flexible fiber optic delivery system combined with the ergonomic handpiece provides access for treating all regions of the left ventricle.

The SoloGrip fiber-optic delivery system has an easy to install connector which screws into the laser base unit, and the device is pre-calibrated in the factory so it requires no special preparation.

The Company s PMR System

The Company s PMR System is currently sold only outside the United States. The PMR System consists of the PMR Laser and ECG Monitor.

Our PMR Laser. The holmium laser base unit generates laser light of a 2.1 micron wavelength in the mid-infrared spectrum. It provides a reliable source for laser energy with low maintenance.

The Axcis Catheter system. The Axcis catheter system is an over-the-wire system that consists of two components, the Axcis laser catheter and Axcis aligning catheter. The Axcis catheter system is designed to provide controlled navigation and access to target regions of the left ventricle. The coaxial Axcis laser catheter has an independent, extendible lens with radiopaque lens markers which show the location and orientation of the tip for optimal contact with the ventricle wall. The Axcis laser catheter also has nitinol petals at the laser-lens tip which are designed for safe penetration of the endocardium and to provide depth control.

Regulatory Status

On February 11, 1999, we received final approval from the FDA for use of our TMR 2000 laser console and SoloGrip handpiece for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to other medical treatments and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

In February 1996, we obtained FDA clearance to undertake Phase I of a clinical study of TMR intended to assess the safety and effectiveness of TMR Used in Conjunction with CABG as compared with CABG alone. In September 1996, the FDA provided us with clearance to begin Phase II of this study, which was subsequently completed. In July 1999, we submitted a PMA supplement to the FDA for an expanded indication to our approved TMR labeling to include TMR in conjunction with CABG. In January 2000, we received a response from the FDA requesting that we either provide more information or modify our labeling request. Since TMR and CABG are each presently utilized to treat separate regions of the heart, we concluded that our present FDA approved labeling is adequate, and that the physician can best decide how to use the laser system within the approved labeling. As a result, in March 2000, we decided that we will not pursue any wording changes to our already approved TMR labeling, and have withdrawn our submission to the FDA for TMR in conjunction with CABG.

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We submitted a PMA supplement for our PMR system to the FDA in December 1999. The PMR study compares PMR to conventional medical therapy in patients with no option for other treatment. As discussed below, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from the agency.

We have decided not to pursue any additional claims for adjunctive procedures. Therefore, all studies involving adjunctive procedures have been halted and terminated.

In addition, we have obtained approval to affix the CE Marking to substantially all of our products, which enables us to commercially distribute our TMR and PMR products throughout the European Community.

On July 9, 2001, the Food and Drug Administration Advisory Panel recommended against approval by the Food and Drug Administration of our PMR device for public sale and use in the United States. The practical effect of the Advisory Panel s recommendation is to delay indefinitely, until such time as the Food and Drug Administration decides differently, the introduction of our PMR device for sale and use in the United States. Consequently, the Advisory Panel s recommendation has effectively delayed potential revenue, if any, that may have been derived in the future from the sale of our PMR device. Moreover, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration s approval of our PMR device. However, we do not expect to conduct further clinical trials.

Sales and Marketing

We have received FDA approval for our surgical TMR laser system. The Health Care Finance Administration has also announced its coverage policy for the TMR with FDA approved systems. We are promoting market awareness of our approved surgical products among opinion leaders in the cardiovascular field and are recruiting physicians and hospitals.

In the United States, we currently offer a laser base unit at a current end user list price of $320,000 per unit, and the disposable TMR handpiece (at least one of which must be used with each TMR procedure) at an end user unit list price of $2,745. In order to accelerate market adoption of the TMR procedure, we intend to continue to either sell lasers to hospitals outright or loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price.

Internationally, we sell our products through a direct sales and support organization and distributors and agents.

We have developed, in conjunction with several major hospitals using our TMR or PMR products, a training program to assist physicians in acquiring the expertise necessary to utilize our products and procedures. This program includes a comprehensive one-day course including didactic training and hands-on performance of TMR or PMR in vivo. To date over 1,000 cardiothoracic surgeons have been trained on the CardioGenesis TMR system.

We exhibit our products at major cardiovascular meetings. Investigators of our products have made presentations at meetings around the world, describing their results. Abstracts and articles have been published in peer-reviewed publications and industry journals to present the results of our clinical trials.

Research and Development

We believe that streamlining our research and product effort is essential to our ability to stimulate growth and maintain our market leadership position. Our ongoing research and product development efforts are focused on the development of new and enhanced lasers and fiber-optic handpieces for TMR and PMR applications.

We believe our future success will depend, in part, upon the success of our research and development programs. There can be no assurance that we will realize financial benefit from these efforts or that products or technologies developed by others will not render our products or technologies obsolete or non-competitive.

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Manufacturing

We outsource the manufacturing and assembly of our TMR and PMR handpiece systems to a contract manufacturer. We are currently exploring manufacturing outsourcing options for the TMR 2000 laser. The PMR laser system is provided to us under a manufacturing agreement with a laser manufacturing company.

Certain components of our laser units and fiber-optic handpieces are generally acquired from multiple sources. Other laser and fiber-optic components and subassemblies are purchased from single sources. Although we have identified alternative vendors, the qualification of additional or replacement vendors for certain components or services is a lengthy process. Any significant supply interruption would have a material adverse effect on the ability to manufacture our products and, therefore, would harm our business. We intend to continue to qualify multiple sources for components that are presently single sourced.

Competition

We expect that the market for TMR and PMR, which is currently in the early stages of development, will be competitive. At this point in time, we believe that our only competitor is PLC Systems, Inc. (PLC) which is selling FDA-approved TMR products in the U.S. and abroad. Other competitors may also enter the market, including large companies in the laser and cardiac surgery markets. Many of these companies have or may have significantly greater financial, research and development, marketing and other resources than we do.

PLC is a publicly traded corporation which uses a CO2 laser and an articulated mechanical arm in its TMR products. PLC obtained a Pre Market Approval for TMR in 1998. PLC has received the CE Marking, which allows sales of its products commercially in all European Union countries. PLC has been issued patents for its apparatus and methods for TMR. PLC recently announced that Edwards Life Sciences has exercised its option to assume full sales and marketing responsibility in the U.S. for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies that was signed in January 2001.

We believe that the factors which will be critical to market success include: the timing of receipt of requisite regulatory approvals, effectiveness and ease of use of the TMR products and applications, breadth of product line, system reliability, brand name recognition, effectiveness of distribution channels and cost of capital equipment and disposable devices.

TMR and PMR also compete with other methods for the treatment of cardiovascular disease, including drug therapy, PTCA and CABG. Even with the FDA approval of our TMR system in patients for whom other cardiovascular treatments are not likely to provide relief, and when used in conjunction with other treatments, we can not assure you that our TMR or PMR products will be accepted. Moreover, technological advances in other therapies for cardiovascular disease such as pharmaceuticals or future innovations in cardiac surgery techniques could make such other therapies more effective or lower in cost than our TMR procedure and could render our technology obsolete. We can not assure you that physicians will use our TMR procedure to replace or supplement established treatments, or that our TMR procedure will be competitive with current or future technologies. Such competition could harm our business.

Our TMR laser system and any other product developed by us that gains regulatory approval will face competition for market acceptance and market share. An important factor in such competition may be the timing of market introduction of competitive products. Accordingly, the relative pace at which we can develop products, complete clinical testing, achieve regulatory approval, gain reimbursement acceptance and supply commercial quantities of the product to the market are expected to be important competitive factors. In the event a competitor is able to obtain a PMA for its products prior to our doing so, we may not be able to compete successfully. We may not be able to compete successfully against current and future competitors even if we obtain a PMA prior to our competitors.

Government Regulation

Laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through TMR are considered medical devices, and as such are subject to regulation in

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the U.S. by the FDA and comparable international regulatory agencies. Our devices require the rigorous PMA process for approval to market the product in the U.S. and must bear the CE Marketing for commercial distribution in the European Community.

To obtain a Pre Market Approval (PMA) for a medical device, we must file a PMA application that includes clinical data and the results of pre-clinical and other testing sufficient to show that there is a reasonable assurance of safety and effectiveness of the product for its intended use. To begin a clinical study, an Investigational Device Exemption (IDE) must be obtained and the study must be conducted in accordance with FDA regulations. An IDE application must contain preclinical test data demonstrating the safety of the product for human investigational use, information on manufacturing processes and procedures, and proposed clinical protocols. If the FDA clears the IDE application, human clinical trials may begin. The results obtained from these trials are accumulated and, if satisfactory, are submitted to the FDA in support of a PMA application. Prior to U.S. commercial distribution, premarket approval is required from the FDA. In addition to the results of clinical trials, the PMA application must include other information relevant to the safety and effectiveness of the device, a description of the facilities and controls used in the manufacturing of the device, and proposed labeling. By law, the FDA has 180 days to review a PMA application. While the FDA has responded to PMA applications within the allotted time frame, reviews more often occur over a significantly longer period and may include requests for additional information or extensive additional trials. There can be no assurance that we will not be required to conduct additional trials which may result in substantial costs and delays, nor can there be any assurance that a PMA will be obtained for each product in a timely manner, if at all. In addition, changes in existing regulations or the adoption of new regulations or policies could prevent or delay regulatory approval of our products. Furthermore, even if a PMA is granted, subsequent modifications of the approved device or the manufacturing process may require a supplemental PMA or the submission of a new PMA which could require substantial additional clinical efficacy data and FDA review. After the FDA accepts a PMA application for filing, and after FDA review of the application, a public meeting is frequently held before an FDA advisory panel in which the PMA is reviewed and discussed. The panel then issues a favorable or unfavorable recommendation to the FDA or recommends approval with conditions. Although the FDA is not bound by the panel s recommendations, it tends to give such recommendations significant weight. In February 1999, we received a PMA for our TMR laser system for use in certain indications. As discussed above under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from that agency.

Products manufactured or distributed by us pursuant to a PMA will be subject to pervasive and continuing regulation by the FDA, including, among other things, postmarket surveillance and adverse event reporting requirements. Failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, suspensions or delays of approvals, seizures or recalls of products, operating restrictions or criminal prosecutions. The Federal Food, Drug and Cosmetic Act requires us to manufacture our products in registered establishments and in accordance with Good Manufacturing Practices (GMP) regulations and to list our devices with the FDA. Furthermore, as a condition to receipt of a PMA, our facilities, procedures and practices will be subject to additional pre-approval GMP inspections and thereafter to ongoing, periodic GMP inspections by the FDA. These GMP regulations impose certain procedural and documentation requirements upon us with respect to manufacturing and quality assurance activities. Labeling and promotional activities are subject to scrutiny by the FDA. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses. Changes in existing regulatory requirements or adoption of new requirements could harm our business. We may be required to incur significant costs to comply with laws and regulations in the future and current or future laws and regulations may harm our business.

We are also regulated by the FDA under the Radiation Control for Health and Safety Act, which requires laser products to comply with performance standards, including design and operation requirements, and manufacturers to certify in product labeling and in reports to the FDA that our products comply with all such standards. The law also requires laser manufacturers to file new product and annual reports, maintain

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manufacturing, testing and sales records, and report product defects. Various warning labels must be affixed and certain protective devices installed, depending on the class of the product. In addition, we are subject to California regulations governing the manufacture of medical devices, including an annual licensing requirement. Our facilities are subject to ongoing, periodic inspections by the FDA and California regulatory authorities.

Sales, manufacturing and further development of our TMR and PMR systems also may be subject to additional federal regulations pertaining to export controls and environmental and worker protection, as well as to state and local health, safety and other regulations that vary by locality and which may require obtaining additional permits. We can not predict the impact of these regulations on our business.

Sales of medical devices outside of the U.S. are subject to foreign regulatory requirements that vary widely by country. In addition, the FDA must approve the export of devices to certain countries. To market in Europe, a manufacturer must obtain the certifications necessary to affix to its products the CE Marking. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain and to maintain a CE Marking, a manufacturer must be in compliance with appropriate ISO 9001 standards and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within Europe require further approval by their national regulatory agencies. We have achieved International Standards Organization and European Union certification for our manufacturing facility. In addition, we have completed CE mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our TMR and PMR products in member countries of the European Union or elsewhere.

Intellectual Property Matters

Our success will depend, in part, on our ability to obtain patent protection for our products, preserve our trade secrets, and operate without infringing the proprietary rights of others. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our technology, inventions and improvements that are important to the development of our business. We have over 80 U.S. and foreign patents or allowed patent applications and more than 150 U.S. and foreign patent applications pending relating to various aspects of TMR, PMR and other cardiovascular therapies. Our patents or patent applications may be challenged, invalidated or circumvented in the future or the rights granted may not provide a competitive advantage. We intend to vigorously protect and defend our intellectual property. We do not know if patent protection will continue to be available for surgical methods in the future. Costly and time-consuming litigation brought by us may be necessary to enforce our patents and to protect our trade secrets and know-how, or to determine the enforceability, scope and validity of the proprietary rights of others.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We typically require our employees, consultants and advisors to execute confidentiality and assignment of inventions agreements in connection with their employment, consulting, or advisory relationships with us. These agreements may be breached and we may not have adequate remedies for any breach. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our proprietary technology, or we may not be able to meaningfully protect our rights in unpatented proprietary technology.

The medical device industry in general, and the industry segment that includes products for the treatment of cardiovascular disease in particular, have been characterized by substantial competition and litigation regarding patent and other intellectual property rights. In this regard, our competitors have been issued a number of patents related to TMR and PMR. There can be no assurance, however, that claims or proceedings will not be initiated by a competitor, or that claims by other parties will not arise in the future. In particular, the introduction in the United States market of the Company s PMR technology, should that occur, may create new exposures to claims of infringement of third party patents. Any such claims in the future, with or without merit, could be time-consuming and expensive to respond to and could divert the attention of our

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technical and management personnel. We may be involved in litigation to defend against claims of our infringement, to enforce our patents, or to protect our trade secrets. If any relevant claims of third party patents are upheld as valid and enforceable in any litigation or administrative proceeding, we could be prevented from practicing the subject matter claimed in such patents, or we could be required to obtain licenses from the patent owners of each such patent or to redesign our products or processes to avoid infringement.

Until recently, patent applications in the U.S. were maintained in secrecy until patents issue, and patent applications in foreign countries are maintained in secrecy for a period after filing. Most of our U.S. applications are maintained in secrecy unless they have issued. Publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries and the filing of related patent applications. Accordingly, we can not assure that our current and potential competitors and other third parties have not filed or in the future will not file applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights that will prevent, limit or interfere with our ability to make, use or sell our products either in the U.S. or internationally. In the event we were to require licenses to patents issued to third parties, such licenses may not be available or, if available, may not be available on terms acceptable to us. In addition, we may not be successful in any attempt to redesign our products or processes to avoid infringement or that any such redesign could be accomplished in a cost-effective manner. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would harm our business.

Third Party Reimbursement

We expect that sales volumes and prices of our products will depend significantly on the availability of reimbursement for surgical procedures using our products from third party payors such as governmental programs, private insurance and private health plans. Reimbursement is a significant factor considered by hospitals in determining whether to acquire new equipment. Reimbursement rates from third party payors vary depending on the third party payor, the procedure performed and other factors. Moreover, third party payors, including government programs, private insurance and private health plans, have in recent years been instituting increasing cost containment measures designed to limit payments made to healthcare providers by, among other measures, reducing reimbursement rates, limiting services covered, negotiating prospective or discounted contract pricing and carefully reviewing and increasingly challenging the prices charged for medical products and services.

Medicare reimburses hospitals on a prospectively determined fixed amount for the costs associated with an in-patient hospitalization based on the patient s discharge diagnosis, and reimburses physicians on a prospectively determined fixed amount based on the procedure performed, regardless of the actual costs incurred by the hospital or physician in furnishing the care and unrelated to the specific devices used in that procedure. Medicare and other third party payors are increasingly scrutinizing whether to cover new products and the level of reimbursement for covered products. In addition, Medicare traditionally has considered items or services involving devices that have not been approved or cleared for marketing by the FDA to be precluded from Medicare coverage. In July 1999, Centers for Medicare and Medicaid Services (CMS), formerly known as HCFA, began coverage of FDA approved TMR systems for any manufacturer s TMR procedures. In October of 1999, CMS further clarified its coverage policy to include coverage of TMR when performed as an adjunctive to Coronary Artery Bypass Graft.

We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. Private insurance and private health plans may not approve reimbursement for TMR or PMR. The lack of private insurance and health plans reimbursement may harm our business. Based on physician feedback, we know that private insurers are reimbursing hospitals and physicians when the procedure is performed on non-Medicare patients. In May 2001, Blue Cross/ Blue Shield s Technology Evaluation Center (TEC) assessed our therapy and confirmed that both TMR and TMR used as an adjunct to bypass surgery, improves net health outcomes. While TEC decisions are not binding, many Blue Cross/ Blue Shield plans and other third-party payers use the center as a benchmark and adopt into policy those therapies that meet the TEC assessment.

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In foreign markets, reimbursement is obtained from a variety of sources, including governmental authorities, private health insurance plans and labor unions. In most foreign countries, there are also private insurance systems that may offer payments for alternative therapies. Although not as prevalent as in the U.S., health maintenance organizations are emerging in certain European countries. We may need to seek international reimbursement approvals, and we may not be able to attain these approvals in a timely manner, if at all. Failure to receive foreign reimbursement approvals could make market acceptance of our products in the foreign markets in which such approvals are sought more difficult.

We believe that reimbursement in the future will be subject to increased restrictions such as those described above, both in the U.S. and in foreign markets. We also believe that the escalating cost of medical products and services has led to and will continue to lead to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including products offered by us. Third party reimbursement and coverage may not be available or adequate in U.S. or foreign markets, current levels of reimbursement may be decreased in the future or future legislation, regulation, or reimbursement policies of third party payors may reduce the demand for our products or our ability to sell our products on a profitable basis. Fundamental reforms in the healthcare industry in the U.S. and Europe that could affect the availability of third party reimbursement continue to be proposed, and we cannot predict the timing or effect of any such proposal. If third party payor coverage or reimbursement is unavailable or inadequate, our business may suffer.

Product Liability and Insurance

We maintain insurance against product liability claims in the amount of $10 million per occurrence and $10 million in the aggregate. We may not be able to obtain additional coverage or continue coverage in the amount desired or on terms acceptable to us, and such coverage may not be adequate for liabilities actually incurred. Any uninsured or underinsured claim brought against us or any claim or product recall that results in a significant cost to or adverse publicity against us could harm our business.

Employees

As of December 31, 2001 we had 59 employees, of which 30 employees were in sales and marketing. In January 2002, we reduced our staff by approximately 28%. In November 2001, we entered into an employment agreement with Michael J. Quinn, our Chief Executive Officer. Darrell F. Eckstein, our Interim Chief Financial Officer, was provided with a letter employment agreement when he was hired in December 2000. None of our employees are covered by a collective bargaining agreement and we have not experienced any work stoppages to date.

Our executive officers as of April 15, 2002 are as follows:

Name	Age	Position
Michael J. Quinn	58	Chief Executive Officer, President, Chairman of the Board and Director
Darrell F. Eckstein	44	Interim Chief Financial Officer, Vice President, Chief Accounting Officer, Treasurer and Secretary
Richard P. Lanigan	43	Vice President of Government Affairs and Business Development
Michael A. Tuckerman	35	Vice President of Sales
Christopher M. Owens	33	Vice President of Marketing

Michael J. Quinn has served as our Chief Executive Officer, President, Chairman of the Board and Director since October 2000. From November 1999 to September 2000, Mr. Quinn served as Chief Executive Officer, President and a member of the Board of Directors for Premier Laser Systems, a manufacturer of surgical and dental products. From January 1998 to November 1999, Mr. Quinn served as President and Chief Operating Officer of Imagyn Medical Technologies, Inc., a manufacturer of minimally invasive surgical specialty products. From 1995 through December 1997, Mr. Quinn served as President and Chief Operating Officer of Fisher Scientific Company. Prior to 1995, Mr. Quinn held senior operating management positions at

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major healthcare organizations including American Hospital Supply Corporation, Picker International, Cardinal Health Group and Bergen Brunswig.

Darrell F. Eckstein has served as our Interim Chief Financial Officer, Vice President, Chief Accounting Officer, Treasurer and Secretary since January 2002 and Vice President of Operations since December 2000. From 1996 to 2000 he served as Vice President and General Manager of the Surgical Products Division of Imagyn Medical Technologies, a manufacturer of minimally invasive surgical specialty products. From 1995 to 1996, Mr. Eckstein was Vice President of Finance, Chief Financial Officer and an Executive Committee member of Richard-Allen Medical Industries Inc., a medical devices company. From 1991 to 1995, Mr. Eckstein was Vice President of Finance, Chief Financial Officer and an Executive Committee member of National Emergency Services Inc., a health care services company that provides physician contract management, medical billing and insurance services. Prior to 1991, Mr. Eckstein worked for Deloitte and Touche, most recently as a Senior Audit Manager, for 11 years. He received his Bachelor of Science degree in Accounting from Indiana University.

Richard P. Lanigan has been our Vice President of Government Affairs and Business Development since March 2001, Vice President of Sales and Marketing since March 2000 and Director of Marketing since 1997. From 1992 to 1997, Mr. Lanigan served in various positions, most recently Marketing Manager, at Stryker Endoscopy. From 1987 to 1992, Mr. Lanigan served in Manufacturing and Operations management at Raychem Corporation. From 1981 to 1987, he served in the U.S. Navy where he completed six years of service as Lieutenant in the Supply Corps. Mr. Lanigan has a Bachelors of Arts in Finance from Notre Dame and a Masters degree in Systems Management from the University of Southern California.

Michael A. Tuckerman has been our Vice President of Sales since January 2002 and General Manager, Central Area since May 2001. From 1997 to 2001, Mr. Tuckerman served in various positions, most recently National Manager of Sales, at Heartport Inc. From 1995 to 1997, he served as Technical Sales Representative at Schneider, Inc., a division of Pfizer, Inc., and from 1991 to 1995, Mr. Tuckerman was the Midwest Area Manager for U.S. Surgical Corporation. Mr. Tuckerman has a Bachelors of Science in Marketing from Indiana University.

Christopher M. Owens has been our Vice President of Marketing since March 2001. Prior to CardioGenesis, Mr. Owens was Director of Marketing for the global Lamellar Surgery business of Bausch & Lomb. The Lamellar Surgery business provides surgical products for vision correction procedures. From 1997 to 2000, Mr. Owens served in a variety of sales related positions (most recently National Sales Manager) at Imagyn Medical Technologies, Inc., a manufacturer of minimally invasive surgical specialty products. From 1996 to 1997, Mr. Owens was Marketing Product Manager for Stackhouse, Inc. From 1990 to 1996 he also served as a Product Development Engineer at Baxter Healthcare Corp. He has both a Bachelors and Masters degree in Plastics Engineering from the University of Massachusetts and a Masters in Business Administration from the University of Phoenix.

Item 2. ***Description of Property.***

Our headquarters, located in Foothill Ranch, California, are comprised of 17,845 square feet of leased space. The lease expires in July 2006. We believe our facilities are adequate to meet our foreseeable requirements. There can be no assurance that additional facilities will be available to us, if and when needed, thereafter.

Item 3. ***Legal Proceedings.***

There are no pending legal proceedings against us other than ordinary litigation incidental to our business, the outcome of which, individually or in the aggregate, is not expected to have a material adverse effect on our business or financial condition.

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

None.

PART II

Item 5. ***Market for Registrants Shares and Related Shareholder Matters.***

(a) Our common stock is traded on the Nasdaq National Market under the symbol CGCP (and, prior to our name change, under the symbol ESTI), since May 31, 1996. For the periods indicated, the following table presents the range of high and low sale prices for the common stock as reported by the Nasdaq National Market.

2001	High	Low
First Quarter	$2.28	$0.81
Second Quarter	$3.12	$0.91
Third Quarter	$2.98	$0.60
Fourth Quarter	$1.65	$0.65

2000	High	Low
First Quarter	$11.50	$6.75
Second Quarter	$ 7.69	$2.88
Third Quarter	$ 4.69	$3.31
Fourth Quarter	$ 4.06	$0.50

As of December 31, 2001 shares of our common stock were held by 203 shareholders of record.

We have never paid a cash dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future, as we intend to retain our earnings, if any, to generate increased growth and for general corporate purposes.

Pursuant to a Share Purchase Agreement, dated April 11, 2001, we sold 2,000,000 shares of common stock to the State of Wisconsin Investment Board for a total price of $2,000,000, in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended (the Securities Act), and Rule 506 under the Securities Act.

In connection with entering into our facilities lease at 26632 Towne Centre Dr., Suite 320, Foothill Ranch, California, we issued a Common Stock Purchase Warrant covering 75,000 shares of common stock for an exercise price of $1.63 a share. The warrants are immediately exercisable at any time prior to May 7, 2006 at 5:00 pm (Eastern Time). This Common Stock Purchase Warrant was issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 under the Securities Act.

Pursuant to a Share Purchase Agreement, dated December 21, 2001, we sold 2,222,225 shares of common stock to the State of Wisconsin Investment Board for a total price of $2,000,000 in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 under the Securities Act.

Item 6. ***Selected Consolidated Financial Data.***

The following selected consolidated statement of operations data for fiscal years ended 2001, 2000 and 1999 and the consolidated balance sheet data for 2001 and 2000 set forth below are derived from our

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consolidated financial statements and are qualified by reference to our consolidated financial statements included herein.

The selected consolidated statement of operations data for fiscal years ended 1998 and 1997 and the consolidated balance sheet data for 1999, 1998 and 1997 have been derived from our audited consolidated financial statements not included herein. These historical results are not necessarily indicative of the results of operations to be expected for any future period. As a result of our 1999 pooling of interest with the former CardioGenesis, all prior period data has been restated as if the combined entity existed for all periods presented.

Selected Consolidated Financial Data

(in thousands, except per share amounts)

	Years Ended December 31,				
	2001	**2000**	**1999(1)**	**1998**	**1997**
Consolidated Statement of Operations Data:					
Net revenues	$ 14,153	$ 22,210	$ 25,324	$ 15,080	$ 13,058
Cost of revenues	5,777	10,055	13,246	7,868	7,295
Gross profit	8,376	12,155	12,078	7,212	5,763
Operating expenses:					
Research and development	1,863	5,065	11,353	29,861	26,217
Sales, general and administrative	15,119	22,009	24,581	28,484	21,004
Restructuring and merger-related costs	1,033		5,214		
Total operating expenses	18,015	27,074	41,148	58,345	47,221
Operating loss	(9,639)	(14,919)	(29,070)	(51,133)	(41,458)
Interest and other income (expense), net	(608)	310	737	3,366	5,240
Net loss	$ (10,247)	$ (14,609)	$ (28,333)	$ (47,767)	$ (36,218)
Net loss per share basic and diluted	$ (0.31)	$ (0.48)	$ (0.99)	$ (1.77)	$ (1.39)
Shares used in per share calculation	33,311	30,166	28,629	27,000	26,027
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 2,629	$ 3,357	$ 13,313	$ 27,941	$ 75,729
Working capital	1,048	4,662	10,031	22,243	68,999
Total assets	11,309	16,965	34,019	52,978	91,714
Long-term debt, less current portion	32	405	815	114	10
Accumulated deficit	(164,080)	(153,833)	(139,224)	(110,891)	(63,124)
Total shareholders equity	3,582	7,974	18,573	37,276	82,374

(1) Cost of revenues includes $2.5 million of inventory write-offs and upgrades associated with the March 1999 merger.

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations.***

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon

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the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please read the section below titled Factors Affecting Future Results to review conditions which we believe could cause actual results to differ materially from those contemplated by the forward-looking statements. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, may and sim expressions. In addition, any statements that refer to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. Our business may have changed since the date hereof and we undertake no obligation to update these forward looking statements.

The following discussion should be read in conjunction with financial statements and notes thereto included in this Annual Report on Form 10-K.

Overview

CardioGenesis Corporation, formerly known as Eclipse Surgical Technologies, Inc. (CardioGenesis , Company), incorporated in California in 1989, designs, develops, manufactures and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization (TMR) and percutaneous transluminal myocardial revascularization (PMR).

On February 11, 1999, we received final approval from the FDA for our TMR products for certain indications, and we are now able to sell those products in the U.S. on a commercial basis. We have also received the European Conforming Mark (CE Mark) allowing the commercial sale of our TMR laser systems and our PMR catheter system to customers in the European Community. Effective July 1, 1999, Health Care Financial Administration began providing Medicare coverage for TMR. Hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures.

We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre Market Approval (PMA) application in December of 1999 along with subsequent amendments. As discussed above under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. However, we will continue to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from the agency.

As of December 31, 2001, we had an accumulated deficit of $164,080,000. We expect to continue to incur operating losses. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

Results of Operations

Year Ended December 31, 2001 Compared to Year Ended December 31, 2000

Net Revenues

Net revenues of $14,153,000 for the year ended December 31, 2001 decreased $8,057,000, or 36%, when compared to net revenues of $22,210,000 for the year ended December 31, 2000. The decrease in net revenues was due to a reduction in sales of laser systems and disposable handpiece sales.

For the year ended December 31, 2001, domestic laser revenue decreased by $4,800,000 and domestic disposable handpiece revenue decreased by $2,100,000. In 2001, domestic handpiece revenue consisted of $4,700,000 in sales of product to customers operating under the loaned laser program, of which $1,400,000 was attributed to premiums associated with such sales. In 2000, domestic handpiece revenue consisted of $5,100,000 in sales of product to customers operating under the loaned laser program, of which $2,000,000 was attributed to premiums associated with such sales. In 2001 and 2000, sales of product to customers not operating under the loaned laser program was $5,900,000 and $7,600,000, respectively. International sales, accounting for approximately 7% of total sales for the year ended December 31, 2001, decreased $1,200,000 from the prior year when international sales accounted for 10% of total sales. This reduction can be explained

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by a reduction in international sales representation. We define international sales as sales to customers located outside of the United States.

Gross Profit

Gross profit increased to 59% of net revenues for the year ended December 31, 2001 as compared to 55% of net revenues for the year ended December 31, 2000. Gross profit in absolute dollars decreased by $3,779,000 to $8,376,000 for the year ended December 31, 2001, as compared to $12,155,000 for the year ended December 31, 2000. The increase in gross profit as a percent of sales resulted from improved margins on lasers and disposables partially as a result of the outsourcing of the manufacturing process for disposables which occurred in the second half of 2001. The decrease in gross margin in absolute terms resulted from the decrease in sales volumes.

Research and Development

Research and development expenditures of $1,863,000 decreased $3,202,000 or 63% for the year ended December 31, 2001 when compared to $5,065,000 for the year ended December 31, 2000. The decrease in overall research and development expense is comprised of a decrease in employee expenses of $1,400,000 related to reductions in force and a reduction in clinical trials expenses of $785,000 related to the conclusion of several of our major clinical trials. Additionally, the allocation for facilities overhead costs decreased by $620,000 and expenditures for engineering have decreased by $400,000 due to a reduction in development activities.

Sales, General and Administrative

Sales, general and administrative expenditures of $15,119,000 decreased $6,890,000 or 31% for the year ended December 31, 2001 when compared to $22,009,000 for the year ended December 31, 2000. The decrease in expenses resulted primarily from a decrease in employee expenses of $2,700,000 related to reductions in work force and a decrease in travel costs. Additionally, facilities and office expenses decreased by $1,950,000, costs for consulting and outside services decreased by $1,100,000 and marketing expenses decreased by $760,000.

Restructuring and Merger-Related Costs

During the year ended December, 31 2001, we recognized restructuring charges of $1,303,000, which were partially offset by a change in estimate of $270,000 in connection with merger-related costs that were incurred in 1999. The current year restructuring charges related to the company-wide restructuring which began in the second quarter of 2001. The restructuring included a reduction in headcount, the closing of our facilities in Sunnyvale, California and the move to a new facility located in Foothill Ranch, California. As a result of the restructuring, 48 employees were identified to be terminated under the original restructuring plan and have since been terminated, primarily from the finance and manufacturing departments.

The following table summarizes the restructuring activity and the remaining restructuring reserve balance:

	Personnel and Severance Costs	Lease and Other Contractual Commitments	Other Miscellaneous Costs	Total
		(in thousands)		
Provisions	$ 655	$ 344	$ 304	$ 1,303
Payments	(655)	(252)	(176)	(1,083)
Non-cash charges		(52)	(116)	(168)
Balance as of December 31, 2001	$	$ 40	$ 12	$ 52

Personnel and severance costs are comprised of severance, retention and relocation costs. Certain employees were offered a retention incentive to stay employed through a certain date while we were going

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through the restructuring phase. Lease and other contractual commitments are comprised primarily of the termination penalties associated with the early lease termination on our manufacturing and office facilities.

Interest and Other Income (Expense), Net

Interest income of $62,000 decreased $338,000 or 85% for the year ended December 31, 2001 when compared to $400,000 for the year ended December 31, 2000. This decrease was due to lower interest rates and lower investments in cash equivalents.

Interest expense of $18,000 decreased $14,000 or 44% for the year ended December 31, 2001 when compared to $32,000 for the year ended December 31, 2000. This decrease reflects a lower level of debt outstanding.

Equity in net loss of investee of $652,000 for the year ended December 31, 2001, compared to $58,000 for the year ended December 31, 2000, represents our share of the net loss of Microheart, Inc., formerly known as Microheart Holdings, Inc., a privately-held company, of which our ownership was 30.3% as of December 31, 2001.

Year Ended December 31, 2000 Compared to Year Ended December 31, 1999

Net Revenues

Net revenues of $22,210,000 for the year ended December 31, 2000 decreased $3,114,000, or 12%, when compared to net revenues of $25,324,000 for the year ended December 31, 1999. The decrease in net revenues was mainly due to a reduction in sales of laser systems resulting from a change, made at the end of 1999, to a new sales model, which emphasizes laser system placements to develop the disposable handpiece market more rapidly. The reduction in laser sales is partially offset by an increase in disposable handpiece sales generated from the new sales model.

Domestic laser revenue fell by $8,750,000 while domestic disposable handpiece revenue increased by $8,000,000. Domestic handpiece revenue consisted of $5,100,000 in sales of product to customers operating under the loaned laser program, of which $2,000,000 was attributed to premiums associated with those handpieces and $7,600,000 in handpiece sales to customers not operating under the loaned laser program. Compared to the prior year, handpiece sales under the loaned laser program increased $4,500,000 and handpiece sales to customers not operating under the loaned laser program increased $3,500,000. Other domestic changes in revenue from 2000 to 1999 were caused by no revenue recognized in the year 2000 for revenue producing activities such as research revenue of $730,000 recognized in 1999 associated with the sale of intellectual property and revenue of $600,000 recognized in 1999 for product sold in conjunction with active PMR clinical trials. These reductions in revenue were offset by a $300,000 increase in service revenue associated with extended service contracts and service calls. International sales, accounting for approximately 10% of total sales for the year ended December 31, 2000, fell $1,300,000 from the prior year when international sales accounted for 14% of total sales. This reduction is a result of a reduction in international sales representation. We define international sales as sales to customers located outside of the United States.

Gross Profit

Gross profit increased to $12,155,000 or 55% of net revenues for the year ended December 31, 2000 as compared to $12,078,000 or 48% of net revenues for the year ended December 31, 1999. In 1999, we incurred $2,523,000 in cost of revenues for inventory write-offs and a laser upgrade program resulting from our merger with the former CardioGenesis Corporation. Excluding these one-time charges, gross margin in the year ended December 31, 2000 decreased $2,446,000 compared to the prior year. This decrease in gross margin in absolute terms and as a percentage of sales resulted from the fixed component of cost of goods sold becoming a larger portion of sales, due to the decrease in sales volumes.

We began using a new sales model in the quarter ended December 31, 1999. The new sales model was derived to expedite the process of laser system placement and the adoption of TMR. Under the new model, hospitals were given the opportunity to bypass the capital approval process and, as a result, we were able to

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place more lasers than we would have placed if we had continued to sell lasers to hospitals. Given that product margins of lasers and disposable handpieces vary only slightly, the change in composition of our revenue did not significantly affect our gross margin.

Research and Development

Research and development expenditures of $5,065,000 decreased $6,288,000 or 55% for the year ended December 31, 2000 when compared to $11,353,000 for the year ended December 31, 1999. The decrease in overall research and development expense is comprised of a $4,875,000 reduction in expenses related to clinical trials, a $675,000 reduction in engineering project expenses and a $725,000 reduction in employee related expenses as headcount had fallen through general attrition.

Sales, General and Administrative

Sales, general and administrative expenses of $22,009,000 decreased $2,572,000 or 10% for the year ended December 31, 2000 when compared to $24,581,000 for the year ended December 31, 1999. The decrease is due to a $1,500,000 reduction in salary and commissions expense associated with both the elimination of redundant positions that existed between the former CardioGenesis Corporation and us prior to the merger and a decrease in commission payments directly related to the decrease in laser revenue from 2000 compared to 1999. In addition, there was a significant decrease in bad debt expense of $850,000 in the year 2000 compared to 1999.

Restructuring and Merger-Related Costs

There were merger-related costs in 1999 of $5,214,000 associated with the merger between us and the former CardioGenesis Corporation. In March 1999, we recognized merger-related costs of $6,893,000 for financial advisory and legal fees, personnel severance, terminated relationships and other costs including write-offs of fixed assets and inventory. A majority of the 40 employees that were terminated as a result of the merger were located in California and worked in operations, sales, marketing, quality, research and development and administrative functions. In addition, we recognized merger-related costs of $844,000, which were primarily due to an upgrade program to replace customer owned equipment rendered unusable by the merger. The total merger-related costs for the twelve months ended December 31, 1999 were $7,737,000, which included costs attributed to inventory write-offs and a laser upgrade program totaling $2,523,000 that were recorded as a component of cost of revenues.

There were no restructuring related costs recognized in the year 2000 or 1999.

Interest and Other Income (Expense), Net

Interest income of $400,000 decreased $401,000 or 50% for the year ended December 31, 2000 when compared to $801,000 for the year ended December 31, 1999. This decrease was due to lower investments in marketable securities and cash equivalents.

Interest expense of $32,000 decreased $32,000 or 50% for the year ended December 31, 2000 when compared to $64,000 for the year ended December 31, 1999. This decrease reflects a lower level of debt outstanding.

Equity in loss of investee of $58,000 for the year ended December 31, 2000 represents our share of the net loss of Microheart, Inc., a privately-held company, resulting from our November 2000 exercise of warrants which increased our ownership percentage to approximately 32%.

Liquidity and Capital Resources

Cash and cash equivalents were $2,629,000 at December 31, 2001 compared to $3,357,000 at December 31, 2000, a decrease of 22%. We used $6,213,000 of cash for operating activities, including funding our operating loss and changes in accounts receivable, inventories and accrued liabilities. Accounts receivable was $2,330,000 at December 31, 2001 compared to $3,654,000 at December 31, 2000, a decrease of 36%. The

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decrease in accounts receivable is partly attributed to a net increase of $761,000 in the allowance for doubtful accounts. Inventories decreased by $2,185,000 or 40% to $3,215,000 at December 31, 2001 from a level of $5,400,000 at December 31, 2000. This decrease is mainly due to depreciation on lasers loaned to hospitals of $1,100,000 million and a reduction in inventory levels. Accrued liabilities decreased by $1,322,000 or 23% to $4,467,000 at December 31, 2001 compared to $5,789,000 at December 31, 2000, primarily due to payments on obligations and an overall decrease in our operating expenses.

Investing activities, consisting primarily of additions to property and equipment, used cash of $269,000 in the fiscal year 2001. Since our inception, we have satisfied our capital requirements through sales of our equity securities. In addition, our operations have been funded through sales of our products. In the fiscal year 2001, financing activities provided cash of $5,777,000, primarily from the issuance of common stock pursuant to exercise of stock options and various sales of our common stock.

In March 2001, we sold 898,202 shares of common stock to Acqua Wellington North American Equities Fund, Ltd. at a negotiated purchase price of $1.1133 per share. In April 2001, we sold 2,000,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share. In August 2001, we established a receivables-based financing arrangement with a finance company. As of December 31, 2001, we have borrowing capacity of approximately $1.2 million based on qualifying accounts receivable and have outstanding borrowings of $100,000. The term of this arrangement is one year from the date of inception, July 25, 2001, and is renewable annually at the mutual consent of both parties. The agreement provides us with the option of borrowing at an annual rate of 12% plus an administrative fee of 0.50% on all outstanding borrowings. In December 2001, we sold 2,222,225 shares of common stock to a governmental entity at a negotiated purchase price of $0.90 per share. In April 2002, we sold our ownership interest in Microheart, Inc. for $2,285,150. In April 2002, we sold 500,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share.

We have incurred significant losses for the last several years and at December 31, 2001 have an accumulated deficit of $164,080,000. The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. Our ability to continue as a going concern is dependent upon achieving profitable operations in the future. Our plans include increasing sales through increased direct sales and marketing efforts on existing products and achieving timely regulatory approval for certain other products.

We also plan to continue our cost containment efforts by focusing on reducing cost of revenues and on reducing sales, general and administrative expenses. With regard to reducing cost of revenues, we completed the outsourcing of a significant portion of our manufacturing, which allows us to purchase products at lower costs. With regard to reducing operating expenses, we have focused our efforts on reducing headcount and overall expenses in functions that are not essential to core and critical activities.

Currently, one of our primary goals is to achieve break-even operations followed by profitability. Our actions have been guided by this imperative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been eliminated.

We believe our cash balance as of December 31, 2001, the borrowing capacity available under our receivable financing arrangement and the infusions to our cash balance in April 2002 will be sufficient to meet our capital and operating requirements through the end of 2002. We believe that if revenue from sales or new funds from debt or equity instruments is insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

Quarterly Results of Operations

The following table sets forth certain quarterly financial information for the periods indicated. This information has been derived from unaudited financial statements that, in the opinion of management, have been prepared on the same basis as the audited information, and includes all normal recurring adjustments

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necessary for a fair presentation of such information. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future periods.

	Three Months Ended							
	2001				2000			
	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sept. 30	Dec. 31
Net revenues	$ 3,111	$ 4,030	$ 4,221	$ 2,791	$ 5,677	$ 6,608	$ 5,014	$4,911
Gross profit	1,576	2,447	2,594	1,759	3,346	3,910	2,554	2,345
Operating loss	(2,105)	(2,705)	(2,494)	(2,335)	(4,546)	(3,398)	(3,800)	(3,175)
Net loss	(2,437)	(2,967)	(2,481)	(2,362)	(4,439)	(3,262)	(3,744)	(3,164)
Net loss per share:								
Basic and diluted	(0.08)	(0.09)	(0.07)	(0.07)	(0.15)	(0.11)	(0.13)	(0.10)
Weighted average shares outstanding	30,837	33,631	34,209	34,415	29,664	30,064	30,191	30,729

Critical Accounting Policies and Estimates

We consider certain accounting policies related to use of estimates and revenue recognition to be critical accounting policies.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

We recognize revenue on product sales upon receipt of a purchase order, subsequent shipment of the product and the price is fixed or determinable and collection of sales proceeds is reasonably assured. Where purchase orders allow customers an acceptance period or other contingencies, revenue is recognized upon the earlier of acceptance or removal of the contingency.

Revenues from sales to distributors and agents are recognized upon shipment when there is evidence that an arrangement exists, delivery has occurred, the sales price is fixed or determinable and the ability to collect sales proceeds is reasonably assured. The contracts regarding these sales do not include any rights of return or price protection clauses.

We frequently loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. Loaned lasers are depreciated to cost of revenues over a useful life of 24 months. Revenue on handpieces is recognized upon shipment at an amount equal to the list price. The premium over the list price represents revenue related to the use of the laser unit and is recognized ratably, generally over the 24-month useful life of the placed lasers.

Revenues from service contracts are recognized upon performance or over the terms of the contract as appropriate.

Recently Issued Accounting Standards

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141 Business Combinations, and SFAS No. 142 Goodwill and Other Intangible Assets, which change the accounting for business combinations and goodwill. SFAS No. 141 requires that the purchase method of accounting be used for business combinations initiated after June 30, 2001. Use of the pooling-of-interests method is now prohibited. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including

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goodwill recorded in past business combinations, will therefore cease upon adoption of this statement, which for us will be January 1, 2002. We do not expect the adoption of these standards will have a material effect on our consolidated financial statements.

In August 2001, the FASB issued SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. SFAS No. 144 develops one accounting model for long-lived assets that are to be disposed of by sale, requires that long-lived assets that are to be disposed by sale be measured at the lower of book value or fair value less cost to sell and expands the scope of discontinued operations to include all components of an entity with operations that (a) can be distinguished from the rest of the entity and (b) will be eliminated from the ongoing operations of the entity in a disposal transaction. SFAS No. 144 is effective for all fiscal years beginning after December 15, 2001 and is therefore effective for us beginning with our fiscal quarter ending March 31, 2002. We do not expect the adoption of this standard will have a material effect on our consolidated financial statements.

Factors Affecting Future Results

In addition to the other information included in this Form 10-K, the following risk factors should be considered carefully in evaluating us and our business.

Our ability to continue as a going concern is dependent upon achieving profitable operations in the future.

We will have a continuing need for new infusions of cash until revenues are increased to meet our operating expenses. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If we are unable to increase our sales or achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and will not have sufficient cash to fund our operations.

We may fail to obtain required regulatory approvals to market our products including our PMR laser system in the United States.

Our business could be harmed if any of the following events, circumstances or occurrences related to the regulatory process occurred thereby causing a reduction in our revenues:

the failure to obtain regulatory approvals for our PMR system;

any significant limitations in the indicated uses for which our products may be marketed; and

substantial costs incurred in obtaining regulatory approvals.

The Food and Drug Administration has not approved our PMR laser systems for any application in the United States. The PMR study compares PMR to conventional medical therapy in patients with no option for other treatment. The Food and Drug Administration may not accept the study as safe and effective, and PMR may not be approved for commercial use in the United States. Responding to Food and Drug Administration requests for additional information could require substantial financial and management resources and take several years.

In the future, the Food and Drug Administration could restrict the current uses of our TMR product.

The Food and Drug Administration has approved our TMR product for sale and use by physicians in the United States. At the request of the Food and Drug Administration, we are currently conducting post-market surveillance of our TMR product. We received a letter from the Food and Drug Administration expressing

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concern about the progress of our post-market surveillance study for our TMR product. We have submitted a plan to the Food and Drug Administration to enable the timely completion of our post-market surveillance study. However, if we should fail to meet the requirements mandated by the Food and Drug Administration or fail to complete our post-market surveillance study in an acceptable time period, the Food and Drug Administration could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, though we are not aware of any safety concerns during our on-going post-market surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the Food and Drug Administration could possibly restrict the currently approved uses of our TMR product. In the future, if the Food and Drug Administration were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians, such as restricting TMR s use with the coronary artery bypass grafting procedure which occurs in more than half the procedures in which TMR is used, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be adversely affected.

The Circulatory Devices Panel of the Food and Drug Administration in July 2001 recommended against approval of our PMR device for public sale and use in the United States, which has effectively delayed potential revenue, if any, that may have been derived in the future from the sale of that device in the United States and which may have other adverse effects.

The Circulatory Devices Panel of the Food and Drug Administration recommended in July 2001 that the Food and Drug Administration not approve our PMR device for public sale and use in the United States based on concerns related to the safety of the device and the data regarding adverse events in the clinical trials. Although we do not expect to conduct further clinical trials of our PMR device, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration s approval of our PMR device. We will not be able to derive any revenue from the sale of that device in the United States until such time, if any, that the Food and Drug Administration approves the device. Such inability to realize revenue from sales of our PMR device in the United States may have an adverse effect on our results of operations. Additionally, the trading price of our common stock on the NASDAQ National Market fell substantially after the panel s recommendation became public.

The medical community has not broadly adopted our products, and unless our products are broadly adopted, our business will suffer.

Our TMR products and PMR products have not yet achieved broad commercial and clinical adoption. We cannot predict whether or at what rate and how broadly our products will be adopted by the medical community. Our business would be harmed if our TMR and PMR systems fail to achieve significant market acceptance.

The receipt of positive endorsements by physicians is essential for the success of our products in the market place.

Positive endorsements, by physicians, are essential for clinical adoption of our TMR and PMR laser systems. Physicians may elect not to recommend TMR and PMR laser systems for any number of reasons.

Clinical adoption of these products will depend upon:

our ability to facilitate training of cardiothoracic surgeons and interventional cardiologists in TMR and PMR therapy;

willingness of such physicians to adopt and recommend such procedures to their patients; and

raising the awareness of TMR and PMR with the targeted patient population.

Patient acceptance of the procedure will depend on:

physician recommendations;

the degree of invasiveness;

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the effectiveness of the procedure; and

the rate and severity of complications associated with the procedure as compared to other procedures.

To expand our business, we must establish effective sales, marketing and distribution systems.

To expand our business, we must establish effective systems to sell, market and distribute products. To date, we have had limited sales which have consisted primarily of U.S. sales of our TMR lasers and disposable handpieces on a commercial basis since February 1999 and PMR lasers and disposable catheters outside of the U.S. through international distributors.

If our sales force is not successful in increasing market share and selling our disposable handpieces, our business will suffer.

With Food and Drug Administration approval of our TMR laser system, we are marketing our products primarily through our direct sales force. If the sales force is not successful in increasing market share and selling our disposable handpieces, our business will suffer.

Expansion of our business may put added pressure on our management and operational infrastructure affecting our ability to meet any increased demand for our products and possibly having an adverse effect on our operating results.

The growth in our business may place a significant strain on our limited personnel, management, financial systems and other resources. The evolving growth of our business presents numerous risks and challenges, including:

the dependence on the growth of the market for our TMR and PMR systems;

our ability to successfully and rapidly expand sales to potential customers in response to potentially increasing clinical adoption of the TMR procedure;

the costs associated with such growth, which are difficult to quantify, but could be significant;

domestic and international regulatory developments;

rapid technological change;

the highly competitive nature of the medical devices industry; and

the risk of entering emerging markets in which we have limited or no direct experience.

To accommodate any such growth and compete effectively, we may need to obtain additional funding to improve information systems, procedures and controls and expand, train, motivate and manage our employees, and such funding may not be available in sufficient quantities, if at all. If we are not able to manage these activities and implement these strategies successfully to expand to meet any increased demand, our operating results could suffer.

Our operating results are expected to fluctuate and quarter-to-quarter comparisons of our results may not indicate future performance.

Our operating results have fluctuated significantly from quarter-to-quarter and are expected to fluctuate significantly from quarter-to-quarter due to a number of events and factors, including:

the level of product demand and the timing of customer orders;

changes in strategy;

delays associated with the Food and Drug Administration and other regulatory approval processes;

personnel changes including our ability to continue to attract, train and motivate additional qualified personnel in all areas;

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the level of international sales;

changes in competitive pricing policies;

the ability to develop, introduce and market new and enhanced versions of products on a timely basis;

deferrals in customer orders in anticipation of new or enhanced products;

product quality problems; and

the enactment of health care reform legislation and any changes in third party reimbursement policies.

We believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. Due to the emerging nature of the markets in which we compete, forecasting operating results is difficult and unreliable. Over the past year, our revenue has been lower than anticipated, largely attributable to the transition to our new sales strategy. It is likely or possible that our operating results for a future quarter will fall below the expectations of public market analysts and investors. When this occurred in the past, the price of our common stock fell substantially, and if this occurs again, the price of our common stock may fall again, perhaps substantially.

Growth in our future operating results is highly contingent and subject to significant risks.

Our future operating results will be significantly affected by our ability to:

successfully and rapidly expand sales to potential customers;

implement operating, manufacturing and financial procedures and controls;

improve coordination among different operating functions; and

achieve manufacturing efficiencies as production volume increases.

We may not be able to successfully market our products if third party reimbursement for the procedures performed with our products is not available for our health care provider customers.

Few individuals are able to pay directly for the costs associated with the use of our products. In the United States, hospitals, physicians and other healthcare providers that purchase medical devices generally rely on third party payors, such as Medicare, to reimburse all or part of the cost of the procedure in which the medical device is being used.

Effective July 1, 1999 the Health Care Financing Administration commenced Medicare coverage for TMR systems for any manufacturer s TMR procedures. Hospitals and physicians are now eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. The Health Care Financing Administration has not approved reimbursement for PMR. If it does not in the future provide reimbursement, our ability to successfully market and sell our PMR products will be harmed.

Currently there are over 2,000 private health insurers and managed care organizations in the United States. Even though Medicare beneficiaries appear to account for approximately 52% of all patients treated with the TMR procedure, the remaining 48% are beneficiaries of private insurance and private health plans. We have limited data on the reimbursement of our TMR procedures by private insurance and private health plans. If they do not provide reimbursement, our business will suffer.

Based on physician feedback, we know that private insurers are reimbursing hospitals and physicians when the procedure is performed on non-Medicare patients. In May 2001, Blue Cross/ Blue Shield s Technology Evaluation Center (TEC) assessed our therapy and confirmed that both TMR and TMR used as an adjunct to bypass surgery, improves net health outcomes. While TEC decisions are not binding, many Blue Cross/ Blue Shield plans and other third-party payors use the Center as a benchmark and adopt into policy those therapies that meet the TEC assessment.

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We face competition from our competitor s products which could limit market acceptance of our products and render our products obsolete.

The market for TMR laser systems is competitive. If our competitor is more effective in developing new products and procedures and marketing existing and future products, our business will suffer. The market for TMR laser systems is characterized by rapid technical innovation. Accordingly, our current or future competitors may succeed in developing TMR products or procedures that:

- are more effective than our products;
- are more effectively marketed than our products; or
- may render our products or technology obsolete.

We currently compete with PLC Systems. PLC recently announced that Edwards Life Sciences has exercised its option to assume full sales and marketing responsibility in the U.S. for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies that was signed in January 2001.

If we obtain the Food and Drug Administration s approval for our PMR laser system, we will face competition for market acceptance and market share for that product. Our ability to compete may depend in significant part on the timing of introduction of competitive products into the market, and will be affected by the pace, relative to competitors, at which we are able to:

- develop products;
- complete clinical testing and regulatory approval processes;
- obtain third party reimbursement acceptance; and
- supply adequate quantities of the product to the market.

Our products depend on TMR technology that is rapidly changing which may require us to incur substantial product development expenditures to prevent our products from becoming obsolete.

The medical device industry is characterized by rapid and significant technological change. Our future success will depend in large part on our ability to respond to such changes through further product research and development. In addition, we must expand the indications and applications for our products by developing and introducing enhanced and new versions of our TMR and PMR laser systems. Product research and development requires substantial expenditures and is inherently risky. We may not be able to:

- identify products for which demand exists; or
- develop products that have the characteristics necessary to treat particular indications.

Overall increases in medical costs could adversely affect our business.

We believe that the overall escalating cost of medical products and services has led, and will continue to lead, to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including products offered by them. We cannot assure you that in either United States or international markets that:

- third party reimbursement and coverage will be available or adequate;
- current reimbursement amounts will not be decreased in the future; or
- future legislation, regulation or reimbursement policies of third party payors will not otherwise adversely affect the demand for our products or our ability to profitably sell our products.

Fundamental reforms in the healthcare industry in the United States and Europe continue to be considered. We cannot predict whether or when any healthcare reform proposals will be adopted and what effect such proposals might have on our business.

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We have a history of losses and may not be profitable in the future.

We have incurred significant losses since inception. Our revenues and operating income will be constrained:

until such time, if ever, as we obtain broad commercial adoption of our TMR laser systems by healthcare facilities in the United States;

until such time, if ever, as we obtain Food and Drug Administration and other regulatory approvals for our PMR laser systems; and

for an uncertain period of time after such approvals are obtained.

We may not achieve or sustain profitability in the future.

Third parties may limit the development and protection of our intellectual property, which could adversely affect our competitive position.

Our success is dependent in large part on our ability to:

obtain patent protection for our products and processes;

preserve our trade secrets and proprietary technology; and

operate without infringing upon the patents or proprietary rights of third parties.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Certain competitors and potential competitors of ours have obtained United States patents covering technology that could be used for certain TMR and PMR procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other TMR or PMR technology. In addition, international patents may not be interpreted the same as any counterpart United States patents.

While we periodically review the scope of our patents and other relevant patents of which we are aware, the question of patent infringement involves complex legal and factual issues. Any conclusion regarding infringement may not be consistent with the resolution of any such issues by a court.

Costly litigation may be necessary to protect intellectual property rights.

We may have to engage in time consuming and costly litigation to protect our intellectual property rights or to determine the proprietary rights of others. In addition, we may become subject to patent infringement claims or litigation, or interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions.

Defending and prosecuting intellectual property suits, United States Patent and Trademark Office interference proceedings and related legal and administrative proceedings are both costly and time-consuming. We may be required to litigate further to:

enforce our issued patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Any litigation or interference proceedings will result in substantial expense and significant diversion of effort by technical and management personnel. If the results of such litigation or interference proceedings are adverse to us, then the results may:

subject us to significant liabilities to third parties;

require us to seek licenses from third parties;

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prevent us from selling our products in certain markets or at all; or

require us to modify our products.

Although patent and intellectual property disputes regarding medical devices are often settled through licensing and similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. Furthermore, we may not be able to obtain the necessary licenses on satisfactory terms, if at all.

Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products. This would harm our business.

The United States patent laws have been amended to exempt physicians, other health care professionals, and affiliated entities from infringement liability for medical and surgical procedures performed on patients. We are not able to predict if this exemption will materially affect our ability to protect our proprietary methods and procedures.

We rely on patent and trade secret laws, which are complex and may be difficult to enforce.

The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. Issued patent or patents based on pending patent applications or any future patent application may not exclude competitors or may not provide a competitive advantage to us. In addition, patents issued or licensed to us may not be held valid if subsequently challenged and others may claim rights in or ownership of such patents.

Furthermore, we cannot assure you that our competitors:

have not developed or will not develop similar products;

will not duplicate our products; or

will not design around any patents issued to or licensed by us.

Because patent applications in the United States were historically maintained in secrecy until the patents are issued, we cannot be certain that:

others did not first file applications for inventions covered by our pending patent applications; or

we will not infringe any patents that may issue to others on such applications.

We may not be able to meet future product demand on a timely basis and may be subject to delays and interruptions to product shipments because we depend on single source third party suppliers and manufacturers.

Certain critical products and components for lasers and disposable handpieces are purchased from single sources. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of some of these products to third parties. We may experience harm to our business if these sources have difficulties supplying our needs for these products and components. In addition, we do not have long term supply contracts. As a result, these sources are not obligated to continue to provide these critical products or components to us. Although we have identified alternative suppliers and manufacturers, a lengthy process would be required to qualify them as additional or replacement suppliers or manufacturers. Also, it is possible some of our suppliers or manufacturers could have difficulty meeting our needs if demand for our TMR and PMR laser systems were to increase rapidly or significantly. In addition, any defect or malfunction in the laser or other products provided by such suppliers and manufacturers could cause a delay in regulatory approvals or adversely affect product acceptance. Further, we cannot predict:

if materials and products obtained from outside suppliers and manufacturers will always be available in adequate quantities to meet our future needs; or

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whether replacement suppliers and/or manufacturers can be qualified on a timely basis if our current suppliers and/or manufacturers are unable to meet our needs for any reason.

Our products could contain defects which could delay regulatory approval or market acceptance of our products.

We may experience future product defects, malfunctions, manufacturing difficulties or recalls related to the lasers or other components used in our TMR and PMR laser systems. Any such occurrence could cause a delay in regulatory approvals or adversely affect the commercial acceptance of our products. We are unable to quantify the likelihood or costs of any such occurrences, but they could potentially be significant. Our business could be harmed because we may be unable to sufficiently remedy a significant product recall while still maintaining our daily manufacturing quotas.

We must comply with Food and Drug Administration manufacturing standards or face fines or other penalties including suspension of production.

We are required to demonstrate compliance with the Food and Drug Administration s current good manufacturing practices regulations if we market devices in the United States or manufacture finished devices in the United States. The Food and Drug Administration inspects manufacturing facilities on a regular basis to determine compliance. If we fail to comply with applicable Food and Drug Administration or other regulatory requirements, we can be subject to:

fines, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

The impact on the company of any such failure to comply would depend on the impact of the remedy imposed on us.

We may suffer losses from product liability claims if our products cause harm to patients.

We are exposed to potential product liability claims and product recalls. These risks are inherent in the design, development, manufacture and marketing of medical devices. We could be subject to product liability claims if the use of our TMR or PMR laser systems is alleged to have caused adverse effects on a patient or such products are believed to be defective. Our products are designed to be used in life-threatening situations where there is a high risk of serious injury or death. We are not aware of any material side effects or adverse events arising from the use of our TMR product. Though we are in the process of responding to the Food and Drug Administration s Circulatory Devices Panel s recent recommendation against approval of our PMR product because of concerns over the safety of the device and the data regarding adverse events in the clinical trials, we believe there are no material side effects or adverse events arising from the use of our PMR product. When being clinically investigated, it is not uncommon for new surgical or interventional procedures to result in a higher rate of complications in the treated population of patients as opposed to those reported in the control group. In light of this, we believe that the difference in the rates of complications between the treated groups and the control groups in the clinical trials for our PMR product are not statistically significant, which is why we believe that there are no material side effects or material adverse events arising from the use of our PMR product.

Any regulatory clearance for commercial sale of these products will not remove these risks. Any failure to comply with the Food and Drug Administration s good manufacturing practices or other regulations could hurt our ability to defend against product liability lawsuits. Although we have not experienced any product liability claims to date, any such claims could cause our business to suffer.

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Our insurance may be insufficient to cover product liability claims against us.

Our product liability insurance may not be adequate for any future product liability problems or continue to be available on commercially reasonable terms, or at all.

If we were held liable for a product liability claim or series of claims in excess of our insurance coverage, such liability could harm our business and financial condition. We maintain insurance against product liability claims in the amount of $10 million per occurrence and $10 million in the aggregate.

We may require increased product liability coverage as sales of approved products increase and as additional products are commercialized. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all.

We depend heavily on key personnel and turnover of key employees and senior management could harm our business.

Our future business and results of operations depend in significant part upon the continued contributions of our key technical and senior management personnel. They also depend in significant part upon our ability to attract and retain additional qualified management, technical, marketing and sales and support personnel for our operations. If we lose a key employee or if a key employee fails to perform in his or her current position, or if we are not able to attract and retain skilled employees as needed, our business could suffer.

During the last two years, we have had significant change in our senior management team. Our former Chief Executive Officer, Allen Hill, resigned from the company in December 1999. One of our former Directors, Alan Kaganov, acted as interim Chief Executive Officer until we hired our current Chief Executive Officer, Michael Quinn, in October of 2000. Our former Chief Financial Officer, Dick Powers, resigned from the company in July 2000. Ian Johnston, our then Vice President of Finance who resigned in June 2001, acted as interim Chief Financial Officer until our former Chief Financial Officer, J. Stephen Wilkins, was hired in May 2001. In January 2002, our former Chief Financial Officer, J. Stephen Wilkins, resigned and was replaced by Darrell Eckstein who was originally hired in December 2000 as our Vice President of Operations, originally replacing Bill Picht, who resigned earlier in 2000. Additionally, Richard Lanigan moved from Vice President of Sales to Vice President of Government Affairs and Business Development in March 2001 and Michael A. Tuckerman was promoted to Vice President, U.S. Sales, after Thomas Kinder, our former Vice President of Worldwide Sales resigned in January 2002. In addition, Christopher M. Owens was hired as Vice President of Marketing in March 2001. William Von Brendel, who was hired in August 2001 as Vice President and General Manager of the International Business Unit, resigned in January 2002 and is currently providing international sales support under a consulting agreement with us.

Our future business could be harmed by our turnover in senior management if we have difficulty familiarizing and training our new management with respect to our business. Further significant turnover in our senior management could significantly deplete our institutional knowledge held by our existing senior management team. We depend on the skills and abilities of these key employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover.

We may fail to comply with international regulatory requirements and could be subject to regulatory delays, fines or other penalties.

Regulatory requirements in foreign countries for international sales of medical devices often vary from country to country. In addition, the Food and Drug Administration must approve the export of devices to certain countries. The occurrence and related impact of the following factors would harm our business:

delays in receipt of, or failure to receive, foreign regulatory approvals or clearances;

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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To market in Europe, a manufacturer must obtain the certifications necessary to affix to its products the CE Marking. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain and to maintain a CE Marking, a manufacturer must be in compliance with the appropriate quality assurance provisions of the International Standards Organization and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within Europe require further approval by their national regulatory agencies.

We have completed CE mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our products in member countries of the European Union or elsewhere. Any enforcement action by international regulatory authorities with respect to past or future regulatory noncompliance could cause our business to suffer. Noncompliance with international regulatory requirements could result in enforcement action such as not being allowed to market our product in the European Union, which would significantly reduce international revenue.

We sell our products internationally which subjects us to specific risks of transacting business in foreign countries.

In future quarters, international sales may become a significant portion of our revenue if our products become more widely used outside of the United States. Our international revenue is subject to the following risks, the occurrence of any of which could harm our business:

foreign currency fluctuations;

economic or political instability;

foreign tax laws;

shipping delays;

various tariffs and trade regulations;

restrictions and foreign medical regulations;

customs duties, export quotas or other trade restrictions; and

difficulty in protecting intellectual property rights.

We may not achieve wide acceptance of our products in foreign markets if we fail to obtain third party reimbursement for the procedures performed with our products.

If we obtain the necessary foreign regulatory registrations or approvals, market acceptance of our products in international markets would be dependent, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement is a significant factor considered by hospitals in determining whether to acquire new equipment. A hospital is more inclined to purchase new equipment if third-party reimbursement can be obtained. Reimbursement and health care payment systems in international markets vary significantly by country. They include both government sponsored health care and private insurance. Although we expect to seek international reimbursement approvals, any such approvals may not be obtained in a timely manner, if at all. Failure to receive international reimbursement approvals could hurt market acceptance of our TMR and PMR products in the international markets in which such approvals are sought, which would significantly reduce international revenue.

We may engage in future acquisitions that could distract our management, cause us to incur debt, or dilute our shareholders.

We may, from time to time, acquire or invest in other complementary businesses, products or technologies. While there are currently no commitments with respect to any particular acquisition or investment, our management frequently evaluates the strategic opportunities available in complementary

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businesses, products or technologies. The process of integrating an acquired company s business into our operations may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. Moreover, the anticipated benefits of any acquisition or investment may not be realized. Any future acquisitions or investments by us could result in potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities and impairment/amortization expenses related to goodwill and other intangible assets, any of which could materially harm our operating results.

The price of our common stock may fluctuate significantly, which may result in losses for investors.

The market price of our common stock has been and may continue to be volatile. For example, during 52-week period ended December 31, 2001, the closing prices of our common stock as reported on the NASDAQ National Market ranged from a high of $3.12 to a low of $0.60. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

actual or anticipated variations in our quarterly operating results;

announcements of technological innovations or new products or services by us or our competitors;

announcements relating to strategic relationships or acquisitions;

changes in financial estimates by securities analysts;

statements by securities analysts regarding us or our industry;

conditions or trends in the medical device industry; and

changes in the economic performance and/or market valuations of other medical device companies.

Because of this volatility, we may fail to meet the expectations of our shareholders or of securities analysts at some time in the future, and our stock price could decline as a result.

In addition, the stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of these companies. Any negative change in the public s perception of medical device companies could depress our stock price regardless of our operating results. Our common stock could be subject to certain consequences in the future established by the NASDAQ National Market such as being delisted if we do not meet the Nasdaq s continued listing standards. For instance, if our common stock were to trade under $1.00 for 30 consecutive days on the NASDAQ National Market, or our current net tangible assets fell below $4 million, or if we do not in the future meet the Nasdaq s $10 million in stockholder s equity test starting November 1, 2002, we would be in violation of the Nasdaq s continued listing standards. If our common stock were delisted from the NASDAQ National Market, then we could apply for listing on the Nasdaq SmallCap Market or explore becoming listed on an alternative market. Delisting from the Nasdaq National Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future.

Recently, when the market price of a stock has been volatile, holders of that stock have often instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought such a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Quantitative Disclosures

The Company is exposed to market risks inherent in its operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of

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business. The Company does not use derivatives to alter the interest characteristics of its marketable securities or its debt instruments. The Company has no holdings of derivative or commodity instruments.

Interest Rate Risk. The Company is subject to interest rate risks on cash and cash equivalents and any future financing requirements. The long-term debt at December 31, 2001 consists of an outstanding balance on a lease obligation.

The following table presents the future principal cash flows or amounts and related weighted average interest rates expected by year for the Company s existing cash and cash equivalents and long-term debt instruments:

	2002	2003	2004	2005	2006	Total Fair Value
		(In Thousands)				
Assets						
Cash, cash equivalents	$2,629	$	$	$	$	$2,629
Weighted average interest rate	3.0%					3.0%
Liabilities						
Fixed Rate Debt Lease obligation	$ 32	$ m">				

	Maturity Date	Fixed Interest Rate*
USD $250,000,000	October 14, 2010	October 14, 2015	3.31%
USD $100,000,000	April 14, 2011	October 14, 2013	2.86%
USD $60,000,000	November 30, 2011	October 31, 2016	2.95%
USD $60,000,000	November 30, 2011	October 31, 2016	2.94%
USD $50,000,000	December 30, 2011	December 30, 2016	2.94%
GBP £50,000,000	November 30, 2011	October 30, 2016	3.11%
CAD $25,000,000	December 30, 2011	March 24, 2016	3.17%

* Includes applicable margin of 1.75% per annum on LIBOR or CDOR-based debt in effect as of March 31, 2012 under the Credit Agreement.

As of March 31, 2012, the fair market value of the CAD $25 million notional amount swap was an asset of $0.2 million included in Other Assets on our Unaudited Consolidated Condensed Balance Sheets, while the fair market value of the other swap contracts was a liability of $10.3 million included in Other Noncurrent Liabilities. As of December 31, 2011, the fair market value of the interest rate swap contracts was a liability of $10.6 million included in Other Noncurrent Liabilities.

Changes in Accumulated Other Comprehensive Income (Loss) related to our interest rate swap agreements were as follows (in thousands):

	Three Months Ended March 31,	
	2012	2011
Balance as of January 1	$ (6,890)	$ 2,176
Pretax (loss) gain	(991)	1,481
Income tax benefit (expense)	389	(533)
Reversal of unrealized loss	1,476	2,046
Reversal of deferred income taxes	(524)	(737)
Hedge ineffectiveness		(225)
Income tax benefit		81
Balance as of March 31	$ (6,540)	$ 4,289

In connection with the execution of our credit agreement on March 25, 2011 as discussed in Note 4, Long-Term Obligations, we temporarily experienced differences in critical terms between the interest rate swaps and the underlying debt. As a result, we incurred a loss of $0.2 million related to hedge ineffectiveness for the three months ended March 31, 2011. Beginning on April 14, 2011, we have held, and expect to continue to hold through the maturity of the respective interest rate swap agreements, at least the notional amount of each agreement in the respective variable-rate debt, such that future ineffectiveness will be immaterial and the swaps will continue to be highly effective in hedging our variable rate debt.

As of March 31, 2012, we estimate that $3.9 million of derivative losses (net of tax) included in Accumulated Other Comprehensive Loss will be reclassified into interest expense within the next 12 months.

Foreign Currency Forward Contracts

In order to manage the risk of changes in exchange rates associated with certain foreign currency transactions in our European operations, such as our purchases of inventory denominated in a currency other than the pound sterling, we have entered into short-term foreign currency forward contracts. As of March 31, 2012, we had four contracts outstanding to purchase 7.0 million for £5.8 million and nine contracts to purchase $8.0 million for £5.2 million, all of which expire prior to the end of 2012. These contracts are adjusted to fair value each balance sheet date. As we have elected not to apply hedge accounting for these transactions, the changes in fair value are recorded in Other Income, net. The fair value of these contracts at March 31, 2012 and December 31, 2011, along with the effect on our results of operations for the three month period ended March 31, 2012, were immaterial. We did not hold any foreign currency forward contracts during the three month period ended March 31, 2011.

Note 6. Fair Value Measurements

Financial Assets and Liabilities Measured at Fair Value

We use the market and income approaches to value our financial assets and liabilities, and there were no significant changes in valuation techniques or inputs during the three months ended March 31, 2012. The tiers in the fair value hierarchy include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The following tables present information about our financial assets and liabilities measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation inputs we utilized to determine such fair value as of March 31, 2012 and December 31, 2011 (in thousands):

	Balance as of March 31, 2012	Fair Value Measurements as of March 31, 2012		
		Level 1	Level 2	Level 3
Assets:				
Cash surrender value of life insurance	$ 17,725	$	$ 17,725	$
Interest rate swaps	150		150	
Total Assets	$ 17,875	$	$ 17,875	$
Liabilities:				
Contingent consideration liabilities	$ 82,909	$	$	$ 82,909
Deferred compensation liabilities	17,860		17,860	
Interest rate swaps	10,294		10,294	
Foreign currency forwards	339		339	
Total Liabilities	$ 111,402	$	$ 28,493	$ 82,909

	Balance as of December 31, 2011	Fair Value Measurements as of December 31, 2011		
		Level 1	Level 2	Level 3
Assets:				
Cash surrender value of life insurance	$ 13,413	$	$ 13,413	$
Total Assets	$ 13,413	$	$ 13,413	$
Liabilities:				
Contingent consideration liabilities	$ 82,382	$	$	$ 82,382
Deferred compensation liabilities	14,071		14,071	
Interest rate swaps	10,576		10,576	
Total Liabilities	$ 107,029	$	$ 24,647	$ 82,382

The cash surrender value of life insurance and deferred compensation liabilities are included in Other Assets and Other Noncurrent Liabilities, respectively, on our Unaudited Consolidated Condensed Balance Sheets. The contingent consideration liabilities are classified as separate line items in both current and noncurrent liabilities on our Unaudited Consolidated Condensed Balance Sheets based on the expected timing of the related payments.

Our Level 2 assets and liabilities are valued using inputs from third parties and market observable data. We obtain valuation data for the cash surrender value of life insurance and deferred compensation liabilities from third party sources, which determine the net asset values for our accounts using quoted market prices, investment allocations and reportable trades. We value the interest rate swaps using a third party valuation model that performs a discounted cash flow analysis based on the terms of the contracts and market observable inputs such as current and forward interest rates. The fair value of our foreign currency forward contracts is estimated based on quoted foreign exchange rates, forward foreign exchange rates and interest rates.

Our contingent consideration liabilities are related to our business acquisitions as further described in Note 9, Business Combinations. Under the terms of the contingent consideration agreements, payments may be made at specified future dates dependent on the performance of the acquired business subsequent to the acquisition. The liabilities for these payments are classified as Level 3 liabilities because the related fair value measurement, which is determined using an income approach, includes significant inputs not observable in the market. These unobservable inputs include internally-developed assumptions of the probabilities of achieving specified targets, which are used to determine the resulting cash flows, and the applicable discount rate. When assessing the fair value of these contingent consideration liabilities on a quarterly basis, we evaluate the performance of the business during the period compared to our previous expectations, along with any changes to our future projections, and update the estimated cash flows accordingly. In addition, we consider changes to our cost of capital and changes to the

probability of achieving the earnout payment targets when updating our discount rate on a quarterly basis.

The significant unobservable inputs used in the fair value measurements of our Level 3 contingent consideration liabilities were as follows:

Unobservable Input	March 31, 2012 Weighted Average	December 31, 2011 Weighted Average
Probability of achieving payout targets	79.3%	78.1%
Discount rate	6.5%	3.0%

A significant decrease in the assessed probabilities of achieving the targets or a significant increase in the discount rate, in isolation, would result in a significantly lower fair value measurement. Changes in the values of the liabilities are recorded in Change in Fair Value of Contingent Consideration Liabilities within Other Expense (Income) on our Unaudited Consolidated Condensed Statements of Income.

Changes in the fair value of our contingent consideration obligations for the three month periods ended March 31, 2012 and 2011 were as follows (in thousands):

	Three Months Ended March 31,	
	2012	2011
Balance as of January 1	$ 82,382	$ 2,000
Contingent consideration liabilities recorded for business acquisitions	107	600
Payments	(600)	
Gain included in earnings	(1,345)	
Exchange rate effects	2,365	
Balance as of March 31	$ 82,909	$ 2,600

The gain included in earnings for the three months ended March 31, 2012 is related to contingent consideration obligations outstanding as of March 31, 2012 and is a result of the quarterly assessment of the fair value inputs, along with the adoption of FASB ASU No. 2011-04 as described in Note 2, Financial Statement Information (which adoption did not have a material impact).

Financial Assets and Liabilities Not Measured at Fair Value

Our debt is reflected on the Unaudited Consolidated Condensed Balance Sheets at cost. Based on current market conditions as of March 31, 2012, the fair value of our credit facility borrowings (see Note 4, Long-Term Obligations) reasonably approximated the carrying value of $843 million. This fair value measurement is classified as Level 2 within the fair value hierarchy since it is determined based upon significant inputs observable in the market including interest rates on recent financing transactions to entities with a credit rating similar to ours. We estimated the fair value of our credit facility borrowings by calculating the upfront cash payment a market participant would require to assume our obligations. The upfront cash payment, excluding any issuance costs, is the amount that a market participant would be able to lend at March 31, 2012 to an entity with a credit rating similar to ours and achieve sufficient cash inflows to cover the scheduled cash outflows under our credit facility.

Note 7. Commitments and Contingencies

Operating Leases

We are obligated under noncancelable operating leases for corporate office space, warehouse and distribution facilities, trucks and certain equipment.

The future minimum lease commitments under these leases at March 31, 2012 are as follows (in thousands):

Nine months ending December 31, 2012	$ 65,277
Years ending December 31:	
2013	81,230
2014	69,744
2015	59,961
2016	46,857
2017	36,751
Thereafter	98,676
Future Minimum Lease Payments	$ 458,496

Litigation and Related Contingencies

We are a plaintiff in a class action lawsuit against several aftermarket product suppliers. Our recovery is expected to be approximately $16 million in the aggregate. In January 2012, we reached a settlement agreement with certain of the defendants, under which we recognized a gain of $8.3 million, which was recorded in Cost of Goods Sold during the three month period ended March 31, 2012. We will recognize the gains from the settlements with the remaining defendants when substantially all uncertainties regarding the timing and the amount of the settlements are resolved and realization is assured.

We also have certain contingencies resulting from litigation, claims and other commitments and are subject to a variety of environmental and pollution control laws and regulations incident to the ordinary course of business. We currently expect that the resolution of such contingencies will not materially affect our financial position, results of operations or cash flows.

Note 8. Earnings Per Share

The following chart sets forth the computation of earnings per share (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2012	**2011**
Net income	$ 80,991	$ 58,182
Denominator for basic earnings per share Weighted-average shares outstanding	147,139	145,611
Effect of dilutive securities:		
RSUs	219	116
Stock options	2,289	2,169
Restricted stock	24	24
Denominator for diluted earnings per share Adjusted weighted-average shares outstanding	149,671	147,920
Earnings per share, basic	$ 0.55	$ 0.40
Earnings per share, diluted	$ 0.54	$ 0.39

The following table sets forth the number of employee stock-based compensation awards outstanding but not included in the computation of diluted earnings per share because their effect would have been antidilutive (in thousands):

	Three Months Ended March 31,	
	2012	2011
Antidilutive securities:		
Stock options		1,608

Note 9. Business Combinations

During the three months ended March 31, 2012, we made four acquisitions in North America, which enabled us to expand our geographic presence and enter new markets. Total acquisition date fair value of the consideration for the acquisitions during the first quarter of 2012 was $22.0 million. We recorded $11.5 million of goodwill related to these acquisitions and immaterial adjustments to

preliminary purchase price allocations related to certain of our 2011 acquisitions. Approximately $2.0 million of the $11.5 million of goodwill recorded is expected to be deductible for income tax purposes. As the acquisitions during the three months ended March 31, 2012 are immaterial to our business, we have omitted the detailed disclosures for these acquisitions prescribed by the accounting guidance on business combinations.

On October 3, 2011, LKQ Corporation, LKQ Euro Limited (LKQ Euro), a subsidiary of LKQ Corporation, and Draco Limited (Draco) entered into an Agreement for the Sale and Purchase of Shares of Euro Car Parts Holdings Limited (the Sale and Purchase Agreement). Under the terms of the Sale and Purchase Agreement, effective October 1, 2011, LKQ Euro acquired all of the shares in the capital of Euro Car Parts Holdings Limited (ECP), an automotive aftermarket products distributor in the U.K., from Draco and the other shareholders of ECP. With the acquisition of ECP, we expanded our geographic presence beyond North America into the European market. Our acquisition of ECP established our Wholesale Europe operating segment. Total acquisition date fair value of the consideration for the ECP acquisition was £261.6 million ($403.7 million), composed of £190.3 million ($293.7 million) of cash (net of cash acquired), £18.4 million ($28.3 million) of notes payable, £2.7 million ($4.1 million) of other purchase price obligations (non-interest bearing) and a contingent payment to the former owners of ECP. Pursuant to the contingent payment terms, if certain annual performance targets are met by ECP, we will be obligated to pay between £22 million and £25 million and between £23 million and £30 million for the years ending December 31, 2012 and 2013, respectively. We have assessed the acquisition date fair value of these contingent payments to be £50.2 million ($77.5 million at the exchange rate on October 3, 2011). Refer to Note 6, Fair Value Measurements for information on changes to the fair value of the contingent consideration liabilities between December 31, 2011 and March 31, 2012.

We recorded goodwill of $337.0 million for the ECP acquisition, which will not be deductible for income tax purposes.

In addition to our acquisition of ECP, we made 20 acquisitions in North America in 2011 (12 wholesale businesses, five recycled heavy-duty truck products businesses and three self service retail operations). Our acquisitions included the purchase of two engine remanufacturers, which expanded our presence in the remanufacturing industry that we entered in 2010. Additionally, our acquisition of an automotive heating and cooling component distributor supplements our expansion into the automotive heating and cooling aftermarket products market. Our North American wholesale business acquisitions also included the purchase of the U.S. vehicle refinish paint distribution business of Akzo Nobel Automotive and Aerospace Coatings (the Akzo Nobel paint business), which allowed us to increase our paint and related product offerings and expand our geographic presence in the automotive paint market. Our other 2011 acquisitions enabled us to expand our geographic presence and enter new markets.

Total acquisition date fair value of the consideration for these 20 acquisitions was $207.3 million, composed of $193.2 million of cash (net of cash acquired), $5.9 million of notes payable, $4.5 million of other purchase price obligations (non-interest bearing) and $3.7 million of contingent payments to former owners. In conjunction with the acquisition of the Akzo Nobel paint business on May 26, 2011, we entered into a wholesaler agreement under which we became an authorized distributor of Akzo Nobel products in the acquired markets. Included in this agreement is a requirement to make an additional payment to Akzo Nobel in the event that our purchases of Akzo Nobel product do not meet specified thresholds from June 1, 2011 to May 31, 2014. This contingent payment will be calculated as the difference between our actual purchases and the targeted purchase levels outlined in the agreement for the specified period with a maximum payment of $21.0 million. The contingent consideration liability recorded in 2011 also includes two additional arrangements that have a maximum potential payout of $4.6 million. The acquisition date fair value of these contingent consideration agreements is immaterial. Refer to Note 6, Fair Value Measurements for information on changes to the fair value of the contingent consideration liabilities between December 31, 2011 and March 31, 2012.

During the year ended December 31, 2011, we recorded $105.2 million of goodwill related to these 20 acquisitions and immaterial adjustments to preliminary purchase price allocations related to certain of our 2010 acquisitions. Of this amount, approximately $88.3 million is expected to be deductible for income tax purposes.

The acquisitions are being accounted for under the purchase method of accounting and are included in our unaudited consolidated condensed financial statements from the dates of acquisition. The purchase prices were allocated to the net assets acquired based upon estimated fair market values at the dates of acquisition. The purchase price allocations for the acquisitions made during the quarter ended March 31, 2012 and the last three quarters of 2011 are preliminary as we are in the process of determining the following: 1) valuation amounts for certain of the inventories acquired; 2) valuation amounts for certain intangible assets acquired; 3) the acquisition date fair value of certain liabilities assumed; and 4) the final estimation of the tax basis of the entities acquired.

The purchase price allocations for the acquisitions completed during the year ended December 31, 2011 are as follows (in thousands):

	Year Ended December 31, 2011		
	ECP (Preliminary)	Other Acquisitions (Preliminary)	Total (Preliminary)
Receivables	$ 54,225	$ 23,538	$ 77,763
Receivable reserves	(3,832)	(1,121)	(4,953)
Inventory	93,835	59,846	153,681
Prepaid expenses and other current assets	3,189	2,820	6,009
Property and equipment	41,830	10,614	52,444
Goodwill	337,031	105,177	442,208
Other intangibles	39,583	7,683	47,266
Other assets	13	9,420	9,433
Deferred income taxes	(13,218)	7,235	(5,983)
Current liabilities assumed	(135,390)	(17,257)	(152,647)
Debt assumed	(13,564)		(13,564)
Other noncurrent liabilities assumed		(619)	(619)
Contingent consideration liabilities	(77,539)	(3,700)	(81,239)
Other purchase price obligations	(4,136)	(4,510)	(8,646)
Notes issued	(28,302)	(5,917)	(34,219)
Cash used in acquisitions, net of cash acquired	$ 293,725	$ 193,209	$ 486,934

The primary reason for our acquisitions made during the three months ended March 31, 2012 and the year ended December 31, 2011 was to leverage our strategy of becoming a one-stop provider for alternative vehicle replacement products. These acquisitions enabled us to expand our market presence, expand our product offerings and enter new markets. These factors contributed to purchase prices that included, in many cases, a significant amount of goodwill.

Most notably, our acquisition of ECP in 2011 marks our entry into the European automotive aftermarket business, which provides an opportunity to us as that market has historically had a low penetration of alternative collision parts. Additionally, ECP is a leading distributor of alternative automotive products reaching most major markets in the U.K., with a developed distribution network, experienced management team, and established workforce. These factors contributed to the $337 million of goodwill recognized related to this acquisition.

The following pro forma summary presents the effect of the businesses acquired during the first three months of 2012 and the year ended December 31, 2011 as though the businesses had been acquired as of January 1, 2011, and is based upon unaudited financial information of the acquired entities (in thousands, except per share data):

	Three Months Ended March 31,	
	2012	2011
Revenue, as reported	$ 1,031,777	$ 786,648
Revenue of purchased businesses for the period prior to acquisition:		
ECP		130,576
Other acquisitions	7,249	71,865
Pro forma revenue	$ 1,039,026	$ 989,089
Net income, as reported	$ 80,991	$ 58,182
Net income of purchased businesses for the period prior to acquisition, including pro forma purchase accounting adjustments:		
ECP		4,900
Other acquisitions	327	2,818
Pro forma net income	$ 81,318	$ 65,900
Earnings per share-basic, as reported	$ 0.55	$ 0.40
Effect of purchased businesses for the period prior to acquisition:		
ECP		0.03
Other acquisitions	0.00	0.02
Pro forma earnings per share-basic [(a)]	$ 0.55	$ 0.45
Earnings per share-diluted, as reported	$ 0.54	$ 0.39
Effect of purchased businesses for the period prior to acquisition:		
ECP		0.03
Other acquisitions	0.00	0.02
Pro forma earnings per share-diluted [(a)]	$ 0.54	$ 0.45

(a) The sum of the individual earnings per share amounts may not equal the total due to rounding.

Unaudited pro forma supplemental information is based upon accounting estimates and judgments that we believe are reasonable. The unaudited pro forma supplemental information includes the effect of purchase accounting adjustments, such as the adjustment of inventory acquired to net realizable value, adjustments to depreciation on acquired property and equipment, adjustments to amortization on acquired intangible assets, adjustments to interest expense, and the related tax effects. These pro forma results are not necessarily indicative either of what would have occurred if the acquisitions had been in effect for the period presented or of future results.

Note 10. Restructuring and Acquisition Related Expenses

During the three months ended March 31, 2012, we incurred approximately $0.2 million of restructuring and acquisition related expenses resulting from the integration of our 2011 acquisitions into our existing business. The restructuring expenses included primarily excess facility costs, which were expensed at the cease-use date for the facilities, and moving expenses for the closure of duplicate facilities. We expect approximately $0.2 million of additional charges, primarily for moving costs and excess facility reserves, as we complete our integration plans during the remainder of 2012. Additionally, we may record adjustments to the excess facility reserves related to our 2011 integration activities if we determine revisions are required to the underlying assumptions.

Related to our acquisitions during the first quarter of 2012, we expect to incur approximately $0.8 million of restructuring expenses as we integrate the acquired facilities into our existing business. Our integration plan includes the closure of a duplicate facility and termination of employees in connection with the consolidation of overlapping facilities with our existing business. We expect these integration activities to be completed in 2012.

Note 11. Income Taxes

At the end of each interim period, we estimate our annual effective tax rate and apply that rate to our interim earnings. We also record the tax impact of certain unusual or infrequently occurring items, including changes in judgment about valuation allowances and the effects of changes in tax laws or rates, in the interim period in which they occur.

The computation of the annual estimated effective tax rate at each interim period requires certain estimates and significant judgment including, but not limited to, the expected operating income for the year, projections of the proportion of income earned and taxed in state and foreign jurisdictions, permanent and temporary differences between book and taxable income, and the likelihood of recovering deferred tax assets generated in the current year. The accounting estimates used to compute the provision for income taxes may change as new events occur, additional information is obtained or as the tax environment changes.

Our effective income tax rate for the three months ended March 31, 2012 was 36.8% compared with 39.2% for the comparable prior year period. The effective income tax rate for the three months ended March 31, 2012 reflects the larger proportion of pretax income generated in lower rate jurisdictions, primarily as a result of the expansion of our international operations in the fourth quarter of 2011 through our acquisition of ECP. Our effective income tax rate during the three months ended March 31, 2011 reflected a discrete charge of $0.2 million for the revaluation of deferred taxes in response to changes in state tax rates.

Note 12. Segment and Geographic Information

We have four operating segments: Wholesale North America; Wholesale Europe; Self Service; and Heavy-Duty Truck. Our operations in North America, which include our Wholesale North America, Self Service and Heavy-Duty Truck operating segments, are aggregated into one reportable segment because they possess similar economic characteristics and have common products and services, customers, and methods of distribution. Our Wholesale Europe operating segment, formed with our acquisition of ECP effective October 1, 2011, marks our entry into the European automotive aftermarket business, and is presented as a separate reportable segment. Although the Wholesale Europe operating segment shares many of the characteristics of our North American operations, including types of products offered, distribution methods, and procurement, we have provided separate financial information as we believe this data would be beneficial to users in understanding our results. Therefore, we present our reportable segments on a geographic basis.

The following table presents our financial performance, including revenue, earnings before interest, taxes, depreciation and amortization (EBITDA), and depreciation and amortization by reportable segment for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2012	2011
Revenue		
North America	$ 871,084	$ 786,648
Europe	160,693	
Total revenue	$ 1,031,777	$ 786,648
EBITDA		
North America	$ 132,188	$ 119,403
Europe	19,533	
Total EBITDA	$ 151,721	$ 119,403
Depreciation and Amortization		
North America	$ 14,002	$ 11,926
Europe	2,255	
Total depreciation and amortization	$ 16,257	$ 11,926

The EBITDA during the three months ended March 31, 2012 for our North American segment is inclusive of a gain of $8.3 million resulting from a lawsuit settlement with certain of our aftermarket product suppliers as discussed in Note 7, Commitments and Contingencies. Included within the EBITDA during the three months ended March 31, 2012 for our European segment is the change in fair value of contingent

consideration liabilities of $1.3 million. Refer to Note 6, Fair Value Measurements, for further information on this gain recorded in earnings during the period.

The table below provides a reconciliation from EBITDA to Net Income (in thousands):

	Three Months Ended March 31,	
	2012	2011
EBITDA	$ 151,721	$ 119,403
Depreciation and amortization	16,257	11,926
Interest expense, net	7,367	6,409
Loss on debt extinguishment		5,345
Provision for income taxes	47,106	37,541
Net income	$ 80,991	$ 58,182

The key measure of segment profit or loss reviewed by our chief operating decision maker, who is our Chief Executive Officer, is EBITDA. Segment EBITDA includes revenue and expenses that are controllable by the segment. Corporate and administrative expenses are allocated to the segments based on usage, with shared expenses apportioned based on the segment s percentage of consolidated revenue. Segment EBITDA excludes depreciation, amortization, interest (including loss on debt extinguishment) and taxes. Loss on debt extinguishment is considered a component of interest in calculating EBITDA, as the write-off of debt issuance costs is similar to the treatment of debt issuance cost amortization.

The following table presents capital expenditures, which includes additions to property and equipment, by reportable segment (in thousands):

	Three Months Ended March 31,	
	2012	2011
Capital Expenditures		
North America	$ 18,134	$ 18,093
Europe	3,195	
	$ 21,329	$ 18,093

The following table presents assets by reportable segment (in thousands):

	March 31, 2012	December 31, 2011
Receivables, net		
North America	$ 251,527	$ 230,871
Europe	59,025	50,893
Total receivables, net	310,552	281,764
Inventory		
North America	628,319	636,145
Europe	108,322	100,701
Total inventory	736,641	736,846
Property and Equipment, net		
North America	383,217	380,282
Europe	47,560	43,816

Total property and equipment, net	430,777	424,098
Other unallocated assets	1,782,031	1,756,996
Total assets	$ 3,260,001	$ 3,199,704

We report net trade receivables, inventories, and net property and equipment by segment as that information is used by the chief operating decision maker in assessing segment performance. These assets provide a measure for the operating capital employed in each segment. Unallocated assets include cash, prepaid and other current and noncurrent assets, goodwill, intangibles and income taxes.

Our operations are primarily conducted in the U.S. Our European operations, which we started with the acquisition of ECP in the fourth quarter of 2011, are located in the U.K. Our operations in other countries include recycled and aftermarket operations in Canada, engine remanufacturing and bumper refurbishing operations in Mexico, and other alternative parts operations in Guatemala and Costa Rica.

The following table sets forth our revenue by geographic area (in thousands):

	Three Months Ended March 31,	
	2012	2011
Revenue		
United States	$ 820,965	$ 739,326
United Kingdom	160,693	
Other countries	50,119	47,322
	$ 1,031,777	$ 786,648

The following table sets forth our tangible long-lived assets by geographic area (in thousands):

	March 31, 2012	December 31, 2011
Long-lived Assets		
United States	$ 362,658	$ 360,961
United Kingdom	47,560	43,816
Other countries	20,559	19,321
	$ 430,777	$ 424,098

The following table sets forth our revenue by product category (in thousands):

	Three Months Ended March 31,	
	2012	2011
Aftermarket, other new and refurbished products	$ 565,344	$ 381,116
Recycled, remanufactured and related products and services	325,704	275,782
Other	140,729	129,750
	$ 1,031,777	$ 786,648

All of the product categories include revenue from our North American reportable segment, while our European segment, which is composed of ECP, an automotive aftermarket products distributor, generates revenue only from the sale of aftermarket products. Revenue from other sources includes scrap sales, bulk sales to mechanical remanufacturers (including cores) and sales of aluminum ingots and sows from our furnace operations.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Overview

We provide replacement parts, components and systems needed to repair vehicles (cars and trucks). Buyers of vehicle replacement products have the option to purchase from primarily five sources: new products produced by original equipment manufacturers (OEMs), which are commonly known as OEM products; new products produced by companies other than the OEMs, which are sometimes referred to as aftermarket products; recycled products originally produced by OEMs; used products that have been refurbished; and used products that have been remanufactured.

We distribute a variety of products to collision and mechanical repair shops, including aftermarket collision and mechanical products, recycled collision and mechanical products, refurbished collision replacement products such as wheels, bumper covers and lights, and remanufactured engines. Collectively, we refer to our products as alternative parts. We are the nation s largest provider of alternative vehicle collision replacement products, and a leading provider of alternative vehicle mechanical replacement products. Our sales, processing, and distribution facilities reach most major markets in the U.S. and Canada. We expanded our operations effective October 1, 2011 with our acquisition of Euro Car Parts Holdings Limited (ECP), the largest distributor of automotive aftermarket products in the United Kingdom. In addition to our foregoing wholesale operations, we operate self service retail facilities that sell recycled automotive products. We also sell recycled heavy-duty truck products and used heavy-duty trucks. We have organized our businesses into four operating segments: Wholesale North America; Wholesale Europe; Self Service; and Heavy-Duty Truck. We aggregate our North American operating segments (Wholesale North America, Self Service and Heavy-Duty Truck) into one reportable segment, resulting in two reportable segments: North America and Europe.

Our revenue, cost of goods sold and operating results have fluctuated on a quarterly and annual basis in the past and can be expected to continue to fluctuate in the future as a result of a number of factors, some of which are beyond our control. Please refer to the factors discussed in Forward-Looking Statements below. Due to these factors and others, which may be unknown to us at this time, our operating results in future periods can be expected to fluctuate. Accordingly, our historical results of operations may not be indicative of future performance.

Acquisitions

Since our inception in 1998 we have pursued a growth strategy through both organic growth and acquisitions. We have pursued acquisitions that we believe will help drive profitability, cash flow and stockholder value. Our principal focus for acquisitions is companies that will expand our geographic presence and our ability to provide a wider choice of alternative vehicle replacement products to our customers.

During the three months ended March 31, 2012, we made four acquisitions in North America, which enabled us to expand our geographic presence and enter new markets. We expect to make additional strategic acquisitions in 2012 as we continue to expand our integrated distribution network offering a broad range of alternative parts.

Effective October 1, 2011, we acquired ECP, which marks our entry into the European automotive aftermarket business. ECP operates out of approximately 100 branches, supported by eight regional hubs and a national distribution center from which multiple deliveries are made each day. ECP s product offerings are primarily focused on automotive aftermarket mechanical products, many of which are sourced from the same suppliers that provide products to the OEMs. The expansion of our geographic presence beyond North America into the European market offers an opportunity to us as that market has historically had a low penetration of alternative collision parts.

In addition to our acquisition of ECP, we made 20 acquisitions in North America in 2011 (12 wholesale businesses, five recycled heavy-duty truck products businesses and three self service retail operations). Our acquisitions included the purchase of two engine remanufacturers, which expanded our presence in the remanufacturing industry that we entered in 2010. Additionally, our acquisition of an automotive heating and cooling component distributor supplements our expansion into the automotive heating and cooling aftermarket products market. Our North American wholesale business acquisitions also included the purchase of the U.S. vehicle refinish paint distribution business of Akzo Nobel Automotive and Aerospace Coatings, which allowed us to increase our paint and related product offerings and expand our geographic presence in the automotive paint market. Our other 2011 acquisitions enabled us to expand our geographic presence and enter new markets.

Sources of Revenue

We report our revenue in three categories: (i) aftermarket, other new and refurbished products, (ii) recycled, remanufactured and related products and services, and (iii) other.

Our revenue from the sale of vehicle replacement products and related services includes sales of (i) aftermarket, other new and refurbished products and (ii) recycled, remanufactured and related products and services. During the three months ended March 31, 2012, sales of vehicle replacement products and services represented approximately 86% of our consolidated sales. Of these sales, approximately 63% were derived from the sales of aftermarket, other new and refurbished products, while 37% were composed of recycled and remanufactured products and services sales.

We sell the majority of our vehicle replacement products to collision and mechanical repair shops. Our vehicle replacement products include engines, transmissions, front-ends, doors, trunk lids, bumper covers, hoods, fenders, grilles, valances, wheels, head lamps and tail lamps. For an additional fee, we sell extended warranty contracts for certain mechanical products. These contracts cover the cost of parts and labor and are sold for periods of six months, one year, two years or a non-transferable lifetime warranty. We defer the revenue from such contracts and recognize it ratably over the term of the contracts or three years in the case of lifetime warranties. The demand for our products and services is influenced by several factors, including the number of vehicles in operation, the number of miles being driven, the frequency and severity of vehicle accidents, the age profile of vehicles in accidents, availability and pricing of new OEM parts, seasonal weather patterns and local weather conditions. Additionally, automobile insurers exert significant influence over collision repair shops as to how an insured vehicle is repaired and the cost level of the products used in the repair process. Accordingly, we consider automobile insurers to be key demand drivers of our products. While they are not our direct customers, we do provide insurance carriers services in an effort to promote the increased usage of alternative replacement products in the repair process. Such services include the review of vehicle repair order estimates, direct quotation services to insurance company adjusters and an aftermarket parts quality and service assurance program. We neither charge a fee to the insurance carriers for these services nor adjust our pricing of products for our customers when we perform these services for insurance carriers.

There is no standard price for many of our products, but rather a pricing structure that varies from day to day based upon such factors as product availability, quality, demand, new OEM product prices, the age of the vehicle from which the part was obtained and competitor pricing.

For the three months ended March 31, 2012, revenue from other sources represented approximately 14% of our consolidated sales. These other sources include scrap sales and sales of aluminum ingots and sows. We derive scrap metal from several sources, including vehicles that have been used in both our wholesale and self service recycling operations and from OEMs and other entities that contract with us to dismantle and scrap certain vehicles (which we refer to as crush only vehicles). Revenue from scrap sales will vary from period to period based on fluctuations in commodity prices, the speed with which they fluctuate and the volume of vehicles we sell for scrap.

Cost of Goods Sold

Our cost of goods sold for aftermarket products includes the price we pay for the parts, freight, and overhead costs including labor, fuel expense, and facility and machinery costs related to the purchasing, warehousing and distribution of our inventory. Our aftermarket products are acquired from a number of vendors. Our cost of goods sold for refurbished products includes the price we pay for inventory, freight, and costs to refurbish the parts, including direct and indirect labor, facility costs including rent and utilities, machinery and equipment costs including equipment rental, repairs and maintenance, depreciation and other overhead related to refurbishing operations.

Our cost of goods sold for recycled products includes the price we pay for the salvage vehicle and, where applicable, auction, storage, and towing fees. Prices for salvage vehicles may be impacted by a variety of factors, including the number of buyers competing to purchase the vehicles, the demand and pricing trends for used vehicles, the number of vehicles designated as total losses by insurance companies, the production level of new vehicles (which provides the source from which salvage vehicles ultimately come), and the status of laws regulating bidders or exporters of salvage vehicles. Due to a variety of factors, we have seen the prices we pay for salvage vehicles increase on average over the past three years. Our cost of goods sold also includes labor and other costs we incur to acquire and dismantle such vehicles. Our labor and labor-related costs related to acquisition and dismantling account for approximately 8% of our cost of goods sold for vehicles we dismantle. The acquisition and dismantling of salvage vehicles is a manual process and, as a result, energy costs are not material. Our cost of goods sold for remanufactured products includes the price we pay for cores, freight, costs to remanufacture the products, including direct and indirect labor, rent, depreciation and other overhead related to remanufacturing operations.

Some of our salvage mechanical products are sold with a standard six-month warranty against defects. Additionally, some of our remanufactured engines are sold with a standard three-year warranty against defects. We record the estimated warranty costs at the time of sale using historical warranty claims information to project future warranty claims activity and related expenses. We also sell separately priced extended warranty contracts for certain mechanical products. The expense related to extended warranty claims is recognized when the claim is made.

Expenses

Our facility and warehouse expenses primarily include our costs to operate our aftermarket warehouses, wholesale and heavy-duty truck salvage yards and self service retail facilities. These costs include labor for plant management and facility and warehouse personnel and related incentive compensation and employee benefits, rent, other facility expenses such as utilities, property insurance,

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and taxes, and repairs and maintenance costs related to our facilities and equipment. The costs included in facility and warehouse expenses do not relate to inventory processing or conversion activities and, as such, are classified below the gross margin line on our Unaudited Consolidated Condensed Statements of Income.

Our distribution expenses primarily include our costs to prepare and deliver our products to our customers. Included in our distribution expense category are labor costs for drivers, fuel, third party freight costs, local delivery and transfer truck leases or rentals, vehicle repairs and maintenance, supplies and insurance.

Our selling and marketing expenses primarily include salary, commission and other incentive compensation expenses for sales personnel, advertising, promotion and marketing costs, telephone and other communication expenses, credit card fees and bad debt expense. Personnel costs account for approximately 80% of our selling and marketing expenses. Most of our product sales personnel are paid on a commission basis. The number and quality of our sales force is critical to our ability to respond to our customers needs and increase our sales volume. Our objective is to continually evaluate our sales force, develop and implement training programs, and utilize appropriate measurements to assess our selling effectiveness.

Our general and administrative expenses primarily include the costs of our corporate offices and field support center that provide corporate and field management, treasury, accounting, legal, payroll, business development, human resources and information systems functions. These costs include wages and benefits for corporate, regional and administrative personnel, stock-based compensation and other incentive compensation, accounting, legal and other professional fees, IT system support and maintenance expenses, and telephone and other communication costs.

Seasonality

Our operating results are subject to quarterly variations based on a variety of factors, influenced primarily by seasonal changes in weather patterns. During the winter months, we tend to have higher demand for our products because there are more weather related accidents, which generate repairs. In addition, the cost of salvage vehicles tends to be lower as the weather related accidents also generate a larger supply of total loss vehicles.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our unaudited consolidated condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, which we filed with the Securities and Exchange Commission on February 27, 2012, includes a summary of the critical accounting policies we believe are the most important to aid in understanding our financial results. There have been no changes to those critical accounting policies that have had a material impact on our reported amounts of assets, liabilities, revenues or expenses during the three months ended March 31, 2012.

Recently Issued Accounting Pronouncements

See Recent Accounting Pronouncements in Note 2, Financial Statement Information to the unaudited consolidated condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for information related to the new accounting standards that are effective for interim and annual periods beginning in 2012.

Financial Information by Geographic Area

See Note 12, Segment and Geographic Information to the unaudited consolidated condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for information related to our revenue and long-lived assets by geographic region.

Results of Operations Consolidated

The following table sets forth statement of operations data as a percentage of total revenue for the periods indicated:

	Three Months Ended March 31,	
	2012	2011
Statements of Income Data:		
Revenue	100.0%	100.0%
Cost of goods sold	56.6%	56.3%
Gross margin	43.4%	43.7%
Facility and warehouse expenses	8.2%	8.9%
Distribution expenses	8.9%	8.4%
Selling, general and administrative expenses	11.8%	11.4%
Restructuring and acquisition related expenses	0.0%	0.0%
Depreciation and amortization	1.4%	1.4%
Operating income	12.9%	13.6%
Other expense, net	0.5%	1.5%
Income before provision for income taxes	12.4%	12.2%
Provision for income taxes	4.6%	4.8%
Net income	7.8%	7.4%

Three Months Ended March 31, 2012 Compared to Three Months Ended March 31, 2011

Revenue. Our revenue increased 31.2% to $1.03 billion for the three month period ended March 31, 2012 from $786.6 million for the comparable period of 2011. The increase in revenue was primarily due to business acquisitions, which increased revenue by $220.3 million or 28.0%, as well as 3.6% organic growth in parts and services revenue. Acquisition related revenue growth reflects $158.1 million from our fourth quarter 2011 acquisition of ECP, a U.K.-based automotive aftermarket product distributor. ECP also generated $2.6 million in revenue growth from new branch openings since the acquisition, which we include in our organic revenue growth. While our organic growth in recycled and remanufactured products revenue was 8.5%, our revenue from the sales of aftermarket, other new and refurbished products, excluding the effect of acquisitions, remained flat compared to the first quarter of 2011. Our revenue from the sales of recycled and remanufactured products increased primarily as a result of higher volumes, which resulted from higher inventory purchases that contributed to a greater volume of parts available for sale. We believe that aftermarket, other new and refurbished organic revenue was flat compared to the first quarter of 2011 primarily as a result of milder winter weather conditions, which contributed to fewer and less severe vehicle accidents in 2012. Shifts in product mix toward products with a higher average sales price offset the revenue effect from the decrease in insurance claims activity. Other revenue, which includes sales of scrap metal and other metals, grew 1.6% compared to the prior year period due to increased volumes of scrap sold. Our first quarter 2012 revenue also reflects a 0.1% unfavorable impact from foreign exchange in our Canadian operations.

Cost of Goods Sold. Our cost of goods sold increased to 56.6% of revenue in the three month period ended March 31, 2012 from 56.3% of revenue in the comparable period of 2011. Our acquisition of ECP, which generates lower gross margins than our North American business because of a greater weighting on lower margin mechanical products, increased our cost of goods sold as a percentage of revenue by 0.6%. In addition, we experienced gross margin compression in the first quarter of 2012 as scrap prices remained flat with the comparable prior year period while vehicle acquisition costs, mostly in our self service business, continued to increase, resulting in cost of goods sold increasing by 0.5% of revenue. These increases in our cost of goods sold were partially offset by a gain on a lawsuit settlement with certain of our aftermarket product suppliers of $8.3 million, which reduced cost of goods sold by 0.8% of revenue. Refer to Note 7, Commitments and Contingencies to the unaudited consolidated condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information on the lawsuit settlement. We expect to recognize an additional $8 million gain related to settlements with certain other defendants in this lawsuit in the last nine months of 2012.

Facility and Warehouse Expenses. As a percentage of revenue, facility and warehouse expenses for the three month period ended March 31, 2012 decreased to 8.2% of revenue compared to 8.9% for the comparable period of 2011. The decrease reflects the lower facility and warehouse expense as a percentage of revenue in our European operations. The branch locations in the U.K. are typically smaller and less costly than the warehouse locations in North America since the majority of the inventory is stored in the national distribution center in the U.K., which supplies the branch locations daily. In the North American locations, most of the inventory is stored on site rather than in regional or national distribution centers. The cost of the national distribution center in the U.K. is capitalized into inventory and expensed through cost of goods sold. This classification contributes to the relatively lower gross margin in our European operations as discussed in *Cost of Goods Sold* above.

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Distribution Expenses. Distribution expenses as a percentage of revenue for the first quarter of 2012 increased to 8.9% of revenue, compared to 8.4% of revenue for the comparable prior year period. Distribution expenses in the first quarter of 2012 reflect an increase of 0.2% over the prior year period due to relatively higher distribution costs as a percentage of revenue in our European operations. Our European operations, which generate a greater proportion of revenue from sales to mechanical repair shops compared to our North American operations, incur relatively higher delivery expenses as garage customers demand faster delivery times than our North American collision repair customers. In our North American operations, distribution costs increased by 0.3% of revenue compared to the prior year first quarter, primarily as a result of higher compensation costs.

Selling, General and Administrative Expenses. As a percentage of revenue, our selling, general and administrative expenses increased to 11.8% for the three month period ended March 31, 2012 from 11.4% for the comparable prior year period. The increase was primarily driven by 0.4% higher personnel expenditures in our European operations, which has a relatively larger sales force compared to our North American operations. In our North American operations, the fixed cost component of our sales personnel expenditures resulted in a 0.2% increase in costs as a percentage of revenue. We continued to grow our sales force throughout 2011 and into 2012 to support our expanding operations, while our revenue growth in the first quarter of 2012 did not increase as rapidly as the prior year first quarter. The increase in sales personnel expenditures was offset by a 0.3% decrease in general and administrative personnel expenditures, as we continued to leverage our corporate workforce expenditures in periods of rising total revenue.

Depreciation and Amortization. As a percentage of revenue, depreciation and amortization expense was 1.4% for each of the three month periods ended March 31, 2012 and 2011. Higher expense in 2012 resulting from our increased levels of property and equipment and higher levels of intangible assets as a result of business acquisitions was offset by continued leveraging of our existing facilities to support organic and acquisition related revenue growth.

Other Expense, Net. Total other expense, net decreased to $5.5 million during the three month period ended March 31, 2012 from $11.6 million for the comparable prior year period. The relatively higher other expense, net in the prior year period was primarily due to a $5.3 million loss on debt extinguishment related to the write off of debt issuance costs in conjunction with the execution of our current senior secured credit agreement in March 2011. During the three months ended March 31, 2012, interest expense increased by $1.0 million compared to the prior year period. Our average outstanding credit facility borrowings increased to $900 million for the first quarter of 2012 from $590 million in the prior year period, primarily due to additional borrowings to finance our acquisition of ECP in the fourth quarter of 2011. The effect of our higher average debt levels was partially offset by a reduction in our average effective interest rate on bank borrowings to 3.0% from 4.6% during the first quarter of 2011, resulting from lower interest rates under the new credit agreement executed in March 2011 combined with the impact of lower fixed interest rates under our outstanding interest rate swaps in the first quarter of 2012 compared to the first quarter of 2011. Also during the three month period ended March 31, 2012, we recorded a net gain of $1.3 million related to a revaluation of our contingent consideration liabilities. The remeasurement of our contingent consideration liabilities may cause variability in our results of operations, as changes in the assumptions used to measure the fair value of the liabilities may result in net gains or losses from period to period.

Provision for Income Taxes. Our effective income tax rate was 36.8% and 39.2% for the three months ended March 31, 2012 and 2011, respectively. Our international operations, which we expanded in the fourth quarter of 2011 with the ECP acquisition, contributed to a lower effective tax rate as a larger proportion of our pretax income was generated in lower rate jurisdictions. Our effective tax rate for the first quarter of 2011 reflected a discrete charge of $0.2 million for the revaluation of deferred taxes in response to changes in state tax rates.

Results of Operations Segment Reporting

We have four operating segments: Wholesale North America; Wholesale Europe; Self Service; and Heavy-Duty Truck. Our operations in North America, which include our Wholesale North America, Self Service and Heavy-Duty Truck operating segments, are aggregated into one reportable segment because they possess similar economic characteristics and have common products and services, customers, and methods of distribution. Our Wholesale Europe operating segment, formed with our acquisition of ECP effective October 1, 2011, marks our entry into the European automotive aftermarket business, and is presented as a separate reportable segment. Although the Wholesale Europe operating segment shares many of the characteristics of our North American operations, we have provided separate financial information as we believe this data would be beneficial to users in understanding our results.

The following table presents our financial performance, including revenue and earnings before interest, taxes, and depreciation and amortization (EBITDA) by reportable segment for the periods indicated (in thousands):

	Three Months Ended March 31, 2012	2011
Revenue		
North America	$ 871,084	$ 786,648
Europe	160,693	
Total revenue	$ 1,031,777	$ 786,648
EBITDA		
North America[1]	$ 132,188	$ 119,403
Europe[2]	19,533	
Total EBITDA	$ 151,721	$ 119,403

(1) EBITDA for the three months ended March 31, 2012 includes a gain of $8.3 million resulting from the settlement of a class action lawsuit against several of our suppliers as discussed in Note 7, Commitments and Contingencies to the unaudited consolidated condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

(2) EBITDA for the three months ended March 31, 2012 includes $1.3 million in other income from the change in fair value of the ECP contingent consideration liability as discussed in Note 6, Fair Value Measurements to the unaudited consolidated condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q. We will adjust the fair value of contingent consideration liabilities each quarter, and the change in the fair value may be either an increase or decrease to EBITDA for the segment based on changes to the underlying assumptions used in the fair value calculation.

The key measure of segment profit or loss reviewed by our chief operating decision maker is EBITDA. Segment EBITDA includes revenue and expenses that are controllable by the segment. Corporate and administrative expenses are allocated to the segments based on usage, with shared expenses apportioned based on the segment s percentage of consolidated revenue. Segment EBITDA excludes depreciation, amortization, interest (including loss on debt extinguishment) and taxes. Loss on debt extinguishment is considered a component of interest in calculating EBITDA, as the write-off of debt issuance costs is similar to the treatment of debt issuance cost amortization. See Note 12, Segment and Geographic Information to the unaudited consolidated condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for a reconciliation of total EBITDA to Net Income.

Since we presented a single reportable segment (North America) until the acquisition of ECP effective October 1, 2011 the discussion of the consolidated results of operations covers the factors driving the year over year performance of our North American segment, and discusses the effect of the European results of operations on our consolidated results. Results for our European segment will not have a comparative period until the fourth quarter of 2012. However, compared to its unaudited first quarter 2011 results, ECP has achieved revenue growth of over 20% primarily through higher sales volumes at existing locations as well as new branches. ECP continued to expand its branch network by opening nine new locations in the United Kingdom during the first quarter of 2012.

2012 Outlook

We estimate that full year 2012 net income and diluted earnings per share, excluding the impact of any restructuring and acquisition related expenses and any gains or losses related to acquisitions or divestitures (including changes in the fair value of contingent consideration liabilities), will be in the range of $262 million to $282 million and $1.75 to $1.88, respectively.

Liquidity and Capital Resources

Our primary sources of ongoing liquidity are cash flows from our operations and our credit agreement. Our credit agreement, which was executed on March 25, 2011 and subsequently amended and restated on September 30, 2011, provides for total borrowings of up to $1.4 billion, consisting of a $950 million revolving credit facility (including up to $500 million available in foreign currencies) and up to $450 million of term loan borrowings. In the three months ended March 31, 2012, we borrowed $200 million of available term loans under the credit agreement,

which were used to pay down a portion of our outstanding revolving credit facility borrowings. As of March 31, 2012, the outstanding obligations under the facilities were $842.7 million, composed of $437.5 million of term loans and $405.2 million of revolver borrowings. After giving effect to outstanding letters of credit, our availability under the revolving credit facility at March 31, 2012 was $503.7 million. We do not expect to utilize the revolver as a primary source of funding for working capital needs as we expect our cash flows from operations to be sufficient for that purpose, but we do maintain availability as we continue to expand our facilities and network. Cash and cash equivalents at March 31, 2012 totaled $55.2 million.

Borrowings under the credit agreement accrue interest at variable rates, which depend on the currency and the duration of the borrowing, plus an applicable margin rate. The weighted-average interest rate on borrowings outstanding against our credit agreement at March 31, 2012 (after giving effect to the interest rate swap contracts in force, described in Note 5, Derivative Instruments and Hedging Activities to the unaudited consolidated condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q) was 2.91%. Of our outstanding credit agreement borrowings of $842.7 million and $901.4 million at March 31, 2012 and December 31, 2011, $22.5 million and $12.5 million were classified as current maturities, respectively. The increase in the current portion of outstanding credit agreement borrowings was a result of the draw of the additional $200 million term loan during the three months ended March 31, 2012.

The procurement of inventory is the largest operating use of our funds. We normally pay for aftermarket product purchases at the time of shipment or on standard payment terms, depending on the manufacturer and the negotiated payment terms. Our purchases of aftermarket products totaled approximately $303.0 million and $179.3 million during the three months ended March 31, 2012 and 2011, respectively. We normally pay for salvage vehicles acquired at salvage auctions and under some direct procurement arrangements at the time that we take possession of the vehicles. We acquired approximately 59,000 and 55,000 wholesale salvage vehicles in the three months ended March 31, 2012 and 2011, respectively. In addition, we acquired approximately 89,000 and 81,000 lower cost self service and crush only vehicles in the three month periods ended March 31, 2012 and 2011, respectively. Our heavy-duty truck purchases included 1,800 and 1,000 heavy and medium-duty trucks in the first quarters of 2012 and 2011, respectively.

Net cash provided by operating activities totaled $110.2 million for the three months ended March 31, 2012, compared to $77.3 million for the same period of 2011. In 2012, our EBITDA increased by $32.3 million compared to the prior year period, due to both acquisition related growth and organic growth. Our net cash outflow for our primary working capital accounts (receivables, inventory, and payables) decreased from $26.0 million during the first quarter of 2011 to $12.3 million in the first quarter of 2012, due to a greater cash inflow from inventory combined with the effects of the timing of cash payments and receipts on receivables and payables. While our inventory purchasing levels during the first quarter of 2012 exceeded prior year levels, our increased product sales during the quarter resulted in a net cash inflow related to inventory. The relatively lower cash outflows for our primary working capital accounts were partially offset by $5.9 million of payments made under our long term incentive plan and $1.8 million in higher bonus payments compared to the first quarter of 2011. Additionally, we made a U.K. corporate tax payment of $3.6 million in the first quarter of 2012. Similar to 2011, we did not make an estimated U.S. federal tax payment in the first quarter of 2012. We will make estimated federal tax payments in the second quarter, which are expected to exceed those remitted in the second quarter of 2011 as a result of our higher pretax income.

Net cash used in investing activities totaled $46.0 million for the three months ended March 31, 2012, compared to $61.5 million for the same period of 2011. We invested $24.9 million of cash, net of cash acquired, in business acquisitions during the first quarter of 2012, compared to $43.5 million for business acquisitions in the comparable prior year period. Property and equipment purchases were $21.3 million in the three months ended March 31, 2012 compared to $18.1 million in the prior year period.

Net cash used in financing activities totaled $57.7 million for the three months ended March 31, 2012, compared to $47.0 million in the same period of 2011. In March 2011, we entered into a new credit agreement, under which our initial draw of $591.8 million (including $250.0 million of term loan borrowings and $341.8 million of revolver borrowings) was used to pay off amounts outstanding under the previous credit facility. In the first quarter of 2012, we drew $200 million of term loan borrowings available under the amended credit agreement, which were used to pay down a portion of our outstanding revolving credit facility borrowings. In the first quarter of 2012, we also made additional net repayments on the revolving credit facility of $59.9 million, compared to $44.3 million additional net repayments in the prior year period. During the three months ended March 31, 2012, we also made scheduled term loan payments totaling $3.1 million. Related to the execution of the credit agreement in the first quarter of 2011, we paid $7.7 million of debt issuance costs. Cash generated from exercises of stock options provided $4.6 million and $2.6 million in the three month periods ended March 31, 2012 and 2011, respectively. The excess tax benefit from share-based payment arrangements reduced income taxes payable by $2.6 million and $2.5 million in the three months ended March 31, 2012 and 2011, respectively.

We intend to continue to evaluate markets for potential growth through the internal development of distribution centers, processing and sales facilities, and warehouses, through further integration of our facilities, and through selected business acquisitions. Our future liquidity and capital requirements will depend upon numerous factors, including the costs and timing of our internal development efforts and the success of those efforts, the costs and timing of expansion of our sales and marketing activities, and the costs and timing of future business acquisitions. Our credit agreement provides additional sources of liquidity to fund acquisitions, which we expect will support our strategy to supplement our organic growth with acquisitions.

We believe that our current cash and equivalents, cash provided by operating activities and funds available under our credit agreement will be sufficient to meet our current operating and capital requirements. However, we may, from time to time, raise additional funds through public or private financing, strategic relationships or other arrangements. There can be no assurance that additional funding, or refinancing of our credit facility, if needed, will be available on terms attractive to us, or at all. Furthermore, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Our failure to raise capital if and when needed could have a material adverse impact on our business, operating results, and financial condition.

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2012 Outlook

We estimate that our capital expenditures for 2012, excluding business acquisitions, will be between $100 million and $115 million. We expect to use these funds for several major facility expansions, improvement of current facilities, real estate acquisitions and systems development projects. Maintenance or replacement capital expenditures are expected to be approximately 20% of the total for 2012. We anticipate that net cash provided by operating activities for 2012 will be in the range of $250 million to $280 million.

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements. Words such as may, will, plan, should, expect, anticipate, be estimate, intend, project and similar words or expressions are used to identify these forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. However, these forward-looking statements are subject to risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different. These factors include, among other things, those described under Risk Factors in Item 1A of our 2011 Annual Report on Form 10-K, filed with the SEC on February 27, 2012, as supplemented in subsequent filings, including this Quarterly Report on Form 10-Q.

Other matters set forth in this Quarterly Report may also cause our actual future results to differ materially from these forward-looking statements. We cannot assure you that our expectations will prove to be correct. In addition, all subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements mentioned above. You should not place undue reliance on these forward-looking statements. All of these forward-looking statements are based on our expectations as of the date of this Quarterly Report. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our results of operations are exposed to changes in interest rates primarily with respect to borrowings under our credit facility, where interest rates are tied to the prime rate, the London InterBank Offered Rate, or the Canadian Dealer Offered Rate. In March 2008, we implemented a policy to manage our exposure to variable interest rates on a portion of our outstanding variable rate debt instruments through the use of interest rate swap contracts. These contracts convert a portion of our variable rate debt to fixed rate debt, matching effective and maturity dates to specific debt instruments. All of our interest rate swap contracts have been executed with banks that we believe are creditworthy (JP Morgan ChaseBank, N.A., Bank of America, N.A., and RBS Citizens, N.A.) and are denominated in currency that matches the underlying debt instrument. Net interest payments or receipts from interest rate swap contracts will be included as adjustments to interest expense. As of March 31, 2012, we held seven interest rate swap contracts representing a total of $520 million of U.S. dollar-denominated notional amount debt, £50 million of pound sterling-denominated notional amount debt, and CAD $25 million of Canadian dollar-denominated notional amount debt. In total, we had 74% and 69% of our variable rate debt under our credit facility at fixed rates at March 31, 2012 and December 31, 2011, respectively. These swaps have maturity dates ranging from October 2013 through December 2016. These contracts are designated as cash flow hedges and modify the variable rate nature of that portion of our variable rate debt. As of March 31, 2012, the fair market value of the CAD $25 million notional amount swap was an asset of $0.2 million, while the fair market value of the other swap contracts was a liability of $10.3 million. The values of such contracts are subject to changes in interest rates.

At March 31, 2012, we had unhedged variable rate debt of $217.5 million. Using sensitivity analysis to measure the impact of a 100 basis point movement in the interest rate, interest expense would change by $2.2 million over the next twelve months. To the extent that we have cash investments earning interest, a portion of the increase in interest expense resulting from a variable rate change would be mitigated by higher interest income.

We are also exposed to market risk related to price fluctuations in scrap metal and other metals. Market prices of these metals affect the amount that we pay for our inventory as well as the revenue that we generate from sales of these metals. As both our revenue and costs are affected by the price fluctuations, we have a natural hedge against the changes. However, there is typically a lag between the effect on our revenue from metal price fluctuations and inventory cost changes. Therefore, we can experience positive or negative margin effects in periods of rising or falling metal prices, particularly when such prices move rapidly. If market prices were to fall at a greater rate than our salvage acquisition costs, we could experience a decline in gross margin rate.

Additionally, we are exposed to currency fluctuations with respect to the purchase of aftermarket products from foreign countries. The majority of our foreign inventory purchases are from manufacturers based in Taiwan. While our transactions with manufacturers based in Taiwan are conducted in U.S. dollars, changes in the relationship between the U.S. dollar and the Taiwan

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dollar might impact the purchase price of aftermarket products. Our aftermarket operations in Canada, which also purchase inventory from Taiwan in U.S. dollars, are further subject to changes in the relationship between the U.S. dollar and the Canadian dollar. Our recently acquired aftermarket operations in the U.K. also source a portion of their inventory from Taiwan, as well as from other European countries and China, resulting in exposure to changes in the relationship of the pound sterling against the euro and the U.S. dollar. With our acquisition of ECP in the fourth quarter, we began hedging our exposure to foreign currency fluctuations for certain of our purchases for our U.K. operations. As of March 31, 2012, we held foreign currency forward contracts on a notional amount of 7.0 million and $8.0 million. The fair value of these foreign currency forward contracts at March 31, 2012 was immaterial. We do not currently attempt to hedge our foreign currency exposure related to our foreign currency denominated inventory purchases in our North American operations, and we may not be able to pass on any price increases to our customers.

Other than a portion of our foreign currency denominated inventory purchases in the U.K., we do not attempt to hedge our foreign currency risk related to our foreign operations. Under the terms of our credit agreement, we have amounts outstanding under our revolver facility denominated in pounds sterling of £68.5 million and Canadian dollars of CAD $55.5 million as of March 31, 2012. We have elected not to hedge the foreign currency risk related to these borrowings as we generate pound sterling and Canadian dollar cash flows that can be used to fund debt payments.

Item 4. Controls and Procedures

As of March 31, 2012, the end of the period covered by this Quarterly Report on Form 10-Q, an evaluation was carried out under the supervision and with the participation of LKQ Corporation s management, including our Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the design and operation of these disclosure controls and procedures were effective as of March 31, 2012 to ensure that we are able to record, process, summarize and report the information we are required to disclose in the reports we file with the Securities and Exchange Commission within the required time periods. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Securities Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. There were no significant changes in our internal controls over financial reporting during the three months ended March 31, 2012 that were identified in connection with the evaluation referred to above that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties that could adversely affect our business, financial condition and results of operations, and the trading price of our common stock. Please refer to our Annual Report on Form 10-K for fiscal year 2011 for information concerning risks and uncertainties that could negatively impact us. The following statements represent changes and/or additions to the risks and uncertainties previously disclosed in the Annual Report.

An adverse change in our relationships with our suppliers or auction companies could increase our expenses and hurt our ability to serve our customers.

We are dependent on a relatively small number of suppliers of aftermarket products, most of which are located in Taiwan. Due to the concentration of these suppliers in a relatively small geographic area, a major weather-related catastrophe in that region could materially disrupt our supply. Although alternative suppliers exist for substantially all aftermarket products distributed by us, the loss of any one supplier could have a material adverse effect on us until alternative suppliers are located and have commenced providing products. Moreover, our operations are subject to the customary risks of doing business abroad, including, among other things, transportation costs and delays, political instability, currency fluctuations and the imposition of tariffs, import and export controls and other non-tariff barriers (including changes in the allocation of quotas), as well as the uncertainty regarding future relations between China and Taiwan. Because a substantial volume of our sales involves products manufactured from sheet metal, we can be adversely impacted if sheet metal becomes unavailable or is only available at higher prices, which we may not be able to pass on to our customers.

Most of our salvage inventory is obtained from vehicles offered at salvage auctions operated by several companies that own auction facilities in numerous locations across the U.S. We do not typically have contracts with any auction company. According to industry analysts, a small number of companies control a large percentage of the salvage auction market in the U.S. If an auction company prohibited us from participating in its auctions, began competing with us, or significantly raised its fees, our business could be adversely affected through higher costs or the resulting potential inability to service our customers. Moreover, we are facing increased competition in the purchase of salvage vehicles from direct competitors, rebuilders, exporters, and others. This increase in the number of bidders has increased and may continue to increase our cost of goods sold for wholesale recycled products. Most states regulate bidders to help ensure that salvage vehicles are purchased for legal purposes by qualified buyers. Auction companies have been actively seeking to reduce, circumvent or eliminate these regulations, which would further increase the number of bidders.

We also acquire inventory directly from insurance companies, OEMs, and others. To the extent that these suppliers decide to discontinue these arrangements, our business could be adversely affected through higher costs or the resulting potential inability to service our customers.

Item 6. Exhibits

Exhibits

Exhibit Number	**Description of Exhibit**
3.1	Amended and Restated Bylaws of LKQ Corporation (incorporated herein by reference to Exhibit 3.1 to the Company s report on Form 8-K filed with the SEC on March 9, 2012).
10.1	Change of Control Agreement between LKQ Corporation and Robert L. Wagman, as amended and restated as of March 21, 2012 (incorporated herein by reference to Exhibit 10.1 to the Company s report on Form 8-K filed with the SEC on March 23, 2012).
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on April 27, 2012.

LKQ CORPORATION

/s/ JOHN S. QUINN
John S. Quinn
Executive Vice President and Chief Financial Officer
(As duly authorized officer and Principal Financial Officer)

/s/ MICHAEL S. CLARK
Michael S. Clark
Vice President Finance and Controller

(As duly authorized officer and Principal Accounting Officer)