CARDIOGENESIS CORP /CA
Form S-1/A
January 12, 2005

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AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON JANUARY 12, 2005

Registration No. 333-121625

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1/A

REGISTRATION STATEMENT
under
The Securities Act of 1933, as amended

CARDIOGENESIS CORPORATION

(Exact name of registrant as specified in its charter)

California	3845	77-0223740
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

CARDIOGENESIS CORPORATION
26632 TOWNE CENTER DRIVE, SUITE 320
FOOTHILL RANCH, CA 92610
(714) 649-5000
(Name, address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

MICHAEL J. QUINN
CHIEF EXECUTIVE OFFICER, CHAIRMAN & PRESIDENT
26632 TOWNE CENTER DRIVE, SUITE 320
FOOTHILL RANCH, CA 92610
(714) 649-5000
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:

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JEFFER MANGELS BUTLER & MARMARO LLP
1900 AVENUE OF THE STARS, 7TH FLOOR
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. [x]

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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The information in this prospectus is not complete and may be changed. The selling shareholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 12, 2005

26,781,250 Shares

CardioGenesis Corporation

The shares of common stock of CardioGenesis covered by this prospectus may be sold from time to time by the selling shareholders identified in this prospectus. This prospectus relates to up to 26,781,250 shares of CardioGenesis common stock, of which:

Up to 24,141,250 shares are issuable upon conversion of the principal and interest of a convertible term note issued to Laurus Master Fund, Ltd.; and

2,640,000 shares may in the future be issued to upon the exercise of a currently outstanding warrant issued to Laurus having an exercise price of $.50 per share

Of the 24,141,250 shares being registered in respect of the note, 16,881,250 shares are being registered in connection with potential conversions under the $3,000,000 unrestricted portion of the note, based on a minimum conversion price of $.20 per share, and 7,260,000 shares are being registered in connection with potential conversions under the $3,000,000 restricted portion of the note, based on our expectation that it is unlikely that conversions on the unrestricted portion will be effected during the term of the note at less than $.50 per share. If all conversions under the unrestricted portion were effected at the target conversion price of $.50 (which would require that the average trading price of our common stock be no less than $.55 for the five days prior to each such conversion), we would only issue 6,752,500 shares, rather than 16,881,250 shares, under the unrestricted portion.

We will not receive any of the proceeds from the sale of the shares of common stock by the selling shareholders. We may receive proceeds from the exercise of the warrants if the selling shareholders opt to pay the exercise price in cash rather than executing a cashless exercise.

The shares of common stock may be sold through broker-dealers or in privately negotiated transactions in which commissions and other fees may be charged. These fees, if any, will be paid by the selling shareholders. We have no agreement with any broker-dealer with respect to these shares and we are unable to estimate the commissions that may be paid in any given transaction. For a more complete description of the methods of distribution that the selling shareholders may use, see Plan of Distribution beginning on page 54.

Our common stock is traded on the OTC Bulletin Board of the National Association of Securities Dealers, Inc. under the symbol CGCP.OB. On January 11, 2005, the last sale price of our common stock was $.52 per share.

Investing in our common stock involves risks. See Risk Factors beginning on page 5.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Prospectus dated January , 2005

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ABOUT THIS PROSPECTUS

You should rely only upon the information contained in this prospectus and the registration statement of which this prospectus is a part. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus is based on information provided by us and other sources that we believe are reliable. We have summarized certain documents and other information in a manner we believe to be accurate, but we refer you to the actual documents for a more complete understanding of what we discuss in this prospectus. In making an investment decision, you must rely on your own examination of our business and the terms of the offering, including the merits and risks involved.

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SUMMARY

The following summary highlights certain significant aspects of our business and the offering, but you should read this entire prospectus, including the information set forth under the heading Risk Factors, the financial statements and related notes and the other financial data included herein, before making an investment decision. In this prospectus, unless the context otherwise requires, the terms we, us, our or other similar terms refer to CardioGenesis Corporation and its subsidiaries.

Our Business

According to the American Heart Association, cardiovascular disease is the leading cause of death and disability in the U.S. We design, develop and distribute laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization, or TMR, and percutaneous myocardial channeling, or PMC (which was previously known as percutaneous myocardial revascularization). TMR and PMC are laser-based heart treatments in which channels are made in the heart muscle. Many scientific experts believe these procedures encourage new vessel formation. TMR is performed by a cardiac surgeon through a small incision in the chest under general anesthesia. PMC is performed by a cardiologist in a catheter-based procedure which utilizes local anesthesia.

We have received CE Mark approval for our TMR and PMC products, which allows us to commercially distribute these products within the European Community. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. We have received final approval from the Food and Drug Administration, or FDA, to market and sell our TMR products in the United States for treatment of stable patients with certain types of angina. In December 2004, we received FDA approval on our next generation TMR laser, SolarGen 2100s. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel, or MDDRP. In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute can not be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

Corporate Information

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, or TMR, and percutaneous myocardial channeling, or PMC. On March 17, 1999, we merged with the former CardioGenesis Corporation. Under the terms of the combination, each share of the former CardioGenesis Corporation was converted into 0.8 of a share of our common stock, and the former CardioGenesis Corporation became a wholly owned subsidiary of ours. Our principal executive offices are located at 26632 Towne Center Drive, Suite 320, Foothill Ranch, California 92610 and our telephone number is (714) 649-5000. Our website address is www.cardiogenesis.com. Information contained on our web site does not constitute part of this prospectus.

The Offering

On October 27, 2004, we entered into a Securities Purchase Agreement with Laurus Master Fund, Ltd. in connection with our private placement of a convertible term note, due October 26, 2007, in the principal amount of $6,000,000, and a common stock purchase warrant. The note is convertible into shares of our common stock, at a fixed conversion rate of $0.50, subject to certain limitations and adjustments, and bears an interest rate of prime plus 2%. The warrant provides for the purchase of up to 2,640,000 shares of our common stock at an exercise

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price of $0.50, expiring October 26, 2011. After payment of fees and expenses to Laurus and its affiliates, we received $2,875,250 in cash from Laurus and $2,875,250 was deposited in a restricted account in our name but under the sole dominion and control of Laurus as security for our obligations under the note and related agreements. Funds will be released to us from this restricted account upon conversion of principal as follows: (i) to the extent Laurus elects to convert principal amounts in excess of the monthly conversion amount on the unrestricted portion ($3,000,000) of the note, (ii) to the extent our stock price exceeds certain levels and we require Laurus to convert portions of the restricted amount ($3,000,000), subject to certain limitations related to our aggregate dollar trading volume, and/or (iii) once we have repaid the unrestricted principal amount of the note, again subject to certain limitations related to our aggregate dollar trading volume. A more detailed discussion of the terms of the Laurus financing is contained in the Management Discussion and Analysis of Financial Condition and Results of Operations under the heading Secured Convertible Debt Financing With Laurus.

Up to an aggregate of 26,781,250 shares of common stock may be offered under this prospectus, including up to 24,141,250 shares that are issuable upon conversion of the principal and interest of the convertible term note and 2,640,000 shares of common stock issuable upon exercise of the warrant. All proceeds of this offering will be received by the selling security holders for their own accounts. We may receive proceeds in connection with the exercise of the warrant whose underlying shares may in turn be sold by the selling stockholders.

Use of Proceeds

We will not receive any of the proceeds from the sale of the shares of common stock by the selling shareholders. We may receive proceeds from the exercise of the warrant if Laurus opts to pay the exercise price in cash rather than executing a cashless exercise. In addition, we will receive cash proceeds from the restricted account to the extent conversions are effected therefrom. We will use such proceeds (if any) for general working capital purposes.

Risk Factors

You should carefully read and consider the information set forth in the section entitled Risk Factors beginning on page 5 before investing in our common stock.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information contained in this prospectus, before you decide to buy our common stock. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business. Any adverse effect on our business, financial condition, or results of operations could result in a decline in the trading price of our common stock and the loss of all or part of your investment.

Our ability to maintain current operations is dependent upon sustaining profitable operations or obtaining financing in the future.

We have incurred significant losses since inception. For example, for the fiscal years 2003, 2002 and 2001 we incurred net losses of $348,000, $530,000 and $10,247,000 respectively. We will have a continuing need for new infusions of cash if we continue to incur losses in the future. We plan to increase our revenues through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to 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, including our sales and marketing efforts and research and development. If we are required to significantly reduce our operations, our business will be harmed.

We have recently obtained $6.0 million of convertible debt financing which we believe will be sufficient to satisfy our capital needs for at least the next 15 months. However, changes in our business, financial performance or the market for our products may require us to seek additional sources of financing, which could include short-term debt, long-term debt or equity. Although in the past we have been successful in obtaining financing, there is a risk that we may be unsuccessful in obtaining financing in the future on terms acceptable to us and that we will not have sufficient cash to fund our continued operations.

Our revenues and operating income may be constrained:

if commercial adoption of our TMR laser systems by healthcare providers in the United States declines;

until such time, if ever, as we obtain FDA and other regulatory approvals for our PMC laser systems; and

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

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 Centers for Medicare and Medicaid Services, or CMS, formerly the Health Care Financing Administration, commenced Medicare coverage for TMR systems for any manufacturer s TMR procedures. Hospitals and physicians are eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. If CMS were to materially reduce or terminate Medicare coverage of TMR procedures, our business and results of operation would be harmed.

In July 2004, CMS convened the Medicare Advisory Committee, or MCAC, to review the clinical evidence regarding laser myocardial revascularization as a treatment option for Medicare patients. The MCAC meeting was a

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non-binding public hearing to consider the body of scientific evidence concerning the safety and efficacy of laser myocardial revascularization and to provide advice and recommendations to the CMS on clinical issues. The MCAC reviewed more than six years of clinical evidence on laser myocardial revascularization and heard testimony from a group of leading physicians regarding TMR. CMS does not have a pending National Coverage Determination relating to laser myocardial revascularization. In September 2004, we confirmed that CMS does not intend to commence any action on TMR coverage at this time.

As PMC has not been approved by the FDA, the CMS has not approved reimbursement for PMC. If we obtain FDA approval for PMC in the future and CMS does not provide reimbursement, our ability to successfully market and sell our PMC products may be affected.

Even though Medicare beneficiaries appear to account for a majority of all patients treated with the TMR procedure, the remaining patients are beneficiaries of private insurance and private health plans. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. If private insurance and private health plans do not provide reimbursement, our business will suffer.

If we obtain the necessary foreign regulatory registrations or approvals for our products, market acceptance in international markets would be dependent, in part, upon the availability of reimbursement within prevailing healthcare 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 PMC products in the international markets in which such approvals are sought, which would significantly reduce international revenue.

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

The FDA has not approved our PMC laser system for any application in the United States. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel, or MDDRP. In July 2003, the FDA agreed to an alternative process in which additional data in support of our PMA supplement for PMC could be submitted and reviewed by the FDA in an interactive review process. The data was submitted in August 2003 and the independent panel review by the MDDRP was cancelled. The FDA agreed to reschedule the MDDRP hearing in the future if the dispute cannot be resolved.

In March 2004, the FDA informed us that the data submitted in August 2003 was not adequate to support approval by the FDA of our PMC system. In August 2004, we met with the FDA in an effort to clearly define a workable clinical pathway to move the PMA application for PMC forward in an effort to gain FDA clearance. We came to an agreement with the FDA on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We expect to submit the protocol for review by the FDA before the end of the first quarter of 2005. The final design and size of the trial will determine the resources required to support the trial. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will obtain additional debt or equity financing with acceptable terms or that we will receive an approvable determination on PMC from the FDA.

In August 2004, we decided to change the name the of PMC platform from percutaneous myocardial revascularization to percutaneous myocardial channeling. The new name more literally depicts the immediate

physiologic tissue effect of the percutaneous procedure.

We may not be able to derive any revenue from the sale of our PMC system in the United States until such time,

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if any, that the FDA approves the device. Such inability to realize revenue from sales of our PMC device in the United States may have an adverse effect on our results of operations.

In the future, the FDA could restrict the current uses of our TMR product and thereby restrict our ability to generate revenues.

We currently derive approximately 99% of our revenues from our TMR product. The FDA has approved this product for sale and use by physicians in the United States. At the request of the FDA, we are currently conducting post-market surveillance of our TMR product. If we should fail to meet the requirements mandated by the FDA or fail to complete our post-market surveillance study in an acceptable time period, the FDA could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, although 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 FDA could possibly restrict the currently approved uses of our TMR product. In the future, if the FDA were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians in the United States, such as restricting TMR s use with the coronary artery bypass grafting procedure, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be materially and adversely affected.

We must comply with FDA manufacturing standards or face fines or other penalties including suspension of production.

We are required to demonstrate compliance with the FDA s current Good Manufacturing Practices regulations if we market devices in the United States or manufacture finished devices in the United States. The FDA inspects manufacturing facilities on a regular basis to determine compliance. If we fail to comply with applicable FDA 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 us of any such failure to comply would depend on the impact of the remedy imposed on us.

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 FDA 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.

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

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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 prohibitions against us marketing our products in the European Union, which would significantly reduce international revenue.

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.

We purchase certain critical products and components for lasers and disposable handpieces from single sources. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of our products to third parties. We may experience harm to our business if we cannot timely provide lasers to our customers or if our outsourcing suppliers have difficulties supplying our needs for products and components.

In addition, we do not have long-term supply contracts. As a result, our 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 PMC laser systems were to increase rapidly or significantly. We believe that we have an adequate supply of lasers to meet our expected demand for the next twelve months. However, if demand for our TMR 2000 laser is greater than we currently anticipate and there is a delay in obtaining production capacity, unless we are able to obtain lasers originally placed through our loaned laser program and no longer utilized by a hospital, we may not be able to meet the demand for our TMR 2000 laser. In addition, any defect or malfunction in the laser or other products provided by our suppliers and manufacturers could cause delays 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

- 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.

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.

In 2001 we began a restructuring of our business in order, in part, to bring our cost structure more in line with our revenues. As part of this restructuring we significantly reduced our workforce. 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 PMC 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.

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If an event of default occurs under the convertible note issued to Laurus, it could seriously harm our operations.

On October 27, 2004, we issued a $6,000,000 secured convertible term note to Laurus. The note and related agreements contain numerous events of default which include:

A failure to pay interest and principal payments when due;

a breach by us of any material covenant or term or condition of the note or any agreement made in connection therewith;

a breach by us of any material representation or warranty made in the note or in any agreement made in connection therewith;

if we make an assignment for the benefit of our creditors, or a receiver or trustee is appointed for us;

any form of bankruptcy or insolvency proceeding instituted by or against us and not dismissed within 60 days;

any money judgment entered or filed against us for more than $50,000 and remains unresolved for 30 days;

our failure to timely deliver shares of common stock when due upon conversions of the note;

our common stock is suspended for 5 consecutive days or 5 days during any 10 consecutive days from a principal market;

if we experience an event of default under any other debt obligations; and

if we experience a loss, damage or encumbrance upon collateral securing the Laurus debt which is valued at more than $100,000 and is not timely mitigated.

If we default on the note and the holder demands all payments due and payable, the cash required to pay such amounts would most likely come out of working capital, which may not be sufficient to repay the amounts due. In addition, since we rely on our working capital for our day to day operations, such a default on the note could materially adversely effect our business, operating results or financial condition to such extent that we are forced to restructure, file for bankruptcy, sell assets or cease operations. Further, our obligations under the note are secured by all of our assets. Failure to fulfill our obligations under the note and related agreements could lead to loss of these assets, which would be detrimental to our operations.

The restrictions on our activities contained in the Laurus financing documents could negatively impact our ability to obtain financing from other sources.

The Laurus financing documents restrict us from obtaining additional debt financing, subject to certain specified exceptions. To the extent that Laurus declined to approve a debt financing that does not otherwise qualify for an exception to the consent requirement, we would be unable to obtain such debt financing. In addition, subject to certain exceptions, we have granted to Laurus a right of first refusal to provide additional financing to us in the event that we propose to engage in additional debt financing or to sell any of our equity securities. Laurus s right of first refusal could act as a deterrent to third parties which may be interested in providing us with debt financing or purchasing our equity securities. To the extent that such a financing is required for us to conduct our operations, these restrictions could materially adversely impact our ability to achieve our operational objectives.

Low market prices for our common stock would result in greater dilution to our shareholders, and could negatively impact our ability to convert the Laurus debt into equity

The market price of our common stock significantly impacts the extent to which we are permitted to convert the unrestricted and restricted portions of the Laurus debt into shares of our common stock. The lower the market price of our common stock as of the respective times of conversion, the more shares we will need to issue to Laurus to convert the principal and interest payments then due on the unrestricted portion of the debt. If the market price of our common stock falls below certain thresholds, we will be unable to convert any such repayments of principal and interest into equity, and we will be required to make such repayments in cash. Our operations could be materially adversely impacted if we are required to make repeated cash payments on the unrestricted portion of the Laurus debt. Further, prior to the full repayment of the

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unrestricted portion of the Laurus debt, we will only be able to require conversions of the $3,000,000 restricted cash amount to the extent the market price of our common stock exceeds certain levels. To the extent that the market price of our common stock does not reach such specified levels, we will be not be entitled to take possession of any of the restricted cash during the term of the Laurus note. Our inability to access such cash could limit our ability to achieve our operational objectives. The restricted portion of the debt will continue to accrue interest during the entire period that we are unable to require conversion. In addition, to the extent that conversions of the restricted portion of the debt are not effected during the term of the note, we have only a limited ability to convert a specified amount of the restricted debt (subject to meeting certain minimum market price thresholds and volume requirements), and we will be required to repay the remaining restricted principal and interest in cash. The cash required to pay the interest portion of such amounts would most likely come out of working capital, which may not be sufficient to repay the amounts due.

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 continue to fluctuate significantly from quarter-to-quarter in future periods. 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. It is likely or possible that our operating results for a future quarter will fall below the expectations of public market analysts that may cover our stock and investors. When this occurred in the past, the price of our common stock fell substantially, and if this occurs in the future, the price of our common stock may fall again, perhaps substantially.

Our common stock is listed on the OTC Bulletin Board which may have an unfavorable impact on our stock price and liquidity.

Effective April 3, 2003 our common stock was delisted from The Nasdaq SmallCap Market and became quoted on the OTC Bulletin Board on the same day. The OTC Bulletin Board is a significantly more limited market in comparison to the Nasdaq system. The listing of our shares on the OTC Bulletin Board may result in a less liquid market available for existing and potential shareholders to trade shares of our common stock, could ultimately further depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future.

The trading prices of many high technology companies, and in particular medical device companies, have been volatile which may result in large fluctuations in the price of our common stock.

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 many 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.

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 the 52-week period ended December 17, 2004, the closing prices of our common stock as reported on the OTC Bulletin Board ranged from a high of $1.26 per share to a low of $.35 per share. 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;

the timing and amount of conversions and subsequent sales of common stock issuable upon conversion of outstanding convertible promissory notes and warrants

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

announcements relating to strategic relationships or acquisitions;

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additions or terminations of coverage of our common stock 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.

The prices at which our common stock trades will affect our ability to raise capital, which may have an adverse affect on our ability to fund our operations.

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

The market for TMR laser systems is competitive. We currently compete with PLC Systems, a publicly traded company which uses a CO2 laser and an articulated mechanical arm in its TMR products. Edwards Lifesciences, a well known, publicly traded provider of products and technologies to treat cardiovascular disease, has assumed 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 executed in January 2001. Through its significantly greater financial and human resources, including a well-established and extensive sales representative network, we believe Edwards has the potential to market to a greater number of hospitals and doctors that we currently can. If PLC, or any new competitor, is more effective than we are in developing new products and procedures and marketing existing and future products similar to ours, our business will suffer.

The market for TMR laser systems is characterized by rapid technological innovation. 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.

If we obtain the FDA s approval for our PMC 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.

Third party intellectual property rights 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 PMC procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other TMR or PMC technology. In addition, international patents may not be interpreted the same as any counterpart United States patents.

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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 our 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;

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.

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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 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 PMC 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 FDA s Circulatory Devices Panel s recent recommendation against approval of our PMC 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 PMC 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 PMC 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 PMC product.

Any regulatory clearance for commercial sale of these products will not remove these risks. Any failure to comply with the FDA s Good Manufacturing Practices or other regulations could hurt our ability to defend against product liability lawsuits.

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. Significant turnover in our senior management could significantly deplete our institutional knowledge held by our existing senior management team. For example, in November 2003, our employment relationship with Darrell Eckstein, our former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. 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.

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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.

This offering and future sales of our common stock could lower our stock price.

The sale of our common stock by the selling shareholders in this offering could cause the market price of our common stock to decline. In addition, if our shareholders sell substantial amounts of our common stock, including shares issuable upon exercise of options or warrants, in the public market following this offering, the market price of our common stock could decline. If these sales were to occur, we may also find it more difficult to sell equity or equity-related securities in the future at a time and price that we deem appropriate and desirable.

In the future, we may issue additional shares in public or private offerings. We cannot predict the size of future issuances of our common stock or the effect, if any, that future issuances and sales of our common stock would have on the market price of our common stock. We expect that Laurus will promptly sell any shares into which the Laurus indebtedness is converted, and that the market price of our common stock could decline as a result of such sales.

Provisions of our certificate of incorporation as well as our rights agreement could discourage potential acquisition proposals and could deter or prevent a change of control.

Our articles of incorporation authorize our board of directors, subject to any limitations prescribed by law, to issue shares of preferred stock in one or more series without shareholder approval. On August 17, 2001 we adopted a shareholder rights plan, as amended, and under the rights plan, our board of directors declared a dividend distribution of one right for each outstanding share of common stock to shareholders of record at the close of business on August 30, 2001. Pursuant to the Rights Agreement, in the event (a) any person or group acquires 15% or more of our then outstanding shares of voting stock (or 21% or more of our then outstanding shares of voting stock in the case of State of Wisconsin Investment Board), (b) a tender offer or exchange offer is commenced that would result in a person or group acquiring 15% or more of our then outstanding voting stock, (c) we are acquired in a merger or other business combination in which we are not the surviving corporation or (d) 50% or more of our consolidated assets or earning power are sold, then the holders of our common stock are entitled to exercise the rights under the Rights Plan, which include, based on the type of event which has occurred, (i) rights to purchase preferred shares from us, (ii) rights to purchase common shares from us having a value twice that of the underlying exercise price, and

(iii) rights to acquire common stock of the surviving corporation or purchaser having a market value of twice that of the exercise price. The rights expire on August 17, 2011, and may be redeemed prior thereto at $.001 per right under certain circumstances. The Board s ability to issue preferred stock without shareholder approval while providing desirable flexibility in connection with financings, acquisitions and other corporate purposes, and the existence of the rights plan might discourage, delay or prevent a change in the ownership of our company or a change in our management. In addition, these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The words believes, anticipates, plans, expects, intends, estimates and similar expressions are to identify forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance and achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statement. These factors include, but are not limited to, the following:

our financial prospects;

our financing requirements and plans;

trends affecting our financial condition or operating results;

our strategies for growth, operations, and product development and commercialization;

our maintenance and receipt of regulatory approvals;

the availability of third party reimbursement for procedures performed with our products; and

our ability to develop and protect our intellectual property.

The foregoing does not represent an exhaustive list of risks. Other sections of this prospectus include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those contained in any forward-looking statements.

All forward-looking statements included in this prospectus are based on information available to us on the date of this prospectus. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. 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 contained throughout this prospectus.

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USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares of common stock by the selling shareholders, except to the extent that we receive cash proceeds from the restricted account for conversions that are effected therefrom. We will use such proceeds (if any) for general working capital purposes. When all or a portion of the warrants held by the selling shareholders are exercised, we will receive the proceeds from the exercise of those warrants to the extent that the exercise price is paid in cash. However, the warrants held by the selling shareholders may be exercised through a cashless exercise, in which event, we will not receive any proceeds from the exercise. If these warrants are exercised and the exercise price is paid in cash, we will receive $1,320,000, which we intend to use for working capital and other general corporate purposes. We will use such proceeds (if any) for general working capital purposes.

MARKET PRICE AND DIVIDEND INFORMATION

Since April 2003, our common stock is currently traded on the OTC Bulletin Board under the symbol CGCP.OB (after earlier having traded first on the Nasdaq National Market and subsequently on the Nasdaq SmallCap Market). For the periods indicated, the following table presents the range of high and low sale prices for the common stock as reported by the OTC Bulletin Board and Nasdaq SmallCap Market for the respective market on which our common stock was listed during the quarter being reported.

2003	**High**	**Low**
First Quarter	$0.66	$0.22
Second Quarter	$0.85	$0.24
Third Quarter	$1.49	$0.72
Fourth Quarter	$1.92	$0.70
2004	**High**	**Low**
First Quarter	$1.26	$0.72
Second Quarter	$0.87	$0.46
Third Quarter	$0.72	$0.47
Fourth Quarter	$0.70	$0.36
2005	**High**	**Low**
First Quarter (through January 11, 2005)	$0.60	$0.49

As of December 17, 2004 shares of our common stock were held by 236 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. In addition, the documents governing our debt obligations to Laurus restrict us from paying dividends without Laurus s prior written approval.

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BUSINESS

General

CardioGenesis Corporation, incorporated in California in 1989, designs, develops and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization, or TMR, and percutaneous transluminal myocardial channeling, or PMC. TMR and PMC are recent laser-based heart treatments in which channels are made in the heart muscle. Many scientific experts believe 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. PMC 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 PMC plus medications, when compared with patients who received medications alone.

We received CE Mark approval for our TMR system in May 1997 and our PMC system in April 1998, which allows us to commercially distribute these products within the European Community. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. On February 11, 1999, we received final approval from the Food and Drug Administration, or FDA, for our TMR products for treatment of stable patients with certain types of angina. In December 2004, we received approval on our next generation TMR laser, SolarGen 2100s. Effective July 1, 1999, Centers for Medicare and Medicaid Services, or CMS, formerly known as the Health Care Financial Administration, or HCFA, began to provide Medicare coverage for any manufacturer s TMR procedures. As a result, hospitals and physicians are eligible to receive Medicare reimbursement for TMR equipment and procedures for Medicare patients.

We have completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a Pre Market Approval, or PMA application, in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel, or MDDRP. In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

As of September 30, 2004, we had an accumulated deficit of $165,879,000. We may incur operating losses in the future. The timing and amounts of our expenditures will depend upon a number of factors, including the costs incurred for the launch of new products, the timing of market acceptance of our products and the status and timing of regulatory approvals.

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 financial information included in this report has been restated as if the combined entity existed for the 1999 period prior to the merger.

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Background

According to the American Heart Association, cardiovascular disease is the leading cause of death and disability in the U.S. 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, 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 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.

Introduced in the early 1980s, PTCA is a less-invasive alternative to CABG 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 PMC, 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.

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The TMR and PMC Procedures

TMR 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 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.

PMC is an interventional procedure performed by a cardiologist. PMC is based upon the same principles as TMR, but the procedure is much less invasive. The procedure is performed under local anesthesia and the patient 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). PMC has received the CE Marking approving its use within the European Union. See our discussion below under the caption Regulatory Status, for the status of our PMA application with the FDA seeking approval of PMC for public sale and use in the United States.

Business Strategy

Our objective is to become a recognized leader in the field of myocardial revascularization, with TMR and PMC 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 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 currently intend to expand our marketing efforts in Europe and to the rest of the world through the establishment and expansion of direct international sales and support organizations and third party distributors and agents. In addition, we have developed a comprehensive training program to assist physicians in acquiring the expertise necessary to utilize our TMR and PMC products and procedures.

Demonstrate Clinical Utility of PMC . We are seeking to demonstrate the clinical safety and effectiveness of PMC. We have completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a PMA application in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel, or MDDRP. In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

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 PMC procedures. We are seeking to develop additional proprietary technologies for TMR, PMC and related procedures. We have over 100 foreign and U.S. patents or allowed patent applications and more than 200 U.S. and foreign patent applications pending relating to various aspects of TMR, PMC and other cardiovascular therapies.

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Products and Technology

TMR System

Our TMR system consists of a holmium 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. The compact base unit occupies a small amount of operating room floor space, operates on standard 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.

Holmium Laser. Our TMR 2000 laser base unit and our next generation TMR laser, SolarGen 2100s generates 2.1 micron wavelength laser light 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 that screws into the laser base unit, and the device is pre-calibrated in the factory so it requires no special preparation.

PMC System

Our PMC system is currently sold only outside the United States. The PMC system consists of the PMC Laser and ECG Monitor.

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

Axcis Catheter System. Our Axcis catheter system is an over-the-wire system that consists of two components, the Axcis laser catheter and Axcis aligning catheter. Our 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

United States. On February 11, 1999, we received 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.

We have completed pivotal clinical trials involving PMC and study results were submitted to the FDA in a PMA application in December 1999 along with subsequent amendments. The PMC study compares PMC to conventional medical therapy in patients with no option for other treatment. In July 2001, the FDA Advisory Panel

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recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel, or MDDRP. In July 2003, the FDA agreed to an alternative process in which additional data in support of our PMA supplement for PMC could be submitted and reviewed by the FDA in an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

European Union. We have obtained approval to affix the CE Marking to substantially all of our products, which enables us to commercially distribute our TMR and PMC products throughout the European Community.

Sales and Marketing

We have received FDA approval for our surgical TMR laser systems, the TMR 2000 and SolarGen 2100s. In July 1999, the Centers for Medicare and Medicaid Services announced its coverage policy for TMR equipment and procedures. We are promoting market awareness of our approved surgical products among opinion leaders in the cardiovascular field and are recruiting physicians and hospitals to use our TMR products.

In the United States, we currently offer a laser base unit at a current end user list price of $355,000 per unit and the new SolarGen 2100s at an end user list price of $395,000, 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 $3,300. In addition to sales of lasers to hospitals outright, in an effort to accelerate market adoption of the TMR procedure, we developed a program in which we 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 TMR and PMC products through a direct sales and support organization and through distributors and agents. We currently intend to expand our marketing efforts in Europe and to the rest of the world through the establishment and expansion of direct international sales and support organizations and third party distributors and agents. We can not assure you, however, that we will be successful in increasing our international sales.

We have developed, in conjunction with several major hospitals using our TMR or PMC 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 PMC in vivo. To date over 1,200 cardiothoracic surgeons have been trained on the CardioGenesis TMR system.

We exhibit our products at major meetings of cardiovascular medicine practitioners. Evaluators 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 efforts and product offerings 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 PMC 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 PMC handpiece systems to a single contract manufacturer. We believe that we have an adequate supply of lasers to meet our expected demand for the next twelve months. The next generation TMR laser system, or SolarGen, approved by the FDA in December 2004, and the PMC laser system are 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 PMC, 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., or PLC, which markets 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. Edwards Lifesciences, a well known, publicly traded provider of products and technologies to treat cardiovascular disease, has assumed 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 executed in January 2001. Through its significantly greater financial and human resources, including a well-established and extensive sales representative network, we believe Edwards has the potential to market to a greater number of hospitals and doctors than we currently can.

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 PMC 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 cannot assure you that our TMR or PMC products will be accepted by cardiovascular professionals. 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 cannot 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 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.

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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 the U.S. by the FDA and outside the U.S. by 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 Marking for commercial distribution in the European Community.

To obtain a Pre Market Approval, or PMA, for a medical device, we must file a PMA application that includes clinical data and the results of preclinical 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, or 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 PMC for public sale and use in the United States and further informed us that they believe the data submitted in August 2003 in connection with the interactive review process is still not adequate to support approval by the FDA of our PMC system. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

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, or 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.

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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 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 PMC 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 cannot 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 PMC products in member countries of the European Union or elsewhere.

Intellectual Property Matters

Our success depends, 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 100 U.S. and foreign patents or allowed patent applications and more than 200 U.S. and foreign patent applications pending relating to various aspects of TMR, PMC 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. If any of these agreements are breached, we may not have adequate remedies available thereunder to protect our intellectual property or we may incur substantial expenses enforcing our rights. 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

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related to TMR and PMC. There can be no assurance that claims or proceedings will not be initiated against us by competitors or other third parties in the future. In particular, the introduction in the United States market of our PMC technology, should that occur, may create new exposures to claims of infringement of third party patents. Any such claims in the future, regardless of whether they have merit, could be time-consuming and expensive to respond to and could divert the attention of our 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.

We cannot assure that our current and potential competitors and other third parties have not filed or in the future will not file patent 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 cannot assure you that we would 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 continue to 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 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 CABG.

In contrast to Medicare, which covers a significant portion of the patients who are candidates for TMR, private insurers and health plans each make any individual decision whether or not to provide reimbursement for TMR and, if so, at what reimbursement level. We have limited experience to date ascertaining 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 PMC. The lack of private insurance and health plans reimbursement may harm our business. Based on physician feedback, we believe many 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, or 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 healthcare 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 and 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 17, 2004 we had 38 employees, of which 20 employees were in sales and marketing. None of our employees is covered by a collective bargaining agreement and we have not experienced any work stoppages to date.

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SELECTED HISTORICAL FINANCIAL AND OTHER DATA

The following selected consolidated financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, and our financial statements and related notes thereto included elsewhere in this prospectus.

The selected consolidated statement of operations data for the nine months ended September 30, 2004 and 2003 and the fiscal years ended 2003, 2002 and 2001, and the consolidated balance sheet data at September 30, 2004 and the fiscal years 2003 and 2002 set forth below are derived from our consolidated financial statements and are qualified by reference to our consolidated financial statements included herein.

The selected consolidated statement of operations data for the nine months ended September 30, 2003 and the fiscal years ended 2000 and 1999 and the consolidated balance sheet data for 2001, 2000 and 1999 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 data prior to the pooling has been restated as if the combined entity existed for the entire period presented.

Selected Consolidated Financial Data
(in thousands, except per share amounts)

	Nine Months Ended September 30,		Years Ended December 31,				
	2004	2003	2003	2002	2001	2000	1999(1)
Net revenues	$ 10,254	$ 10,106	$ 13,518	$ 13,048	$ 14,153	$ 22,210	$ 25,324
Cost of revenues	1,570	1,745	2,295	2,935	5,777	10,055	13,246
Gross profit	8,684	8,361	11,223	10,113	8,376	12,155	12,078
Operating expenses:							
Research and development	1,189	1,836	1,944	657	1,863	5,065	11,353
Sales, general and administrative	8,398	7,406	9,590	12,297	15,119	22,009	24,581
Restructuring and merger-related costs					1,033		5,214
Total operating expenses	9,587	9,242	11,534	12,954	18,015	27,074	41,148
Operating loss	(903)	(881)	(311)	(2,841)	(9,639)	(14,919)	(29,070)
Interest and other income (expense), net	(18)	(5)	(37)	2,311	(608)	310	737
Net loss	$ (921)	$ (886)	$ (348)	$ (530)	$ (10,247)	$ (14,609)	$ (28,333)
Net loss per share basic and diluted	$ (.02)	$ (.02)	$ (0.01)	$ (0.01)	$ (0.31)	$ (0.48)	$ (0.99)
	41,054	37,203	37,303	36,911	33,311	30,166	28,629

Shares used in per share calculation							
Consolidated Balance Sheet Data:							
Cash, cash equivalents and marketable securities	$ 2,920	$ 1,113	$ 1,013	$ 1,490	$ 2,629	$ 3,357	$ 13,313
Working capital	8,568	2,001	1,614	1,048	4,662	10,031	
Total assets	8,457	6,733	6,460	7,755	11,309	16,965	34,019
Long-term debt, less current portion	19		6	1	32	405	815
Accumulated deficit	(165,879)	(165,496)	(164,958)	(164,610)	(164,080)	(153,833)	(139,224)
Total shareholders equity	$ 5,450	$ 3,094	$ 3,820	$ 3,711	$ 3,582	$ 7,974	$ 18,573

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

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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 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 similar 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 prospectus.

Overview

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, or TMR, and percutaneous myocardial channeling, or PMC.

On February 11, 1999, we received final approval from the FDA for our TMR products for certain indications, and we are permitted to sell those products in the U.S. on a commercial basis. In December 2004, we received approval on our next generation TMR laser, SolarGen 2100s. We have also received the European Conforming Mark, or CE Mark, allowing the commercial sale of our TMR laser systems and our PMC catheter system to customers in the European Community. Effective July 1, 1999, Centers for Medicare and Medicaid Services, or CMS, began providing Medicare coverage for TMR. As a result, hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures performed on Medicare recipients.

We have completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a Pre Market Approval, or PMA application, in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel, or MDDRP. In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

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As of December 31, 2003, we had an accumulated deficit of $164,958,000. We may 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

Nine Months Ended September 30, 2004 Compared to Nine Months Ended September 30, 2003

Net revenues were $10,254,000 for the nine months ended September 30, 2004, an increase of $148,000, or 1%, when compared to net revenues of $10,106,000 for the nine months ended September 30, 2003.

For the nine months ended September 30, 2004, domestic handpiece revenue increased by $508,000 compared to the nine months ended September 30, 2003. For the nine months ended September 30, 2004, domestic handpiece revenue consisted of $1,487,000 in sales to customers operating under the loaned laser program and $5,866,000 in sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaner laser program, $471,000 was attributed to premiums associated with handpiece sales. For the nine months ended September 30, 2003, domestic handpiece revenue consisted of $1,990,000 in sales of product to customers operating under the loaned laser program and $4,855,000 of sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaned laser program, $540,000 was attributed to premiums associated with the handpiece sales.

For the nine months ended September 30, 2004, domestic laser revenue decreased by $325,000 compared to the same period in 2003. International sales, accounting for approximately 4% of net revenues for the nine months ended September 30, 2004, increased $36,000 from the same period in the prior year when international sales accounted for 4% of total sales. In addition, service and other revenue of $725,000 decreased $71,000 or 9% for the nine months ended September 30, 2004 when compared to $796,000 for the nine months ended September 30, 2003.

Gross Profit

Gross profit increased to 85% of net revenues for the nine months ended September 30, 2004 as compared to 83% of net revenues for the nine months ended September 30, 2003. Gross profit in absolute dollars increased by $323,000 to $8,684,000 for the nine months ended September 30, 2004, as compared to $8,361,000 for the nine months ended September 30, 2003. The increase in gross margin as a percent of net revenues for the nine months ended September 30, 2004 resulted from higher average selling prices of our products, ongoing improvements in manufacturing by our contract manufacturer, and lower net book values associated with the sale of our lasers.

Research and Development

Research and development expenditures of $1,189,000 decreased $647,000 for the nine months ended September 30, 2004 when compared to $1,836,000 for the nine months ended September 30, 2003. The decrease in overall research and development expense during the quarterly and nine month periods was primarily attributed to a decrease in the expenses related to our pursuit of PMC approval.

Sales, General and Administrative

Sales, general and administrative expenditures of $8,398,000 increased $992,000 or 13% for the nine months ended September 30, 2004 when compared to $7,406,000 for the nine months ended September 30, 2003. The increase in expenses resulted primarily from an $810,000 increase in employee related expenses due to additional

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headcount, a $215,000 increase in marketing costs and a $114,000 increase in physician training costs. These increases were offset by a decrease in facilities and office expense of $143,000 due to cost containment efforts.

Net Loss

The net loss for the nine months ended September 30, 2004 was $921,000 compared to a net loss of $886,000 for the nine months ended September 30, 2003. The increase in net loss is primarily related to an increase in selling, general, and administrative costs of $992,000 offset by a decrease in research and development expenses of $647,000 and an increase in gross profit of $323,000.

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Net Revenues

We generate our revenues primarily through the sale of our TMR laser base units and related handpieces, and related services . Net revenues of $13,518,000 for the year ended December 31, 2003 increased $470,000, or 4%, when compared to net revenues of $13,048,000 for the year ended December 31, 2002. The increase in net revenues was due to an increase in domestic handpiece and laser revenues of $268,000 and $286,000, respectively, offset by a decrease in international handpiece and laser sales of $9,000 and $69,000, respectively.

The increase in handpiece revenue is primarily related to a higher average per unit selling price in 2003 as compared to 2002. In an effort to accelerate market adoption of the TMR procedure, we developed a program pursuant to which we loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. In the year ended December 31, 2003, domestic handpiece revenue consisted of $2,649,000 in sales to customers operating under our loaned laser program, of which $781,000 was attributed to premiums associated with such sales. In the year ended December 31, 2002, domestic handpiece revenue consisted of $2,832,000 in sales of product to customers operating under our loaned laser program, of which $756,000 was attributed to premiums associated with such sales. In the years ended December 31, 2003 and 2002, sales of product to customers not operating under our loaned laser program were $6,387,000 and $5,937,000, respectively.

For the year ended December 31, 2003, domestic laser sales increased by $286,000 compared to the year ended December 31, 2002 primarily from a moderate increase in the conversion of loaned lasers to outright sales. International sales, accounting for approximately 3% of total sales for the year ended December 31, 2003, decreased $78,000 from the prior year when international sales accounted for 4% of total sales. The decrease in international sales occurred primarily as a result of fewer handpiece sales resulting from decreased sales and marketing efforts in the international market compared to 2002. Service and other revenue of $971,000 slightly decreased by $6,000 for the year ended December 31, 2003 when compared to $977,000 for the year ended December 31, 2002.

Gross Profit

Gross profit increased to 83% of net revenues for the year ended December 31, 2003 as compared to 78% of net revenues for the year ended December 31, 2002. Gross profit in absolute dollars increased by $1,110,000 to $11,223,000 for the year ended December 31, 2003, as compared to $10,113,000 for the year ended December 31,

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2002. The increase in gross profit as a percent of sales, and in absolute terms, resulted from improved margins on lasers sold. These margins improved primarily due to sales of lasers originally placed under our laser loan program that were converted to outright sales. In addition, margins on disposable handpieces increased due to improvements in manufacturing which resulted in higher yields.

Research and Development

Research and development expenditures of $1,944,000 increased $1,287,000 or 196% for the year ended December 31, 2003 when compared to $657,000 for the year ended December 31, 2002. The increase in overall research and development expense resulted primarily from an increase in costs for outside services of $463,000 related to the PMC approval process. For the year ended December 31, 2003, a reduction of $601,000 of accrued liabilities was recorded for estimated clinical trial obligations. This reduction of accrued liabilities decreased $828,000 for the year ended December 31, 2002 and contributed to the overall increase in research and development expenditures.

Sales, General and Administrative

Sales, general and administrative expenditures of $9,590,000 decreased $2,707,000 or 22% for the year ended December 31, 2003 when compared to $12,297,000 for the year ended December 31, 2002. The decrease in expenses resulted primarily from a decrease in employee expenses of $1,077,000 primarily related to reductions in our workforce. Additionally, outside services, advertising and marketing, training and clinical research, and facilities and office expense decreased $564,000, $396,000, $152,000, $118,000, respectively, due to overall cost cutting efforts.

Interest and Other Income (Expense), Net

Interest and other income (expense), net is comprised of interest income, interest expense and our former ownership interest in Microheart, Inc., a privately-held company.

Interest income of $7,000 decreased $32,000 or 82% for the year ended December 31, 2003 when compared to $39,000 for the year ended December 31, 2002. This decrease was due to lower interest rates and lower investments in cash equivalents.

Interest expense of $44,000 increased $31,000 or 238% for the year ended December 31, 2003 when compared to $13,000 for the year ended December 31, 2002. This increase is primarily due to a higher level of financing for equipment under capital lease and amortization of debt issue costs.

A gain on the sale of an investee of $2,285,000 for the year ended December 31, 2002 resulted from the sale of our ownership interest in Microheart in April 2002.

Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Net Revenues

Net revenues of $13,048,000 for the year ended December 31, 2002 decreased $1,105,000, or 8%, when compared to net revenues of $14,153,000 for the year ended December 31, 2001. The decrease in net revenues was due to a reduction in domestic handpiece revenues of $1,810,000 and international sales of $547,000 offset by an increase in domestic laser sales of $761,000 and in service and other revenue of $491,000.

The decrease in handpiece revenue was primarily related to our then current strategy of concentrating our sales resources on increasing procedure volume in our existing installed base, which had the effect of reducing handpiece revenues from loaned laser placements, when compared to the levels attained in the year ended December 31, 2001. The decline in loaned laser placements in 2002, when compared to the prior year, resulted in a year-over-year reduction in the number of handpieces sold as each shipped laser is normally accompanied by an order for handpieces. In the year ended December 31, 2002, domestic handpiece revenue consisted of $2,832,000 in sales to customers operating under our loaned laser program, of which $756,000 was attributed to premiums associated with

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such sales. In the year ended December 31, 2001, domestic handpiece revenue consisted of $4,677,000 in sales of product to customers operating under our loaned laser program, of which $1,424,000 was attributed to premiums associated with such sales. In the years ended December 31, 2002 and 2001, sales of product to customers not operating under our loaned laser program was $5,937,000 and $5,902,000, respectively.

For the year ended December 31, 2002, domestic laser sales increased by $761,000 compared to the year ended December 31, 2001 primarily from an increase in sales of lasers that were previously on loan in our installed base. International sales, accounting for approximately 4% of total sales for the year ended December 31, 2002, decreased $547,000 from the prior year when international sales accounted for 7% of total sales. This reduction in international sales occurred primarily as a result of fewer handpiece sales due to decreased shipments to distributors in the international market compared to 2001. Service and other revenue of $976,000 increased $491,000 for the year ended December 31, 2002 when compared to $485,000 for the year ended December 31, 2001 due primarily to an increase in the number of service contracts sold.

Gross Profit

Gross profit increased to 78% of net revenues for the year ended December 31, 2002 as compared to 59% of net revenues for the year ended December 31, 2001. Gross profit in absolute dollars increased by $1,737,000 to $10,113,000 for the year ended December 31, 2002, as compared to $8,376,000 for the year ended December 31, 2001. The increase in gross profit as a percent of sales, and in absolute terms, resulted from improved margins on lasers sold as well as improved margins on disposable handpieces. We achieved these improved margins through due to the outsourcing of disposables manufacturing which took place in the second half of 2001.

Research and Development

Research and development expenditures of $657,000 decreased $1,206,000 or 65% for the year ended December 31, 2002 when compared to $1,863,000 for the year ended December 31, 2001. While actual expenditures for research and development remained fairly constant from 2001 to 2002, the decrease in overall research and development expense resulted primarily from the effects of recording a total of $1.3 million in reductions of accrued liabilities recorded in prior years for estimated clinical trial obligations.

Sales, General and Administrative

Sales, general and administrative expenditures of $12,297,000 decreased $2,822,000 or 19% for the year ended December 31, 2002 when compared to $15,119,000 for the year ended December 31, 2001. The decrease in expenses resulted primarily from a decrease in employee expenses of $1,956,000. We achieved this decrease in expenses primarily related to reductions in our work force and overall cost cutting efforts. Additionally, facilities and office expenses decreased by $685,000 primarily as a result of the relocation of our corporate headquarters which was completed in the third quarter of 2001.

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 2001 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, primarily from the finance and manufacturing departments.

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The following table summarizes the restructuring activity *(in thousands)*:

	Personnel and Severance Costs	Lease and Other Contractual Commitments	Other Miscellaneous Costs	Total
Provisions	$ 655	$ 344	$ 304	$ 1,303
Payments	(655)	(252)	(176)	(1,083)
Non-cash charges		(52)	(116)	(168)
Reserve balance as of December 31, 2001		40	12	52
Payments		(40)		(40)
Non-cash charges			(12)	(12)
Reserve balance as of December 31, 2002	$	$	$	$

Interest and Other Income (Expense), Net

Interest and other income (expense), net is comprised of interest income, interest expense and our ownership interest in Microheart.

Interest income of $39,000 decreased $23,000 or 37% for the year ended December 31, 2002 when compared to $62,000 for the year ended December 31, 2001. This decrease was due to lower interest rates and lower investments in cash equivalents.

Interest expense of $13,000 decreased $5,000 or 28% for the year ended December 31, 2002 when compared to $18,000 for the year ended December 31, 2001. This decrease reflected a lower level of debt outstanding.

A gain on the sale of an investee of $2,285,000 for the year ended December 31, 2002 was related to the sale of our ownership interest in Microheart in April 2002. For the year ended December 31, 2001, the equity in net loss of $652,000 represented our share of the net loss of Microheart, in which our ownership was approximately 30% at the time the net loss was recorded.

Liquidity and Capital Resources

Cash and cash equivalents were $2,920,000 at September 30, 2004 compared to $1,013,000 at December 31, 2003, an increase of $1,907,000. We used $189,000 of cash for operating activities in the nine months ended September 30, 2004 primarily to fund our operating loss and to purchase laser inventory. Net inventories increased $367,000 to $1,706,000 at September 30, 2004 compared to $1,339,000 at December 31, 2003. This increase was primarily related to $386,000 in purchases of laser inventory.

Cash used in investing activities in the nine months ended September 30, 2004 was $235,000 due to the acquisition of property and equipment. Cash provided by financing activities was $2,331,000 due to sales of common stock from the exercise of stock options as well as the sale of equity securities described below.

On January 22, 2004, we sold 3,139,535 shares of common stock to private investors for a total price of $2,700,000. We also issued warrants to purchase 3,139,535 additional shares of common stock at a price of $1.37 per share. The warrants are immediately exercisable and have a term of five years.

We have incurred significant losses for the last several years and at September 30, 2004 we have an accumulated deficit of $165,879,000. Our ability to maintain current operations 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 sales, general and administrative expenses. Over the past three years, we have significantly reduced our cost of revenues, primarily due to the outsourcing of a significant portion of our manufacturing, which allows us to purchase products at lower costs. To reduce operating expenses, we have focused our efforts on reducing overall expenses in functions that are not essential to core and critical activities.

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Currently, our primary goals are to increase revenues, further clinical adoption of the TMR procedure, develop new products for our TMR platform, and achieve consistent profitability. Our actions have been guided by this initiative, 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.

On October 27, 2004, we completed a financing transaction with Laurus, pursuant to which we issued a secured convertible term note in the aggregate principal amount of $6.0 million and a warrant to purchase an aggregate of 2,640,000 shares of our common stock to Laurus in a private offering. Net proceeds to us from the financing, after payment of fees and expenses to Laurus and its affiliates, were $5,752,500, of which we received $2,875,250, with the remaining $2,877,250 deposited in a restricted cash account. Funds deposited in the restricted cash account will only be released to us, if at all, upon satisfaction of certain conditions.

The note matures on October 26, 2007 absent earlier redemption by us or earlier conversion by Laurus. Annual interest on the note is equal to the prime rate published in The Wall Street Journal from time to time, plus two percent (2.0%), provided, that, such annual rate of interest may not be less than six and one-half percent (6.5%), subject to certain downward adjustments resulting from certain increases in the market price of our common stock. Interest on the note is payable monthly in arrears on the first day of each month during the term of the note, commencing November 1, 2004. In addition, commencing May 1, 2005, we are required to make monthly principal payments of $100,000 per month. To the extent that funds are released from the restricted cash account prior to repayment in full of the unrestricted portion of the note proceeds, the monthly payment amount may be increased by an amount equal to the amount released from the restricted cash account divided by the remaining number of monthly principal payments due on or prior to the maturity date. The note is convertible into shares of our common stock at the option of Laurus and, in certain circumstances, at our option. A more detailed discussion of the terms of the Laurus financing is contained below under the heading Secured Convertible Debt Financing With Laurus.

We believe our cash balance as of September 30, 2004, when coupled with the proceeds of the note financing described above, will be sufficient to meet our capital and operating requirements through the next 15 months. We will have a continuing need for new infusions of cash if we incur losses in the future. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to 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 revenues or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented. We may be required to seek additional sources of financing in addition to the convertible debt financing described above, 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 that we will not have sufficient cash to fund our operations.

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The following summarizes our contractual obligations at September 30, 2004, and the effect, if any, such obligations are expected to have on our liquidity and cash flow in future periods:

		Payments due by period (In Thousands)			
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Long Term Debt (1)					
Capital Lease Obligations	$ 24	$ 5	$ 11	$ 8	
Operating Leases	758	364	394		
Purchase Obligations					
Other Long Term Liabilities Reflected on the Registrant s Balance Sheet under GAAP					
Total (1)	$782	$ 369	$ 405	$ 8	$

(1) Does not reflect the promissory note in the amount of $6,000,000 issued to Laurus Master Fund, Ltd. after September 30, 2004

Secured Convertible Debt Financing With Laurus

On October 27, 2004, we completed a financing transaction with Laurus, pursuant to which we issued a secured convertible term note (the Note) in the aggregate principal amount of $6.0 million and a warrant to purchase an aggregate of 2,640,000 shares of our common stock to Laurus in a private offering pursuant to exemption from registration under Section 4(2) of the Securities Act of 1933, as amended. The warrant has a fair value of approximately $900,000 at its grant date which will be recorded as deferred financing fees and is being amortized over the three year life of the Note. The Note may contain a beneficial conversion feature as well as a contingent beneficial conversion feature which may require the Company to record a discount on the Note related to the intrinsic value of the beneficial conversion feature(s). The amount of the discount(s), if any, would then be amortized to interest expense using the effective interest method over the life of the Note, or, in the event of conversion, to the first conversion date. Various features of the Note, explained in more detail below, may each represent an embedded derivative. Each embedded derivative would need to be initially recorded at fair value and then marked-to-market through the income statement each reporting period. As part of the financing, we paid Laurus Capital Management, LLC, the manager of Laurus, a closing payment equal to $216,000 plus due diligence and legal expenses of $29,500.

Net proceeds to us from the financing, after payment of fees and expenses to Laurus and its affiliates, were $5,752,500, of which we received $2,875,250, while the remaining $2,877,250 was deposited in a restricted cash account. Funds deposited in the restricted cash account will only be released to us, if at all, upon satisfaction of certain conditions described below.

The following describes certain of the material terms of the financing transaction with Laurus. The description below is not a complete description of the material terms of the financing transaction and is qualified in its entirety by reference to the agreements entered into in connection with the financing which are incorporated by reference as exhibits hereto.

Note Maturity Date and Interest Rate. The note matures on October 26, 2007 absent earlier redemption by us or earlier conversion by Laurus, as described below. Annual interest on the note is equal to the prime rate published in The Wall Street Journal from time to time, plus two percent (2.0%), provided, that, such annual rate of interest may

not be less than six and one-half percent (6.5%), subject to certain downward adjustments resulting from certain increases in the market price of the Common Stock.

Payment of Interest and Principal. Interest on the note is payable monthly in arrears on the first day of each month during the term of the note, commencing November 1, 2004. In addition, commencing May 1, 2005, we are required to make monthly principal payments of $100,000 per month (together, with monthly interest payments, the Monthly Payment Amount) on the portion of the $3,000,000 in principal that was not deemed restricted cash (the Amortizing Principal Amount). To the extent that funds are released from the restricted cash account prior to repayment in full of the Amortizing Principal Amount, the Monthly Payment Amount may be increased by an amount equal to the amount released from the restricted cash account divided by the remaining number of monthly principal payments due on or prior to the maturity date.

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Note Conversion Rights. All or a portion of the outstanding principal and interest due under the note may be converted into shares of our common stock upon satisfaction of certain conditions. The initial fixed conversion price under the note is $0.50 per share. The fixed conversion price is subject to anti-dilution protection adjustments, on a weighted average basis, upon our issuance of additional shares of Common Stock at a price that is less than the then current fixed conversion price (the fixed conversion price, together with any adjustments, is referred to hereunder as the Fixed Conversion Price).

Laurus may, at any time, convert the outstanding indebtedness of the Note into shares of our common stock at the then applicable conversion price.

Subject to the restrictions on conversion described below, Laurus shall be required to convert into shares of common stock the Monthly Payment Amount in the event that the average closing price of our common stock for the five trading days preceding the due date of a Monthly Payment Amount is greater than 110% of the Fixed Conversion Price, and the amount of such conversion does not exceed 35% of the aggregate dollar trading volume of our common stock for the 22 trading days preceding the payment date.

Subject to the restrictions on conversion described below, in the event that the average closing price of our common stock for the five trading days preceding the due date of a Monthly Payment Amount is less than 110% of the Fixed Conversion Price, then we may elect to require the conversion of the Monthly Payment Amount into shares of Common Stock at a conversion price equal to 90% of the average of the five lowest closing prices of the Common Stock during the twenty trading days immediately prior to the repayment; provided, however, that such conversion cannot exceed 35% of the aggregate dollar trading volume of our common stock for the 22 trading days preceding the payment date, and such conversion cannot be made if the conversion price for such conversion would be less than $.20 per share.

In the event that all or any portion of the Monthly Payment Amount is paid in cash, we shall be required to pay Laurus an amount equal to 103% of the principal amount of the cash portion of the Monthly Payment Amount being paid.

Release from Restricted Cash Account. $2,877,250 of the note proceeds have been deposited in a restricted cash account. To the extent that Laurus elects to voluntarily convert any portion of the note in excess of any amounts necessary to satisfy any Monthly Amounts then due and payable by us, the principal amount converted shall be deemed a conversion of the funds contained in the restricted cash account and a corresponding amount of cash shall be released to us from the restricted cash account.

Following repayment in full of the Amortizing Principal Amount, we may require Laurus to convert all or a portion of the remaining principal amount of the note (and release an equivalent amount of cash from the restricted cash account) (the Non-Amortizing Principal Amount). The conversion price in such circumstance shall be the Fixed Conversion Price if the average closing price of our common stock for the five trading days preceding the notice of conversion is greater than 110% of the Fixed Conversion Price, or a conversion price equal to 90% of the average of the five lowest closing prices of our Common Stock during the 20 trading days immediately prior to the conversion notice; provided, however, that in either case such conversion cannot exceed 35% of the aggregate dollar trading volume of our common stock for the 22 trading days preceding the payment date, and such conversion cannot be made if the conversion price for such conversion would be less than $.20 per share.

If the average closing price of our common stock is

greater than 125% of the Fixed Conversion Price for the 11 consecutive trading day period following payment in full of the Amortizing Principal Amount, upon receipt of notice from us, Laurus shall be required to convert the Non

Amortizing Principal Amount at the Fixed Conversion Price, provided, however, that such conversion shall not exceed 15% of the aggregate dollar trading volume of the common stock for the 22 trading days immediately preceding delivery of such notice;

greater than 150% of the then applicable Fixed Conversion Price for the 11 consecutive trading day period following payment in full of the Amortizing Principal Amount, upon receipt of notice from us, Laurus shall be required to convert the Non Amortizing Principal Amount at the then applicable Fixed Conversion Price, provided, however, that conversion of such Non Amortizing Principal Amount shall not exceed 25% of the aggregate dollar trading volume of the common stock for the 22 trading days immediately preceding delivery of such notice; or

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greater than 175% of the then applicable Fixed Conversion Price for the 11 consecutive trading day period following payment in full of the Amortizing Principal Amount, upon receipt of notice from us, Laurus shall be required to convert the Non Amortizing Principal Amount at the then applicable Fixed Conversion Price, provided, however, that conversion of such Non Amortizing Principal Amount shall not exceed 35% of the aggregate dollar trading volume of the common stock for the 22 trading days immediately preceding delivery of such notice.

Notices of conversion of the Non-Amortizing Principal Amount may not be delivered by us more than once per calendar month.

As a result of the foregoing restrictions, there can be no assurances that we will have access to or use of the funds in the restricted cash accounts if and when needed.

Warrant Terms. The Warrant grants Laurus the right to purchase up to 2,640,000 shares of our common stock at an exercise price of $0.50 per share. The Warrant expires on October 26, 2011 and may be exercised by the payment of cash or on a cashless basis through a reduction in the shares otherwise issuable upon exercise having a fair market value equal to the aggregate exercise price for the portion of the Warrant being exercised on a cashless basis.

Restrictions on Conversion of Note and Exercise of Warrant. Notwithstanding anything to the contrary set forth above, we may pay amounts due under the note in shares of our common stock only so long as there is an effective registration statement on file covering the resale of such shares or an exemption from such registration is available under Rule 144 of the Securities Act. In addition, Laurus is not entitled to receive shares upon exercise of the Warrant, upon payment of principal and interest on the note, or upon conversion of the note if such receipt would cause Laurus to be deemed to beneficially own in excess of 4.99% of the outstanding shares of our common stock on the date of issuance of such shares. Such provision may be waived by Laurus upon 75 days prior written notice to us.

Right to Redeem Note. We have the option of prepaying the outstanding Amortizing Principal Amount in whole or in part by paying an amount equal to 130% of the principal amount being redeemed by giving at least 12 business days prior written notice of redemption to Laurus. In addition, we have the option of prepaying the outstanding Non-Amortizing Principal Amount in whole or in part by paying an amount equal to 120% of the Non-Amortizing Principal Amount to be redeemed by giving at least seven business days prior written notice of redemption.

Security for Note. The note is secured by a blanket lien on substantially all of our assets, including the restricted cash account, pursuant to the terms of a security agreement executed by us. If an event of default occurs under the security agreement or note, Laurus has the right to accelerate payments under the note and, in addition to any other remedies available to it, foreclose upon the assets securing the note.

Registration Rights. Pursuant to the terms of a Registration Rights Agreement between Laurus and us, we are obligated to file this registration statement and have the registration statement declared effective on or prior to February 23, 2005. If the registration statement is not declared effective by that date, or if the registration is suspended other than as permitted, in the registration rights agreement, we will be obligated to pay Laurus a fee equal to 1.5% of the aggregate original principal amount of the note for each 30 day period (pro rated for partial periods) that such registration conditions are not satisfied.

Right of Laurus to Make an Additional Investment. We have granted Laurus the right, until February 23, 2005, to complete an additional financing of up to $2 million on substantially the same terms and conditions as the financing transaction described above. We and Laurus have agreed that $1 million of such additional financing was completed as part of the initial financing.

Right of First Refusal. Subject to certain exceptions, we have granted Laurus a right of first refusal to provide additional financing to us in the event that we propose to complete additional debt financing or to sell any of our equity securities.

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Additional Restrictions. The financing documents contain certain restrictions regarding our operations while the note remains outstanding. Such restrictions include our agreement that, except with Laurus prior written consent (such consent not to be unreasonably withheld), we will not issue any debt securities with a continuously variable/floating conversion feature which are or could be (by conversion or registration) free-trading securities, or any equity securities with a continuously variable/floating conversion feature which are or could be (by conversion or registration) free-trading securities, provided that no consent shall be necessary on the issuance of equity securities having such a variable/floating conversion feature where the conversion price is subject to a specified minimum floor price per share.

In addition, the financing documents, among other things prohibit us from paying dividends or redeeming shares, and prohibit us from incurring additional debt other than

- inventory and equipment financing of $1.5 million in any 12 month period;
- trade debt arising in the ordinary course of business;
- subordinated unsecured debt less than $5 million in the aggregate;
- debt incurred in connection with the purchase of assets in the ordinary course;
- debt subordinated to the debt to Laurus (on terms reasonably acceptable to Laurus) incurred in connection with acquisitions, product launches, research and development projects and similar purposes;

Critical Accounting 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.

The following presents a summary of our critical accounting policies, defined as those policies we believe are: (i) the most important to the portrayal of our financial condition and results of operations, and (ii) that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

Revenue Recognition:

We recognize revenue on product sales upon receipt of a purchase order, shipment of the products, 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 under our standard FOB shipping point terms, 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. The loaned lasers are depreciated to cost of revenues over a useful life of 24 months. The revenue on the 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, rentals, and per procedure fees are recognized upon performance or over the terms of the contract as appropriate.

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Accounts Receivable:

We regularly evaluate the collectability of accounts receivable based upon our knowledge of customers and compliance with credit terms. The allowance for doubtful accounts is adjusted based on such evaluation, with a corresponding provision included in general and administrative expenses.

Inventories:

Inventories are stated at the lower of cost (principally standard cost, which approximates actual cost on a first-in, first-out basis) or market value.

Income Taxes:

We account for income taxes using the liability method under which deferred tax assets or liabilities are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

Quantitative and Qualitative Disclosures About Market Risk

Quantitative Disclosures

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of its marketable securities or its debt instruments. We have no holdings of derivative or commodity instruments.

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents and any future financing requirements. The long-term debt at September 30, 2004 consists of an outstanding balance on a lease obligation. On October 26, 2004, we completed a financing transaction pursuant to which we issued a $6.0 million secured convertible promissory note to an investment fund. Interest on such promissory note is adjustable based on changes in the applicable prime rate. Accordingly, in future quarters, we may be subject to increased interest rate risks as a result of such financing.

The following table presents the future principal cash flows or amounts and related weighted average interest rates expected by year for our existing cash and cash equivalents and long-term debt instruments as of September 30, 2004:

In Thousands, unaudited	**2004**	**2005**	**2006**	**2007**	**2008**	**Total Fair Value**
Assets						