CARDIOGENESIS CORP /CA
Form 424B3
January 18, 2005

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This filing is made pursuant to
Rule 424(b)(3) under the Securities Act of 1933
in connection with Registration No. 333-121625

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 14, 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,

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

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

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 eotal permanent

disability, a holder may request that we repurchase one or more of the holders' notes prior to maturity, in whole and not in part, at any time by giving us written notice. Subject to approval, at our sole discretion, and the limitations described below, we will repurchase the holder's note(s) specified in the notice within 10 days of receipt of the notice. The repurchase price, in the event we elect to repurchase the notes, will be the principal amount of the note, plus interest accrued and not previously paid (up to but not including the date of repurchase), minus a repurchase penalty. The early repurchase penalty for a note with a three month maturity is the interest accrued on such note up to the date of repurchase, not to exceed three months of simple interest at the existing rate. The early repurchase penalty for a note with a maturity of six months or longer is the interest accrued on such note up to the date of repurchase, not to exceed six months of simple interest at the existing rate. The penalty for early repurchase may be waived or reduced at the discretion of our servicing agent.

Limitations on requirements to repurchase. Our obligation to repurchase notes prior to maturity for any reason will be subject to a calendar quarter limit equal to the greater of $1 million or 2% of the total principal amount of all notes outstanding at the end of the previous calendar quarter. This limit includes any notes we repurchase upon death or total permanent disability of the holder and any notes that we repurchase pursuant to the holders' right to elect repurchase. Repurchase requests will be honored in the order in which they are received, to the extent possible, and any repurchase request not honored in a calendar quarter will be honored in the next calendar quarter, to the extent possible, since repurchases in the next calendar quarter are also subject to these limits. For purposes of determining the order in which repurchase requests are received, a repurchase request will be deemed made on the later of the date on which it is received by us or, if applicable, the date on which the death or total permanent disability is established to our reasonable satisfaction.

Modifications to repurchase policy. We may modify the policies on repurchase in the future. No modification will affect the right of repurchase applicable to any note outstanding at the time of any such modification.

Transfers

The notes are not negotiable debt instruments and, subject to certain exceptions, will be issued only in book-entry form. The purchase confirmation issued upon our acceptance of a subscription is not a certificated security or negotiable instrument, and no rights of record ownership can be transferred without our prior written consent. Ownership of notes may be transferred on our register only as follows:

The holder must deliver written notice requesting a transfer to our servicing agent signed by the holder(s) or such holder's duly authorized representative on a form to be supplied by our servicing agent.

We must provide our written consent to the proposed transfer.

We or our servicing agent may require a legal opinion from counsel satisfactory to the servicing agent that the proposed transfer will not violate any applicable securities laws.

We or our servicing agent may require a signature guarantee in connection with such transfer.

Upon transfer of a note, our servicing agent will provide the new holder of the note with a purchase confirmation that will evidence the transfer of the account on our records. We or our servicing agent may charge a reasonable service charge in connection with the transfer of any note.

Quarterly Statements; Investor Relations

Our servicing agent will provide holders of the notes with quarterly statements, which will indicate, among other things, the account balance at the end of the quarter, interest credited, redemptions or repurchases made, if any, and the interest rate paid during the quarter. These statements will be mailed not later than the 10th business day following the end of each calendar quarter. Our servicing agent may charge such holders a reasonable fee to cover the charges incurred in providing such information.

Our servicing agent will also manage customer service and investor relations with respect to the notes. The servicing agent will manage:

Prospectus delivery and subscription procedures;

Inquiries from note holders;

Changes in address or account changes for note holders;

Preparing and issuing renewal and maturity notices for outstanding notes;

Reports and analyses to us, the trustee and note holders as applicable.

The servicing agent will also direct the paying agent to make interest and principal payments on the notes, and direct the trustee to issue Form 1099INTs to note holders. The servicing agent expects to develop a web site to facilitate online offers and sales of notes.

Subordination

The indebtedness evidenced by the notes, and any interest thereon, is subordinated in right of payment to all of our senior debt. "Senior debt" means all of our secured, unsecured, senior or subordinate indebtedness including commitments to extend senior debt, as well as other financial obligations of the company, whether outstanding on the date of this prospectus or incurred after the date of this prospectus, whether such indebtedness is or is not specifically designated as being senior debt in its defining instruments, other than the existing notes and future offerings of additional renewable unsecured subordinated notes issued under this indenture which will rank equally with the notes. Senior debt also includes discounted lease rentals that we have incurred in the past and will incur in the future from time to time.

The provisions of the indenture governing subordination of the notes to senior debt may not be amended or terminated without the consent of each holder of senior debt. Also, the subordination provisions cannot be terminated or revoked until all senior debt is paid in full and all commitments to extend senior debt have terminated.

Until all of our senior debt has been fully paid and all obligations of any senior lender to extend credit to us have terminated, we cannot provide holders of the notes or the trustee with any security or guarantee of payment of the notes. In addition, if the trustee or note holders obtain any security for repayment from us while senior debt is outstanding, any senior debt holder is entitled to have such security terminated and assigned to senior debt holders. The indenture prevents note holders or the trustee from challenging the priority or validity of any senior debt holders' lien over our assets or senior debt holders' priority over note holders in any legal proceeding. Any documents, agreements or instruments evidencing or relating to any senior debt may be amended, restated, supplemented and/or renewed from time to time without requiring any notice to or consent of any holder of notes or any person or entity acting on behalf of any such holder or the trustee.

The indenture does not prevent holders of senior debt from disposing of, or exercising any other rights with respect to, any or all of the collateral securing the senior debt. As of December 29, 2007, we had approximately $16.2 million of outstanding indebtedness under a facility that permits us to draw up to $25 million from time to time and up to $50 million if we satisfy certain conditions. We and our

subsidiaries have granted LaSalle Bank a continuing security interest in all assets that we currently hold or subsequently acquire to secure our obligations under the credit facility.

We have in the past, and expect in the future to enter into payment arrangements in connection with acquisitions or investments that may involve contingent obligations or commitments. We also have in the past, and will in the future enter into non-recourse discounting of lease rentals with financial institutions at fixed interest rates. Our obligations under these types of arrangements may continue for several years following an acquisition, investment or lease, and will rank senior to your notes. The terms of the notes or the indenture do not impose any limitation on the amount of senior debt or other indebtedness we may incur, although our existing senior debt agreements may restrict us from incurring new senior debt.

The notes are not guaranteed by any of our subsidiaries. Accordingly, in the event of a liquidation or dissolution of one of our subsidiaries, creditors of that subsidiary will be paid in full, or provision for such payment will be made, from the assets of that subsidiary prior to distributing any remaining assets to us as a shareholder of that subsidiary. Therefore, in the event of liquidation or dissolution of a subsidiary, no assets of that subsidiary may be used to make payment to the holders of the notes until the creditors of that subsidiary are paid in full from the assets of that subsidiary.

In the event of any liquidation, dissolution or any other winding up of us, or of any receivership, insolvency, bankruptcy, readjustment, reorganization or similar proceeding under the U.S. Bankruptcy Code or any other applicable federal or state law relating to bankruptcy or insolvency, or during the continuation of any event of default on the senior debt, no payment may be made on the notes until all senior debt has been paid in full or provision for such payment has been made to the satisfaction of the senior debt holders. If any of the above events occurs, holders of senior debt may also submit claims on behalf of holders of the notes and retain the proceeds for their own benefit until they have been fully paid, and any excess will be turned over to the holders of the notes. If any distribution is nonetheless made to holders of the notes, the money or property distributed to them must be paid over to the holders of the senior debt to the extent necessary to pay senior debt in full.

We will not make any payment, direct or indirect (whether for interest, principal, as a result of any redemption or repurchase, at maturity, on default, or otherwise), on the notes and any other indebtedness being subordinated to the payment of the notes, and neither the holders of the notes nor the trustee will have the right, directly or indirectly, to sue on or to enforce the indenture or the notes, if a default or event of default under any senior debt has occurred and is continuing, or if any default or event of default under any senior debt would result from such payment, in each case unless and until:

- all defaults and events of default have been cured or waived or have ceased to exist and would not result from any payment on the notes; or
- the end of the period commencing on the date the trustee receives written notice of default from a holder of the senior debt and ending on the earlier of:
  - the trustee's receipt of a valid waiver of default from the holder of senior debt; or
  - the trustee's receipt of a written notice from the holder of senior debt terminating the payment blockage period.

Provided, however, that if any of the blockage events described above has occurred, a senior debt holder may not block payments for more than 180 days out of any 360 day period. But, this 180-day limit applies only to senior debt holders that join in a notice to block payment due to a senior debt default. If other senior debt holders do not join or give notice of a payment blockage, these non-joining senior debt holders may, if applicable, assert a default and a 180-day period will be calculated in accordance with the notice of default provided by such non-joining senior debt holder.

In addition to being unable to make payments on the notes, in case of default on any senior debt, we cannot issue any new notes or renew any existing notes without a waiver from the holder of senior debt or a written notice from the senior debt holder terminating the payment blockage period.

Following, waiver or termination of all blockage periods described above, the trustee may thereafter sue on and enforce the indenture and the notes as long as any funds paid as a result of any such suit or enforcement action shall be paid toward the senior debt until it is indefeasibly paid in full before being applied to the notes.

Until all senior debt is paid in full or commitments to extend senior debt have terminated, note holders cannot exercise any right to subrogate, or stand in the shoes, of a senior debt holder with respect to any distributions on senior debt. The indenture also requires that note holders agree that senior debt holders have no liability to note holders for actions that senior debt holders take in good faith to assert a default on senior debt, collect senior debt or foreclose on security on senior debt.

No Security; No Sinking Fund

The notes are unsecured, which means that none of our tangible or intangible assets or property, nor any of the assets or property of any of our subsidiaries, has been set aside or reserved to make payment to the holders of the notes in the event that we default on our obligations to the holders. In addition, we will not contribute funds to any separate account, commonly known as a sinking fund, to repay principal or interest due on the notes upon maturity or default.

Restrictive Covenants

The indenture contains certain limited restricted covenants that require us to maintain certain financial standards and restrict us from certain actions as set forth below.

The indenture provides that, so long as the notes are outstanding:

- we will maintain a positive net worth; and
- we will not declare or pay any dividends or other payments of cash or other property to our shareholders (other than a dividend paid in shares of our capital stock on a pro rata basis to all our shareholders) unless no default and no event of default with respect to the notes exists or would exist immediately following the declaration or payment of the dividend or other payment.

Consolidation, Merger or Sale

The indenture generally permits a consolidation or merger between us and another entity. It also permits the sale or transfer by us of all or substantially all of our property and assets. These transactions are permitted if:

- the resulting or acquiring entity, if other than us, is a United States corporation, limited liability company or limited partnership and assumes all of our responsibilities and liabilities under the indenture, including the payment of all amounts due on the notes and performance of the covenants in the indenture; and
- immediately after the transaction, and giving effect to the transaction, no event of default under the indenture exists.

If we consolidate or merge with or into any other entity or sell or lease all or substantially all of our assets, according to the terms and conditions of the indenture, the resulting or acquiring entity will be substituted for us in the indenture with the same effect as if it had been an original party to the indenture. As a result, the successor entity may exercise our rights and powers under the indenture, in

our name and we will be released from all our liabilities and obligations under the indenture and under the notes.

Events of Default

The indenture provides that each of the following constitutes an event of default:

- failure to pay interest on a note within 15 days after the due date for such payment (whether or not prohibited by the subordination provisions of the indenture);
- failure to pay principal on a note within 10 days after the due date for such payment (whether or not prohibited by the subordination provisions of the indenture);
- our failure to observe or perform any material covenant, condition or agreement or our breach of any material representation or warranty, but only after we have been given notice of such failure or breach and such failure or breach is not cured within 30 days after our receipt of notice;
- defaults in certain of our other financial obligations that are not cured within 30 days; and
- certain events of bankruptcy or insolvency with respect to us.

If any event of default occurs and is continuing (other than an event of default involving certain events of bankruptcy or insolvency with respect to us), the trustee or the holders of at least a majority in principal amount of the then outstanding notes may by notice to us declare the unpaid principal of and any accrued interest on the notes to be due and payable immediately. So long as any senior debt is outstanding, however, and a payment blockage on the notes is in effect, a declaration of this kind will not be effective, and neither the trustee nor the holders of notes may enforce the indenture or the notes, except as otherwise set forth above in " Subordination". In the event senior debt is outstanding and no payment blockage on the notes is in effect, a declaration of this kind will not become effective until the earlier of:

- the day which is five business days after the receipt by us and the holders of senior debt of such written notice of acceleration; or
- the date of acceleration of any senior debt.

In the case of an event of default arising from certain events of bankruptcy or insolvency, with respect to us, all outstanding notes will become due and payable without further action or notice. Holders of the notes may not enforce the indenture or the notes except as provided in the indenture. Subject to certain limitations, holders of a majority in principal amount of the then outstanding notes may direct the trustee in its exercise of any trust or power. The trustee may withhold from holders of the notes notice of any continuing default or event of default (except a default or event of default relating to the payment of principal or interest) if the trustee in good faith determines that withholding notice would have no material adverse effect on the holders.

The holders of a majority in aggregate principal amount of the notes then outstanding by notice to the trustee may, on behalf of the holders of all of the notes, waive any existing default or event of default and its consequences under the indenture, except:

- a continuing default or event of default in the payment of interest on, or the principal of, a note held by a non-consenting holder; or
- a waiver that would conflict with any judgment or decree.

We are required to deliver to the trustee within 120 days of the end of our fiscal year a certificate regarding compliance with the indenture, and we are required, upon becoming aware of any default or

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event of default, to deliver to the trustee a certificate specifying such default or event of default and what action we are taking or propose to take with respect to the default or event of default.

Amendment, Supplement and Waiver

Except as provided in this prospectus or the indenture, the terms of the indenture or the notes then outstanding may be amended or supplemented with the consent of the holders of at least a majority in principal amount of the notes then outstanding, and any existing default or compliance with any provision of the indenture or the notes may be waived with the consent of the holders of a majority in principal amount of the then outstanding notes.

Notwithstanding the foregoing, an amendment or waiver with any of the following consequences will not be effective unless each note holder consents:

reduces the aggregate principal amount of notes whose holders must consent to an amendment, supplement or waiver;

reduces the principal of or changes the fixed maturity of any note or alters the repurchase or redemption provisions or the price at which we shall offer to repurchase or redeem the note;

reduces the rate of or changes the time for payment of interest, including default interest, on any note;

waives a default or event of default in the payment of principal or interest on the notes, except a rescission of acceleration of the notes by the holders of at least a majority in aggregate principal amount of the then outstanding notes and a waiver of the payment default that resulted from such acceleration;

makes any note payable in money other than that stated in this prospectus;

makes any change in the provisions of the indenture relating to waivers of past defaults or the rights of holders of notes to receive payments of principal of or interest on the notes;

makes any change to the subordination provisions of the indenture that has a material adverse effect on holders of notes;

modifies or eliminates the right of the estate of a holder or a holder to cause us to repurchase a note upon the death or total permanent disability of a holder; or

makes any change in the foregoing amendment and waiver provisions.

Notwithstanding the foregoing, without the consent of any holder of the notes, we and the trustee may amend or supplement the indenture or the notes:

to cure any ambiguity, defect or inconsistency;

to provide for assumption of our obligations to holders of the notes in the case of a merger, consolidation or sale of all or substantially all of our assets;

to provide for additional uncertificated or certificated notes;

to make any change that does not adversely affect the legal rights under the indenture of any such holder, including but not limited to an increase in the aggregate dollar amount of notes which may be outstanding under the indenture;

to modify our policy regarding repurchases elected by a holder of notes prior to maturity and our policy regarding repurchase of the notes prior to maturity upon the death or total permanent disability of any holder of the notes, but such modifications shall not materially adversely affect any then outstanding notes; or

to comply with requirements of the SEC in order to effect or maintain the qualification of the indenture under the Trust Indenture Act.

The Trustee

Wells Fargo Bank, National Association has agreed to be the trustee under the indenture. The indenture contains certain limitations on the rights of the trustee, should it become one of our creditors, to obtain payment of claims in certain cases, or to realize on certain property received in respect of any claim as security or otherwise. The trustee will be permitted to engage in other transactions with us.

Subject to certain exceptions, the holders of a majority in principal amount of the then outstanding notes will have the right to direct the time, method and place of conducting any proceeding for exercising any remedy available to the trustee. The indenture provides that in case an event of default specified in the indenture shall occur and not be cured, the trustee will be required, in the exercise of its power, to use the degree of care of a reasonable person in the conduct of his own affairs. Subject to such provisions, the trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request of any holder of notes, unless the holder shall have offered to the trustee security and indemnity satisfactory to it against any loss, liability or expense.

Resignation or Removal of the Trustee

The trustee may resign at any time, or may be removed by the holders of a majority of the aggregate principal amount of the outstanding notes. In addition, upon the occurrence of contingencies relating generally to the insolvency of the trustee or the trustee's ineligibility to serve as trustee under the Trust Indenture Act of 1939, as amended, we may remove the trustee. However, no resignation or removal of the trustee may become effective until a successor trustee has accepted the appointment as provided in the indenture.

Reports to Trustee

Our servicing agent will provide the trustee with quarterly reports containing any information reasonably requested by the trustee. These quarterly reports will include information on each note outstanding during the preceding quarter, including outstanding principal balance, interest credited and paid, transfers made, any redemption or repurchase and interest rate paid.

No Personal Liability of our or our Servicing Agent's Directors, Officers, Employees and Shareholders

No director, officer, employee, incorporator or shareholder of ours or our servicing agent, will have any liability for any of our obligations under the notes, the indenture or for any claim based on, in respect to, or by reason of, these obligations or their creation. Each holder of the notes waives and releases these persons from any liability, including any liability arising under applicable securities laws. The waiver and release are part of the consideration for issuance of the notes. We have been advised that the waiver may not be effective to waive liabilities under the federal securities laws and it is the view of the SEC that such a waiver is against public policy.

Service Charges

We and our servicing agent may assess service charges for changing the registration of any note to reflect a change in name of the holder, multiple changes in interest payment dates or transfers (whether by operation of law or otherwise) of a note by the holder to another person.

Additional Securities

We may offer additional classes of securities with terms and conditions different from the notes currently being offered in this prospectus. We will amend or supplement this prospectus if and when we decide to offer to the public any additional class of security under this prospectus. If we sell the entire

principal amount of notes offered in this prospectus, we may register and sell additional notes by amending this prospectus, but we are under no obligation to do so.

Variations by State

We may offer different securities and vary the terms and conditions of the offer (including, but not limited to, different interest rates and service charges for all notes) depending upon the state where the purchaser resides.

Interest Withholding

We will withhold 28% (which rate is scheduled to increase to 31% for payments made after December 31, 2010) of any interest paid to any investor who has not provided us with a social security number, employer identification number, or other satisfactory equivalent in the subscription agreement (or another document) or where the Internal Revenue Service has notified us that backup withholding is otherwise required. See "Material Federal Income Tax Consequences Reporting and Backup Withholding."

Lack of Liquidity

There is not currently a trading market for the notes, and we do not expect that a trading market for the notes will develop.

Satisfaction and Discharge of Indenture

The indenture shall cease to be of further effect upon the payment in full of all of the outstanding notes and the delivery of an officer's certificate to the trustee stating that we do not intend to issue additional notes under the indenture or, with certain limitations, upon deposit with the trustee of funds sufficient for the payment in full of all of the outstanding notes.

Reports

We currently file annual reports on Form 10-K containing financial statements and quarterly reports on Form 10-Q containing financial information for the first three quarters of each fiscal year. We also furnish or file current reports on Form 8-K for certain events involving our business. We will send copies of these reports, at no charge, to any holder of notes who requests them in writing.

Paying Agent

We have appointed Wells Fargo to serve as paying agent for the notes. At our or the servicing agent's direction, Wells Fargo will pay principal and interest on the notes under the terms of any applicable note, pursuant to the indenture and prospectus. Wells Fargo must pay only amounts that we deposit for payment on the notes. We will pay all fees and expenses in connection with the paying agent's services. Wells Fargo must maintain certain records of note holders' subscriptions and payments. We have also agreed to indemnify Wells Fargo against any claims that arise from its services as paying agent except for claims resulting from the paying agent's negligence, bad faith or willful misconduct.

MATERIAL FEDERAL INCOME TAX CONSEQUENCES

The following discussion describes the material federal income tax consequences relating to the purchase of the notes from us and ownership and disposition of the notes. The discussion is based upon the current provisions of the Internal Revenue Code of 1986, as amended (the "Code"), regulations issued under the Code and judicial or ruling authority, all of which are subject to change that may be applied retroactively. The discussion does not deal with note owners other than original

purchasers from us. The discussion assumes that the notes are held as capital assets within the meaning of Section 1221 of the Code and does not discuss the federal income tax consequences applicable to all categories of investors, including banks, tax-exempt organizations, insurance companies, dealers in securities or currencies, persons that will hold notes as a position in a hedging, straddle or conversion transactions, or persons that have a functional currency other than the U.S. dollar, some of which may be subject to special rules. If a partnership holds notes, the tax treatment of a partner will generally depend on the status of the partner and on the activities of the partnership. Our counsel is of the opinion that the following discussion of federal income tax consequences is correct in all material respects. An opinion of our counsel, however, is not binding on the Internal Revenue Service or the courts, and no rulings on any of the issues discussed below will be sought from the Internal Revenue Services. **You should consult your own tax advisor to determine the specific federal, state, local and any other tax consequences applicable to you relating to your purchase, ownership and disposition of the notes.**

Interest Income On The Notes

Subject to the discussion below applicable to "non-U.S. holders," stated interest on a note will be includible in your gross income as ordinary interest income at the time it is accrued or received in accordance with your method of accounting for United States federal income tax purposes.

If you hold a note issued with original issue discount ("OID"), the provisions of Sections 1271 through 1273 and 1275 of the Code will apply to that note. In general, a note will be issued with OID if its term exceeds one year and interest is paid at maturity. Even if you are a cash method holder, you must include in your gross income, as ordinary income, the daily portion of such OID attributable to each day that you hold the note pursuant to the applicable Code Sections and Treasury regulations promulgated thereunder. This requirement generally will result in the accrual of income before the receipt of cash attributable to that income.

Treatment Of Dispositions Of Notes

Upon the sale, exchange, retirement or other taxable disposition of a note, you will recognize taxable gain or loss in an amount equal to the difference between the amount realized on the disposition and your adjusted tax basis in the note. Your adjusted tax basis of a note generally will equal your original cost for the note, increased by any accrued but unpaid interest you previously included in income with respect to the note and reduced by any principal payments you previously received with respect to the note. Any gain or loss will be capital gain or loss, except for gain representing accrued interest not previously included in your income. The capital gain or loss will be long-term capital gain or loss if the note has been held for more than one year. Capital gain or loss from a note held for one year or less will be short-term capital gain or loss. Capital losses generally may be used only to offset capital gains.

Non-U.S. Holders

Generally, if you are a nonresident alien individual or a non-U.S. corporation and do not hold the note in connection with a United States trade or business, interest paid or accrued on the notes will be treated as "portfolio interest" and therefore will be exempt from United States federal income tax. In that case, you will be entitled to receive interest payments on the notes free of United States federal income tax provided that you periodically provide us with a statement on applicable IRS forms certifying under penalty of perjury that you are not a United States person and provide your name and address. In addition, in that case you will not be subject to United States federal income tax on gain from the disposition of a note unless you are an individual who is present in the United States for 183 days or more during the taxable year in which the disposition takes place and certain other requirements are met. Interest paid to or accrued by a non-U.S. person are not subject to

U.S. withholding tax if the income is effectively connected with a United States trade or business conducted by that person and we are provided a properly executed IRS Form W-8ECI. Such "effectively connected income" will, however, generally be subject to the regular United States income tax. Holders of notes should consult their tax advisors regarding the procedures whereby they may establish an exemption from withholding.

Reporting And Backup Withholding

We will report annually to the Internal Revenue Service and to holders of record that are not exempted from the reporting requirements any information that may be required with respect to interest paid or required to be accrued on the notes. Under certain circumstances, as a holder of a note, you may be subject to "backup withholding" currently at a 28% rate. Under current law, after December 31, 2010, the backup withholding rate is scheduled to increase to 31%. Backup withholding may apply to you if you are a United States person and, among other circumstances, you fail to furnish on IRS Form W-9 or a substitute Form W-9 your Social Security number or other taxpayer identification number to us. Backup withholding may apply, under certain circumstances, if you are a non-U.S. person and fail to provide us with the statement necessary to establish an exemption from federal income and withholding tax on interest on the note. Backup withholding, however, does not apply to payments on a note made to certain exempt recipients, such as corporations and tax-exempt organizations, and to certain non-U.S. persons. Backup withholding is not an additional tax and may be refunded or credited against your United States federal income tax liability, provided that you furnish certain required information.

This federal tax discussion is included for general information only and may not be applicable depending upon your particular situation. You should consult your own tax advisor with respect to the specific tax consequences to you of the purchase, ownership and disposition of the notes, including the tax consequences under state, local, foreign and other tax laws and the possible effects of changes in federal or other tax laws.

PLAN OF DISTRIBUTION

Under the terms and subject to the conditions contained in a distribution and management agreement between us and Sumner Harrington Ltd., Sumner Harrington Ltd. has agreed to serve as our selling agent and to use its best efforts to sell the notes on the terms set forth in this prospectus. The selling agent is not obligated to sell any minimum amount of notes or to purchase any of the notes.

The selling agent proposes to offer the notes to the public on our behalf on the terms set forth in this prospectus and the prospectus supplements that we file from time to time. The selling agent plans to market the notes directly to the public through newspaper, radio, internet, direct mail and other advertising. In addition, our selling agent will manage certain administrative and customer service functions relating to the notes, including handling all inquiries from potential investors, mailing investment kits, meeting with investors, processing subscription agreements and responding to all written and telephonic questions relating to the notes. Upon prior written notice to the selling agent, we may elect to use a different selling agent or perform these duties ourselves. The selling agent's servicing responsibilities are described under "Description of the Notes Servicing Agent."

We have agreed to reimburse the selling agent for its out-of-pocket expenses incurred in connection with the offer and sale of the notes, including document fulfillment expenses, legal and accounting fees, regulatory fees, due diligence expenses and marketing costs. Under the terms of the distribution and management agreement, we also will pay our selling agent a commission equal to 3.00% of the principal amount of all notes sold other than on notes sold to certain of our affiliates for which we pay no commission. For notes with maturities of two years or more, the entire

3.00% commission will be paid to the selling agent at the time of issuance and no additional commission will be paid upon renewal. For notes with maturities of less than two years, the gross 3.00% commission will be paid in pro rata installments upon the original issuance and each renewal, if any, over the first two years. Accordingly, the selling agent will not receive the entire 3.00% gross commission on notes with terms of less than two years unless the notes are successively renewed for two years. The selling agent may engage or allow selected brokers or dealers to sell notes for a commission, at no additional cost to us.

Under the distribution and management agreement, we have also agreed to pay Sumner Harrington Ltd. an annual portfolio management fee equal to 0.25% of the weighted average principal balance of the notes outstanding for its services as servicing agent. In exchange for the annual portfolio management fee, Sumner Harrington Ltd. will manage all customer service functions concerning the notes and act as an agent between us and the purchasers and holders of the notes. The annual portfolio management fee also covers all costs relating to maintenance of the investor relationship after the purchase of notes. This includes, among other things, addressing all investor inquires regarding the notes, the preparation of all confirmations, notices and statements to purchasers and holders of the notes, the coordination of interest payments with us and the paying agent, the establishment and maintenance of records relating to the notes, the preparation of all reports, statements and analyses regarding the notes, and all out-of-pocket expenses for the printing and mailing of confirmations, notices and statements to the purchasers and holders of the notes. See "Description of the Notes Servicing Agent." This ongoing fee will be paid monthly. The amount of this fee will depend upon a number of variables, including the pace at which notes are sold, the terms of the notes sold and whether the notes are redeemed or repurchased.

The distribution and management agreement may be terminated by either us or Sumner Harrington Ltd. upon giving prior notice.

The selling agent will only be compensated to the extent that notes are sold in the offering. The table below summarizes the maximum possible amounts of compensation or reimbursement that we will pay the selling agent for services rendered in offering and selling the notes and serving as the servicing agent with regard to the notes. While actual amounts may differ from the percentages and amounts shown in the table, in no event will the total commission plus the total cost of the remaining line items exceed 6.00% of the aggregate principal amount of the notes sold. Further, in no event will the aggregate portfolio management fee exceed 2.25% of the aggregate principal amount of the notes sold, nor will the total of all other items of compensation or reimbursement exceed 0.75% of the aggregate principal amount of the notes sold.

Compensation and Reimbursement	% of Offering	Amount(1)
Total commissions	3.00%(2)	$ 1,500,000
Selling agent's legal counsel fees	0.15%	$ 75,000
Document fulfillment expenses	0.60%	$ 300,000
Maximum portfolio management fee	2.25%	$ 1,125,000
Total	6.00%	$ 3,000,000

(1) All amounts assume the sale of 100% of aggregate principal amount of notes offered and represent the maximum possible amount payable to the selling agent or its affiliate over the entire term of the offering. If less than 100% of the aggregate principal amount of the notes are sold in the offering, the amounts actually paid to the agent for commissions and annual portfolio management fees will be less. In no event will the compensation paid to the selling agent for commissions, annual portfolio management fees and other categories exceed the percentage amounts shown, as applied to the notes actually sold.

(2) Assumes that each note with a term of less than two years is successively renewed for a total of two years.

The distribution and management agreement provides for reciprocal indemnification between us and the selling agent, including the selling agent's and our officers, directors and controlling persons, against civil liabilities in connection with this offering, including certain liabilities under the Securities Act of 1933, as amended. Insofar as indemnification for liabilities arising under the Securities Act may be permitted pursuant to such indemnification provisions, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Prior to the offering, there has been no public market for the notes. We do not intend to list the notes on any securities exchange or include them for quotation on Nasdaq. The selling agent is not obligated to make a market in the notes and does not intend to do so. We do not anticipate that a secondary market for the notes will develop.

The foregoing is a summary of the material provisions relating to selling and distribution of the notes in the distribution and management agreement. The provisions of the distribution and management agreement relating to our retention of Sumner Harrington Ltd. to act as our servicing agent in performing our ongoing administrative responsibilities for the notes are described under "Description of the Notes." Any amendment to the distribution and management agreement will be filed as an exhibit to an amendment to the registration statement of which this prospectus is a part.

LEGAL OPINIONS

Lindquist & Vennum P.L.L.P. will issue an opinion regarding the legality of the securities offered by this prospectus.

EXPERTS

The consolidated financial statements as of December 29, 2007 and December 30, 2006 and for the years then ended incorporated by reference in this Post-Effective Amendment No. 4 to Form S-1 have been audited by Grant Thornton LLP, independent registered public accountants, as indicated in their report with respect thereto, and are incorporated by reference herein in reliance upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's web site at http://www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

We "incorporate by reference" into this prospectus certain information that we have filed with the SEC, which means that we disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. Some information contained in this prospectus updates the information incorporated by reference. In case of a conflict or inconsistency between information set forth in this prospectus and information incorporated by reference into this prospectus, you should rely on the information contained in the document that was filed later. We incorporate by reference the documents and information from documents listed below:

Annual report on Form 10-K for the year ended December 29, 2007 filed on March 18, 2008 (including information specifically incorporated by reference into our Form 10-K from our 2007 annual report to shareholders and from our definitive proxy statement for our 2008 annual meeting of shareholders filed on March 19, 2008);

Definitive proxy statement for our 2008 annual meeting of shareholders filed on March 19, 2008; and

Current Report or Form 8-K filed on February 11, 2008.

We will provide to each person, including any beneficial owner of the notes, to whom this prospectus is delivered, a copy of any or all reports or documents that have been incorporated by reference in this prospectus contained in the registration statement but not delivered with the prospectus upon written or oral request. We will deliver these reports or documents at no cost to the requester. You may request these reports or documents by writing to or telephoning us at:

Winmark Corporation
Attn: Chief Financial Officer
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You may also request these documents via email at Winmark.information@WinmarkCorporation.com.

You may also get these documents from our website under "Investor Relations," click on "SEC Filings," at http://ir.10kwizard.com/files.php?source=1295.

You should rely only on the information included or incorporated by reference in this prospectus or the prospectus supplement. We have not authorized anyone else to provide you with different information. We may only use this prospectus to sell securities if we also deliver a prospectus supplement. We are only offering these securities in states where the offer is permitted. You should not assume that the information in this prospectus or the prospectus supplement is accurate as of any date other than the dates on the front of those documents. Information on our website is not a part of this prospectus or a prospectus supplement.

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