CARDIOGENESIS CORP /CA
Form S-1
March 12, 2004

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AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON MARCH 12, 2004

Registration No. 333-_____

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
under
The Securities Act of 1933, as amended

CARDIOGENESIS CORPORATION
(Exact name of registrant as specified in its charter)

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

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

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

With copies to:
CRAIG W. ADAS, ESQ.
WEIL, GOTSHAL & MANGES LLP
201 REDWOOD SHORES PARKWAY
REDWOOD SHORES, CA 94065
(650) 802-3000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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

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

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

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

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CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount of Shares to be Registered (1)	Proposed Maximum Aggregate Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, no par value per share	3,139,535	$ 1.12	$ 3,516,280	$ 446

(1) This registration statement shall also cover any additional shares of common stock which become issuable in connection with the shares registered for sale in this registration statement by reason of any stock dividend, stock split, recapitaliaztion or other transaction effected without the receipt of consideration which results in an increase of our outstanding shares of common stock.

(2) Pursuant to Rule 457(c) under the Securities Act, this per share amount is based on the average high and low prices of our common stock on March 8, 2004, as reported on the OTCBB. Estimated solely for the purpose of calculating the registration fee.

(3) Issuable upon exercise of a warrant having an exercise price of $1.37 per share.

(4) Issuable upon exercise of a warrant having an exercise price of $1.00 per share.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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Subject to Completion, Dated March 12, 2004

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

PROSPECTUS

7,848,838 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 7,848,838 shares of CardioGenesis common stock, of which:

3,139,535 shares are currently outstanding and held by the selling shareholders;

3,139,535 shares may in the future be issued to the selling shareholders upon the exercise of currently outstanding warrants having an exercise price of $1.37 per share; and

1,569,768 shares may in the future be issued to the selling shareholders upon the exercise of currently outstanding warrants having an exercise price of $1.00 per share.

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 43.

Our common stock is traded on the OTC Bulletin Board of the National Association of Securities Dealers, Inc. under the symbol CGCP.OB. On March 11, 2004, the last sale price of our common stock was $1.05 per share.

Investing in our common stock involves risks. See Risk Factors beginning on page 2.

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 _____, 2004

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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 (TMR) and percutaneous myocardial revascularization (PMR). TMR and PMR 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. PMR is performed by a cardiologist in a catheter-based procedure which utilizes local anesthesia.

We have received CE Mark approval for our TMR and PMR 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 July 2001, the FDA recommended against approval of our PMR products for public sale and use in the United States. In July 2003, the FDA agreed to an alternative process in which additional data in support of our application for approval of PMR could be submitted and reviewed by the FDA in an interactive review process. We submitted additional data in August 2003, and the FDA has informed us that they believe this additional data submitted in August 2003 is still not adequate to support approval by the FDA of our PMR system. We are currently scheduled to meet with the FDA in March 2004 as part of the ongoing interactive review process. There can be no assurance, however, that we will receive a favorable determination from the FDA for our PMR products.

Corporate Information

We incorporated in California in 1989. 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

This prospectus relates to the registration for resale of up to 7,848,838 shares of our common stock by the selling shareholders identified in this prospectus. The prices at which the selling shareholders may sell their shares will be determined by the prevailing market for the shares or in negotiated transactions. See Selling Shareholders on page 42.

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 warrants if the selling shareholders opt to pay the exercise price in cash rather than executing a cashless exercise.

Risk Factors

You should carefully read and consider the information set forth in the section entitled Risk Factors beginning on page 2 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.

Risks Related to our Business and Industry

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 may be required 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, most recently through the private placement of equity securities in January 2004, 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 PMR laser systems; and
- for an uncertain period of time after such approvals are obtained.

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

The FDA has not approved our PMR laser system for any application in the United States. In July 2001, the FDA Advisory Panel recommended against approval of PMR 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 PMR 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 PMR 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. The FDA has informed us that they believe the data submitted in August 2003 in connection with the interactive review process is still not adequate to support approval by the FDA of our PMR system. We are currently scheduled to meet with the FDA in March 2004 as part of the ongoing interactive review process. There can be no assurance, however,

that we will receive a favorable determination from the FDA.

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We will not be able to derive any revenue from the sale of our PMR 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 PMR 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.

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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 successfully market our products if third party reimbursement for the procedures performed with our products is not available for our healthcare 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 (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.

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

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 PMR products in the international markets in which such approvals are sought, 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. Moreover, we are currently exploring manufacturing outsourcing options for the TMR 2000 laser. 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 PMR 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 and currently expect to have

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production capacity for our TMR 2000 laser by the fourth quarter of 2004. 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 PMR systems;
- our ability to successfully and rapidly expand sales to potential customers in response to potentially increasing clinical adoption of the TMR procedure;
- the costs associated with such growth, which are difficult to quantify, but could be significant;
- domestic and international regulatory developments;
- rapid technological change;
- the highly competitive nature of the medical devices industry; and
- the risk of entering emerging markets in which we have limited or no direct experience.

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

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

Our operating results have fluctuated significantly from quarter-to-quarter and are expected to 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

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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 February 13, 2004, the closing prices of our common stock as reported on Nasdaq and on the OTC Bulletin Board ranged from a high of $1.92 per share to a low of $0.24 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;

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

announcements relating to strategic relationships or acquisitions;

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 carbon dioxide, or CO_2, 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 technical 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.

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

develop products;

complete clinical testing and regulatory approval processes;

obtain third party reimbursement acceptance; and

supply adequate quantities of the product to the market.

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

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

Costly litigation may be necessary to protect 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;

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

require us to modify our products.

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

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

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

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

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

Furthermore, we cannot assure you that our competitors:

have not developed or will not develop similar products;

will not duplicate our products; or

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

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

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

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

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

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

there are no material side effects or material adverse events arising from the use of our PMR product.

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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.

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.

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Risks Relating to this Offering

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

The sale of our common stock by our 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.

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

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one right for each outstanding share of common stock to shareholders of record at the close of business on August 30, 2001. Each right initially entitles holders to buy one unit of preferred stock for $15.00 and entitles the holder to certain preferential dividends and conversion rights. The rights are generally not transferable apart from the common stock and will not be exercisable until an until a person or group acquires or commences a tender or exchange offer to acquire beneficial ownership of 15% or more of our common stock. 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. 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 $5,870,931, which we intend to use for working capital and other general corporate purposes.

MARKET PRICE AND DIVIDEND INFORMATION

Our common stock is currently traded on the OTC Bulletin Board under the symbol CGCP.OB. In 2002, our common stock was listed on the Nasdaq SmallCap Market and Nasdaq National 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, Nasdaq National Market and Nasdaq SmallCap Market for the respective market on which our common stock was listed during the quarter being reported.

2002	**High**	**Low**
First Quarter	$1.25	$0.65
Second Quarter	$1.20	$0.67
Third Quarter	$0.99	$0.56
Fourth Quarter	$0.93	$0.25
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 (through March 11, 2004)	$1.26	$0.82

As of March 5, 2004 shares of our common stock were held by 217 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.

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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 (TMR) and percutaneous transluminal myocardial revascularization (PMR). TMR and PMR are recent laser-based heart treatments in which channels are made in the heart muscle. 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. PMR is performed by a cardiologist in a catheter-based procedure which utilizes local anesthesia. Clinical studies have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with TMR or PMR plus medications, when compared with patients who received medications alone.

We received CE Mark approval for our TMR system in May 1997 and our PMR 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 (FDA) for our TMR products for treatment of stable patients with certain types of angina. Effective July 1, 1999, Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financial Administration (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 PMR, 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 PMR 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 PMR 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 PMR 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. The FDA has informed us that they believe the data submitted in August 2003 in connection with the interactive review process is still not adequate to support approval by the FDA of our PMR system. We are currently scheduled to meet with the FDA in March 2004 as part of the ongoing interactive review process. There can be no assurance, however, that we will receive a favorable determination from the FDA.

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.

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.

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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 (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 PMR, which bears the CE Marking and for which we are continuing to pursue FDA approval for use in the U.S., offer potential relief to a large population of patients with severe cardiovascular disease.

The TMR and PMR Procedures

TMR 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.

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PMR is an interventional procedure performed by a cardiologist. PMR is based upon the same principles as TMR, but the procedure is much less invasive. The 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). PMR 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 PMR 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 PMR established as well-known and acceptable therapies. Our strategies to achieve this goal are as follows:

Expand Market for our Products. We are seeking to expand market awareness of our products among 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 PMR products and procedures.

Demonstrate Clinical Utility of PMR. We are seeking to demonstrate the clinical safety and effectiveness of PMR. We have completed a pivotal clinical trial regarding PMR, and the study results were submitted to the FDA in a PMA application in December 1999, along with subsequent supplements. As discussed below under the caption Regulatory Status, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States and further informed us that they believe the data submitted in August 2003 in connection with the interactive review process is still not adequate to support approval by the FDA of our PMR system. We are currently scheduled to meet with the FDA in March 2004 as part of the ongoing interactive review process of our PMA application for PMR. We cannot assure you, 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 PMR procedures. We are seeking to develop additional proprietary technologies for TMR, PMR 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, PMR and other cardiovascular therapies.

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 or PMR catheter. 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

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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 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.

PMR System

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

PMR 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 PMR and study results were submitted to the FDA in a PMA application in December 1999 along with subsequent amendments. The PMR study compares PMR to conventional medical therapy in patients with no option for other treatment. In July 2001, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. In July 2003, the FDA agreed to an alternative process in which additional data in support of our PMA supplement for PMR 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. The FDA has