

CARDIOGENESIS CORP /CA  
Form S-3/A  
July 25, 2001

1

As filed with the Securities and Exchange Commission on July 25, 2001

=====

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

-----

PRE-EFFECTIVE AMENDMENT NO. 3

TO

FORM S-3

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

-----

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

CALIFORNIA  
(State or other jurisdiction of incorporation or organization)

77-0223740  
(I.R.S. Employer Identification No.)

26632 TOWNE CENTER DRIVE  
SUITE 320  
FOOTHILL RANCH, CALIFORNIA 92610  
(714) 649-5000  
(Address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

-----

J. STEPHEN WILKINS  
CHIEF FINANCIAL OFFICER  
26632 TOWNE CENTER DRIVE  
SUITE 320  
FOOTHILL RANCH, CALIFORNIA 92610  
(714) 649-5000  
(NAME, ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER,  
INCLUDING AREA CODE, OF AGENT FOR SERVICE)

COPIES TO:  
ROBERT K. MONTGOMERY, ESQ.  
CASEY M. NAULT, ESQ.  
2029 CENTURY PARK EAST  
LOS ANGELES, CALIFORNIA 90067

Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

(310) 552-8500

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC:  
From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

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

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. [ ]\_\_\_\_\_

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

-----

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, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

2

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. YOU MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

PROSPECTUS

2,000,000 SHARES

CARIOGENESIS CORPORATION

COMMON STOCK

The selling stockholder described in this prospectus is offering and selling up to 2,000,000 shares of common stock, no par value per share, of CardioGenesis Corporation (formerly known as Eclipse Surgical Technologies,

Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

Inc.) under this prospectus.

Our common stock is quoted on the Nasdaq Stock Market's National Market under the symbol: "CGCP." On July 23, 2001, the last reported sale price of our common stock was \$.80 per share.

INVESTING IN OUR COMMON STOCK INVOLVES RISKS. SEE "RISK FACTORS" ON PAGE 4.

-----

The shares of common stock offered or sold under this prospectus have not been approved or disapproved by the SEC or any state securities commission, nor have these organizations determined that this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

-----

The date of this prospectus is July 25, 2001

2

3

TABLE OF CONTENTS

Company Description.....	3
Risk Factors.....	4
Material Changes.....	16
Where You Can Find Additional Information.....	16
Information Incorporated by Reference.....	17
Special Note Regarding Forward Looking Statements.....	18
Use Of Proceeds.....	18
Plan Of Distribution.....	18
Selling Stockholder.....	19
Legal Matters.....	20
Experts.....	20

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information that is different. This prospectus may only be used in jurisdictions where it is legal to offer or sell these securities. You should not assume that the information in this prospectus or any prospectus supplement or any document incorporated by reference in this prospectus is accurate as of any date other than the date on the front of those documents.

COMPANY DESCRIPTION

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

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 throughout Europe, Asia and North America. Cardiovascular disease is the leading cause of death and disability in the U.S. according to the American Heart Association. Coronary artery disease is the principal form of cardiovascular disease and is characterized by a progressive narrowing of the coronary arteries which supply blood to the heart. This narrowing process is usually due to atherosclerosis, which is the buildup of fatty deposits, or plaque, on the inner lining of the arteries. Coronary artery disease reduces the available supply of oxygenated blood to the heart muscle, 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 the Canadian Heart Association standards, a patient's severe chest pain or angina is typically classified into four classes, ranging from Class 1, in which angina pain results only from strenuous exertion, to the most severe class, Class 4, in which the patient is unable to conduct any physical activity without angina and angina may be present even at rest. The American Heart Association estimates that more than six million Americans experience angina symptoms.

The primary therapeutic options for treatment of coronary artery disease are drug therapy, balloon angioplasty, other interventional techniques which augment or replace balloon angioplasty such as stent placement, and coronary artery bypass grafting which is more commonly referred to as bypass. 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 fatty deposits which line the coronary arteries or by decreasing the rate of formation of additional fatty deposits by reducing blood levels of cholesterol. Because of the progressive nature of the disease, however, many patients with angina ultimately undergo either balloon angioplasty or bypass.

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.

3

4

The laser-based surgical products designed, developed, manufactured and distributed by CardioGenesis Corporation are used for the treatment of advanced cardiovascular disease through two procedures, transmyocardial revascularization known as TMR and percutaneous transluminal myocardial revascularization known as PMR. TMR and PMR are recent laser-based heart treatments in which channels are made in the heart muscle. It is believed that the TMR and PMR procedures encourage new blood vessel formation in the heart region known as angiogenesis. Clinical studies have demonstrated a significant reduction in angina and an increase in exercise duration in patients treated with TMR and PMR plus medications when compared with patients who received medications alone.

We distribute a laser system, called the TMR laser system, which is used in the TMR surgical procedure. TMR, or transmyocardial revascularization, is a surgical procedure performed by a cardiac surgeon on the beating or non-beating

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

heart, in which a laser device is used to create channels through the myocardium, i.e. heart muscle, directly into the heart chamber. The channels are intended to supply blood to oxygen-deprived, or ischemic, 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 cardiac patients suffering from severe angina who have regions in the heart that are oxygen-deprived but cannot be treated by balloon angioplasty or bypass.

On February 11, 1999, we received final approval from the Food and Drug Administration for our TMR products and procedures. They have been approved for the treatment of a specific type of patient suffering from severe coronary artery disease and so not all patients suffering from coronary artery disease will qualify for our TMR treatment. As of July 1, 1999, the Health Care Financial Administration began authorizing Medicare coverage for our TMR products and procedures. Hospitals and physicians are now eligible to receive Medicare reimbursement for the full costs of TMR equipment and procedures.

PMR, or percutaneous transluminal myocardial revascularization (formerly referred to as PTMR), is an interventional procedure performed by a cardiologist. PMR is based upon the same principles as TMR, but the procedure is much less invasive. PMR is not performed using open chest surgery (which is invasive), rather, the patient is under local anesthesia and is treated through a catheter inserted in the femoral artery at the top of the leg. From the femoral artery, a laser transmitting catheter is threaded up into the heart chamber, where channels are created in the inner portion of the myocardium (i.e. heart muscle).

We distribute a laser system, called the PMR laser system, which is used in the PMR procedure. PMR is currently being distributed in Europe and parts of Asia. In the United States, we have offered our PMR laser systems for sale in limited numbers for investigational use only pursuant to Investigational Device Exemptions from the United States Food and Drug Administration. We have completed pivotal clinical trials involving PMR, and study results were submitted to the Food and Drug Administration in a Pre Market Approval application in December of 1999. On July 9, 2001, the Food and Drug Administration's Circulatory Devices Panel recommended to the Food and Drug Administration against approval of our PMR device in the United States. We are continuing to gather and submit additional evidence on the effectiveness of our PMR procedure to the Food and Drug Administration to gain their approval. There can be no assurance, however, that we will receive a favorable decision from that agency.

Our principal executive offices are located at 26632 Towne Center Drive, Suite 320, Foothill Ranch, California 92610. Our telephone number is (714) 649-5000.

### RISK FACTORS

Before you invest in our common stock, you should be aware of the various risks and uncertainties described below associated with such an investment which are all of the material risks and uncertainties that we can identify. You should consider carefully these risk factors together with all of the other information included in this prospectus and in the documents incorporated by reference before you decide to purchase our common stock.

OUR ABILITY TO CONTINUE AS A GOING CONCERN IS DEPENDENT UPON ACHIEVING PROFITABLE OPERATIONS IN THE FUTURE.

We will have a continuing need for new infusions of cash until revenues are increased to meet our operating expenses. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving timely regulatory approval for other products under clinical trials. If we are unable to increase our sales or achieve timely 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. This would raise substantial doubt about our ability to continue as a going concern. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and will not have sufficient cash to fund our operations.

WE MAY FAIL TO OBTAIN REQUIRED REGULATORY APPROVALS TO MARKET OUR PRODUCTS INCLUDING OUR PMR LASER SYSTEM IN THE UNITED STATES.

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

- the failure to obtain regulatory approvals for our PMR system;
- any significant limitations in the indicated uses for which our products may be marketed; and,
- substantial costs incurred in obtaining regulatory approvals.

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

In October 2000, preliminary results from a competitor's clinical trial of a catheter-based device employing Direct Myocardial Revascularization also known as DMR were presented at a medical conference in Washington D.C. The trial's principal investigator concluded that this catheter-based device did not show significant evidence of clinical benefit with regard to angina class reduction or exercise tolerance, and questioned the efficacy of other devices and procedures relying on TMR. We believe that the preliminary results of that catheter-based device study should not call the results of our PMR study into question because the devices and procedures are substantially different. We cannot assure you, however, that the preliminary results of that catheter-based device study will impact the Food and Drug Administration's decision on our PMR system.

IN THE FUTURE, THE FOOD AND DRUG ADMINISTRATION COULD RESTRICT THE CURRENT USES OF OUR TMR PRODUCT.

The Food and Drug Administration has approved our TMR product for sale

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

and use by physicians in the United States. At the request of the Food and Drug Administration, we are currently conducting post-market surveillance of our TMR product. Though we are not aware of any safety concerns during our on-going postmarket surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the Food and Drug Administration could possibly restrict the currently approved uses of our TMR product. In the future, if the Food and Drug Administration were to restrict the range of uses for which our TMR product can be used by physicians, such as restricting TMR's use with the coronary artery bypass grafting procedure which occurs in more than half the procedures in which TMR is used, it could lead to reduced sales of our TMR product and our business could be adversely affected.

THE CIRCULATORY DEVICES PANEL OF THE FOOD AND DRUG ADMINISTRATION RECENTLY RECOMMENDED AGAINST APPROVAL OF OUR PMR DEVICE FOR PUBLIC SALE AND USE IN THE UNITED STATES, WHICH HAS EFFECTIVELY DELAYED POTENTIAL REVENUE, IF ANY, THAT MAY HAVE BEEN DERIVED IN THE FUTURE FROM THE SALE OF THAT DEVICE IN THE UNITED STATES AND WHICH MAY HAVE OTHER ADVERSE EFFECTS.

The Circulatory Devices Panel of the Food and Drug Administration recently recommended that the Food and Drug Administration not approve our PMR device for public sale and use in the United States based on concerns related to the safety of the device and the data gathered regarding adverse events in clinical trials. Although we do not expect to conduct further clinical trials of our PMR device, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration's approval of our PMR device. If the Food and Drug Administration accepts the recommendation of the Advisory Panel and does not approve our PMR device for public sale and use in the United States, we will not be able to derive any revenue from the sale of that device in the United States until such time, if any, that the Food and Drug Administration approves the device. Such inability to realize revenue from sales of our PMR device in the United States will have an adverse effect on our results of operations. Additionally, the trading price of our common stock on the NASDAQ National Market fell substantially after the panel's recommendation became public. As discussed elsewhere in this prospectus, if our common stock were to trade under \$1.00 for 30 consecutive days on the NASDAQ National Market, our common stock could be subject to certain consequences established by the NASDAQ National Market, such as being delisted. If our common stock were delisted, then we could apply for listing on the Nasdaq SmallCap Market, subject to Nasdaq's approval. If our common stock is not approved for trading on the Nasdaq SmallCap Market, then our common stock

5

6

would trade only in the secondary markets in the so-called "pink sheets" or Nasdaq's "OTC Bulletin Board." Delisting from the Nasdaq National Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future.

THE MEDICAL COMMUNITY HAS NOT BROADLY ADOPTED OUR PRODUCTS, AND UNLESS OUR PRODUCTS ARE BROADLY ADOPTED, OUR BUSINESS WILL SUFFER.

Our TMR products have not yet achieved broad commercial adoption, and our PMR products are experimental and have not yet achieved broad clinical adoption. We cannot predict whether or at what rate and how broadly our products

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

will be adopted by the medical community. Our business would be harmed if our TMR and PMR systems fail to achieve significant market acceptance.

THE RECEIPT OF POSITIVE ENDORSEMENTS BY PHYSICIANS IS ESSENTIAL FOR THE SUCCESS OF OUR PRODUCTS IN THE MARKET PLACE.

Positive endorsements, by physicians, are essential for clinical adoption of our TMR and PMR laser systems. Even if the clinical efficacy of TMR and PMR laser systems is established, physicians may elect not to recommend TMR and PMR laser systems for any number of reasons.

Clinical adoption of these products will depend upon:

- our ability to facilitate training of cardiothoracic surgeons and interventional cardiologists in TMR and PMR therapy;
- willingness of such physicians to adopt and recommend such procedures to their patients; and
- raising the awareness of TMR and then PMR with the targeted patient population.

Patient acceptance of the procedure will depend on:

- physician recommendations;
- the degree of invasiveness;
- the effectiveness of the procedure; and
- the rate and severity of complications associated with the procedure as compared to other procedures.

TO EXPAND OUR BUSINESS, WE MUST ESTABLISH EFFECTIVE SALES, MARKETING AND DISTRIBUTION SYSTEMS.

To expand our business, we must establish effective systems to sell, market and distribute products. To date, we have had limited sales which have consisted primarily of U.S. sales of our TMR lasers and disposable handpieces on a commercial basis since February 1999 and PMR lasers and disposable catheters for investigational use only. We have been expanding our operations by hiring additional sales and marketing personnel. This has required and will continue to require substantial management effort and financial resources.

IF OUR SALES FORCE IS NOT SUCCESSFUL IN INCREASING MARKET SHARE AND SELLING OUR DISPOSABLE HANDPIECES, OUR BUSINESS WILL SUFFER.

With Food and Drug Administration approval of our TMR laser system, we are marketing our products primarily through our direct sales force. If the sales force is not successful in increasing market share and selling our disposable handpieces, our business will suffer. In the fourth quarter of 1999, we changed our U.S. sales strategy to include both selling lasers to hospitals outright, as well as loaning lasers to hospitals in return for the hospital purchasing a minimum number of disposable handpieces at a higher price. During the current year, the majority of lasers shipped have been under this loan program. The purpose of this strategy is to focus our sales force on increasing market penetration and selling disposable handpieces used in connection with our TMR procedure.



## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

THE EXPANSION OF OUR BUSINESS MAY PUT ADDED PRESSURE ON OUR MANAGEMENT AND OPERATIONAL INFRASTRUCTURE AFFECTING OUR ABILITY TO MEET ANY INCREASED DEMAND FOR OUR PRODUCTS AND POSSIBLY HAVING AN ADVERSE EFFECT ON OUR OPERATING RESULTS.

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

- the dependence on the growth of the market for our TMR and PMR systems;
- our ability to successfully and rapidly expand sales to potential customers in response to 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;
- completing the clinical trials that are currently in progress as well as developing and preparing additional products for clinical trials;
- 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 must obtain additional funding to improve information systems, procedures and controls and expand, train, motivate and manage our employees, and such funding may not be available in sufficient quantities, if at all. If we are not able to manage these activities and implement these strategies successfully to expand to meet any increased demand, our operating results could suffer.

OUR OPERATING RESULTS ARE EXPECTED TO FLUCTUATE AND QUARTER-TO-QUARTER COMPARISONS OF OUR RESULTS MAY NOT INDICATE FUTURE PERFORMANCE.

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

- the level of product demand and the timing of customer orders;
- changes in strategy;
- delays associated with the Food and Drug Administration and other regulatory approval processes;
- personnel changes including our ability to continue to attract, train and motivate additional qualified personnel in all areas;
- the level of international sales;
- changes in competitive pricing policies;
- the ability to develop, introduce and market new and enhanced

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

versions of products on a timely basis;

- deferrals in customer orders in anticipation of new or enhanced products;
- product quality problems; and
- the enactment of health care reform legislation and any changes in third party reimbursement policies.

We believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. Due to the emerging nature of the markets in which we compete, forecasting operating results

7

8

is difficult and unreliable. Over the past year, our revenue has been lower than anticipated, largely attributable to the transition to our new sales strategy. It is likely or possible that our operating results for a future quarter will fall below the expectations of public market analysts and investors. When this occurred in the past, the price of our common stock fell substantially, and if this occurs again, the price of our common stock may fall again, perhaps substantially.

GROWTH IN OUR FUTURE OPERATING RESULTS IS HIGHLY CONTINGENT AND SUBJECT TO SIGNIFICANT RISKS.

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

- successfully and rapidly expand sales to potential customers;
- implement operating, manufacturing and financial procedures and controls;
- improve coordination among different operating functions; and
- achieve manufacturing efficiencies as production volume increases.

WE MAY NOT BE ABLE TO SUCCESSFULLY MARKET OUR PRODUCTS IF THIRD PARTY REIMBURSEMENT FOR THE PROCEDURES PERFORMED WITH OUR PRODUCTS IS NOT AVAILABLE FOR OUR HEALTH CARE PROVIDER CUSTOMERS.

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

Effective July 1, 1999 the Health Care Financing Administration commenced Medicare coverage for TMR systems for any manufacturer's TMR procedures. Hospitals and physicians are now eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures and equipment. The Health Care Financing Administration may not approve reimbursement for PMR. If it does not provide reimbursement, our ability to successfully market and sell our PMR products will be harmed. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans and thus do not have reliable data as to the success of our

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

patients in obtaining reimbursement for the costs of our TMR products outside of the Medicare system. Private insurance and private health plans may not approve reimbursement TMR or PMR procedures. If they do not provide reimbursement, our business will suffer.

Potential purchasers must determine whether the clinical benefits of our TMR and PMR laser systems justify:

- the additional cost or the additional effort required to obtain prior authorization or coverage; and
- the uncertainty of actually obtaining such authorization or coverage.

WE FACE COMPETITION FROM OUR COMPETITOR'S PRODUCTS WHICH COULD LIMIT MARKET ACCEPTANCE OF OUR PRODUCTS AND RENDER OUR PRODUCTS OBSOLETE.

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

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

8

9

We currently compete with PLC Systems. PLC recently announced a co-marketing agreement with Edwards Life Sciences to distribute their lasers and disposables which is expected to add another 18 direct domestic sales representatives involved in promoting the PLC technology.

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

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

OUR PRODUCTS DEPEND ON TMR TECHNOLOGY THAT IS RAPIDLY CHANGING WHICH MAY REQUIRE US TO INCUR SUBSTANTIAL PRODUCT DEVELOPMENT EXPENDITURES TO PREVENT OUR PRODUCTS FROM BECOMING OBSOLETE.

The medical device industry is characterized by rapid and significant technological change. Our future success will depend in large part on our ability to respond to such changes through further product research and development. In addition, we must expand the indications and applications for our products by developing and introducing enhanced and new versions of our TMR

## Edgar Filing: CARDIOGENESIS CORP /CA - Form S-3/A

and PMR laser systems. Product research and development requires substantial expenditures and is inherently risky. We may not be able to:

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

OVERALL INCREASES IN MEDICAL COSTS COULD ADVERSELY AFFECT OUR BUSINESS.

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

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

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

WE HAVE A HISTORY OF LOSSES AND MAY NOT BE PROFITABLE IN THE FUTURE.

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

- until such time, if ever, as we obtain broad commercial adoption of our TMR laser systems by healthcare facilities in the United States;
- until such time, if ever, as we obtain Food and Drug Administration and other regulatory approvals for our PMR laser systems; and
- for an uncertain period of time after such approvals are obtained.

We may not achieve or sustain profitability in the future.

THIRD PARTIES MAY LIMIT THE DEVELOPMENT AND PROTECTION OF OUR INTELLECTUAL PROPERTY, WHICH COULD ADVERSELY AFFECT OUR COMPETITIVE POSITION.

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

- obtain patent protection for our products and processes;

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

- 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.

In September 1995, one of our competitors sent us a notice of potential infringement of their patent regarding a method for TMR utilizing synchronization of laser pulses to the electrical signals from the heart. After discussion with patent counsel, we concluded that we did not utilize the process and/or apparatus that was the subject of the patent at issue, and we provided a response to the competitor to that effect. We have not received any additional correspondence from this competitor on these matters.

In 1996, prior to the merger with us, the company formerly known as CardioGenesis Corporation initiated a suit in the United States against PLC seeking a judgment that the PLC patent is invalid and unenforceable. In 1997, PLC counterclaimed in that suit alleging infringement by the former CardioGenesis Corporation of the PLC patent. Also in 1997, PLC initiated suit in Germany against the former CardioGenesis Corporation and the former CardioGenesis Corporation's former German sales agent alleging infringement of a European counterpart to the PLC patent. In 1997, the former CardioGenesis Corporation filed an Opposition in the European Patent Office to a European counterpart to the PLC patent, seeking to have the European patent declared invalid.

On January 5, 1999, before trial on the United States suit commenced, the company formerly known as CardioGenesis Corporation and PLC settled all litigation between them, both in the United States and in Germany, with respect to the PLC patent and the European patents. Under the Settlement and License Agreement signed by the parties, the former CardioGenesis Corporation stipulated to the validity of the PLC patents and PLC granted the former CardioGenesis Corporation a non-exclusive worldwide license to the PLC patents. The former CardioGenesis Corporation agreed to pay PLC a license fee, and minimum royalties, totaling \$2.5 million in equal monthly installments over an approximately forty-month period, with a running royalty credited against the minimums.

The Settlement and License Agreement applies only to those products or that technology covered by the PLC patents, and the agreement does not provide PLC any rights to any former CardioGenesis Corporation intellectual property. Our TMR 2000 laser system does not use the technology associated with the PLC patents.

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

**COSTLY LITIGATION MAY BE NECESSARY TO PROTECT INTELLECTUAL PROPERTY RIGHTS.**

We may have to engage in time consuming and costly litigation to protect our intellectual property rights or to determine the proprietary rights of

others. In addition, we may become subject to patent infringement claims or

10

11

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.

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

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, until recently, maintained in secrecy until patents issue, 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.

11

12

WE DEPEND ON SINGLE SOURCE SUPPLIERS FOR KEY COMPONENTS AND PRODUCTION WOULD BE INTERRUPTED IF A KEY SUPPLIER HAD TO BE REPLACED.

We currently purchase critical laser and fiber-optic components from single sources. These sources may have difficulties supplying our needs for these components. In addition, we do not have long term supply contracts. As a result, these sources are not obligated to continue to provide these critical components to us. Although we have identified alternative suppliers, a lengthy process would be required to qualify them as additional or replacement suppliers. Any significant interruption in the supply of critical materials or components could delay our ability to manufacture our products and could disrupt our manufacturing operations and harm our business.

LEAD TIMES FOR MATERIALS AND COMPONENTS VARY SIGNIFICANTLY WHICH COULD LEAD TO EXCESS INVENTORY LEVELS AS WELL AS SHORTAGES OF CRITICAL COMPONENTS IF OUR SUPPLY FORECASTS ARE INACCURATE.

We anticipate that products will be manufactured based on forecasted demand and will seek to purchase subassemblies and components in anticipation of the actual receipt of purchase orders from customers. Lead times for materials and components vary significantly and depend on factors such as the business practices of each specific supplier and the terms of particular contracts, as well as the overall market demand for such materials and components at any given time. If the forecasts are inaccurate, we could experience fluctuations in inventory levels, resulting in excess inventory, or shortages of critical components, either of which could cause our business to suffer.

WE MAY NOT BE ABLE TO MEET FUTURE DEMAND INCREASES ON TIMELY BASIS BECAUSE SOME OF OUR SUPPLIERS COULD HAVE DIFFICULTY MEETING SIGNIFICANT OR RAPIDLY INCREASING ORDER AMOUNTS.

Some of our suppliers could have difficulty expanding their manufacturing capacity to meet our needs if demand for our TMR and PMR laser systems were to increase rapidly or significantly. In addition, any defect or malfunction in the laser or other products provided by such suppliers could cause a delay in regulatory approvals or adversely affect product acceptance. We cannot predict if:

- materials obtained from outside suppliers will be available in adequate quantities to meet our future needs; or

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

- replacement suppliers can be qualified on a timely basis if our current suppliers are unable to meet our needs.

WE HAVE LIMITED MANUFACTURING EXPERIENCE WHICH COULD PREVENT US FROM SUCCESSFULLY INCREASING CAPACITY IN RESPONSE TO MARKET DEMAND.

We have limited experience in manufacturing products. In the course of manufacturing our products, we may encounter difficulties in increasing production, including problems involving:

- production yields;
- adequate supplies of components;
- achieving manufacturing efficiencies as production volume increases;
- quality control and assurance (including failure to comply with good manufacturing practices regulations, international quality standards and other regulatory requirements); and
- shortages of qualified personnel.

OUR PRODUCTS MAY CONTAIN DEFECTS WHICH COULD DELAY REGULATORY APPROVAL OR MARKET ACCEPTANCE OF OUR PRODUCTS.

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

12

13

because we may be unable to sufficiently remedy a significant product recall while still maintaining our daily manufacturing quotas.

WE MUST COMPLY WITH FOOD AND DRUG ADMINISTRATION MANUFACTURING STANDARDS OR FACE FINES OR OTHER PENALTIES INCLUDING SUSPENSION OF PRODUCTION.

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

- fines, injunctions, and civil penalties;
- recalls or seizures of products;
- total or partial suspensions of production; and
- criminal prosecutions.

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



## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

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 products. Though we are in the process of responding to the Food and Drug Administration's Circulatory Devices Panel's recent recommendation against approval of our PMR product because of concerns over the safety of the device and the data regarding adverse events in the clinical trials, we believe there are no material side effects or adverse events arising from the use of our PMR product. When being clinically investigated, it is not uncommon for new surgical or interventional procedures to result in a higher rate of complications in the treated population of patients as opposed to those reported in the control group. We believe that the difference in the rates of complications between the treated group and the control group in the clinical trials for our PMR product are not statistically significant, which is why we believe that there are no material side effects or material adverse events arising from the use of our PMR product.

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

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, manufacturing, technical, marketing and sales and support personnel for

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

our operations. If we lose a key employee or if a key employee fails to perform in his or her current position, or if we are not able to attract and retain skilled employees as needed, our business could suffer.

During the last two years, we have had significant change in our senior management team. Our former Chief Executive Officer, Allen Hill, resigned from the company in December 1999. One of our current Directors, Alan Kaganov, acted as interim CEO until we hired our current CEO, Michael Quinn, in October of 2000. Our former Chief Financial Officer, Dick Powers, resigned from the company in July 2000. Ian Johnson acted as Interim CFO until our current CFO, J. Stephen Wilkins, was hired in May 2001. Richard Lanigan moved from Vice President of Sales to Vice President of Regulatory and Government Affairs in March 2001 and Thomas Kinder was hired in March 2001 as our new Vice President of Sales. Darrell Eckstein was hired in December 2000 as our Vice President of Operations, replacing Bill Picht, who resigned earlier in 2000.

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

WE MAY FAIL TO COMPLY WITH INTERNATIONAL REGULATORY REQUIREMENTS AND COULD BE SUBJECT TO REGULATORY DELAYS, FINES OR OTHER PENALTIES.

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

- delays in receipt of, or failure to receive, foreign regulatory approvals or clearances;
- the loss of previously obtained approvals or clearances; or
- the failure to comply with existing or future regulatory requirements.

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

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

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 according to our plan. 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;

14

15

- foreign tax laws;
- shipping delays;
- various tariffs and trade regulations;
- restrictions and foreign medical regulations;
- customs duties, export quotas or other trade restrictions; and
- difficulty in protecting intellectual property rights.

WE MAY NOT ACHIEVE WIDE ACCEPTANCE OF OUR PRODUCTS IN FOREIGN MARKETS IF WE FAIL TO OBTAIN THIRD PARTY REIMBURSEMENT FOR THE PROCEDURES PERFORMED WITH OUR PRODUCTS.

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

WE MAY ENGAGE IN FUTURE ACQUISITIONS THAT COULD DISTRACT OUR MANAGEMENT, CAUSE US TO INCUR DEBT, OR DILUTE OUR SHAREHOLDERS.

We may, from time to time, acquire or invest in other complementary businesses, products or technologies. While there are currently no commitments with respect to any particular acquisition or investment, our management frequently evaluates the strategic opportunities available in complementary businesses, products or technologies. The process of integrating an acquired company's business into our operations may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. Moreover, the anticipated benefits of any acquisition or investment may not be realized. Any future acquisitions or investments by us could result in potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities and amortization expenses related to goodwill and other intangible assets, any of which could materially harm our operating results.

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

THE PRICE OF OUR COMMON STOCK MAY FLUCTUATE SIGNIFICANTLY, WHICH MAY RESULT IN LOSSES FOR INVESTORS.

The market price for our common stock has been and may continue to be volatile. For example, during the 52-week period ended July 10, 2001, the closing prices of our common stock as reported on the NASDAQ National Market ranged from a high of \$4.68 to a low of \$0.50. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

- actual or anticipated variations in our quarterly operating results;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements relating to strategic relationships or acquisitions;
- changes in financial estimates by securities analysts;
- statements by securities analysts regarding us or our industry;
- conditions or trends in the medical device industry; and
- changes in the economic performance and/or market valuations of other medical device companies.

15

16

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

In addition, the stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of these companies. Any negative change in the public's perception of medical device companies could depress our stock price regardless of our operating results. If our common stock were to trade under \$1.00 for 30 consecutive days on the NASDAQ National Market, our common stock could be subject to certain consequences established by the NASDAQ National Market such as being delisted. If our common stock were delisted, then we could apply for listing on the Nasdaq SmallCap Market, subject to Nasdaq's approval. If our common stock is not approved for trading on the Nasdaq SmallCap Market, then our common stock would trade only in the secondary markets in the so-called "pink sheets" or Nasdaq's "OTC Bulletin Board." Delisting from the Nasdaq National Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future.

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

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

### MATERIAL CHANGES

On July 9, 2001, the Food and Drug Administration's Circulatory Devices Panel recommended against approval by the Food and Drug Administration of our PMR device for public sale and use in the United States based on concerns related to the safety of the device and the data regarding adverse events in clinical trials. The Advisory Panel cited a concern about the complications reported in the treated patients. While these individual events were not statistically significant between the treated group and the control group, they were still a concern for the Advisory Panel. CardioGenesis expects to be able to provide additional follow up data and analysis to address these safety concerns.

The practical effect of the Advisory Panel's recommendation is to delay indefinitely, until such time as the Food and Drug Administration decides differently, the introduction of our PMR device for sale and use in the United States. Consequently, the Advisory Panel's recommendation has effectively delayed potential revenue, if any, that may have been derived in the future from the sale of our PMR device. Moreover, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration's approval of our PMR device. However, we do not expect to conduct further clinical trials as we intend to gather our clinical data from the trials that have already been performed. Additionally, the trading price of our common stock on the NASDAQ National Market fell substantially after the Advisory Panel's recommendation became public. As discussed in our risk factor section, if our common stock were to trade under \$1.00 for 30 consecutive days on the NASDAQ National Market, our common stock could be subject to certain consequences established by the NASDAQ National Market, such as being delisted. If our common stock were delisted, then we could apply for listing on the Nasdaq SmallCap Market, subject to Nasdaq's approval. If our common stock is not approved for trading on the Nasdaq SmallCap Market, then our common stock would trade only in the secondary markets in the so-called "pink sheets" or Nasdaq's "OTC Bulletin Board." Delisting from the Nasdaq National Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future.

### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-3 under the Securities Act of 1933, as amended, with respect to the shares of common stock offered in this prospectus. This prospectus does not contain all of the information contained in the registration statement and the exhibits and schedules filed with the registration statement. For further information with respect to CardioGenesis and the common stock offered in this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any

16

17

contract or any other document referred to are not necessarily complete. We refer you to the copy of such contract or document filed as an exhibit to the registration statement.

Our registration statement, including exhibits and schedules attached thereto, may be inspected without charge at the Securities and Exchange Commission's public reference facilities in Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, and at the Securities and Exchange Commission's regional

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

offices located at the Northwest Atrium Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661 and Seven World Trade Center, 13th Floor, New York, New York 10048. You may also obtain copies of all or any part of our registration statement from such offices after payment of fees prescribed by the Securities and Exchange Commission. The Securities and Exchange Commission maintains a worldwide website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission at <http://www.sec.gov>.

We are subject to the information and periodic requirements of the Securities Exchange Act of 1934 and accordingly, file periodic reports, proxy statements and other information with the Securities and Exchange Commission. Such periodic reports, proxy statements and other information are available for inspection and copying at the Securities and Exchange Commission's public reference rooms, and the website of the Securities and Exchange Commission referred to above.

### INFORMATION INCORPORATED BY REFERENCE

The Securities and Exchange Commission allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and the information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below, as well as the information contained in all filings made by us pursuant to the Securities Exchange Act of 1934, as amended, after the date of the initial registration statement and prior to the effectiveness of the registration statement, and any future filings after the effectiveness of the registration statement made with the Securities and Exchange Commission under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act until our offering is completed.

- (a) Our Registration Statement on Form 8-A filed with the SEC on April 18, 1996;
- (b) Our Annual Report on Form 10-K, filed April 17, 2001, as amended by Amendment No. 1 to Form 10-K, filed April 27, 2001, Amendment No. 2 to Form 10-K, filed June 13, 2001, and Amendment No. 3 to Form 10-K, filed July 13, 2001, for the year ended December 31, 2000;
- (c) Our Quarterly Report on Form 10-Q, filed May 15, 2001, as amended by Amendment No. 1 to Form 10-Q, filed June 13, 2001, Amendment No. 2 to Form 10-Q, filed July 13, 2001, for the quarterly period ended March 31, 2001;
- (d) Current Reports on Form 8-K filed April 23, 2001 and June 20, 2001; and,
- (e) Our preliminary proxy statement, dated May 2, 2001, and our definitive proxy statement, dated May 14, 2001, both on Schedule 14A.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address:

CardioGenesis Corporation  
26632 Towne Center Drive  
Suite 320

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

Foothill Ranch, California 92610  
Attention: Vice President -- Finance  
Tel: (714) 649-5000

17

18

### FORWARD-LOOKING INFORMATION

This prospectus contains or incorporates by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. Forward-looking statements can typically be identified by the use of forward-looking words, such as "may," "will," "could," "project," "believe," "anticipate," "expect," "estimate," "continue," "potential," "plan," "forecasts," and the like. These statements appear in a number of places in this prospectus and include statements regarding our intentions, plans, strategies, beliefs or current expectations and those of our directors or our officers with respect to, among other things:

- our financial prospects;
- our financing plans;
- trends affecting our financial condition or operating results;  
and
- our strategies for growth, operations, and product development  
and commercialization.

Forward-looking statements do not guarantee future performance and involve risks and uncertainties that could cause actual results to differ materially from those anticipated. The information contained in this prospectus, or incorporated by reference, identifies important factors that could cause such differences.

### USE OF PROCEEDS

All net proceeds from the sale of the shares of common stock covered by this prospectus will go to the selling stockholder who is offering and selling its shares. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholder. See "Plan of Distribution."

### PLAN OF DISTRIBUTION

CardioGenesis is registering the shares of common stock covered by this prospectus for the selling stockholder. These shares have been issued and sold by us in a transaction exempt from the registration requirements of the Securities Act of 1933 to the selling stockholder in connection with a share purchase agreement dated April 11, 2001. Pursuant to the terms of that share purchase agreement, we have filed a Registration Statement on Form S-3 (Reg. No. 333-59572) to register these 2,000,000 shares for resale by the selling stockholder. As used in this prospectus, "selling stockholder" includes the pledgees, donees, transferees or others who later receive the selling stockholder's interest for no additional consideration. We will pay the costs and fees of registering the shares of common stock, but the selling stockholder will pay any brokerage commissions, discounts or other expenses relating to the sale of the shares of common stock.

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

The selling stockholder may sell the shares of common stock on the Nasdaq National Market, in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, or at negotiated prices. The selling stockholder may sell some or all of the shares of common stock in one or more of the following ways:

- a block trade in which a broker-dealer may resell a part of the block, as principal, in order to facilitate the transaction;
- purchases by a broker-dealer, as principal, and resale by the broker-dealer for its account;
- ordinary brokerage transactions and transactions in which a broker solicits purchasers; or,
- privately negotiated transactions.

When selling the shares of common stock, the selling stockholder may enter into hedging transactions. For example, the selling stockholder may:

18

19

- enter into transactions involving short sales of the shares of common stock by broker-dealers;
- sell shares of common stock short themselves and redeliver such shares to close out their short positions;
- enter into option or other types of transactions that require the selling stockholder to deliver shares of common stock to a broker-dealer, who will then resell or transfer the shares of common stock under this prospectus; or
- loan or pledge the shares of common stock to a broker-dealer, who may sell the loaned shares or, in the event of default, sell the pledged shares.

In addition to selling its shares of common stock under this prospectus, the selling stockholder may transfer its shares of common stock in other ways not involving market makers or established trading markets, including directly by gift, distribution, or other transfer.

The selling stockholder may negotiate and pay broker-dealers commissions, discounts or concessions for their services. Broker-dealers engaged by the selling stockholder may allow other broker-dealers to participate in resales. The selling stockholder and any broker-dealers involved in the sale or resale of the shares of common stock may qualify as "underwriters" within the meaning of the Section 2(11) of the Securities Act. In addition, the broker-dealers' commissions, discounts or concessions may qualify as underwriters' compensation under the Securities Act. The selling stockholder will be responsible for compliance with any applicable prospectus delivery requirements under the Securities Act.

The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in some states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.



## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

Under the applicable rules and regulations of the Securities and Exchange Act, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our shares of common stock for a period of two business days prior to the commencement of such distribution. In addition, the selling stockholder will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of shares by the selling stockholder. We will make copies of this prospectus available to the selling stockholder and have informed it of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of the shares.

We may suspend the use of this prospectus and any supplements due to pending corporate developments, public filings with the SEC or similar events.

### SELLING STOCKHOLDER

The selling stockholder described below is a stockholder that is offering and selling these shares covered by this prospectus which were purchased by the selling stockholder in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended, pursuant to Rule 506 from CardioGenesis pursuant to a share purchase agreement dated April 11, 2001 which closed on April 12, 2001. As part of this share purchase agreement, we agreed, for ninety (90) days after the closing date, not to sell shares of our common stock, options, warrants or any other securities that could have been converted into, or otherwise exchanged for, shares of our common stock at a conversion or exercise price less than the per share price for which we sold these shares pursuant to this share purchase agreement. In the event we had, during the ninety (90) day period, sold any shares of our common stock at, or any instruments that could have been converted into or otherwise exchanged for our common stock exercisable at, a price per share less than the per share price under this share purchase agreement, we would have had to refund the difference to the selling stockholder. However, no such shares or instruments convertible into shares of our common stock were sold during such period in violation of this share purchase agreement.

19

20

The selling stockholder may donate or transfer as gifts some or all of its CardioGenesis shares, or may transfer its shares for no additional consideration to others. We will include any of these donees or transferees as a selling stockholder in a prospectus supplement, if required.

The selling stockholder has held no position or office or has had any other material relationship with CardioGenesis or any of our affiliates within the past three years other than as a result of its ownership of shares of our common stock. The selling stockholder is not a broker/dealer or an affiliate of a broker/dealer. The selling stockholder is an independent agency in the administrative branch of the Wisconsin state government. Pursuant to s. 15.76, Wis. Stats., it is governed by a board of nine trustees, six of whom are appointed by the Governor with confirmation by the State Senate. Two trustees are appointed by separate boards made up of representatives elected by participants in the Wisconsin Retirement System, the public pension plan managed by the selling stockholder. The remaining trustee is the Secretary of the State Department of Administration or the Secretary's designee. Four of the trustees appointed by the Governor must have at least ten years of investment experience and one of the Governor's appointees must have at least ten years' experience in a local government finance position. This information is based upon information provided by the selling stockholder.

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

The table below sets forth the following information regarding the selling stockholder:

- The name of the selling stockholder;
- The number of shares of our common stock owned by the selling stockholder on the date of this prospectus prior to the offering for resale of any of the shares being registered by the registration statement of which this prospectus is a part;
- The number of shares of our common stock that may be offered for resale by the selling stockholder pursuant to this prospectus; and
- The number of shares of our common stock to be held by the selling stockholder after the resale of the offered shares.

SELLING STOCKHOLDER	SHARES OF COMMON STOCK BENEFICIALLY OWNED PRIOR TO OFFERING -----	SHARES OF COMMON STOCK BEING OFFERED -----	SHARES OF COMMON STOCK BENEFICIALLY OWNED AFTER OFFERING (1) -----
State of Wisconsin Investment Board.....	4,088,000	2,000,000	2,088,000

- (1) Since the selling stockholder may offer all, some or none of its common stock, we cannot provide a definitive estimate of the number of shares the selling stockholder will hold after the offering. The shares beneficially owned after the offering column assumes the sale of all shares offered, and that the selling stockholder acquires no additional shares of common stock before the completion of this offering.
- (2) The percentage owned after offering column is based on 31,696,061 shares of CardioGenesis common stock outstanding as of March 30, 2001.

### LEGAL MATTERS

Certain legal matters with respect to the shares of common stock offered hereby will be passed upon for us by Gibson, Dunn & Crutcher LLP, Los Angeles, California.

### EXPERTS

The financial statements and the related financial statement schedule incorporated in this prospectus by reference from the Company's Annual Report on Amendment No. 3 to Form 10-K for the year ended December 31,

## Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

2000 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

21

22

### PART II INFORMATION NOT REQUIRED IN PROSPECTUS

#### ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the amounts of expenses to be borne by CardioGenesis in connection with the sale of shares of common stock being registered. All amounts are estimates except the SEC registration fee:

	(U.S.\$)
Filing fees - SEC registration fee.....	\$ 785
Legal Fees and Expenses.....	41,000
Accounting Fees and Expenses.....	7,500
Miscellaneous.....	4,000
	-----
Total.....	\$53,285 =====

#### ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 317 of the California Corporations Code authorizes a court to award, or a corporation's Board of Directors to grant, indemnity to directors and officers for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933. Article IV of the Amended and Restated Articles of Incorporation and Article V of the Amended and Restated Bylaws of CardioGenesis provide for indemnification of its directors, officers, employees and other agents to the maximum extent permitted by the California Corporations Code.

In addition, CardioGenesis has entered into indemnification agreements with each director and executive officer which provide indemnification to the directors and executive officers for acts or omissions which may not be covered by directors' and officers' liability insurance.

#### ITEM 16. EXHIBITS

The following exhibits are filed as part of this registration statement:

- 5.1 Opinion of Gibson, Dunn & Crutcher LLP
- 23.1 Consent of PricewaterhouseCoopers LLP, independent accountants

Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

24.1 Powers of Attorney for certain directors and officers of CardioGenesis (signature page).\*

\* Previously Filed.

ITEM 17. UNDERTAKINGS

The undersigned Registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act,
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration

22

23

Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement, and

- (iii) to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement,

provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the Registration Statement;

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;

Edgar Filing: CARIOGENESIS CORP /CA - Form S-3/A

That, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; and

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has 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. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Foothill Ranch, State of California, on July 25, 2001.

CARDIOGENESIS CORPORATION

By: /s/ J. Stephen Wilkins

-----  
J. Stephen Wilkins  
Chief Financial Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Edgar Filing: CARDIOGENESIS CORP /CA - Form S-3/A

Signature -----	Title -----	D ---
/s/ Michael J. Quinn ----- Michael J. Quinn	Chairman of the Board, Chief Executive Officer, President and Director (Principal Executive Officer)	July
/s/ J. Stephen Wilkins ----- J. Stephen Wilkins	Chief Financial Officer (Principal Financial and Accounting Officer)	July
* ----- Jack M. Gill, Ph.D.	Director	July
* ----- Alan L. Kaganov, Sc.D.	Director	July
* ----- Robert L. Mortensen	Director	July
* ----- Robert C. Strauss	Director	July
* BY: /s/ Michael J. Quinn ----- Michael J. Quinn President and Chief Executive Officer	Attorney-in-Fact	

24

25

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
5.1	Opinion of Gibson, Dunn & Crutcher LLP
23.1	Consent of PricewaterhouseCoopers LLP, independent accountants
24.1	Powers of Attorney for certain directors and officers of CardioGenesis (signature page).*

\* Previously Filed.

