

Cardium Therapeutics, Inc.
Form POS AM
May 16, 2007
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As filed with the U.S. Securities and Exchange Commission on May 16, 2007

Registration No. 333-131104

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 2

TO

FORM SB-2

ON

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CARDIUM THERAPEUTICS, INC.

(Name of small business issuer in its charter)

Delaware
(State or jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

27-0075787
(I.R.S. Employer
Identification No.)

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(Address and telephone number of principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable 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:

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If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, 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 of 1933, 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act of 1933, check the following box: "

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, 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 that 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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. Our selling stockholders 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 offers to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 16, 2007

30,021,059 Shares
of
Common Stock

This prospectus relates to resales of shares common stock and shares of common stock underlying warrants previously issued by Cardium Therapeutics, Inc. to the selling stockholders in connection with a private placement of securities and a reverse merger, each of which was completed on October 20, 2005.

The selling stockholders identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. We will receive none of the proceeds from the sale of the shares by the selling stockholders. However, if the warrants are exercised, we will receive cash for the exercise price of the warrants.

The selling stockholders may resell the common stock to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions. The selling stockholders will bear all commissions and discounts, if any, attributable to the sales of shares. We will bear all costs, fees and expenses in connection with the registration of the shares.

Our common stock is quoted on the OTC Bulletin Board under the symbol **CDTP**. On May 15, 2007, the closing sale price of our common stock was \$2.90 per share. You are urged to obtain current market quotations for the common stock.

An investment in our common stock involves a high degree of risk. Please carefully review the section titled **Risk Factors beginning on page 4.**

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The selling stockholders and any broker-dealer executing sell orders on behalf of the selling stockholders may be deemed to be underwriters within the meaning of the Securities Act of 1933 with respect to the shares sold by them. Commissions received by any broker-dealer may be deemed to be underwriting commissions under the Securities Act of 1933.

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

The date of this prospectus is _____, 2007

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You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with information different from the information contained or incorporated by reference in this prospectus. This prospectus may only be used where it is legal to sell these securities. This prospectus is not an offer to sell, or a solicitation of an offer to buy, in any state where the offer or sale is prohibited. The information contained in this prospectus is accurate on the date of this prospectus and may become obsolete later. Neither the delivery of this prospectus, nor any sale made under this prospectus, will under any circumstances, imply that the information in this prospectus is correct as of any date after the date of this prospectus. References to Cardium, we, us or our refer to Cardium Therapeutics, Inc.

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BUSINESS SUMMARY

This summary highlights certain information about Cardium and its business. This summary does not contain all of the information that is important to an investment decision. You should read the entire prospectus carefully, including Risk Factors beginning below on page 4, before deciding to invest in our common stock.

Our Business

We are a medical technology company primarily focused on the development and commercialization of novel biologic therapeutics and medical devices for cardiovascular and ischemic disease. Since we were initially funded in October 2005, we have made three strategic acquisitions and assembled a portfolio of innovative late-stage cardiovascular and regenerative medicine product candidates, together with medical devices having U.S. Food and Drug Administration (FDA) clearances that are marketed and sold through our direct sales force. We have established a pipeline of innovative products that are divided into three operating units, Cardium Biologics, InnerCool Therapies, Inc. and the Tissue Repair Company.

As our current products and product candidates become successfully advanced, we intend to continue to pursue opportunistic acquisitions designed to enhance long-term stockholder value. At the same time, as technologies and product candidates are advanced and businesses are further developed, we may consider various corporate development transactions to enhance and monetize stockholder value such as corporate partnerings, spin-out transactions and equity distribution.

Cardium Biologics

The following describes the leading product candidates in Cardium Biologic s drug development pipeline:

- **GenerxTM (alferminogene tadenovec).** Our lead product candidate, Generx, is a late-stage DNA-based growth factor therapeutic that is in a new class of cardiovascular biologics being developed to leverage the body s natural healing processes in response to repeated ischemic stress (insufficient blood flow and myocardial oxygen supply due to coronary heart disease). Generx is being developed as a one-time treatment to promote and stimulate the growth of collateral circulation in the hearts of patients with ischemic conditions such as recurrent angina. The natural biologic response to repeated transient ischemia is angiogenesis, the growth of new collateral blood vessels, which is orchestrated by a complex and not fully understood cascade involving many myocardial-derived growth factors. These newly formed vessels can effectively augment blood flow and oxygen delivery to parts of the patient s heart downstream from a blockage in a coronary artery. In many patients however, including those with recurrent angina, coronary collateral vessel formation is insufficient to meet the heart s needs during stress. Currently available anti-anginal drugs, which may provide symptomatic relief, are generally designed to alter the oxygen demand of the heart muscle or dilate vessels to temporarily relieve angina. Generx is an angiogenic therapeutic that is designed to promote the heart s natural response of collateral growth and to increase blood flow in the microcirculation. Generx is expected to commence a Phase 3 clinical study in the first half of 2007 that will be a randomized, placebo-controlled, double blind trial in approximately 300 women at multiple medical centers in the U.S. An additional follow-up study of Generx in men with recurrent angina due to myocardial ischemia is expected to commence later. Generx is the first and only DNA-based cardiovascular therapeutic to be advanced to Phase 3, and is believed to be the only current Phase 3 product candidate for the potential treatment of stable angina, a chronic medical condition affecting millions of patients in the U.S. and elsewhere.

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- ***Corgentin [Ad5IGF-I]***. Corgentin, our lead pre-clinical product candidate, is a next-generation DNA-based therapeutic based on myocardial produced insulin-like growth factor-I (ad5IGF-I) which

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could be developed for administration in an acute care setting by interventional cardiologists as a treatment for heart attack patients immediately following percutaneous coronary intervention. Corgentin is designed to enhance myocardial healing in and around the infarct zone when used as an adjunct to existing vascular-directed pharmacologic and interventional therapies. To further confirm the utility of the Corgentin approach and establish its commercialization potential, we are planning additional pre-clinical studies in the porcine acute myocardial infarction model, closely mimicking the clinical setting. If confirmatory, we may seek to initiate clinical studies on our own or with a corporate development partner.

- **Genvascor [Ad5eNOS].** Genvascor is a pre-clinical, DNA-based, endothelial nitric oxide synthase (eNOS) therapeutic. This product candidate is being designed to induce production of nitric oxide directed at mediating the effects of multiple growth factors to enhance neovascularization and increased blood flow for the treatment of patients with critical limb ischemia due to advanced peripheral vascular disease. We may seek to develop additional pre-clinical information through sponsored studies and, if confirmatory, we may consider the further development of Genvascor either alone or through a corporate collaboration.

Innercool Therapies

Our InnerCool Therapies subsidiary is focused on the emerging field of temperature modulation or therapeutic hypothermia, which is designed to rapidly and controllably cool the body in order to reduce cell death and damage following acute ischemic events such as cardiac arrest or stroke, and to potentially lessen or prevent associated injuries such as adverse neurological outcomes. InnerCool's Celsius Control System has received FDA 510(k) clearance for use in inducing, maintaining and reversing mild hypothermia in neurosurgical patients, both in surgery and in recovery or intensive care. The system has also received FDA clearance for use in cardiac patients in order to achieve or maintain normal body temperatures during surgery and in recovery/intensive care, and as an adjunctive treatment for fever control in patients with cerebral infarction and intracerebral hemorrhage. InnerCool has also received a CE mark allowing the Celsius Control System to be marketed in the European Community, and a TGA approval allowing the system to be marketed in Australia.

Studies for additional indications with InnerCool's Celsius Control System are expected to be conducted in collaboration with the National Institutes of Health and other collaborating institutions. Potential future applications of the technology include endovascular cooling for cardiac arrest, acute ischemic stroke and myocardial infarction (heart attack), and acute traumatic injury. We plan to accelerate the commercialization of the Celsius Control System and broaden and expand its temperature modulation technology into other medical indications and applications. Since its acquisition by Cardium, InnerCool's sales force has been expanded, a new cGMP manufacturing facility has been secured to increase production capabilities, and a next-generation console for the Celsius Control System have been developed and a new external temperature modulation system are both being developed for planned launches in mid-2007. InnerCool is also in the process of finalizing a new external temperature modulation system, which is designed to provide a complementary tool for use in less-acute patients and in clinical settings that do not require very rapid cooling or re-warming, or which are best suited to prolonged temperature management. Both the new Celsius Control System and the new external temperature modulation system are expected to be launched in mid-2007.

Tissue Repair Company

Excellerate™ is the lead product candidate of the Tissue Repair Company, our wholly-owned subsidiary. Excellerate is a DNA-activated collagen gel for topical treatment formulated with an adenovector delivery carrier encoding human platelet-derived growth factor-B (PDGF-B) and is designed to stimulate angiogenesis and granulation tissue formation through the recruitment and proliferation of chemotactic cells such as monocytes

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and fibroblasts, which are necessary for the stimulation of a variety of wound healing processes. Excellerate is initially being developed as a single administration for the treatment of non-healing, neuropathic diabetic foot ulcers. Based on the prior pre-clinical and toxicology database, and results from the Phase 1/2 clinical study, we anticipate that Excellerate may be advanced into a randomized, double-blind, placebo-controlled, multi-center Phase 2b clinical study commencing in the second half of 2007.

Excellerate is based on Tissue Repair Company's Gene Activated Matrix™ technology, which is a technology designed to provide a therapeutic level of protein synthesis at a particular site in the body and can be used in soft tissue such as skin, ligament, tendons and cartilage, as well as hard tissue such as bone. The technology is distinctive in that it is an immobilized form of local gene delivery that allows for control of gene uptake. Gene Activated Matrix technology consists of a biocompatible matrix comprising a gene or DNA vector encoding a growth factor or other therapeutic protein. Other potential applications of Gene Activated Matrix technology include therapeutic angiogenesis (cardiovascular ischemia, peripheral arterial disease) and orthopedic products, including hard tissue (bone) and soft tissue (ligament, tendon, cartilage) repair.

Corporate Information

Our principal executive offices are located at 3611 Valley Centre Drive, Suite 525, San Diego, California 92130, and our telephone number is (858) 436-1000. Our website is located at www.cardiumthx.com. Information on our website is not part of this prospectus.

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RISK FACTORS

You should carefully consider the risks described below, as well as the other information in this prospectus, when evaluating our business and future prospects. If any of the following risks actually occur, our business, financial condition and results of operations could be seriously harmed. In that event, the market price of our common stock could decline and you could lose all or a portion of the value of your investment in our common stock.

Risks Related to Our Business and Industry

We are a development stage company formed in December 2003. We have incurred losses since inception and expect to incur significant net losses in the foreseeable future and may never become profitable.

We have sustained operating losses to date and will likely continue to sustain losses as we seek to accelerate our product development efforts. We expect these losses to be substantial in the early years of our operations because our product development and other costs, including significant amounts we expect to spend on development activities and clinical trials for Generx , Excellerate and other product candidates, cannot be offset by our limited revenues during our development stage. As of December 31, 2006, our accumulated deficit was approximately \$24 million, and our cash equivalents were approximately \$5.9 million. To date, we have generated limited revenues, consisting of revenues from sales of our InnerCool Celsius Control System and associated disposables, as well as interest income. A large portion of our expenses are fixed, including expenses related to facilities, equipment, contractual commitments and personnel. As a result, we expect our net losses from operations to continue for at least the next five years. Our ability to generate additional revenues and potential to become profitable will depend largely on our ability, alone or with potential collaborators, to efficiently and successfully complete the development of our product candidates, successfully complete pre-clinical and clinical tests, obtain necessary regulatory approvals, and manufacture and market our products. There can be no assurance that any such events will occur or that we will ever become profitable. Even if we do achieve profitability, we cannot predict the level of such profitability. If we sustain losses over an extended period of time, we may be unable to continue our business.

Our business prospects are difficult to evaluate because we are a new company and are developing complex and novel medical products.

Since we have a short operating history and our product candidates rely on complex technologies, it may be difficult for you to assess our growth, partnering and earnings potential. It is likely we will face many of the difficulties that new technology companies often face. These include, among others: limited financial resources; developing, testing and marketing new products for which a market is not yet established and may never become established; challenges related to the development, approval and acceptance of a new technology or product; delays in reaching our goals; lack of substantial revenues and cash flow; high product development costs; competition from larger, more established companies; and difficulty recruiting qualified employees for management and other positions. We will likely face these and other difficulties in the future, some of which may be beyond our control. If we are unable to successfully address these difficulties as they arise, our future growth and earnings will be negatively affected. We cannot be certain that our business strategies will be successful or that we will successfully address any problems that may arise.

We will need substantial additional capital to develop our products and for our future operations. If we are unable to obtain such funds when needed, we may have to delay, scale back or terminate our product development or our business.

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Conducting the costly and time consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our products to market will require a commitment of substantial funds in excess of our current capital. Our future capital requirements will depend on many factors, including, among others: the progress of our current and new product development programs; the progress, scope and results of our pre-clinical and clinical testing; the time and cost involved in obtaining regulatory approvals; the cost of

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manufacturing our products and product candidates; the cost of prosecuting, enforcing and defending against patent claims and other intellectual property rights; competing technological and market developments; and our ability and costs to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market.

We will need to raise substantial additional capital to fund our future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. To the extent we raise additional capital through the sale of equity securities or we issue securities in connection with another transaction, the ownership position of existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in our assets. Fluctuating interest rates could also increase the costs of any debt financing we may obtain. Raising capital through a licensing or other transaction involving our intellectual property could require us to relinquish valuable intellectual property rights and thereby sacrifice long term value for short-term liquidity.

Our failure to successfully address ongoing liquidity requirements would have a substantially negative impact on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may need to take actions that adversely affect our business, our stock price and our ability to achieve cash flow in the future, including possibly surrendering our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

We acquired the assets and business of InnerCool Therapies, Inc. in March 2006 and rights to develop the Excellerate product candidate of the Tissue Repair Company in August 2006 and may, in the future, pursue acquisitions of other companies or product rights that, if not successful, could adversely affect our business, financial condition and results of operations.

On March 8, 2006, we completed our acquisition of the assets and business of InnerCool Therapies, Inc., a medical technology company focused on the emerging field of therapeutic hypothermia. On August 11, 2006, we acquired rights to develop the Excellerate product candidate of the Tissue Repair Company, a medical technology company focused on the development of growth factor therapeutics for the potential treatment of chronic wounds such as dermal ulcers. These businesses are subject to all of the operational risks that can affect medical technology companies, including those related to regulatory approvals and clinical studies, acceptance of technology, competing technology, intellectual property rights, profitability, suppliers and third party collaborators, adverse publicity, litigation, and retention of key personnel.

In the future, we may pursue additional acquisitions of other companies, technologies or products. Acquisitions of businesses or product rights, including the InnerCool and Tissue Repair Company transactions, involve numerous risks, including:

our limited experience in evaluating businesses and product opportunities and completing acquisitions;

the use of our existing cash reserves or the need to obtain additional financing to pay for all or a portion of the purchase price of such acquisitions and to support the ongoing operations of the businesses acquired;

the potential need to issue convertible debt, equity securities, stock options and stock purchase warrants to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;

potential difficulties related to integrating the technology, products, personnel and operations of the acquired company;

requirements of significant capital infusions in circumstances under which the acquired business, its products and/or technologies may not generate sufficient revenue or any revenue to offset acquisition costs or ongoing expenses;

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entering markets in which we have no or limited prior direct experience and where competitors have stronger market or intellectual property positions;

disruptions to our ongoing business, diversion of resources, increases in our expenses and distraction of management's attention from the normal daily operations of our business;

the potential to negatively impact our results of operations because an acquisition may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or cause adverse tax consequences, substantial depreciation or deferred compensation charges;

an uncertain sales and earnings stream, or greater than expected liabilities and expenses, associated with the acquired company, product or product rights;

failure to operate effectively and efficiently as a combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices;

potential loss of key employees of the acquired company; and

disruptions to our relationships with existing collaborators who could be competitive with the acquired business.

There can be no assurance that our InnerCool or Tissue Repair transactions, or other transactions that we may pursue, will ultimately prove successful. If we pursue an acquisition but are not successful in completing it, or if we complete an acquisition but are not successful in integrating the acquired company's employees, products or operations successfully, our business, financial condition or results of operations could be harmed.

We are an early stage company and, other than InnerCool's Celsius Control System and related disposables that are approved for limited uses, we have no other products available for sale or use. Our product candidates require additional research, development, testing, and regulatory approvals before marketing. We may be unable to develop, obtain regulatory approval or market any of our product candidates or expand the market of our existing products and technology. If our product candidates are delayed or fail, our business and stockholder value will be negatively impacted, and we may have to curtail or cease our operations.

We are in the early stage of product development and, other than InnerCool's Celsius Control System and related disposables that are approved only for limited uses, we currently do not sell any other products and may not have any other products commercially available for several years, if at all. Our product candidates, and the potential expansion of our therapeutic hypothermia products into other medical indications and applications, require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, the U.S. Food and Drug Administration, or FDA, has not yet approved any gene therapy or similar product and there can be no assurance that it will. There are many reasons that our products and product candidates may fail or not advance beyond clinical testing, including the possibility that:

our products and product candidates may be ineffective, unsafe or associated with unacceptable side effects;

our product candidates may fail to receive necessary regulatory approvals or otherwise fail to meet applicable regulatory standards;

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our product candidates may be too expensive to develop, manufacture or market;

physicians, patients, third-party payers or the medical community in general may not accept or use our products;

our potential collaborators may withdraw support for or otherwise impair the development and commercialization of our products or product candidates;

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other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our products or product candidates; or

others may develop equivalent, superior or less expensive products.

In addition, our product candidates are subject to the risks of failure inherent in the development of biologics, gene therapy and other products based on innovative technologies. As a result, we are not able to predict whether our research, development and testing activities will result in any commercially viable products or applications. If our product candidates are delayed or we fail to successfully develop and commercialize our product candidates, or if we are unable to expand the market of our existing products or related technology, our business, financial condition or results of operations will be negatively affected, and we may have to curtail or cease our operations.

We may experience delays in our clinical trials that could adversely affect our business, financial results and commercial prospects.

To obtain regulatory approvals for new products or to expand indications for existing ones, we must, among other things, initiate and successfully complete multiple clinical trials demonstrating to the satisfaction of the FDA that our product candidates are sufficiently safe and effective for a particular indication. We are in ongoing discussions with the FDA regarding clinical trials of our Generx product candidate, and expect to soon be in discussions regarding our recently acquired Excellerate product candidate. While we expect both product candidates to be in clinical trials in 2007, there is no assurance that they will be since the timing of clinical trials is dependent on, among other things, FDA reviews, clinical site approvals, successful manufacturing of clinical materials, sufficient funding and other factors outside of our control. Furthermore, there can be no assurance that our clinical trials will in fact demonstrate to the satisfaction of the FDA and others that our products are sufficiently safe or effective.

The FDA or we may also restrict or suspend our clinical trials at any time if either believes that we are exposing the subjects participating in the trials to unacceptable health risks. We expect to continue to rely on third party clinical investigators at medical institutions and healthcare facilities to conduct and monitor our clinical trials, and, as a result, we may face additional delaying factors outside of our control. Product development costs to us and our potential collaborators will increase, and our business may be negatively impacted, if we experience delays in testing or approvals or if we need to perform more or larger clinical trials than planned, for reasons such as the following:

the FDA or other health regulatory authorities, or institutional review boards, do not approve a clinical study protocol or place a clinical study on hold;

suitable patients do not enroll in a clinical study in sufficient numbers or at the expected rate, or data is adversely affected by trial conduct or patient drop out;

patients experience serious adverse events, including adverse side effects of our drug candidate or device;

patients die during a clinical study for a variety of reasons that may or may not be related to our products, including the advanced stage of their disease and medical problems;

patients in the placebo or untreated control group exhibit greater than expected improvements or fewer than expected adverse events;

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third-party clinical investigators do not perform the clinical studies on the anticipated schedule or consistent with the clinical study protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

service providers, collaborators or co-sponsors do not adequately perform their obligations in relation to the clinical study or cause the study to be delayed or terminated;

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regulatory inspections of manufacturing facilities, which may, among other things, require us or a co-sponsor to undertake corrective action or suspend the clinical studies;

the interim results of the clinical study are inconclusive or negative;

the clinical study, although approved and completed, generates data that is not considered by the FDA or others to be sufficient to demonstrate safety and efficacy; and

changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its results.

Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable.

If we cannot successfully complete the clinical trial process for our product candidates, or products for which we seek expanded approvals, then we will not be able to market them. Even successful clinical trials may not result in a marketable product and may not be predictive of a product's safety or efficacy in a larger and more diverse patient population.

Our Celsius Control System acquired from InnerCool Therapies has received FDA 510(k) clearance for certain specified indications but we may elect to pursue other indications, which would generally require that collaborators or we conduct additional clinical studies and/or testing. Our Generx and Excellerate product candidates are currently in the clinical stage. Other product candidates are in the pre-clinical stage and there can be no assurance they will ever advance to clinical trials. For product candidates that advance to clinical testing, we cannot be certain that a collaborator or we will successfully complete the clinical trials necessary to receive regulatory product approvals. This process is lengthy, unpredictable and expensive. To obtain regulatory approvals, a collaborative partner or we must ultimately demonstrate to the satisfaction of the FDA and others that our product candidates are sufficiently safe and effective for their proposed use.

Many factors, known and unknown, can adversely impact clinical trials and the ability to evaluate a product's safety and efficacy. Such factors may have a negative impact on our business by making it difficult to advance product candidates or by reducing or eliminating their potential or perceived value. Further, if we are forced to contribute greater financial and clinical resources to a study, valuable resources will be diverted from other areas of our business.

Clinical trials for products such as ours are often conducted with patients who have more advanced forms of a particular disease. For example, in clinical trials for our lead product candidate Generx, we expect to study patients who are not only suffering from severe forms of heart disease but are also older and much more likely to develop cancers and other serious adverse conditions. During the course of treatment, these patients could die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Our clinical trials may also be adversely impacted by patient deaths or problems that occur in other trials. However, even if unrelated to our product, such events can nevertheless adversely impact our clinical trials. As a result, our business and ability to ultimately develop and market the products and obtain revenues would suffer.

Deaths and other adverse events that occur in the conduct of clinical trials may also result in an increase in governmental regulations or litigation, and could result in delays or halts being imposed upon clinical trials, including our own. In addition, patients involved in clinical trials such as ours often have unknown as well as known health risks and pre-existing conditions. An adverse event may therefore appear to have been caused or exacerbated by the administration of study product, even if it was not actually related. Such consequences can also increase the risk

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that any potential adverse event in our trial could give rise to claims for damages against us, or could cause further delays or halt our clinical trial, any of which results would negatively impact us. In addition, fears regarding the potential consequences of gene therapy trials or the conduct of such trials could dissuade investigators or patients from participating in our trials, which could substantially delay or prevent our product development efforts.

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Even promising results in pre-clinical studies and initial clinical trials do not ensure successful results in later clinical trials, which test broader human use of our products. Many companies in our industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. Even successful clinical trials may not result in a marketable product or be indicative of the efficacy or safety of a product in the broader patient population. Many factors or variables could affect the results of clinical trials and cause them to appear more promising than they may otherwise be. Product candidates that successfully complete clinical trials could ultimately be found to be unsafe or ineffective or to have poorer risk to benefit or cost to benefit profiles as compared to other potential products or therapies.

Our ability to complete clinical trials depends on many factors, including obtaining adequate clinical supplies and having a sufficient rate of patient recruitment. For example, patient recruitment is a function of many factors, including: the size of the patient population; the proximity of patients to clinical sites; the eligibility criteria for the trial; the perceptions of investigators and patients regarding safety; and the availability of other treatment options. Even if patients are successfully recruited, we cannot be sure they will complete the treatment process. Delays in patient enrollment or treatment in clinical trials may result in increased costs, program delays, or failure, any of which can substantially affect our business or perceived value.

In addition, DNA-based therapies such as those being developed by us are relatively new and are only beginning to be tested in humans. Regulatory authorities may require us or our potential collaborators to demonstrate that our products are improved treatments relative to other therapies or may significantly modify the requirements governing gene therapies, which could result in regulatory delays or rejections that negatively impact our business. Compliance with these regulatory requirements is also time consuming and expensive. If we fail to comply with regulatory requirements, either before approval or in marketing our products after approval, we could be subject to regulatory or judicial enforcement actions. These actions could result in withdrawal of existing approvals, product recalls, injunctions, civil penalties, criminal prosecution, and enhanced exposure to product liabilities.

Ethical, social and legal concerns about gene therapy and genetic research could also result in additional regulations restricting or prohibiting our products and processes we may use. More restrictive government regulations or negative public opinion may have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates.

With respect to markets in other countries, we or a partner will also be subject to regulatory requirements governing clinical trials in those countries. Even if we complete clinical trials, we may not be able to submit a marketing application. If we submit an application, the regulatory authorities may not review or approve it in a timely manner, if at all.

Our technologies and product candidates may have unacceptable side effects that could delay or prevent product approval.

Possible side effects of therapeutic technologies may be serious and life threatening. The occurrence of any unacceptable side effects during or after pre-clinical and clinical testing of our product candidates, or the perception or possibility that our products cause or could cause such side effects, could delay or prevent approval of our products and negatively impact our business. For example, possible serious side effects of viral vector-based gene transfer could potentially include viral or gene product toxicity resulting in inflammation or other injury to the heart or other parts of the body. In addition, the development or worsening of cancer in a patient could potentially be a perceived or actual side effect of gene therapy technologies such as our own. Furthermore, there is a possibility of side effects or decreased effectiveness associated with an immune response toward any viral vector or gene used in gene therapy. The possibility of such response may increase if there is a need to deliver the viral vector more than once.

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Even if approved for marketing, our technologies and product candidates are relatively novel and unproven and they may fail to gain market acceptance.

Our ongoing business and future depends on the success of our technologies and product candidates. Gene-based therapy and endovascular temperature control therapy are new and rapidly evolving medical approaches that have not been shown to be effective on a widespread basis. Biotechnology and pharmaceutical companies have successfully developed and commercialized only a limited number of biologic-based products to date and no gene therapy has yet been successfully commercialized. Our product candidates, and the technology underlying them, are new and unproven and there is no guarantee that health care providers or patients will be interested in our products even if they are approved for use. Our success will depend in part on our ability to demonstrate sufficient clinical benefits, reliability, safety and cost effectiveness of our product candidates and technology relative to other approaches, as well as on our ability to continue to develop our product candidates to respond to competitive and technological changes. If the market does not accept our products or product candidates, when and if we are able to commercialize them, then we may never become profitable. It is difficult to predict the future growth of our business, if any, and the size of the market for our product candidates because the market and technology are continually evolving. There can be no assurance that our technologies and product candidates will prove superior to technologies and products that may currently be available or may become available in the future or that our technologies or research and development activities will result in any commercially profitable products.

We may not successfully establish and maintain collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize our product candidates.

Our strategy for the development, testing, manufacturing and commercialization of our product candidates generally relies on establishing and maintaining collaborations with corporate partners, licensors and other third parties. For example, we have licenses from New York University and the University of California relating to the use and delivery of our Generx product candidates for the treatment of vascular disease, as well as a relationship with Schering AG Group (Germany) regarding the transfer of information about certain manufacturing and regulatory matters concerning our product candidates. We may not be able to maintain or expand these licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

We expect to rely at least in part on third party service providers and collaborators to perform a number of activities relating to the development and commercialization of our product candidates, including the manufacture of product materials, the design and conduct of clinical trials, and potentially the obtaining of regulatory approvals and the marketing and distribution of any successfully developed products. Our collaborative partners also may have or acquire rights to control aspects of our product development and clinical programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate. In addition, if any of these collaborative partners withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

Our success hinges on the proper and effective performance of our service providers and collaborators of their responsibilities under their arrangements with us. Our existing or potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. We and our present and future collaborators may fail to develop or effectively commercialize products covered by our present and future collaborations if, among other things:

we do not achieve our objectives under our collaboration agreements;

we or our collaborators are unable to obtain patent protection for the products or proprietary technologies we develop in our collaborations;

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we are unable to manage multiple simultaneous product discovery and development collaborations;

our collaborators become competitors of ours or enter into agreements with our competitors;

we or our collaborators encounter regulatory hurdles that prevent commercialization of our products; or

we develop products and processes or enter into additional collaborations that conflict with the business objectives of our other collaborators.

In addition, conflicts may arise with our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any conflicts arise with our existing or future collaborators, they may act in their self-interest, which may be adverse to our best interest. If we or our collaborators are unable to develop or commercialize products, or if conflicts arise with our collaborators, we will be delayed or prevented from developing and commercializing products, which will harm our business and financial results.

We will rely on third parties to manufacture our product candidates. There can be no guarantee that we can obtain sufficient and acceptable quantities of our product candidates on acceptable terms, which may delay or impair our ability to develop, test and market such products.

Our business strategy relies on third parties to manufacture and produce our products and product candidates and the catheters used to deliver the products in accordance with good manufacturing practices established by the FDA and other regulators. For example, we entered into a Production Service Agreement with Molecular Medicine Bioservices, Inc. pursuant to which Molecular Medicine agreed to manufacture our lead product candidate, Generx, for late-stage clinical development. These third party manufacturers are subject to extensive government regulation and must receive FDA approval before they can produce clinical material or commercial product.

Our products and product candidates may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority than our products. These third parties also may not deliver sufficient quantities of our products, manufacture our products in accordance with specifications, or comply with applicable government regulations. Successful large-scale manufacturing of gene-based therapy products has been accomplished by very few companies, and it is anticipated that significant process development changes will be necessary before commercializing and manufacturing any of our biologic product candidates. Additionally, if the manufactured products fail to perform as specified, our business and reputation could be severely impacted.

If any manufacturing agreement is terminated or any third party service provider or collaborator experiences a significant problem that could result in a delay or interruption in the supply of product materials to us, there are very few contract manufacturers who currently have the capability to produce our product candidates. There can be no assurance that manufacturers on whom we depend will be able to successfully produce our products or product candidates on acceptable terms, or on a timely or cost-effective basis, or in accordance with our product specifications and applicable FDA or other governmental regulations. We must have sufficient and acceptable quantities of our product materials to conduct our clinical trials and to market our product candidates, if and when such products have been approved by the FDA for marketing. If we are unable to obtain sufficient and acceptable quantities of our product material, we may be required to delay the clinical testing and marketing of our products, which would negatively impact our business.

If we do not comply with applicable regulatory requirements in the manufacture and distribution of our products and product candidates, we may incur penalties that may inhibit our ability to commercialize our products and adversely affect our financial condition and ability to

become profitable.

Our failure or the failure of our potential collaborators or third party manufacturers to comply with applicable FDA or other product-related regulatory requirements including manufacturing, quality control,

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labeling, safety surveillance, promoting and reporting may result in criminal prosecution, civil penalties, recall or seizure of our products, total or partial suspension of production or an injunction, as well as other regulatory action against our products, product candidates or us. Discovery of previously unknown problems with a product, supplier, manufacturer or facility may result in restrictions on the sale of our products, including a withdrawal of such products from the market. The occurrence of any of these events would negatively impact our business and results of operations.

If we are unable to create and maintain sales, marketing and distribution capabilities or enter into agreements with third parties to perform those functions, we will not be able to commercialize our product candidates or market our products.

We currently have limited sales, marketing and distribution capabilities in connection with our InnerCool products and none with respect to our other product candidates, which are not yet approved for marketing. To commercialize our other product candidates, if and when such products have been approved and are ready for marketing, we expect either to collaborate with third parties to perform these functions or develop them internally.

We have little experience in developing, training or managing a sales force and will incur substantial additional expenses for any products that we market directly. Developing a marketing and sales force is also time consuming and could delay the launch of new products or expansion of existing product sales. We expect that we will need to develop additional marketing and sales personnel, and/or work with outside providers, to achieve increased sales of our InnerCool products. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against these companies, in which event our business prospects may suffer.

We face intense and increasing competition and must cope with rapid technological change, which may adversely affect our financial condition and/or our ability to successfully commercialize and/or market our products and product candidates.

Our competitors and potential competitors include large pharmaceutical and medical device companies and more established biotechnology companies. These companies have significantly greater financial and other resources and greater expertise than us in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and marketing. This may make it easier for them to respond more quickly than us to new or changing opportunities, technologies or market needs. Small companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies or through acquisition or development of intellectual property rights. Our larger competitors may be able to devote greater resources to research and development, marketing, distribution and other activities that could provide them with a competitive advantage. Many of these competitors operate large, well-funded research and development programs and have significant products approved or in development. Our potential competitors also include academic institutions, governmental agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for product and clinical development and marketing.

We are engaged in DNA-based therapies and temperature control therapy. Our industry is characterized by extensive research and development, rapid technological change, frequent innovations and new product introductions, and evolving industry standards. Existing products and therapies to treat vascular and cardiovascular disease, including drugs and surgical procedures, as well as competitive approaches to temperature control therapy such as those being developed by Alsius Corporation, Radiant Medical, Medivance, Gaymar Industries and Cincinnati Sub-Zero, will compete directly or indirectly with the products that we are seeking to develop and market. In addition, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization and market penetration than us. As these competitors develop their technologies, they may develop proprietary positions that prevent us from

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successfully commercializing our future products. To be successful, we must be able to adapt to rapidly changing technologies by continually enhancing our products and introducing new products. If we are unable to adapt, products and technologies developed by our competitors may render our products and product candidates uneconomical or obsolete, and we may not be successful in marketing our products and product candidates against competitors. We may never be able to capture and maintain the market share necessary for growth and profitability and there is no guarantee we will be able to compete successfully against current or future competitors.

Changes and reforms in the health care system or reimbursement policies may adversely affect the sale of our products and future products or our ability to obtain an adequate level of reimbursement or acceptable prices for our products or future products.

Other than InnerCool's Celsius Control System and associated disposables, we currently have no products approved for marketing. Our ability to earn sufficient returns on our products and future products, if and when such products are approved and ready for marketing, will depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other third-party payers. If we fail to obtain appropriate reimbursement, it could prevent us from successfully commercializing and marketing our products and future products.

There have been and will continue to be efforts by governmental and third-party payers to contain or reduce the costs of health care through various means, including limiting coverage and the level of reimbursement. We expect that there will continue to be a number of legislative proposals to implement government controls and other reforms to limit coverage and reimbursement. Additionally, third-party payers, including Medicare, are increasingly challenging the price of medical products and services and are limiting the reimbursement levels offered to consumers for these medical products and services. If purchasers or users of our products or future products are not able to obtain adequate reimbursement from third-party payers for the cost of using the products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, including gene therapy and therapeutic hypothermia treatments, and whether adequate third-party coverage will be available. The announcement or considerations of these proposals or reforms could impair our ability to raise capital and negatively affect our business.

If we are unable to attract and retain key personnel and advisors, it may adversely affect our ability to obtain financing, pursue collaborations or develop or market our products or product candidates.

Our future success depends on our ability to attract, retain and motivate highly qualified management and scientific and regulatory personnel and advisors, as well as production, marketing and sales personnel in connection with our InnerCool products. The loss of any of our senior management team, in particular Christopher J. Reinhard, our Chairman of the Board, Chief Executive Officer, President and Treasurer, Tyler M. Dylan, our director, Chief Business Officer, General Counsel, Executive Vice President and Secretary, and Dennis M. Mulroy, our Chief Financial Officer, or our vice presidents, or the operating officers of our subsidiaries, could harm our business.

To pursue our business strategy, we will need to hire or otherwise engage qualified scientific personnel and managers, including personnel with expertise in clinical trials, government regulation, manufacturing, marketing and other areas. Competition for qualified personnel is intense among companies, academic institutions and other organizations. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test, commercialize and market our products and product candidates.

Our facilities are located in or near seismic zones, and an earthquake or other natural disaster or resource shortage could delay our research and development efforts and adversely affect our business.

Our headquarters and research and development facilities in San Diego, California, and our third party manufacturing facilities in Carlsbad, California, are both located in or near seismic zones, and there is a constant

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possibility that an earthquake or other natural disaster or resource shortage could be disruptive to our operations and result in delays in our research and development efforts. In the event of a natural or other disaster such as earthquake, fire, flood or terrorist attack, if our facilities or the equipment in our facilities, or our clinical supplies, are significantly damaged or destroyed, we may not be able to rebuild or relocate our facility or replace any damaged equipment, records or clinical supplies in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

We will use hazardous and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our products and processes will involve the controlled storage, use and disposal of certain hazardous and biological materials and waste products. We and our suppliers and other collaborators are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future environmental laws and regulations.

To the extent we enter markets outside the United States, our business will be subject to political, economic, legal and social risks in those markets, which could adversely affect our business.

There are significant regulatory and legal barriers in markets outside the United States that we must overcome to the extent we enter or attempt to enter markets in countries other than the United States. We will be subject to the burden of complying with a wide variety of national and local laws, including multiple and possibly overlapping and conflicting laws. We also may experience difficulties adapting to new cultures, business customs and legal systems. Any sales and operations outside the United States, including those associated with our InnerCool products, would be subject to political, economic and social uncertainties including, among others:

changes and limits in import and export controls;

increases in custom duties and tariffs;

changes in currency exchange rates;

economic and political instability;

changes in government regulations and laws;

absence in some jurisdictions of effective laws to protect our intellectual property rights; and

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currency transfer and other restrictions and regulations that may limit our ability to sell certain products or repatriate profits to the United States.

Any changes related to these and other factors could adversely affect our business to the extent we enter markets outside the United States.

Risks Related to Our Intellectual Property and Potential Litigation

If our products and product candidates are not effectively protected by valid, issued patents or if we are not otherwise able to protect our proprietary information, or if our right to use intellectual property that we license from third parties is terminated or adversely affected, our financial condition, operations or ability to develop and commercialize our product candidates may be harmed.

The success of our operations will depend in part on our ability and that of our licensors to: obtain patent protection for our gene therapy, therapeutic genes and/or gene-delivery methods, temperature control devices and

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procedures, and other methods or components on which we rely both in the United States and in other countries with substantial markets; defend patents once obtained; maintain trade secrets and operate without infringing upon the patents and proprietary rights of others; and obtain appropriate licenses upon reasonable terms to patents or proprietary rights held by others that are necessary or useful to us in commercializing our technology, both in the United States and in other countries with substantial markets.

Our business substantially relies on our own or in-licensed intellectual property related to various technologies that are material to our products and processes. We depend on our and our licensors' abilities to successfully prosecute and enforce the patents, file patent applications and prevent infringement of those patents and patent applications. The licenses and other intellectual property rights we acquire may or may not provide us with exclusive rights. To the extent we do not have exclusive rights, others may license the same technology and may develop the technology more successfully or may develop products similar to ours and that compete with our products. Even if we are provided with exclusive rights, the scope of our rights under our licenses may be subject to dispute and termination or reduction by our licensors or third parties. Our licenses also contain milestones that we must meet and/or minimum royalty or other payments that we must make to maintain the licenses. There is no assurance that we will be able to meet such milestones and/or make such payments. Our licenses may be terminated if we fail to meet applicable milestones or make applicable payments.

If we are not able to maintain adequate patent protection for our products and product candidates, we may be unable to prevent our competitors from using our technology or technology that we license.

The patent positions of the technologies being developed by us and our collaborators involve complex legal and factual uncertainties. As a result, we cannot be certain that we or our collaborators will be able to obtain adequate patent protection for our products or product candidates. There can be no assurance that (i) any patents will be issued from any pending or future patent applications of ours or our collaborators; (ii) the scope of any patent protection will be sufficient to provide us with competitive advantages; (iii) any patents obtained by us or our collaborators will be held valid if subsequently challenged; or (iv) others will not claim rights in or ownership of the patents and other proprietary rights we or our collaborators may hold. Unauthorized parties may try to copy aspects of our products and technologies or obtain and use information we consider proprietary. Policing the unauthorized use of our proprietary rights is difficult. We cannot guarantee that no harm or threat will be made to our or our collaborators' intellectual property. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may also adversely affect the scope of our patent protection and our competitive situation.

Due to the significant time lag between the filing of patent applications and the publication of such patents, we cannot be certain that our licensors were the first to file the patent applications we license or, even if they were the first to file, also were the first to invent, particularly with regards to patent rights in the United States. In addition, a number of pharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to our operations. Some of these technologies, applications or patents may conflict with our or our licensors' technologies or patent applications. A conflict could limit the scope of the patents, if any, that we or our licensors may be able to obtain or result in denial of our or our licensors' patent applications. If patents that cover our activities are issued to other companies, we may not be able to develop or obtain alternative technology.

Patents issued and patent applications filed internationally relating to gene therapy, temperature control therapy, and other of our technologies are numerous, and we cannot assure you that current and potential competitors or other third parties have not filed or received, or will not file or receive applications in the future for patents or obtain additional proprietary rights relating to products or processes used or proposed to be used by us.

Additionally, there is certain subject matter that is patentable in the United States but not generally patentable outside of the United States. Differences in what constitutes patentable subject matter in various

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countries may limit the protection we can obtain outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may prevent us from obtaining patent protection outside of the United States, which would have a material adverse effect on our business, financial condition and results of operations.

We may be subject to costly claims, and, if we are unsuccessful in resolving conflicts regarding patent rights, we may be prevented from developing, commercializing or marketing our products and/ or product candidates.

There has been, and will likely continue to be, substantial litigation regarding patent and other intellectual property rights in the biotechnology industry. As the biotechnology industry expands and more patents are issued, the risk increases that our processes, technology, products and product candidates may give rise to claims that they infringe on the patents of others. Others could bring legal actions against us claiming damages and seeking to stop clinical testing, manufacturing and marketing of the affected product or use of the affected process. Litigation may be necessary to enforce our or our licensors' proprietary rights or to determine the enforceability, scope and validity of the proprietary rights of others. If we become involved in litigation, it could be costly and divert our efforts and resources. In addition, if any of our competitors file patent applications in the United States claiming technology also invented by us or our licensors, we may need to participate in interference proceedings held by the U.S. Patent and Trademark Office to determine priority of invention and the right to a patent for the technology. Like litigation, interference proceedings can be lengthy and often result in substantial costs and diversion of resources.

For example, in connection with our exclusive license to the University of California's technology for cardiovascular gene therapy (filed by Hammond et al., an international application of which was published as WO96/26742), we and our predecessor in interest Collateral Therapeutics have assisted the University of California in an interference proceeding against a patent application filed by Jeffrey Leiden et al. (a U.S. counterpart of international application PCT/US93/11133, which published as WO94/11506). In the interference, which is essentially a contest to determine priority of invention, a panel of Administrative Patent Judges of the U.S. Board of Patent Appeals and Interferences or BPAI issued judgment against the Leiden applicants, ordering that the interference count, which represents the disputed subject matter, be awarded to Hammond, and that Leiden et al. be held not entitled to any patent containing claims corresponding to those in the interference. However, the patent applicant, Arch Development Corporation, which had licensed the technology to Boston Scientific Corporation, subsequently appealed the decision against them. In May 2006, the U.S. Court of Appeals for the Federal Circuit, which hears appeals in U.S. patent cases, refused requests by Arch and Boston Scientific to reverse the prior decision of the BPAI regarding priority of invention. The Federal Circuit also refused requests to remand the case for reconsideration of previously contested matters such as the novelty, nonobviousness or validity of the Hammond patents, and it summarily issued final judgment against the Leiden applicants. Appeals from decisions of the Federal Circuit to the U.S. Supreme Court are rarely granted under such circumstances and were not sought. In a related matter, Collateral Therapeutics, with our assistance, successfully opposed a European counterpart to the Leiden PCT application (EP-B-668913), which led to a decision to revoke the patent grant in Europe. Although the patentee, Arch Development Corporation, subsequently appealed the adverse decision, a ruling following appeal to the European Patent Office's Technical Board of Appeal has now been rendered and the European patent grant to Arch (which had been licensed to Boston Scientific) has now been revoked. If we do not continue to be successful in defending against these and any other adverse claims, we could be compelled to seek licenses from one or more third parties who could be direct or indirect competitors and who might not make licenses available on terms that we find commercially reasonable or at all. In addition, such proceedings, even if decided in our favor, involve lengthy processes, are subject to appeals, and typically result in substantial costs and diversion of resources.

As more potentially competing patent applications are filed, and as more patents are actually issued, in the fields of gene therapy, wound healing, adenoviral vectors or therapeutic hypothermia or in other fields in which we may become involved and with respect to component methods or compositions that we may employ, the risk increases that we or our licensors may be subjected to litigation or other proceedings that claim damages or seek

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to stop our manufacturing, marketing, product development or commercialization efforts. Even if such patent applications or patents are ultimately proven to be invalid, unenforceable or non-infringed, such proceedings are generally expensive and time consuming and could consume a significant portion of our resources and substantially impair our marketing and product development efforts.

If there were an adverse outcome of any litigation or interference proceeding, we could have a potential liability for significant damages. In addition, we could be required to obtain a license to continue to make or market the affected product or use the affected process, or face an injunction to block our sale or marketing of affected products or use of the affected process. Costs of a license may be substantial and could include up-front payments as well as ongoing royalties. We may not be able to obtain such a license on acceptable terms, or at all, which could substantially impact our business.

We may not have adequate protection for our unpatented proprietary information, which could adversely affect our competitive position.

We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. However, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. To protect our trade secrets, we may enter into confidentiality agreements with employees, consultants and potential collaborators. However, these agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. Likewise, our trade secrets or know-how may become known through other means or be independently discovered by our competitors. Any of these events could prevent us from developing or commercializing our product candidates.

We face the risk of product liability claims, which could adversely affect our business and financial condition.

Our marketing and sale of therapeutic hypothermia products as well as our other operations will expose us to product liability risks that are inherent in the testing, manufacturing and marketing of biotechnology and medical device products. Failure to obtain or maintain sufficient product liability insurance or otherwise protect against product liability claims could prevent or delay the commercialization or marketing of our products or product candidates or expose us to substantial liabilities and diversions of resources, all of which can negatively impact our business. Regardless of the merit or eventual outcome, product liability claims may result in withdrawal of product candidates from clinical trials, costs of litigation, damage to our reputation, substantial monetary awards to plaintiffs and decreased demand for products.

Product liability may result from harm to patients using our products, such as a complication that was either not communicated as a potential side effect or was more extreme than communicated. We will require all patients enrolled in our clinical trials to sign consents, which explain various risks involved with participating in the trial. However, patient consents provide only a limited level of protection, and it may be alleged that the consent did not address or did not adequately address a risk that the patient suffered from. Additionally, we will generally be required to indemnify the clinical product manufacturers, clinical trial centers, medical professionals and other parties conducting related activities in connection with losses they may incur through their involvement in the clinical trials. We may not be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities.

Risks Related to Our Common Stock

The price of our common stock is expected to be volatile and an investment in our common stock could decline substantially in value.

In light of our small size and limited resources, as well as the uncertainties and risks that can affect our business and industry, our stock price is expected to be highly volatile and can be subject to substantial drops, with or even in the absence of news affecting our business. The following factors, in addition to the other risk

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factors described in this prospectus, and the potentially low volume of trades in our common stock, may have a significant impact on the market price of our common stock, some of which are beyond our control:

anticipated or unanticipated changes in financial conditions, operating results or the perceived value of our business;

developments concerning any research and development, clinical trials, manufacturing, and marketing efforts or collaborations;

our announcement of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

announcements of technological innovations;

new products or services that we or our competitors offer;

the initiation, conduct and/or outcome of intellectual property and/or litigation matters;

changes in financial or other estimates by securities analysts or other reviewers or evaluators of our business;

conditions or trends in bio-pharmaceutical or other healthcare industries;

regulatory developments in the United States and other countries;

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

additions or departures of key personnel;

sales or other transactions involving our common stock; and

global unrest, terrorist activities, and economic and other external factors.

The stock market in general has recently experienced relatively large price and volume fluctuations. In particular, the market prices of securities of smaller biotechnology and medical device companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of the common stock, which could cause a decline in the value of the common stock. You should also be aware that price volatility may be worse if the trading volume of the common stock remains limited or declines.

We could be difficult to acquire due to anti-takeover provisions in our charter, our stockholder rights plan and Delaware law.

Our board of directors has adopted a stockholder rights plan in which preferred stock purchase rights were distributed as a dividend. These provisions may make it more difficult for stockholders to take corporate actions and may have the effect of delaying or preventing a change in control. These provisions also could deter or prevent transactions that stockholders deem to be in their interests. In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Subject to specified exceptions, this section provides that a corporation may not engage in any business combination with any interested stockholder during the three-year period following the time that such stockholder becomes an interested stockholder. This provision could have the effect of delaying or preventing a change of control of our company. The foregoing factors could reduce the price that investors or an acquirer might be willing to pay in the future for shares of our common stock.

We have never paid cash dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude or limit our ability to pay any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus, including information incorporated by reference, are forward-looking statements within the meaning of Section 27A of the 33 Act, Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), and the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as may, will, should, could, would, expects, plans, believes, anticipates, intends, approximates, predicts, or projects, or the negative or other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results, are forward-looking statements.

The forward-looking statements in this prospectus speak only as of the date of this prospectus and caution should be taken not to place undue reliance on any such forward-looking statements. Forward-looking statements are subject to certain events, risks, and uncertainties that may be outside of our control. When considering forward-looking statements, you should carefully review the risks, uncertainties and other cautionary statements in this prospectus as they identify certain important factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. These factors include, among others, the risks described under Risk Factors and elsewhere in this prospectus, as well as in other reports and documents we file with the SEC.

USE OF PROCEEDS

We will not receive any proceeds from the sale of shares by the selling stockholders.

The selling stockholders will pay any discounts, commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in connection with the sale of the shares of our common stock offered by this prospectus. We will bear all other costs, fees and expenses incurred in connection with the registration of the shares of our common stock offered by this prospectus, including, without limitation, all registration and filing fees and fees and expenses of our legal counsel and auditors.

A portion of the shares of common stock covered by this prospectus are issuable upon exercise of warrants to purchase common stock. Upon any cash exercise of the warrants, the selling stockholders will pay us the exercise price of the warrants. Under certain circumstances, the holders of our warrants may exercise their warrants on a cashless basis. If all of the warrants are exercised for cash at their initial exercise price, we would receive aggregate gross proceeds of approximately \$4.5 million (2,856,818 shares at a weighted average exercise price of \$1.57 per share). We expect to use any cash we receive upon the exercise of warrants for general corporate purposes.

Table of Contents**SELLING STOCKHOLDERS**

The following table sets forth the common stock ownership and other information relating to the selling stockholders as of May 2, 2006. The selling stockholders obtained the 30,021,059 shares of common stock offered pursuant to this prospectus and/or the warrants which certain of those shares are underlying in connection with a private placement of securities and a reverse merger, each of which was completed on October 20, 2005.

Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
A & S Levy Family Holdings, LLP	150,000	150,000	0	0
Nicholas Abbate	16,667	16,667	0	0
Alan B. Abrams	200,000	200,000	0	0
Dennis M. Abrams	33,334	33,334	0	0
Acclaim Financial Group, LLC	33,334	33,334	0	0
Wayne K. Adams	16,667	16,667	0	0
Joseph Agosta	33,334	33,334	0	0
Agriculture Benefits Assistance III, Inc.	66,666	66,666	0	0
John E. Ahern	33,334	33,334	0	0
Jeffrey C Allard	66,667	66,667	0	0
Marc Alvelo	33,334	33,334	0	0
Karl Ammann	33,334	33,334	0	0
Long Island Auto Realty	70,000	70,000	0	0
Oswald Baer	40,000	40,000	0	0
The Bahr Family Limited Partnership	50,000	50,000	0	0
Martin G Ballweg & Kathleen A Ballweg JTWROS	200,000	200,000	0	0
Robert Baratta IRA	20,000	20,000	0	0
Gregg Barbagallo IRA R/O	24,000	24,000	0	0
Robert W Barnwell	40,000	40,000	0	0
Raymond A Bartolacci III	50,000	50,000	0	0
Raymond A Bartolacci Jr	200,000	200,000	0	0
Charles B Beardsley	80,000	80,000	0	0
James T Bego & Linda J Bego JT TEN	33,334	33,334	0	0
Howard M Bergtraum	70,000	70,000	0	0
Paul F Berlin	66,667	66,667	0	0
David Berman & Murray Berman JTWROS	466,667	466,667	0	0
Louis Best & Madeline Best	33,334	33,334	0	0
Dennis R Bidy	16,667	16,667	0	0
Kevin J Bisceglia	33,334	33,334	0	0
A Lawrence Blahut	50,000	50,000	0	0
Sanfurd G Bluestein MD	200,000	200,000	0	0
Jerald A Blumberg	166,667	166,667	0	0
Anthony Bonanno & Tiscia Bonanno JT TEN	65,000	65,000	0	0
Eric J Bonanno	166,667	166,667	0	0
Marvin R Bortz & Darlene M Bortz TTEES Marvin R Bortz & Darlene M Bortz Liv Tr dtd 11/10/03	33,334	33,334	0	0
Kevin A Boyles	16,667	16,667	0	0
Robert B Brandt	16,667	16,667	0	0
Frank J Broos	33,500	33,500	0	0
Bobby H Bryan	20,000	20,000	0	0

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Thomas Bullock

33,334

33,334

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
John A Byrne	10,000	10,000	0	0
C Lane Company LLC	16,667	16,667	0	0
Arthur G. Caputo & Margaret M. Caputo JT TEN	70,000	70,000	0	0
Angelo J. Carrera	33,334	33,334	0	0
Joseph Cavegn	100,000	100,000	0	0
Che-Hong Chen	33,334	33,334	0	0
Maureen Chilelli	18,000	18,000	0	0
Henrik Vester Christensen Holding APS Attn: Henrik Vester Christensen	33,334	33,334	0	0
Richard E. Clack	50,000	50,000	0	0
Chuan Clark	43,334	43,334	0	0
Cleland C. Landolt M.D., Inc. Profit Sharing Plan	33,334	33,334	0	0
Robert L. Clement	15,334	15,334	0	0
Robert L. Clement IRA	52,667	52,667	0	0
Cline Agency, Inc.	66,667	66,667	0	0
Guy Collins	26,667	26,667	0	0
Christian F. Coluccio IRA	19,000	19,000	0	0
Magnus Coxner	33,334	33,334	0	0
Sharon Crowder	33,334	33,334	0	0
Maureen Crowe	13,334	13,334	0	0
Thomas H. Cruikshank ⁽²⁾	733,333	733,333	0	0
CSL Associates, LP	100,000	100,000	0	0
Dale Stringfellow & Jean Srtringfellow TTEES				
Stringfellow Tr dtd 2/1/1999	400,000	400,000	0	0
Thomas P. Darmstadter	100,000	100,000	0	0
Jose A. Dasilva	23,334	23,334	0	0
Walter Daszkowski	17,000	17,000	0	0
Dan A. Davidson & Brenda T. Davidson JT TEN	33,334	33,334	0	0
John F. Davis & Carolyn L. Davis JT TEN	115,000	115,000	0	0
Michael Dazzo	27,000	27,000	0	0
Michael Dazzo IRA	16,000	16,000	0	0
Peter Debany	50,000	50,000	0	0
Michael A. Denicola & Cheryl A. Denicola JT TEN	26,667	26,667	0	0
Robert J. Des Marais ⁽³⁾	733,333	733,333	0	0
Darshan Dhiman	40,000	40,000	0	0
Jitin Dhiman & Darshan Dhiman JT TEN	25,000	25,000	0	0
Rohan Dhiman & Darshan Dhiman JT TEN	10,000	10,000	0	0
Biagio Didino & Assunta Didino JT WROS	12,667	12,667	0	0
Emanuel J. Diteresi & Rose Diteresi JT TEN	33,334	33,334	0	0
Forrest P. Dixon	33,334	33,334	0	0
Thomas X. Dizio & Jill Dizio JT TEN	20,000	20,000	0	0
Pete A. Dlugosch & Patricia A. Dlugosch JT TEN	35,000	35,000	0	0
John L. Doan	16,667	16,667	0	0
David Drezner	23,334	23,334	0	0
Noah Drezner	23,334	23,334	0	0
Jerry D. Dunning	16,667	16,667	0	0
Tyler M. Dylan ⁽⁴⁾	2,550,000	2,550,000	0	0

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
John E. Ahern & Colleen S. Ahern TTEES Ahern Revocable Tr	33,334	33,334	0	0
East Coast Petroleum, Inc.	33,334	33,334	0	0
Dan Edgerton	16,667	16,667	0	0
Gershon Engel	33,334	33,334	0	0
Richard P. Epifania & Marianne Epifania JTWROS	16,667	16,667	0	0
Edward L. Erline	20,000	20,000	0	0
Irwin J. Eskanos & Vivian M. Eskanos JT TEN	100,000	100,000	0	0
Esta Products Co.	33,334	33,334	0	0
Roger A. Ewald	20,000	20,000	0	0
Carlton Block & Barbara Block TTEES Block Family Tr dtd 12/13/1982	200,000	200,000	0	0
Hugh Webb TTEE Webb Family Tr dtd 9/20/1999	33,334	33,334	0	0
MSB Family Trust dtd 6/25/93	166,667	166,667	0	0
Paul A. Felletti	33,000	33,000	0	0
Anthony Fiorello	26,667	26,667	0	0
Richard D. Fitzgerald & Judy A. Fitzgerald JTWROS	120,000	120,000	0	0
Mason Flemming	16,667	16,667	0	0
Sammie R. Ford IRA	16,667	16,667	0	0
Harry Forman	33,334	33,334	0	0
Denis Fortin	250,000	250,000	0	0
Dudley B. Frank	100,000	100,000	0	0
Thomas B. Frank	16,667	16,667	0	0
Scott A. Frey	16,667	16,667	0	0
Jay Fried	41,500	41,500	0	0
Mitchell A. Fried	33,334	33,334	0	0
Kenneth R. Fry	33,334	33,334	0	0
Salvatore C. Furnari	20,000	20,000	0	0
Edward W. Gabrielson ⁽⁵⁾	33,334	33,334	0	0
Christopher J. Gahman	16,667	16,667	0	0
Barry J. Galt	33,334	33,334	0	0
Stephen A. Geppi & Melinda C. Geppi JTWROS ⁽⁶⁾	743,600	743,600	0	0
Joseph Giardina IRA	22,000	22,000	0	0
Lawrence P. Giardina IRA	20,000	20,000	0	0
Louis M. Giardina IRA	17,000	17,000	0	0
Robert Giardina	29,000	29,000	0	0
Robert L. Giardina & Louis M. Giardina JTWROS	26,000	26,000	0	0
Dave Giobbia	16,667	16,667	0	0
James D. Giobbia	33,334	33,334	0	0
Saul L. Gitomer	16,000	16,000	0	0
Lisa H. Del Giudice	50,000	50,000	0	0
Mark E. Gonwa	40,000	40,000	0	0
John C. Grace	25,000	25,000	0	0
Lester R. Greenwood & Carol A. Greenwood JTWROS	33,334	33,334	0	0
Dean O. Gregg	33,334	33,334	0	0
Phillip S. Gurgone IRA	33,334	33,334	0	0
Brenda Bishop Haller	16,667	16,667	0	0
Lonnie A. Hanson	13,334	13,334	0	0

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
Jack Hart IRA	16,667	16,667	0	0
Raymon A. Heaton	13,334	13,334	0	0
Christer M. Hedstrom	16,667	16,667	0	0
Gary D. Heihn	36,467	36,467	0	0
Charles E. Helsley	63,000	63,000	0	0
Charles E. Helsley IRA	50,000	50,000	0	0
James K. Hendren	100,000	100,000	0	0
Henry A. S. Sandbach	33,334	33,334	0	0
The Henry H. Bahr Qtip Trust	40,000	40,000	0	0
Cesar Hernandez	13,334	13,334	0	0
Daniel H. Hildebrand	20,000	20,000	0	0
Victor Hochberg	16,667	16,667	0	0
Richard F. Houseweart IRA	20,000	20,000	0	0
Tracy L. Howell ⁽⁷⁾	150,000	150,000	0	0
Robert N. Hyams	40,000	40,000	0	0
Italo A. Insalata	33,334	33,334	0	0
International Electronic Business, Inc.	66,000	66,000	0	0
Clayton J. Schultz c/f Ursula Schultz ⁽⁸⁾	36,667	36,667	0	0
Robert J. Des Marais c/f Andre J. Des Marais ⁽⁹⁾	36,667	36,667	0	0
Robert J. Des Marais c/f Daniel J. Des Marais ⁽¹⁰⁾	36,667	36,667	0	0
Alan Jackson IRA	46,586	46,586	0	0
Andrew Jackson & Aura Whitney Jackson JT TEN	33,334	33,334	0	0
Allen F. Jacobson TTEE Allen F. Jacobson Rev Tr dtd 12/12/1996	33,334	33,334	0	0
R. William Jewell	33,334	33,334	0	0
JKG Investment Company, LP	26,000	26,000	0	0
Thomas L. Jones	25,000	25,000	0	0
Justin Kaplan	34,000	34,000	0	0
Hugh M. Kellogg	33,334	33,334	0	0
Christine H. Kempter ⁽¹¹⁾	36,667	36,667	0	0
Robert P. Kern & Burton Landsman TEN COMM	16,667	16,667	0	0
Stephen N. Kitchens & Martha M. Kitchens JT TEN	333,334	333,334	0	0
Robert O. Knight	40,000	40,000	0	0
Goswin G. Koerschen & Heide Koerschen JT TEN	16,667	16,667	0	0
Howard D. Kollinger & Melanie G. Kollinger JT WROS	86,667	86,667	0	0
Sterling G. Koonce	33,334	33,334	0	0
Mike Kooyman	166,667	166,667	0	0
Michael D. Kubersky	70,000	70,000	0	0
John E. Kyees	30,000	30,000	0	0
Lamon L. Bennett Jr. & Elaine Bennett TJ TEN	16,667	16,667	0	0
Ken Lehman & Karen Lehman JT TEN	66,667	66,667	0	0
Stephan J. Lenci & Barbara J. Lenci JT TEN	16,667	16,667	0	0
James A. Lesley & Judy B. Lesley JT TEN	50,500	50,500	0	0
Alex Lethen	33,334	33,334	0	0
Gerald J. Lewis ⁽¹²⁾	33,334	33,334	0	0
Lind Family Investments, LP	20,000	20,000	0	0
Dale E Kann TTEE Dale E. Kann Liv Tr dtd 6/15/1995 ⁽¹³⁾	733,333	733,333	0	0

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
Robert W. Pfeifer & Barbara B. Pfeifer TTEES Pfeifer Liv Tr dtd 12/20/1981	40,000	40,000	0	0
Scott A. Mcpherson & Jolene G. Mcpherson TTEES Scott A. Mcpherson Liv Tr dtd 4/5/2002	33,334	33,334	0	0
Michael D. Lococo	16,667	16,667	0	0
Jeff L. Loftsgaarden IRA	33,334	33,334	0	0
Donald E. Lord	40,000	40,000	0	0
Calmedica Capital, LP	100,000	100,000	0	0
Nite Capital, LP	166,667	166,667	0	0
R. Don Lumley	16,667	16,667	0	0
Lynn Adams Distributing Co., Inc.	65,000	65,000	0	0
Lisa M. Cumming IRA	16,667	16,667	0	0
Harry S. Madoff	50,000	50,000	0	0
George F. Manos	150,000	150,000	0	0
William Martinez	33,334	33,334	0	0
Robert W. Marvin	166,667	166,667	0	0
Robert J. Mastrolia Jr.	16,667	16,667	0	0
Anthony Matrone	33,334	33,334	0	0
Andreas Mauser	26,667	26,667	0	0
James R. Mcclarty & Janice K. Mcclarty JTWROS	20,667	20,667	0	0
Barry J. McDonald	35,000	35,000	0	0
Robert McEntire	133,334	133,334	0	0
James J. McNamara & Margarita McNamara JT TEN	30,000	30,000	0	0
Robert A. Mega	28,000	28,000	0	0
Robert A. Mega IRA	92,000	92,000	0	0
William A. Mega	108,667	108,667	0	0
William A. Mega IRA	28,000	28,000	0	0
Andrew S. Meltzer	67,000	67,000	0	0
Robert Mendelson	16,667	16,667	0	0
Marten J.M. Mertens	33,334	33,334	0	0
John J. Micek	33,334	33,334	0	0
Michael L. Cardinale Veronica C. Bonagura Joseph D. Pitta William S. Leavy Partnership	33,334	33,334	0	0
Paul Michelin & Louise Michelin JT TEN	33,334	33,334	0	0
Mike Miller & Terry Miller JTWROS	38,667	38,667	0	0
Patricia Mizerka & Eugene Mizerka JT TEN	17,000	17,000	0	0
Joseph A. Myers	40,000	40,000	0	0
National Securities Corporation ⁽¹⁴⁾	332,411	332,411	0	0
Gary Nicoletti	66,667	66,667	0	0
Peter Nordin	50,000	50,000	0	0
Rustam Nurkhanov	11,000	11,000	0	0
Edward J. O Connell	16,667	16,667	0	0
Patrick O Leary IRA	20,000	20,000	0	0
Jane A. Osborne	100,000	100,000	0	0
Ryan Osborne	80,000	80,000	0	0
Lon E. Otremba ⁽¹⁵⁾	33,334	33,334	0	0
Joseph B. Panella	34,000	34,000	0	0
Canzio Panichi & Franca Panichi JT TEN	11,167	11,167	0	0

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
Vladimiro M. Panichi & Dana M. Panichi JTWROS	10,000	10,000	0	0
Gero G. Papst	26,667	26,667	0	0
Tim H. Parkes	33,334	33,334	0	0
Lee Roy Pearson	33,334	33,334	0	0
Nelson Penarreta & Patricia Davila JT TEN	13,334	13,334	0	0
Ralph A. Petrozzo & Madeline Petrozzo JT TEN	16,667	16,667	0	0
Sherra Pierre IRA	20,000	20,000	0	0
Tom Clotfelter Per PPT Trust	33,334	33,334	0	0
Nicholas V. Puccia & Barbara Puccia JT TEN	34,000	34,000	0	0
Ron A. Rasch & Janet E. Rasch JT TEN	16,667	16,667	0	0
George M. Reid	100,000	100,000	0	0
Christopher J. Reinhard ⁽¹⁶⁾	2,791,924	2,791,924	0	0
Christopher J. Reinhard & Maureen F. Reinhard JT TEN ⁽¹⁶⁾	71,334	71,334	0	0
Christopher Reinhard IRA ⁽¹⁶⁾	90,000	90,000	0	0
Barry J. West Rev Trust	200,000	200,000	0	0
Frank R. Codispoti & Sarah C. Codispoti TTEES Frank R Codispoti Rev Tr dtd 11/12/2004	50,000	50,000	0	0
Isidore Siegel TTEE Isidore Siegel Rev Tr dtd 4/5/1991	66,667	66,667	0	0
John K. Garvey TTEE John K. Garvey Rev Tr dtd 12/31/1984	7,334	7,334	0	0
Barry Lind Revocable Trust UA dated 12/19/89	200,000	200,000	0	0
Nathaniel Silon TTEE Nathaniel Silon Rev Liv Tr dtd 6/2/1993	116,667	116,667	0	0
Richard & Virginia Shillington Family Trust	70,000	70,000	0	0
Huxley T. Richardson	16,667	16,667	0	0
Robho Properties, Inc. ⁽¹⁷⁾	880,000	880,000	0	0
Bonnie Lewis Rodney & J. Michael Rodney JT TEN	8,334	8,334	0	0
Louis C. Rose	100,000	100,000	0	0
Louis M. Giardina Roth IRA	17,000	17,000	0	0
Eric W. Rothbarth	50,000	50,000	0	0
Parviz Roubeni & Rad Roubeni JT TEN	20,000	20,000	0	0
Claudia C. Rouhana	67,000	67,000	0	0
David G. Ruby	33,334	33,334	0	0
Albert J. Sabini IRA	33,334	33,334	0	0
Andrew H. Sabreen & Carol Sabreen JT TEN	33,334	33,334	0	0
Jose M. Saenz	33,334	33,334	0	0
Carl J. Sagasser TTEE Carl J. Sagasser Tr dtd 9/24/2003	20,000	20,000	0	0
Paul Sallwasser & Teri Sallwasser JT TEN	66,667	66,667	0	0
Hans H. Sammer	33,334	33,334	0	0
Douglas Saunders IRA	33,334	33,334	0	0
Joseph Scaletta	20,000	20,000	0	0
Julian S. Schmidt	16,667	16,667	0	0
Rainer Schmidt	66,667	66,667	0	0
John A. Schulman	34,000	34,000	0	0
Charles N. Schumann	50,000	50,000	0	0
Bernard Francis Schunicht	13,334	13,334	0	0
Christina Petrowski- Schwartz & Mark S. Schwartz JTWROS	16,667	16,667	0	0
Nicholas C. Scott	16,667	16,667	0	0
Suzette T. Seigel	16,667	16,667	0	0

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
Anthony J. Vassallo SEP IRA	66,667	66,667	0	0
Christian F. Coluccio SEP IRA	21,000	21,000	0	0
David A. Wilson SEP IRA	60,000	60,000	0	0
Gregg Zeoli SEP IRA	10,000	10,000	0	0
John F. Davis SEP IRA	60,000	60,000	0	0
William A. Deitch SEP IRA	33,334	33,334	0	0
Phillip Sgobba	25,000	25,000	0	0
Asif J. Shah	10,000	10,000	0	0
Harish H. Shah	16,667	16,667	0	0
Linda S. Sharp	16,667	16,667	0	0
Ben Shaw & Janet Shaw JT TEN	33,334	33,334	0	0
Kevin Sheldon	20,000	20,000	0	0
Jay E. Silberman & Judith L. Silberman JT TEN	70,000	70,000	0	0
Jason Silcox	33,334	33,334	0	0
Lawrence M. Silver	133,334	133,334	0	0
Richard Simms & Cynthia Simms	16,667	16,667	0	0
David M. Simon	20,000	20,000	0	0
Robert E. Simon IRA	16,667	16,667	0	0
Randy Johnson Simple IRA	16,000	16,000	0	0
David H. Slater & Marla S. Slater JT TEN	35,001	35,001	0	0
Mitchell J. Slovik & Ilene S. Slovik JT TEN	30,000	30,000	0	0
Dean A. Snyder Jr.	200,000	200,000	0	0
Jeffrey Sperber	66,667	66,667	0	0
STR Capital Securities, Inc.	38,334	38,334	0	0
John A. Sturgeon & Maryann Sturgeon TTEES John A. Sturgeon Family Tr dtd 11/21/1982	33,334	33,334	0	0
Susan A. Westre c/f Emily L. Schultz ⁽¹⁸⁾	36,667	36,667	0	0
Terri C. Swanston	16,667	16,667	0	0
Mel Thaler	33,334	33,334	0	0
Galileo Tignini	13,334	13,334	0	0
Galileo Tignini	10,000	10,000	0	0
Martine Timmermans	16,667	16,667	0	0
Marshall M. Trabout	33,334	33,334	0	0
Mark D. G. Trainor	16,667	16,667	0	0
Khan D. Tran	25,000	25,000	0	0
Zong H. Tzeng	33,500	33,500	0	0
Charles M. Vanderford & Ginger L. Vanderford JT TEN	65,000	65,000	0	0
Anthony J. Vassallo & Mary Ellen Vassallo JT TEN	33,334	33,334	0	0
Roger Vick & Dana Vick JTWROS	33,334	33,334	0	0
Daniel I. Waki IRA	20,000	20,000	0	0
Roger J. Wall & Jenai Sullivan Wall	66,667	66,667	0	0
John M. Wander	33,334	33,334	0	0
S.B. Warner & A. Warner TTEES Ruth Geller Revocable Trust dtd 11/10/03	16,667	16,667	0	0
Ralph W. Wasik	90,334	90,334	0	0
Ralph W. Wasik & Denise O. Wasik JT TEN	31,334	31,334	0	0
Richard H. Wehner	26,667	26,667	0	0
Harvey P. Weintraub	33,334	33,334	0	0

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
Harold Weisfeld	16,667	16,667	0	0
Susan A. Westre & Clayton J. Schultz JT TEN ⁽¹⁹⁾	660,000	660,000	0	0
William F. Wheeler	66,667	66,667	0	0
Norman J. White	73,334	73,334	0	0
Craig R. Whited	33,334	33,334	0	0
Walter R. Wichern Jr.	66,667	66,667	0	0
Charles P Wilkins	66,667	66,667	0	0
Raymond C. Williamson & Susan K. Williamson JT TEN	16,667	16,667	0	0
David A. Wilson	15,000	15,000	0	0
Hugh S. Wilson	33,334	33,334	0	0
Mary N. Wilson IRA	25,000	25,000	0	0
James Winker & Marlene Winker TTEES Marlene J. Winker Tr	66,667	66,667	0	0
Stefani A Wolff	16,667	16,667	0	0
Alan J. Young	133,334	133,334	0	0
Richard G. Zirkelbach & Nancy E. Zirkelbach JT TEN	33,334	33,334	0	0
Gabor M. Rubanyi ⁽²⁰⁾	2,000,000	2,000,000	0	0
Mark S. Zucker ⁽²¹⁾	936,732	400,000	536,732	1.3
Christopher A. Jones ⁽²²⁾⁽⁶³⁾	85,716	85,716	0	0
Roger Monteforte ⁽²³⁾⁽⁶³⁾	7,521	7,521	0	0
Daniel V. Quinn ⁽²⁴⁾⁽⁶³⁾	4,000	4,000	0	0
Divine Capital Markets LLC ⁽²⁵⁾⁽⁶⁴⁾	10,000	10,000	0	0
Christian Coluccio ⁽²⁶⁾⁽⁶³⁾	471,197	471,197	0	0
Richard Cardinale ⁽²⁷⁾⁽⁶³⁾	206,306	206,306	0	0
Vladimiro Panichi ⁽²⁸⁾⁽⁶³⁾	48,966	48,966	0	0
James Vivona ⁽²⁹⁾⁽⁶³⁾	26,153	26,153	0	0
Gregg Zeoli ⁽³⁰⁾⁽⁶³⁾	270,484	270,484	0	0
Ronald Large ⁽³¹⁾⁽⁶³⁾	8,415	8,415	0	0
Jack Brusciannelli ⁽³²⁾⁽⁶³⁾	8,962	8,962	0	0
John J. Wilson ⁽³³⁾⁽⁶³⁾	20,000	20,000	0	0
Robert H. Daskal ⁽³⁴⁾⁽⁶³⁾	50,000	50,000	0	0
Mark Goldwasser ⁽³⁵⁾⁽⁶³⁾	125,000	125,000	0	0
Andrew Maiorano ⁽³⁶⁾⁽⁶³⁾	300	300	0	0
Mike Burkoff ⁽³⁷⁾⁽⁶³⁾	14,699	14,699	0	0
Frantz Pierre ⁽³⁸⁾⁽⁶³⁾	29,750	29,750	0	0
Troy Fisher ⁽³⁹⁾⁽⁶³⁾	4,533	4,533	0	0
Cory Slovik ⁽⁴⁰⁾⁽⁶³⁾	9,591	9,591	0	0
Bruce Katz ⁽⁴¹⁾⁽⁶³⁾	6,750	6,750	0	0
Andrew Tang ⁽⁴²⁾⁽⁶³⁾	7,050	7,050	0	0
Kevin Clarkin ⁽⁴³⁾⁽⁶³⁾	19,968	19,968	0	0
Hans-Christian Winkler ⁽⁴⁴⁾⁽⁶³⁾	19,968	19,968	0	0
Phillip Gurgone ⁽⁴⁵⁾⁽⁶³⁾	9,422	9,422	0	0
Michael V. Jordan ⁽⁴⁶⁾⁽⁶³⁾	5,416	5,416	0	0
Glenn Kendall ⁽⁴⁷⁾⁽⁶³⁾	510	510	0	0
Michael L. Arnsman ⁽⁴⁸⁾⁽⁶³⁾	600	600	0	0
Andrew Tennent ⁽⁴⁹⁾⁽⁶³⁾	4,609	4,609	0	0
Leo Satriawan ⁽⁵⁰⁾⁽⁶³⁾	10,000	10,000	0	0
Rick Wlasiuk ⁽⁵¹⁾⁽⁶³⁾	10,000	10,000	0	0

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Selling Stockholder	Shares beneficially owned prior to the offering	Number of common shares registered in this prospectus	Shares beneficially owned after the offering ⁽¹⁾	
			Number	Percent
Kay Johnson ⁽⁵²⁾⁽⁶³⁾	10,000	10,000	0	0
Matthew Portes ⁽⁵³⁾⁽⁶³⁾	30,000	30,000	0	0
Brian Friedman ⁽⁵⁴⁾⁽⁶³⁾	100,000	100,000	0	0
Fabio Migliaccio ⁽⁵⁵⁾⁽⁶⁴⁾	2,467	2,467	0	0
Steven Markowitz ⁽⁵⁶⁾⁽⁶⁴⁾	8,308	8,308	0	0
Robert Petrozzo ⁽⁵⁷⁾⁽⁶⁴⁾	64,000	64,000	0	0
Joseph Sorbara ⁽⁵⁸⁾⁽⁶⁴⁾	8,308	8,308	0	0
NYPPE ⁽⁵⁹⁾⁽⁶⁴⁾	2,666	2,666	0	0
Dario Rodriguez ⁽⁶⁰⁾⁽⁶³⁾	1,499	1,499	0	0
Neftali Mercedes ⁽⁶¹⁾⁽⁶³⁾	2,010	2,010	0	0
Stephen Jones ⁽⁶²⁾⁽⁶³⁾	10,000	10,000	0	0
TOTAL SHARES OFFERED		30,021,059		

- (1) Assumes that all securities registered will be sold and that all shares of common stock underlying common stock purchase warrants will be issued and sold. Percentage based on 40,914,425 shares of common stock outstanding on May 16, 2007.
- (2) Shares listed include 66,666 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (3) Shares listed include 66,666 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (4) Dr. Dylan is a director, Chief Business Officer, General Counsel, Executive Vice President and Secretary of the Company.
- (5) Dr. Gabrielson is a director of the Company.
- (6) Shares listed include 67,600 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (7) Ms. Howell is Director Business Affairs of the Company.
- (8) Shares listed include 3,333 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (9) Shares listed include 3,333 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (10) Shares listed include 3,333 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (11) Shares listed include 3,333 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (12) Justice Lewis is a director of the Company.
- (13) Shares listed include 66,666 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (14) Shares listed include 332,411 shares of common stock that may be purchased upon exercise of immediately exercisable warrants. National Securities, an Nasd member, received these warrants in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. National Securities was entitled to receive these securities as partial compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.
- (15) Mr. Otremba is a director of the Company.
- (16) Mr. Reinhard is Chairman of the Board, Chief Executive Officer, President and Treasurer of the Company.
- (17) Shares listed include 80,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.

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- (18) Shares listed include 3,333 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (19) Shares listed include 60,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (20) Dr. Rubanyi is the Chief Scientific Officer of the Company.
- (21) Shares listed include 443,366 shares of common stock that may be purchased upon exercise of immediately exercisable warrants. Mr. Zucker was a director and executive officer of Aries Ventures, Inc. until his resignation in December 2004. At the time of the merger between Aries Ventures and Cardium, Mr. Zucker beneficially owned 46.3% of the outstanding shares of common stock of Aries Ventures.
- (22) Shares listed include 50,716 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (23) Shares listed include 7,521 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (24) Shares listed include 4,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (25) Shares listed include 10,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (26) Shares listed include 471,197 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (27) Shares listed include 206,306 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (28) Shares listed include 48,966 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (29) Shares listed include 26,153 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (30) Shares listed include 270,484 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (31) Shares listed include 8,415 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (32) Shares listed include 8,962 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (33) Shares listed include 20,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (34) Shares listed include 50,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (35) Shares listed include 125,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (36) Shares listed include 300 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (37) Shares listed include 14,699 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (38) Shares listed include 29,750 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (39) Shares listed include 4,533 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (40) Shares listed include 9,591 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (41) Shares listed include 6,750 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.

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- (42) Shares listed include 7,050 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (43) Shares listed include 19,968 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (44) Shares listed include 19,968 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (45) Shares listed include 9,422 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (46) Shares listed include 5,416 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (47) Shares listed include 510 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (48) Shares listed include 600 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (49) Shares listed include 4,609 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (50) Shares listed include 10,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (51) Shares listed include 10,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (52) Shares listed include 10,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (53) Shares listed include 30,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (54) Shares listed include 100,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (55) Shares listed include 2,467 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (56) Shares listed include 8,308 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (57) Shares listed include 64,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (58) Shares listed include 8,308 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (59) Shares listed include 2,666 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (60) Shares listed include 1,499 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (61) Shares listed include 2,010 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (62) Shares listed include 10,000 shares of common stock that may be purchased upon exercise of immediately exercisable warrants.
- (63) National Securities has advised Cardium that the listed selling shareholder is an associated person of National Securities, received these warrants as a designee of National Securities in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. National Securities was entitled to receive these securities as partial compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.

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- (64) National Securities has advised Cardium that the listed selling shareholder is either an NASD member or an associated person of an NASD member, received these warrants as a designee of National Securities in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them. National Securities was entitled to receive these securities as partial compensation for its services as placement agent in the ordinary course of business and at the time of receiving the securities had no agreements or understandings, directly or indirectly, with any person to distribute them.

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PLAN OF DISTRIBUTION

The selling stockholders and any of their respective pledgees, donees, assignees and other successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at various prices determined at the time of sale or at negotiated prices.

The selling stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits the purchaser;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately-negotiated transactions;

short sales effected after the date of this prospectus;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise on the shares;

combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 of the Securities Act, if available, rather than under this prospectus. The selling stockholders shall have the sole and absolute discretion not to accept any purchase offer or make any sale of shares if it deems the purchase price to be unsatisfactory at any particular time.

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The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners of purposes of this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

National Securities Corporation (National Securities) has indicated to us its willingness to act as selling agent on behalf of the selling stockholders named in this prospectus under Selling Stockholders that purchased our privately placed securities. All shares sold, if any, on behalf of selling stockholders by National Securities would be in transactions executed by National Securities on an agency basis and commissions charged to its

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customers in connection with each transaction shall not exceed a maximum of 5% of the gross proceeds. National Securities does not have an underwriting agreement with us and/or the selling stockholders and no selling stockholders are required to execute transactions through National Securities. We have been advised that under the rules and regulations of the NASD, no broker may receive discounts, concessions or commissions in excess of 8% in connection with the sale of any securities registered hereunder.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the position