Cardium Therapeutics, Inc.
Form 10-K
March 30, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011

001-33635

(Commission file number)

CARDIUM THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-0075787**
(State of incorporation)	**(IRS Employer Identification No.)**
12255 El Camino Real, Suite 250	
San Diego, California 92130	**(858) 436-1000**
(Address of principal executive offices)	**(Registrant s telephone number)**

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	**Name of exchange on which registered**
Common Stock, $0.0001 par value per share	**NYSE Amex**

Securities registered under Section 12(g) of the Exchange Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ¨ Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. ¨ Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant for Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ Yes x No

The aggregate market value of common equity held by non-affiliates computed as of the last business day of the registrant s most recently completed second quarter was $21.1 million based on the closing sale price of $0.28 reported by NYSE Amex on June 30, 2011. For this purpose all officers, directors and 10% stockholders of the registrant were assumed to be affiliates.

As of March 20, 2012, 119,617,356 shares of the registrant s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K incorporates by reference portions of the registrant s definitive proxy statement for its Annual Meeting of Stockholders to be filed on or before April 30, 2012.

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

Certain statements in this report, including information incorporated by reference, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, 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, estimates, ap 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 and the development of our products, are forward-looking statements. Forward-looking statements in this report may include statements about:

- our ability to fund operations and business plans, and the timing of any funding or corporate development transactions we may pursue;
- planned development pathways and potential commercialization activities or opportunities;
- the timing, conduct and outcome of discussions with regulatory agencies, regulatory submissions and clinical trials, including the timing for completion of clinical studies;
- our beliefs and opinions about the safety and efficacy of our products and product candidates and the anticipated results of our clinical studies and trials;
- our ability to enter into acceptable relationships with one or more contract manufacturers or other service providers on which may depend, and the ability of such contract manufacturers or other service providers to manufacture biologics, devices, nutraceuticals or other key products or components, or to provide other services, of an acceptable quality on a timely and cost-effective basis;
- our ability to enter into acceptable relationships with one or more development or commercialization partners to advance the commercialization of new products and product candidates and the timing of any product launches;
- our growth, expansion and acquisition strategies, the success of such strategies, and the benefits we believe can be derived from such strategies;
- our ability to pursue and effectively develop new product opportunities and acquisitions and to obtain value from such product opportunities and acquisitions;
- our ability to maintain the listing of our common stock on a national exchange;
- our intellectual property rights and those of others, including actual or potential competitors;
- the outcome of litigation matters;

our personnel, consultants and collaborators;

expectations concerning our operations outside the United States;

current and future economic and political conditions;

overall industry and market performance;

the impact of accounting pronouncements;

management s goals and plans for future operations; and

other assumptions described in this report underlying or relating to any forward-looking statements.

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The forward-looking statements in this report speak only as of the date of this report 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 report 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 Item 1A and elsewhere in this report, as well as in other reports and documents we file with the United States Securities and Exchange Commission (SEC).

Unless the context requires otherwise, all references in this report to the Company, Cardium, we, our, and us refer to Cardium Therapeutics, and, as applicable, Post-Hypothermia Corporation (formerly, InnerCool Therapies, Inc.), Tissue Repair Company, MedPodium Health Sciences, Inc., and Medpodium Health Products, Inc., each a wholly-owned subsidiary of Cardium.

PART I

ITEM 1. BUSINESS

Overview

Cardium Therapeutics, Inc. was organized in Delaware in December 2003. Our business is focused on the acquisition and strategic development of product opportunities or businesses having the potential to address significant unmet medical needs, and definable pathways to commercialization, partnering or other monetization following the achievement of corresponding development objectives. As a development stage company, we have yet to generate positive cash flows from operations and are essentially dependent on debt and equity funding and partnering or other monetization transactions to finance our operations. Key transactions and developments include the following:

In October 2005, we acquired a portfolio of biologic growth factors and related delivery techniques from the Schering AG Group (now part of Bayer AG) for potential use in treating ischemic and other cardiovascular conditions, including Generx®, a product candidate being developed for patients with chronic myocardial ischemia (insufficient blood flow within the heart muscle) due to coronary heart disease.

In March 2006, we acquired the technologies and products of InnerCool Therapies, Inc., a medical technology company in the emerging field of therapeutic hypothermia or patient temperature modulation, whose systems and products are designed to rapidly and controllably cool the body to reduce cell death and damage following acute ischemic events.

In August 2006, we acquired rights to the assets and technologies of Tissue Repair Company, a company focused on the development of therapeutics for the potential treatment of chronic wounds and other tissue injuries. Tissue Repair Company s Excellagen and Excellarate product candidates are initially being developed for the potential treatment of chronically non-healing diabetic foot ulcers. Tissue Repair Company is operated as a wholly-owned subsidiary of Cardium.

In July 2008, Cardium s InnerCool Therapies subsidiary received a CE mark for European commercialization of an enhanced endovascular temperature modulation device, RapidBlue , developed to quickly and controllably cool the body and potentially lessen or prevent associated injuries following acute ischemic events such as cardiac arrest or stroke.

In October 2008, InnerCool received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the RapidBlue System in the United States.

In July 2009, with InnerCool s RapidBlue System cleared for commercialization in the U.S. and Europe, and with the strategic turn-around and expansion of InnerCool s business and products

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essentially complete, InnerCool was acquired by Royal Philips Electronics (NYSE: PHG) for $11.25 million, as well as the assumption by Philips of approximately $1.5 million in InnerCool trade payables (the Philips Transaction). The operations of InnerCool, which is now a part of Philips Healthcare, are shown as a discontinued operation in our consolidated statements of operations.

In November 2010, we announced the launch of our MedPodium healthy lifestyle product platform and web boutique. With additional products and distribution channels, we plan to develop MedPodium into a portfolio of premium science-based, easy-to-use medicinals, neurologics, metabolics, nutraceuticals and aesthetics intended to promote and manage personal health.

In June 2011, Cardium s Generx® product candidate was cleared by the Russian Ministry of Health and Social Development to commence a registration study (ASPIRE) designed to support a commercialization application for its use in the potential treatment of myocardial ischemia due to coronary artery disease.

In October 2011, Tissue Repair Company s Excellagen product received 510(k) premarket notification from the U.S. Food and Drug Administration for the treatment of chronically non-healing diabetic foot ulcers and other dermal wounds.

In December 2011, the MedPodium product platform was expanded to include Nutra-Apps® products, which are small, pharmaceutically-sealed, easy-to-use nutraceutical capsules. In December 2011, the first two Nutra-Apps products, Neo-Energy® and Neo-Carb Bloc®, were introduced for distribution into convenience stores and other channels.

More recent developments since the end of the 2011 reporting year include the following:

In January 2012, we reported initiation of our first international agreement for the commercialization of Excellagen with BL&H Co. Ltd., a South Korean pharmaceutical company.

In March 2012, Nutritional Products International (NPI), a nutraceutical and cosmeceutical firm that provides sales and distribution services for worldwide brands, announced that it would be making MedPodium s Nutra-Apps® products available across the U.S.

In March 2012, we announced initiation of the ASPIRE clinical study designed to demonstrate the effectiveness of Generx® for the potential treatment of myocardial ischemia.

In March 2012, we initiated U.S. market introduction of Excellagen for the management of diabetic foot ulcers and other dermal wounds.

Our business model is designed to create multiple opportunities for success while avoiding reliance on any single technology platform or product type, and to leverage Cardium s skills in late-stage product development in order to bridge the critical gap between promising new technologies and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses. In parallel, as our businesses are advanced and corresponding valuations established, we plan to pursue new product opportunities and acquisitions with strong value enhancement potential.

Cardium Biologics and Tissue Repair Company Therapeutics and Devices for Ischemic Injuries and Other Indications

Cardium Biologics

The lead product candidate from our Cardium Biologics unit is Generx® (alferminogene tadenovec, Ad5FGF-4), which is being developed as a potential treatment for myocardial ischemia (insufficient blood flow

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within the heart muscle) due to coronary heart disease. Generx represents a new therapeutic class of cardiovascular biologics designed to promote collateral angiogenesis, a natural process of blood vessel growth within the heart muscle, to increase blood supply to ischemic areas of the heart following a one-time intracoronary administration.

Generx has already been tested in clinical studies involving 650 patients at more than one hundred medical centers in the U.S., Europe and elsewhere. The FDA also cleared Generx for a Phase 3 clinical study in the U.S. for women with late stage coronary artery disease who are unresponsive to traditional drug therapy and are not appropriate candidates for mechanical revascularization (angioplasty/stents or by-pass surgery). However, in view of published results from an independent 10-year study among men and women with chronic coronary heart disease showing that improved collateral circulation was associated with substantially lower cardiac mortality (Circulation 116:975-983, 2007), and prior studies showing that a one-time infusion of Generx has the potential to achieve improved coronary collateral circulation in both men and women at levels approximately equivalent to bypass surgery as measured by SPECT imaging (J Am Coll Cardiology 42(8):1339-1347, 2003), we believe that Generx could potentially be developed as a cost effective front-line therapy for patients with coronary artery disease in the large markets of newly-industrializing countries who often do not have access to costly procedures such as bypass surgery.

In 2011, we initiated plans for a follow-on clinical study of Generx involving approximately 100 patients at up to six leading medical centers in Russia, and using SPECT imaging as a key clinical endpoint, which began in the first quarter of 2012. We believe that having additional clinical evidence confirming the safety and effectiveness of Generx for improving coronary collateral circulation in men and women with severe coronary artery disease could potentially be used to optimize and broaden commercial development pathways in the U.S. and other industrialized countries.

Tissue Repair Company

Cardium s Tissue Repair Company subsidiary is focused on the development of therapeutics and devices for the potential treatment of chronic wounds such as non-healing diabetic ulcers and other wounds, as well as the repair of other tissues, including both hard tissue injuries such as bone fracture, as well as soft tissue injuries affecting skin, ligaments, tendons or cartilage.

On October 10, 2011, our Tissue Repair Company subsidiary received a 510(k) premarket notification from the U.S. Food and Drug Administration (FDA) for its fibrillar collagen-based Excellagen topical gel for wound healing of diabetic foot ulcers and other dermal wounds. In first quarter 2012, we initiated market introduction of Excellagen in the U.S. and also announced our first international agreement for the sales and marketing of Excellagen with BL&H Co. Ltd., a South Korean pharmaceutical company. Our 510(k) filing covers Excellagen s use as a wound care management medical device for topical application by health care professionals for patients with dermal wounds, which can include diabetic ulcers, pressure ulcers, venous ulcers, tunneled/undermined wounds, surgical and trauma wounds, second degree burns, and other types of wounds. The 510(k) submission was based in part on positive findings from our Phase 2b Matrix clinical study, reported on October 14, 2009, demonstrating substantial improvements in wound healing responses in patients with non-healing diabetic foot ulcers following one or two applications of Excellagen, an enhanced, customized collagen-based gel matrix. Excellagen is designed for use by health care professionals in a clinical setting and as an adjunct to standard of care topical wound therapy, which in the case of diabetic ulcers typically includes surgical debridement and off-loading.

For Tissue Repair Company s Excellarate product candidate, which comprises a mixture of our collagen-based gel with a biologic encoding a stimulatory growth factor (PDGF-B), we plan to introduce a combined formulation that allows for longer term stability without the need to maintain the biologic separately at -70 degrees centigrade, and to introduce the easier to use single-syringe product candidate into clinical studies designed to further evaluate the safety and effectiveness of Excellarate, and to allow for repeat dosing of Excellarate for wounds that are responding to treatment but have not yet achieved complete closure.

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Chronic Wound Care Market

An estimated 18 million patients worldwide suffer from chronic wounds with the U.S. making up 6 million, and over $20 billion is spent annually in the U.S. to treat these wounds.

Over 800,000 patients in the U.S. develop diabetic foot ulcers annually.

Approximately 2.5 million patients suffer from pressure wounds, 1 million from diabetic foot ulcers and 1.6 million from venous status ulcers.

Diabetic ulcers cost the U.S. healthcare system approximately $5 billion per year with treatment and subsequent lower limb amputations adding an additional $1 billion per year.

Of the approximately 25 million diabetic patients, approximately 15 to 20 percent of this patient population will go on to suffer at least one chronic foot ulcer and of those six percent will be hospitalized due to infection or other ulcer-related complications.

Diabetes is the leading cause of non-traumatic lower extremity amputations and approximately 14 to 24 percent of patients with diabetes who develop foot ulcers eventually have an amputation.

Current Treatment Approaches for Chronic Wounds

There are several treatment modalities currently used for severe chronic ulcers in diabetic patients, including topical dressings, off-loading, debridement and skin grafts. Regranex® Gel (becaplermin), which is marketed by Johnson & Johnson s Ethicon Wound Management Division, is considered to be the only FDA-approved prescription medicine to treat such wounds. Regranex® Gel is a recombinant human platelet-derived growth factor (rrPDGF-BB) protein that is used as an adjunct with other current treatment modalities described above and is used to treat lower extremity diabetic neuropathic ulcers. Based on Regranex® Gel s instructions for use, an estimated 70 administrations and 70 wound cleanings and redressings would be required over a 10-week treatment period (once daily administration followed by a subsequent wound cleaning and redressing without gel).

Gene Activated Matrix (GAM) Technology

We believe that patient compliance can be a major factor preventing or limiting improved medical outcomes, particularly when repeated administrations are required at a wound site. Tissue Repair Company s Gene Activated Matrix technology is designed to provide a therapeutic level of protein synthesis at a particular site in the body, including 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. GAM consists of a biocompatible matrix comprising a gene or DNA vector encoding a growth factor or other therapeutic protein.

For tissue repair, the application method involves placement of a GAM gel directly onto a wound site. Tissue Repair Company s studies have shown that proliferative cells in the body can migrate into the GAM, take up the immobilized vector and gene and then transiently express the encoded therapeutic protein. Compared with topical applications of proteins, this *in situ* expression method significantly prolongs the availability of therapeutic protein to the cells involved in tissue repair. Tissue Repair Company s GAM technology may have potential utility in several clinical indications where protein therapeutics have had limited success, including treatment of dermal wounds (such as diabetic foot ulcers), therapeutic angiogenesis (pharmacologically inducing new blood vessel growth), and orthopedic products for repair of various tissues, including hard tissue (bone) and soft tissue (ligament, tendon, cartilage, skin).

MedPodium Modern Lifestyle Product Line

Our MedPodium healthy lifestyle product line and web boutique, launched in November 2010, is expected to incorporate additional products and distribution channels, and to be developed into a portfolio of premium

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science-based, easy-to-use medicinals, neurologics, metabolics, nutraceuticals and aesthetics for promoting and managing personal health. Products selected for the MedPodium portfolio are expected to be substantiated with scientific data supporting an understanding of the mechanism of action, have well-defined manufacturing standardizations, and allow for easy-to-use formulation and dosage. MedPodium products are currently available for sale through our web-based boutique at www.medpodium.com. We are waiting to initiate formal advertising and promotional programs until we have assembled a portfolio of ready-for-sale products.

During 2011, we developed the MedPodium Nutra-Apps® product line (Neo-Energy® and Neo-Carb Bloc®) for distribution in convenience stores and other channels. Neo-Energy®, is a dietary supplement capsule that provides a customized blend of natural caffeine, green tea leaf extract and Vitamin B3 (Niacin). Each of Neo-Energy s small, easy-to-use capsules provide an amount of caffeine comparable to commonly-sold energy shots or a premium coffee, or multiple cans (about 20 ounces) of various energy drinks. A pocket-sized pack containing four Neo-Energy capsules will be sold for approximately the same retail price as a single liquid energy shot or beverage. In addition, Neo-Energy capsules have no sugar, no calories, and no aftertaste as commonly found in various drinks. During 2011, we also launched Neo-Carb Bloc®, a dietary supplement featuring a custom formulation of white kidney bean extract that has been shown to reduce the enzymatic digestion of dietary starches contained in many carbohydrate-rich foods such as pastas, rice, crackers, breads, pastries, potato chips, and donuts. The foregoing statements have not been evaluated by the Food and Drug Administration, these products are not intended to diagnose, treat, or prevent any disease.

In first quarter 2012, we announced that Nutritional Products International (NPI), a nutraceutical and cosmeceutical firm that provides sales and distribution services for worldwide brands, will be making our MedPodium Nutra-Apps® products available across the United States.

Business Strategy

Given the limited nature of our revenues and the high costs we must incur to develop our product candidates, we have yet to generate positive cash flows or income from operations and do not anticipate doing so in the foreseeable future. As a result, we have been dependent on debt and equity funding to finance our operations. During 2011 and the first quarter of 2012, the company raised a total of $11 million of net proceeds through a registered direct equity investment by institutional and accredited investors for net proceeds of $4.6 million and at-the-market transactions of $6.4 million.

Building on our core products and product candidates, our strategic goal is to develop a portfolio of medical products at various stages of development and secure additional financial resources to commercialize these products in a timely and effective manner.

The key elements of our strategy are to:

- initiate market introduction of the Excellagen™ product and consider strategic partnerships to expand the commercialization of Excellagen in the U.S. and other potential markets;
- advance the clinical studies designed to evaluate the potential of Generx® to be a cost effective front-line therapy for patients with coronary artery disease in the large markets of newly-industrializing countries;
- broaden and expand our MedPodium™ portfolio and our product base through corporate development transactions that could include acquiring other medical-related companies or product opportunities or access to additional channels of distribution;
- monetize the economic value of our product portfolio by establishing strategic collaborations and selling businesses and assets at appropriate valuation inflection points; and
- continue to identify and evaluate businesses, product opportunities and technologies for potential acquisition on favorable economic terms.

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Government Regulation

New drugs, biologics, devices, and nutraceuticals, are subject to extensive regulation under the federal Food, Drug, and Cosmetic Act. In addition, biologics are also regulated under the Public Health Service Act. We believe that the pharmaceutical products we are attempting to develop will be regulated either as biological products or as new drugs. Both statutes and their corresponding regulations govern, among other things, the testing, manufacturing, distribution, safety, efficacy, labeling, storage, record keeping, advertising and other promotional practices involving biologics or new drugs. FDA approval or other clearances must be obtained before clinical testing, and before manufacturing and marketing, of biologics and drugs. Obtaining FDA approval has historically been a costly and time-consuming process. Different regulatory regimes are applicable in other major markets.

In addition, any gene therapy and other DNA-based products we develop will require regulatory approvals before human trials and additional regulatory approvals before marketing. New biologics are subject to extensive regulation by the FDA and the Center for Biological Evaluation and Research and comparable agencies in other countries. Currently, each human-study protocol is reviewed by the FDA and, in some instances, the NIH, on a case-by-case basis. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols.

To commercialize our product candidates, we must sponsor and file an investigational new drug (IND) application and be responsible for initiating and overseeing the human studies to demonstrate the safety and efficacy and, for a biologic product, the potency, which are necessary to obtain FDA approval of any such products. For our newly sponsored investigational new drug applications, we will be required to select qualified investigators (usually physicians within medical institutions) to supervise the administration of the products, and we will be required to ensure that the investigations are conducted and monitored in accordance with FDA regulations and the general investigational plan and protocols contained in the IND application.

The FDA receives reports on the progress of each phase of testing, and it may require the modification, suspension, or termination of trials if an unwarranted risk is present to patients. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. The IND application process can thus result in substantial delay and expense. Human gene therapy products, a primary area in which we are seeking to develop products, are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials to establish the safety, efficacy and potency of human gene therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval.

After the completion of trials of a new drug or biologic product, FDA marketing approval must be obtained. If the product is regulated as a biologic, the Center for Biological Evaluation and Research will require the submission and approval, depending on the type of biologic, of either a biologic license application or a product license application and a license application before commercial marketing of the biologic. If the product is classified as a new drug, we must file a new drug application with the Center for Drug Evaluation and Research and receive approval before commercial marketing of the drug. The new drug application or biologic license applications must include results of product development, laboratory, animal and human studies, and manufacturing information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the new drug application or biologic license applications for filing and, even if filed, that any approval will be granted on a timely basis, if at all. In the past, new drug applications and biologic license applications submitted to the FDA have taken, on average, one to two years to receive approval after submission of all test data. If questions arise during the FDA review process, approval can take more than two years.

Notwithstanding the submission of relevant data, the FDA may ultimately decide that the new drug application or biologic license application does not satisfy its regulatory criteria for approval and may require

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additional studies. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness. Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to compliance with current good manufacturing practices (GMPs), reporting of adverse effects, advertising, promotion and marketing. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we or our suppliers may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any such products.

The approval and/or clearance for marketing of medical devices, such as Excellagen and potentially other product candidates of our Tissue Repair Company subsidiary, are also subject to extensive controls by health regulatory and other authorities. Although some devices can be cleared for marketing pursuant to a procedure referred to as an FDA 501(k) clearance, other devices and/or indications may require additional clinical studies and may be subject to even more extensive regulatory and other controls.

Nutraceuticals, dietary supplements and other products intended for human consumption, such as those included or to be included in our MedPodium product portfolio, are also subject to numerous rules and regulations promulgated by the FDA and other food and health regulatory authorities, including regulations governing the sourcing, manufacture, labeling, handling, storage, marketing and use of such products.

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to a variety of other regulations in the United States, including those relating to bioterrorism, taxes, labor and employment, import and export, and intellectual property.

To the extent we have operations outside the United States, any such operations would be similarly regulated by various agencies and entities in the countries in which we operate. The regulations of these countries may conflict with those in the United States and may vary from country to country. In markets outside the United States, we may be required to obtain approvals, licenses or certifications from a country s ministry of health or comparable agency before we begin operations or the marketing of products in that country. Approvals or licenses may be conditioned or unavailable for certain products. These regulations may limit our ability to enter certain markets outside the United States.

Competition

The pharmaceutical, biotechnology, medical device and nutraceutical industries are intensely competitive. Our products and any product candidates developed by us would compete with existing drugs, therapies, devices or procedures and with others under development. There are many pharmaceutical, biotechnology and medical device companies, public and private universities and research organizations actively engaged in research and development of products for the treatment of cardiovascular and related diseases, and/or products for the healing

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of chronic wounds, and many nutraceutical companies with existing and rapidly evolving product lines. Many of these organizations have financial, technical, research, clinical, manufacturing and marketing resources that are greater than ours. If a competing company develops or acquires rights to a more efficient, more effective, or safer competitive approach for treatment of the same or similar diseases or conditions we have targeted, or one that offers significantly lower costs of treatment, our business, financial condition and results of operations could be materially adversely affected.

We believe that the most significant competitive factor in the field of new therapeutics and devices is the effectiveness and safety of a product candidate, and cost as compared to other products, product candidates or approaches that may be useful for treating a particular disease condition. We believe that our product development programs will be subject to significant competition from companies using alternative technologies, some of which are described below, as well as to increasing competition from companies that develop and apply technologies similar to ours. Other companies may succeed in developing products earlier than we do, obtaining approvals for these products from the FDA more rapidly than we do or developing products that are safer, more effective or less expensive than those under development or proposed to be developed by us. We cannot assure you that research and development by others will not render our technology or product candidates obsolete or non-competitive or result in treatments superior to any product candidate developed by us, or that any product candidate developed by us will be preferred to any existing or newly developed technologies.

We are aware of products currently under development by competitors targeting the same or similar cardiovascular and vascular diseases as our Generx product development. These include biologic treatments using forms of genes and therapeutic proteins. For example, CardioVascular BioTherapeutics is developing injectable and topical forms of FGF-1 for the potential treatment of cardiovascular diseases. We will also face competition from entities using other traditional methods, including new drugs and mechanical therapies, to treat cardiovascular and vascular disease.

In the areas of tissue repair and wound healing, as being developed by our Tissue Repair subsidiary, there are a number of approaches being employed, including other collagen-based products, living skin equivalents, vacuum pumps and other devices, and biologics and small molecule drugs designed to promote repair and healing.

Nutraceutical businesses and other providers of healthy lifestyle products represent a very large and intensely competitive industry. Many of these organizations have financial, technical, product development, manufacturing and marketing resources that are far greater than ours or our collaborators, and may offer established and new products for addressing the same or similar conditions that could be safer, more effective and/or less costly than ours, or could be marketed and distributed more effectively and efficiently.

Manufacturing Strategy

To leverage our experience and available financial resources, we do not plan to develop company-owned and operated manufacturing facilities. We plan to outsource all product manufacturing to one or more contract manufacturers of clinical drug products that operate manufacturing facilities in compliance with current Good Manufacturing Practices. We may also seek to refine the current manufacturing process and final product formulation to achieve improvements in storage temperatures and the like.

The FDA has established guidelines and standards for the development and commercialization of molecular and gene-based drug products i.e.: *Guidance for Industry CMC for Human Gene Therapy INDs November 2004, Sterile Drug Products Produced by Aseptic Processing September 2004, Human Somatic Cell Therapy and Gene Therapy March 1998, PTC in the Characterization of Cell Lines Used to Produce Biologicals July 1993*. These industry guidelines, among others, provide essential oversight with regard to process methodologies, product formulations and quality control standards to ensure the safety, efficacy and quality of these drug products.

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Marketing and Sales

Aside from our MedPodium product line and web boutique, which is under development and does not account for substantial revenues at this time, and our Excellagen product for which we expect to engage in sales and marketing principally through or in collaboration with a commercial partner, our other product candidates must generally undergo testing and development in clinical trials and pre-clinical studies, and we do not currently have any other products approved for marketing. If we should obtain any such additional marketing approvals, we expect that we would engage in appropriate marketing or sales efforts through or in collaboration with a commercialization partner.

Licensing and Intellectual Property

As part of our acquisition of a portfolio of cardiovascular growth factor therapeutic assets pursuant to a Technology Transfer Agreement entered into between Cardium and the Schering AG Group (now part of Bayer AG), we acquired from Schering a portfolio of methods and compositions directed at the treatment of cardiovascular diseases, including Generx. Information related to our purchase of technology from the Schering AG Group and a related university licensor is provided below under our Notes to Consolidated Financial Statements, Note 8 Commitments and Contingencies.

In August 2006, we acquired the rights to various technologies and products now part of our Tissue Repair Company subsidiary, including Excellarate. In 2009, we reported that Excellagen, which contains the customized collagen-based gel matrix employed in Excellarate but does not contain the added growth factor DNA used in Excellarate, appeared to be substantially effective for wound healing of debrided diabetic foot ulcers and potentially other wounds, and Excellagen then became the subject of a 510(k) premarket notification filing with the U.S. Food and Drug Administration (FDA), which was approved on October 10, 2011. We do not have any ongoing material commitments or royalty obligations with respect to the new Excellagen product under our prior transaction in which we acquired substantially all of the assets of the Tissue Repair Company.

On December 20, 2011, we, along with our MedPodium Health Sciences, Inc. subsidiary, entered into a strategic partnership agreement with SourceOne Global Partners, LLC. SourceOne is a supplier of exclusive science-based ingredients and proprietary formulas to the nutritional supplement and related functional food and beverage industries. The strategic partnership agreement, which is subject to earlier termination under specified circumstances, is for an initial term of 10 years and automatically renews for additional one-year periods. Under terms of the licensing arrangement, we received a fully-paid-up license to commercialize formulations of various SourceOne ingredients to be marketed as nutraceuticals, pharmaceuticals and/or medical foods. In addition, we can designate up to ten products to be jointly developed by the partners, with cash and other resources to be contributed jointly under a profit-share arrangement. In exchange for the license we issued 1.5 million restricted shares of our common stock, which shares are to be held in escrow for six months and subject to release at future dates thereafter based on our advancement of certain jointly-developed products.

Under the SourceOne agreement, we also made an equity investment in the form of unregistered, restricted shares of our common stock to acquire rights to a 15% ownership interest in SourceOne Global Partners. Our ownership interest was acquired through the issuance into escrow of 1.5 million shares of our common stock based on a $0.50 per share value, representing a 70% premium above the $0.28 closing price of our stock on December 19, 2011. The shares are being held in escrow and are subject to release in four allotments at 6, 9, 12 and 18 months following the closing date. We also have certain rights to maintain our proportionate ownership interest in SourceOne, and to acquire SourceOne in the event SourceOne were to receive an offer from a third-party acquiror.

We expect to continue evaluations of the safety, efficacy and possible commercialization of our product candidates and technologies as they advance in development. On the basis of such evaluations, we may alter our current research and development programs, clinical studies, partnering or other development or commercialization activities. Accordingly, we may elect to amend or cancel, from time to time, one or more of

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our arrangements with third parties, subject to any applicable accrued liabilities and fees. Alternatively, the other parties to such arrangements may, in certain circumstances, be entitled to terminate the arrangements. Further, the amounts payable under certain of our arrangements may depend on the number of products or indications for which any particular technology licensed under such arrangement is used by us. Thus, any statement of potential fees payable by us under each agreement is subject to a high degree of potential variation from the amounts indicated.

Our business strategy includes the establishment of research collaborations to support and supplement our discovery, pre-clinical and clinical research and development phases of the product commercialization cycle, as well as the implementation of long-term strategic partnerships with one or more commercialization partners to support clinical trials and product commercialization activities, including product manufacturing, marketing and distribution.

Although we or our licensors may file and prosecute patent applications related to various technologies under license or development, or seek to protect some technologies in other ways such as through the maintenance of trade secrets, our product candidates are based on complex and rapidly evolving technologies, and none of our biologic product candidates have completed clinical development. There are also a number of additional uncertainties affecting our ability to materially rely on any of our intellectual property rights as described below under ITEM 1A. RISK FACTORS Risks Related to Our Intellectual Property and Potential Litigation. There can be no assurance that any intellectual property assets, or other approaches to marketing exclusivity or priority, would be sufficient to protect our commercialization opportunities, nor that our planned commercialization activities will not infringe any intellectual property rights held or developed by third parties.

Employees

As of December 31, 2011, we employed 15 employees, of which all were full-time. We expect to hire additional employees during the next 12 months as our products and product candidates advance. Our employees are not represented by a collective bargaining agreement and we have not experienced any work stoppages as a result of labor disputes. We believe our relationship with our employees is good. We also rely on various consultants and advisors to provide services to us.

Available Information

Our website address is www.cardiumthx.com. We make available, free of charge, through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file or furnish such reports to the SEC.

For additional financial information, including financial information about our business, please see the consolidated financial statements and accompanying notes to the consolidated financial statements included under Item 8 of this report.

ITEM 1A. RISK FACTORS

You should carefully review and consider the risks described below, as well as the other information in this report and in other reports and documents we file with the SEC when evaluating our business and future prospects. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties, not presently known to us, or that we currently see as immaterial, may also occur. If any of the following risks or any additional risks and uncertainties actually occurs, our business could be materially harmed, and our financial condition, results of operations and future growth prospects could be materially and adversely affected. 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 stock. You should not draw any inference as to the magnitude of any particular risk from its position in the following discussion.

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Risks Related to Our Business and Industry

Our product candidates are subject to ongoing regulatory requirements or require regulatory approvals, and in some cases additional prior development or testing, before marketing. We may be unable to develop, obtain or maintain regulatory approval or market any of our product candidates or expand the market of our existing products and technology.

Our Excellagen collagen-based product and other wound care and biologics products, as well as our nutraceuticals, dietary supplements and other products within our MedPodium healthy lifestyle portfolio, are subject to numerous rules and regulations promulgated by the FDA and other food and health regulatory authorities, including regulations governing the sourcing, manufacture, labeling, handling, storage, marketing and use of such products. In most cases, we will rely on third parties to perform many of these activities, which may not be performed in an effective or timely manner.

Our other product candidates require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, FDA has not yet approved any gene therapy or similar product and there can be no assurance that it will.

Our product candidates may fail, or may not advance beyond clinical testing. If our product candidates are delayed or fail, we will not be able to generate revenues and cash flows from operations, and we may have to curtail or cease our operations.

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;
- 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;
- 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 develop or successfully 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 rely on third party clinical research organizations to manage our clinical trials. Under this business model, we have less control over the clinical trials and may experience delays or errors in our clinical trials that could adversely affect our business, financial results and commercial prospects.

To obtain regulatory approvals for new products, we must, among other things, initiate and successfully complete multiple clinical trials demonstrating to the satisfaction of the FDA that our product candidates are

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sufficiently safe and effective for a particular indication. We currently rely on third party clinical research organizations to assist us in designing, administering and assessing the results of those trials. In relying on those third parties, we are dependent upon them to timely and accurately perform their services. We have experienced, and in the future may experience, delays in our clinical trials. Any such delay will result in additional costs, and defer any prospective opportunities to monetize the product candidate. 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;