

Cardium Therapeutics, Inc.  
Form 10-K  
April 05, 2013  
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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, 2012

001-33635

(Commission file number)

**CARDIUM THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State of incorporation)

27-0075787  
(IRS Employer Identification No.)

12255 El Camino Real, Suite 250

San Diego, California 92130  
(Address of principal executive offices)

(858) 436-1000  
(Registrant's telephone number)

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

Title of each class  
Common Stock, \$0.0001 par value per share

Name of exchange on which registered  
NYSE MKT

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

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**None**

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

Indicate by checkmark 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).  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.

<input type="checkbox"/> Large accelerated filer	<input type="checkbox"/> Accelerated filer	<input type="checkbox"/> Non-accelerated filer	<input checked="" type="checkbox"/> Smaller reporting company
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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

The aggregate market value of common equity held by non-affiliates, computed on the basis of the closing sale price for the common stock as reported on the NYSE MKT on June 30, 2012, was \$24.6 million. Shares of common stock held by executive officers, directors and by persons who own 10% or more of the outstanding common stock of the registrant have been excluded for purposes of the foregoing calculation in that such persons may be deemed to be affiliates. This does not reflect a determination that such persons are affiliates for any other purpose.

As of March 20, 2013, 129,562,061 shares of Cardium'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 Cardium's definitive proxy statement for its Annual Meeting of Stockholders to be filed on or before April 30, 2013.

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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, its wholly owned subsidiaries Post-Hypothermia Corporation (formerly, InnerCool Therapies, Inc.), Tissue Repair Company and To Go Brands, Inc.

### **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, 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 ability to increase revenues, raise sufficient financing and to otherwise maintain the listing of our common stock on a national exchange;

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 we 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;

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our intellectual property rights and those of others, including actual or potential competitors;

the outcome of litigation matters;

the anticipated activities of our personnel, consultants and collaborators;

expectations concerning our operations outside the United States;

current and future economic and political conditions;

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overall industry and market performance;

the impact of new 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.

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 (the "SEC").

## **PART I**

### **ITEM 1. BUSINESS**

#### **Overview**

Cardium is an asset-based health sciences and regenerative medicine company focused on the acquisition and strategic development of innovative products and 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. Our current portfolio includes Cardium Biologics, Tissue Repair Company and To Go Brands, Inc., companies primarily focused on the development of innovative therapeutic products for cardiovascular indications, wound healing and nutraceutical supplements, respectively. 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.

Cardium Therapeutics, Inc. was organized in Delaware in December 2003.

Significant portfolio transactions since that date 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<sup>®</sup>, 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 such as cardiac arrest and stroke, and to potentially lessen or prevent associated injuries such as adverse neurologic outcomes.

In August 2006, we acquired rights to assets and technologies of Tissue Repair Company, a company focused on the development of growth factor therapeutics for the potential treatment of tissue wounds such as chronic diabetic wounds, and whose product candidate, Excellagen<sup>®</sup> is FDA-cleared as a single administration therapeutic for the treatment of non-healing, neuropathic diabetic foot ulcers and other dermal wounds.

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On July 24, 2009, we sold all of the assets and liabilities of our InnerCool Therapies business to Philips Electronics North America Corporation for \$11.25 million, as well as the transfer of approximately \$1.5 million in trade payables.

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In November 2010, we announced the launch of our MedPodium® healthy lifestyle product platform and web boutique. MedPodium is a portfolio of premium science-based, easy to use medicinals, neurologics, metabolics, nutraceuticals and aesthetics intended to promote and manage personal health. In addition, Cardium has developed the MedPodium Nutra-Apps® product line (Neo-Energy®, Neo-Carb Bloc® and Neo-Chill ) for distribution in convenience stores and other channels.

In March 2012, we introduced our FDA-cleared Excellagen® professional-use wound care product for the treatment of diabetic foot ulcers and other dermal wounds, and entered into a logistics and cold chain services agreement with Smith Medical Partners, a subsidiary of H. D. Smith.

In March 2012, we initiated our Generx® ASPIRE Phase 3 registration study involving approximately 100 patients at up to nine leading medical centers in Russia

On September 28, 2012 we acquired substantially all of the assets, business and product portfolio of privately-held To Go Brands, Inc. To Go Brands develops, markets and sells a portfolio of over 25 products, including nutraceutical powder mixes, supplements and chews to support healthy lifestyles. The product line includes antioxidant-rich drink mixes in convenient stick packs that are designed to pour directly into a water bottle, as well as mix packages for home use and capsule-based dietary supplements, including Trim Green Coffee Bean, which supports healthy weight loss. These products are sold through food, drug and mass channels at retailers including Whole Foods, CVS, Kroger, GNC, Jewel-Osco, Ralph s Supermarkets, Meijer, and the Vitamin Shoppe and from the company s web-based store.

In January 2013, we announced the planned partner-enabled clinical development of Genedexa (previously referred to as the Excellerate product candidate and an asset of Tissue Repair Company), a DNA-based Phase 2b/3 product candidate initially for the treatment of chronic, non-healing diabetic foot ulcers and representing the first product extension from our FDA-cleared Excellagen® technology platform.

In January 2013, we announced our in-house product development of, LifeAgain , a partner-enabled medical analytics and e-commerce platform of algorithms and medical-based programs that were developed by our researchers to support a strategically partnered commercialization of specialized survivable risk life insurance underwritings for cancer patients and patients with chronic medical diseases, based on the improvement of early diagnosis and new chronic treatments and curative medical therapies.

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 our 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**

### ***Generx***

Generx (alferminogene tadenovec/CardioNovo®) is a DNA-based angiogenic therapy being developed for the potential treatment of myocardial ischemia due to advanced coronary artery disease. Generx is designed to stimulate and promote the growth of supplemental collateral vessels to enhance myocardial blood flow (perfusion) following a one-time intracoronary administration from a standard cardiac infusion catheter in patients who have insufficient blood flow due to atherosclerotic plaque build-up in the coronary arteries.



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In March 2012, we initiated the Generx ASPIRE Phase 3 / registration study involving approximately 100 patients at up to nine leading medical centers in Russia, and using SPECT imaging as a key clinical endpoint. If the trial is successful, we hope to gain approval to sell Generx in Russia and in the Commonwealth of Independent States. We also 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.

Generx is also cleared by the FDA 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.

### *Incidence of Cardiovascular Disease*

According to the Centers for Disease Control and Prevention, heart disease is the leading cause of death for both men and women in the U.S.

Coronary heart disease costs the U.S. an estimated \$108.9 billion each year, which includes the cost of healthcare services, medications, and lost productivity.

According to the Federal Research Institute for Health Organization and Informatics of the Russian Ministry of Health, cardiovascular disease affects over 30 million people in the Russian Federation. An estimated 3.5 million patients were newly diagnosed with the disease in 2011.

In 2012, approximately one million deaths were attributable to cardiovascular disease in the Russian Federation.

### *Current Treatment Approaches for Coronary Artery Disease*

Current treatments of coronary artery disease include drugs such as ACE inhibitors, beta-blockers, calcium channel blockers, nitrates, such as nitroglycerin, statins, and Ranexar® (Gilead Sciences) known as Ranolazine for the treatment of angina). Surgical and mechanical interventions for the treatment advanced coronary disease include angioplasty and stents (percutaneous coronary interventions), coronary artery bypass surgery (CABG), and robot-assisted coronary artery bypass).

We believe that treatment with Generx may serve as a lower cost alternative to traditional surgery and stents.

## **Tissue Repair Company**

### *Excellagen®*

On October 3, 2011, our Tissue Repair Company subsidiary received a 510(k) premarket notification from the U.S. Food and Drug Administration (FDA) for its Excellagen® highly refined fibrillar collagen-based topical gel for the management of diabetic foot ulcers and other dermal wounds. Our 510(k) clearance covers Excellagen's use by healthcare professions for topical application to dermal wounds, which include diabetic ulcers, pressure ulcers, venous ulcers, tunneled/undermined wounds, surgical and trauma wounds, second degree burns, and other types of wounds. Following FDA approval, in March 2012 we entered into a logistics and cold

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chain services agreement with Smith Medical Partners, a subsidiary of H. D. Smith. We began initial sales of our Excellagen product® in 2012.

In addition to its application for dermal wounds, Excellagen® has been engineered to serve as a delivery platform enabling multiple device and therapeutic product extensions to include antimicrobials, small molecule drugs, peptides, conditioned cell media, stem cells and DNA-based biologic products. We plan to develop extensions for our Excellagen platform internally and with potential development partners.

### *Incidence of Chronic Wounds*

Over 18 million chronic wounds are treated annually worldwide, with 6 million patients developing chronic wounds in the U.S. The costs of chronic wounds to the U.S. healthcare system are estimated to be \$20 billion annually.

Approximately 2 million patients suffer from pressure wounds, 1.2 million from diabetic foot ulcers and up to 2 million patients seek treatment for venous ulcers annually.

An estimated 347 million people worldwide have diabetes. Diabetes affects over 25 million people in the U.S., representing over 8 percent of the population. According to the American Diabetes Association, the costs associated with diabetes in 2012 in the U.S. totaled \$245 billion, including \$175 billion in direct medical costs and \$69 billion in reduced productivity.

Approximately 15-25% of diabetic patients will develop foot ulcers and the recurrence rate of these patients developing new ulcers are 34%, 61%, and 70% after one, three and five years of follow up, respectively. Eventually 15-24% of these patients will require amputation.

### *Current Treatment Approaches for Chronic Wounds*

There are several treatment modalities currently used for chronic ulcers in diabetic patients and other dermal wounds, including topical dressings, dermal substitutes, negative pressure wound therapies, and debridement with offloading. Regranex® Gel (becaplermin), which is currently marketed by Healthpoint Biotherapeutics, now an operating unit of Smith & Nephew, is considered to be the only FDA-approved prescription medicine to treat such wounds. Regranex® is a recombinant human platelet-derived growth factor protein that is used as an adjunct with other current treatment modalities described above to treat lower extremity diabetic neuropathic ulcers.

In addition, human dermal substitute products, including Apligraf® (Organogenesis Inc.), Dermagraft® (Shire Pharmaceuticals), and Graftjacket® Regenerative Tissue Matrix (KCI USA, Inc.) advanced wound care products are currently being used by physicians in the treatment of chronic diabetic foot ulcers and other dermal wounds. Additional wound care treatments include negative pressure, ultra-sound, and transdermal oxygen wound therapies, such as the MIST ultra-sound therapy (Celleration, Inc.), negative pressure systems (Kinetic Concepts Inc. (KCI) and Smith & Nephew), and EPIFLO® Transdermal Oxygen Therapy (Ogenix). Additionally, in certain markets, Excellagen competes with other syringe-based wound care products which include Inegra™ Wound Matrix, marketed by Integra LifeSciences and Graftjacket® Xpress marketed by KCI.

### **To Go Brands**

On September 28, 2012, our Medpodium Health Products subsidiary acquired substantially all of the assets, business and product portfolio of privately-held To Go Brands, Inc., and subsequently changed its corporate name to To Go Brands, Inc. To Go Brands develops, markets and sells a portfolio of over 25 products, including nutraceutical powder mixes, supplements and chews to support healthy lifestyles at over 10,000 food, drug and mass retailers. We have consolidated our nutraceutical initiative, which includes To Go Brands, the MedPodium Nutra-Apps® product line as well as our strategic investment in SourceOne Global Partners, a leading supplier of science-based ingredients and proprietary formulas, into a single operating entity.

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A majority of the revenues we generated in 2012 were derived from sales of our nutritional supplements, including sales of To Go Brands products following the acquisition on September 28, 2012. We anticipate that sales of nutraceutical products will continue to comprise the majority of our revenues over the next 12 months while we advance the commercialization of Excellagen and continue development of our other product candidates.

We plan to (1) realign the To Go Brands products into three segments: Go Active! Go Health! And Go Trim!; (2) increase online customer acquisition and retention via super affiliate programs and social media-based coupon offerings; (3) add new product offerings; and (4) further expand U.S. retail distribution and establish distributors to leverage on the success of To Go Brands Trim Energy Green Coffee Bean dietary supplement featuring Svetol®.

### *Nutraceutical Supplement Market*

According to the Nutrition Business Journal, the U.S. supplement industry grew 7% in 2011 to reach \$30 billion in sales.

Sales by product included meal replacement (10%), specialty (10%), vitamins (34%), herbs and botanicals (17%), sports nutrition (12%), and minerals (8%).

Large pharmaceutical companies have entered the nutraceutical market and are diversifying their product lines with dietary-supplement products with large market potential and without the extensive regulatory hurdles. In February 2012, Pfizer acquired privately-held Alacer Corp., the maker and distributor of Emergen-C®, a vitamin C product. Schiff Nutrition International recently purchased Airborne, Inc., a leading provider of immune support products, and in October 2012, Bayer HealthCare announced its acquisition of Schiff Nutritional International.

### **Business Strategy**

We operate in an industry that is characterized by significant upfront capital costs, with the potential for significant returns for a successful product. 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. 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 2012, we raised net proceeds of \$6.4 million through the completion of a registered direct equity financing with three institutional and accredited investors of 17.9 million shares of Cardium common stock priced at \$0.28 per share with no warrant coverage for net proceeds of approximately \$4.5 million and through the sale of 5.2 million shares of common stock under at-the-market transactions for net proceeds of \$1.9 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. 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.

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

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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.

The key elements of our current business strategy are to:

advance our clinical study for Generx<sup>®</sup>, the APSIRE Phase 3 registration clinical study, in Russia;

commercialize our Excellagen<sup>®</sup> wound care product and develop new product extensions based on our custom formulated collagen product platform for additional wound healing applications;

grow our recently-acquired To Go Brands<sup>®</sup> nutraceutical supplement business by introducing additional product line extensions and further expanding U.S. retail distribution and establishing distributor relationships.;

plan to initiate a partner-enabled clinical development of Genedexa (previously referred to as the Excellerate product candidate), a DNA-based Phase 2b/3 product candidate initially for the treatment of chronic, non-healing diabetic foot ulcers and representing the first product extension from our FDA-cleared Excellagen<sup>®</sup> technology platform;

continue development of our new in-house partner-enabled product, LifeAgain, a medical analytics and e-commerce platform of algorithms and medical-based social media programs that were developed by Cardium researchers to support a strategically partnered commercialization of specialized survivable risk life insurance underwritings for cancer patients and patients with chronic medical diseases, based on the improvement of early diagnosis and new chronic treatments and curative medical therapies; and

continue to review potential acquisitions of other businesses, product opportunities and technologies on favorable economic terms consistent with our long-term business strategy.

## **Government Regulation**

New drugs, biologics, devices, and nutraceuticals, are subject to extensive regulation in the United States 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.



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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 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 To Go Brands and MedPodium product portfolios, 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

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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 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 are aware of products currently under development by competitors targeting the same or similar cardiovascular and vascular diseases as our Generx product. 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, negative pressure wound therapy devices 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.

We believe that the most significant competitive factor in the field of new therapeutics and devices is the effectiveness of a product candidate, as well as its relative safety and cost as compared to other products, product candidates or approaches that may be useful for treating a particular disease condition.

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We believe that our product development programs will be subject to significant competition from companies using alternative technologies, some of which are described above, 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.

## **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.

## **Marketing and Sales**

Our marketing and sales strategy varies by product line. Our product candidates, such as Generx must undergo clinical trials before any marketing and sales can begin. If we should obtain marketing approvals, we expect to engage in marketing and sales efforts through or in collaboration with a partner that specializes in commercialization, marketing and sales of drugs and therapeutics.

For our Excellagen<sup>®</sup> wound care product, we expect to engage in sales principally through or in collaboration with a sales and distribution and strategic partners. In March 2012 we entered into a logistics and cold chain services agreement with Smith Medical Partners, a subsidiary of H. D. Smith. We also entered into sales and distribution agreements with Academy Medical to market, sell and distribute Excellagen to U.S. government medical providers, including Veterans Administration and military hospitals.

For our nutraceutical supplement business, To Go Brands is engaged in sales through food and drug retailers, distributors and our own on-line store.

## **Licensing and Intellectual Property**

Our overall business strategy is principally focused on the acquisition and development of a portfolio of product opportunities which involves a variety of intellectual property rights, including patent prosecution and inbound and outbound licensing transactions.

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. In connection with that portfolio we acquired the rights to certain patents owned by the



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University of California, New York University and Yale University, which would require us to pay royalties on products developed on the basis of those patents. Information related to our purchase from Schering AG Group is provided under Notes to Consolidated Financial Statements, Note 8 Commitments and Contingencies. Our patent portfolio includes allowed and issued patents covering our gene therapy approach both in Europe and in the United States. We have additional patents and patent applications directed to its methods of cardiovascular gene therapy in the U.S., Europe, Russia and elsewhere, and we recently filed new patent applications directed to certain improved techniques for the treatment of heart disease that are currently the subject of Cardium's ASPIRE study in Russia.

In August 2006, we acquired the rights to various technologies and products now part of our Tissue Repair Company subsidiary. In connection with that acquisition we acquired the rights to use certain patented technology related to a growth factor DNA in exchange for royalty payments. Our Excellagen product does not contain the growth factor DNA, and we do not have any ongoing material commitments or royalty obligations with respect to the new Excellagen product candidate under our prior transaction in which we acquired substantially all of the assets of the Tissue Repair Company. We are looking to develop extensions to that platform, including the patented growth factor DNA which would require the payment of royalties if a product is ultimately developed and approved.

In connection with our acquisition of To Go Brands, Inc. we acquired certain proprietary formulations, trade names, and customer lists. We have also licensed rights from third party manufacturers to develop exclusive formulations for our nutraceutical supplement product lines.

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 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.

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 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, 2012 we employed 24 employees (which includes 9 employees who are employed by To Go Brands, Inc.). We do not expect to hire additional employees during the next 12 months while 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](http://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

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to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, 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 occur, 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.

#### ***Risks Related to Our Business and Industry***

***Our products and 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. 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.***

Our Excellagen<sup>®</sup> collagen-based product and other wound care and biologics products, as well as our nutraceuticals, dietary supplements and other products within our Cardium Health Sciences Platform, 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 like that contained in our Generx product candidate, 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;

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 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 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;

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;

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

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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 third party organizations do not accurately collect and assess the trial data we may discontinue development of viable product candidates or continue allocating resources to the development and marketing of product candidates that are not efficacious. Either outcome could result in significant financial harm to our company and damage to our reputation.

***If we are unable to enter into successful sales, marketing and distribution agreements with third parties, we may not be able to successfully commercialize our products.***

In order to commercialize any products successfully, we expect to principally rely on collaborations or other arrangements with third parties to sell, market and distribute our products. To the extent that we enter into licensing, distributorship, co-promotion, co-marketing or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of third parties, whose efforts may not meet our expectations or be successful.

For example, we expect to depend upon the efforts of third parties to promote and sell our Excellagen<sup>®</sup> products, as well our Generx<sup>®</sup> product if it should achieve regulatory approval, but there can be no assurance that the efforts of such third parties will meet our expectations or result in any significant product sales. While third parties would be largely responsible for the timing and extent of sales and marketing efforts, they may not dedicate sufficient resources to our product opportunities, and our ability to cause them to devote additional resources or to otherwise promote sales of our products may be limited. In addition, commercialization efforts could be negatively impacted by the delay or failure to obtain additional supportive data for our products. In some cases, third party partners could be responsible for conducting additional clinical trials to obtain such data and our ability to increase the efforts and resources allocated to these trials may be limited.

***We are a development stage company. We have incurred losses since our inception in December 2003 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 develop our products and product candidates. We expect these losses to be substantial because our product development and other costs, including significant amounts we expect to spend on development activities and clinical trials for our product candidates, cannot be offset by our limited revenues during our development stage. As of December 31, 2012, our accumulated deficit was approximately \$96 million, and our cash and cash equivalents were approximately \$2.3 million. To date, we have generated very limited revenues and 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 few 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 development stage company and are developing complex and novel medical products.***

Since we have a relatively short operating history and our products and product candidates rely on complex technologies, it may be difficult for you to assess our growth, monetization and earnings potential. We have faced and it is likely we will continue to face many of the difficulties new technology companies often face.

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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 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 in the near term. 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.***

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 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 and/or to monetize the economic value of our product portfolio. We expect we will need to raise additional funds in the future. The audit opinion accompanying our consolidated financial statements for the year ended December 31, 2012, included under Item 8 of this report, includes an explanatory paragraph indicating substantial doubt about our ability to continue as a going concern.

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. 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. Anti-dilution adjustments to our securities currently outstanding would cause further dilution. 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.

***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

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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.

*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 is a new and rapidly evolving medical approach that has any 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 recently completed the acquisition of the assets of To Go Brands, Inc. and may pursue acquisitions of other companies or product rights that, if not successful, could adversely affect our business, financial condition and results of operations.*

We recently completed the acquisition of the business assets of To Go Brands, Inc. As part of our business strategy, we may pursue acquisitions of other companies, technologies or products. Acquisitions of businesses or product rights involve numerous risks, including:

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

the use of any 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;

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;





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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 acquisition of To Go Brands, Inc. 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 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 licensors and other third parties. For example, we have various licenses from third parties relating to the use and delivery of our Generx product candidates. We may not be able to maintain or expand these or other 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 collaborators 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 collaborators 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 products and 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. 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, labeling, safety surveillance, promoting and reporting may result in criminal prosecution, civil penalties, recall or

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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.

***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. 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. 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 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.

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 wound healing and tissue repair, 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 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.***

Our ability to earn sufficient returns on our products and future products 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

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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 other therapeutic products and devices, 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. 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-Hyde, 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. We do not maintain any key man life insurance on any of our executive officers.

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 To Go Brand business are in San Diego, California, and our third party manufacturing and storage facilities in Carlsbad, California, are both located in or near seismic zones, and there is a constant 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 an 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.

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*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 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

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, both in the United States and in other countries with substantial markets, to: obtain patent protection for our therapeutics, devices and procedures, and other methods or components on which we rely; 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.

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.

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*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

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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 and biologics, collagen-based products, 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 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.

If we are unsuccessful in defending against any 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



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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, biologics, collagen-based products, wound healing and tissue repair, adenoviral vectors 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 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 sales and marketing 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.

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***Risks Related to Our Common Stock***

***The issuance of our Series A Convertible Preferred Stock may result in substantial dilution to holders of our common stock and may restrict our access to additional financing.***

On April 4, 2013 we entered into a securities purchase agreement with an institutional investor to purchase up to 4,012 shares of our newly authorized Series A Convertible Preferred Stock for maximum proceeds of \$4.0 million. The Series A Convertible Preferred Stock is convertible into shares of our common stock at an initial conversion price of \$0.091 per share. In addition, the conversion price is subject to downward adjustment following our next reverse split, and, subject to certain exceptions, if we issue common stock or common stock equivalents at a price less than the then effective conversion price. In connection with the offering of the Series A Convertible Preferred Stock we granted the investor certain rights of participation in future equity financings. As long as the Series A Convertible Preferred Stock is outstanding, we have also agreed not to incur specified indebtedness without the consent of the holders of the Series A Convertible Preferred Stock. These factors may restrict our ability to raise capital through equity or debt offerings in the future.

***We intend to affect a reverse stock, which impact the price and liquidity of trading in our common stock.***

In connection with the offering of the Series A Convertible Preferred Stock, we intend to seek the approval of our stockholders to a 1 for 20 reverse split of our outstanding common stock. We cannot assure you that the price of our common stock will rise to an amount proportionate with the reverse split. In addition, the planned reverse split will reduce the number of shares of our common stock outstanding from approximately 130 million shares to approximately 6.5 million shares. The decrease in the number of shares outstanding may impact the liquidity and trading volume in our common stock.

***We will need substantial additional capital to develop our products and for our future operations in the near term, which can adversely affect our stock price and valuation***

We will need to raise substantial additional capital to fund our future operations. To the extent we raise additional capital through the sale of equity securities or we issue securities in connection with another transaction, our stock price can be adversely affected and the ownership position of existing stockholders could be substantially diluted. Anti-dilution adjustments to our securities currently outstanding would cause further dilution. 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.

***The exercise of our outstanding warrants will significantly dilute the ownership interest of existing stockholders.***

The exercise of some or all of our outstanding warrants would significantly dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such exercise could adversely affect prevailing market prices of our common stock.

***A delisting from the NYSE MKT could adversely affect the price of our common stock.***

Our common stock is currently listed on the NYSE MKT (the Exchange). To maintain that listing, we must continue to comply with various listing standards of the Exchange, as set forth in Part 10 of the Exchange's Company Guide

In December 2012, we reported on a communication from the staff of our current listing Exchange, that it considered the Company to be noncompliant with certain listing requirements based on our quarterly report for

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the period ended September 30, 2012, and provided that we should submit a plan to staff of the exchange that would re-establish compliance with the listing requirement by March 31, 2013. We reported that we had already submitted a plan designed to re-establish compliance with the Exchange's requirement in advance of the March 31, 2013 timeframe.

Based on our quarterly report on Form 10-Q for the period ended September 30, 2012, noncompliance was noted with respect to the requirement of section 1003(a)(iv) of the Company guide for NYSE MKT issuers in connection with our financial condition and corresponding access to capital based on the company having reported cash and cash equivalents of \$4.5 million at quarter end, taken in view of a statement in the Form 10-Q that it did not have any unused credit or other such capital facilities in place at the time. The Exchange indicated that in order to maintain its NYSE MKT listing, a plan should be submitted by December 31, 2012 addressing regaining compliance with Section 1003(a)(iv) of the Exchange's Company guide by March 31, 2013. Additional information and provisions regarding the NYSE MKT requirements are found in Part 10 of its company guide. We disputed the staff's basis for its determination of deemed noncompliance, but we submitted a plan designed to re-establish compliance with the listing requirement in advance of the timeline requested. On January 16, 2013 we reported that our Exchange listing compliance plan submitted on December 6, 2012 has been accepted by the Exchange.

The notification received from the Exchange had no current effect on the listing of our shares. Rather, we were afforded the opportunity to submit a plan pursuant to which we would seek to establish compliance with the requirements of Section 1003(a)(iv) of the Exchange's Company guide by March 31, 2013. We will be subject to periodic review by the Exchange staff during the period covered by the plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the applicable extension periods could result in our shares being delisted from the Exchange. If our common stock was not traded on the NYSE MKT, it would be expected to trade on the OTCQX, an alternative regulated quotation service that provides quotes, sale prices and volume information in over-the-counter equity securities. The Company's common stock was traded on the OTC until July 2007, when the company elected to instead list its shares on the American Stock Exchange (the predecessor to the NYSE MKT).

*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 factors described in this report, 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:

changes in economic conditions in the United States and worldwide;

the availability to us or other companies of credit;

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

anticipated or unanticipated changes that affect our ability to maintain the listing of our common stock on a national exchange;

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

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

announcements of technological innovations;

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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.

***Our company 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 any future debt or credit facility we obtain also 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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.



**Table of Contents****ITEM 2. PROPERTIES**

We do not own any real property. We lease the following properties, which we believe are adequate to meet our operating requirements for the foreseeable future:

Location	Nature of Use	Square Feet	Monthly Base Rent	Lease Expiration Date
12255 El Camino Real, Suite 250	Corporate Headquarters			
San Diego, CA USA 8505 Commerce Avenue	Principal executive office	11,184	\$ 52,117 <sup>1</sup>	July 31, 2013
San Diego, CA USA	Office and Warehouse for To Go Brands	4,745	\$ 4,571 <sup>2</sup>	May 31, 2014

<sup>1</sup> The monthly base rent increases to \$55,808 in April 2013. In addition to base rent, we are also required to pay our proportionate share of any increase in operating expenses from 2008 levels for the office park in which our space is located. The lease contains an option for one five-year lease renewal.

<sup>2</sup> The monthly base rent increases to \$4,741 in June.

**ITEM 3. LEGAL PROCEEDINGS**

As of December 31, 2012, neither Cardium nor its subsidiaries were a party to any material pending legal proceeding nor was any of their property the subject of any material pending legal proceeding. In the course of our business, however, we could become engaged in various intellectual property, product-related and other matters in connection with the technology we develop or license and the products we develop or sell. To the extent we are not successful in defending against any adverse claims concerning our technology, business relationships or products, 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, or to pay other forms of compensation or expenses. In addition, any 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. In the course of our business, we are also routinely involved in proceedings such as disputes involving goods or services provided by various third parties to Cardium or its subsidiaries, which we do not consider likely to be material to Cardium, but which can nevertheless result in costs and diversions of resources to pursue and resolve.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Table of Contents****PART II****ITEM 5. MARKET FOR OUR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock trades on NYSE MKT under the symbol CXM. Below are the high and low closing prices of our common stock for each quarter of the years ended December 31, 2012 and 2011:

	2012		2011	
	High	Low	High	Low
First Quarter	\$ 0.40	\$ 0.27	\$ 0.43	\$ 0.35
Second Quarter	\$ 0.28	\$ 0.22	\$ 0.38	\$ 0.27
Third Quarter	\$ 0.25	\$ 0.18	\$ 0.28	\$ 0.15
Fourth Quarter	\$ 0.23	\$ 0.18	\$ 0.57	\$ 0.13

In December 2012, we reported on a communication from the staff of the Exchange, that it considered the Company to be noncompliant with certain listing requirements based on our quarterly report for the period ended September 30, 2012, and provided that we should submit a plan to staff of the Exchange that would re-establish compliance with the listing requirement by March 31, 2013. Based on our quarterly report on Form 10-Q for the period ended September 30, 2012, noncompliance was noted with respect to the requirement of section 1003(a)(iv) of the Company Guide for NYSE MKT issuers in connection with our financial condition and corresponding access to capital based on the Company having reported cash and cash equivalents of \$4.5 million at quarter end, taken in view of a statement in the Form 10-Q that it did not have any unused credit or other such capital facilities in place at the time. The Exchange indicated that in order to maintain its NYSE MKT listing, a plan should be submitted by December 31, 2012 addressing regaining compliance with Section 1003(a)(iv) of the Company Guide by March 31, 2013. We disputed the staff's basis for its determination of deemed noncompliance, but we submitted a plan designed to re-establish compliance with the listing requirement in advance of the timeline requested. On January 16, 2013 we reported that our compliance plan submitted on December 6, 2012 has been accepted by the Exchange. The Company reports that the NYSE MKT has granted an additional quarterly extension of the listing exchange compliance plan from March 31, 2013 to June 30, 2013, although as is normal course, the Company's exchange compliance would continue to be evaluated on an ongoing basis. However, failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the applicable extension periods could result in our shares being delisted from the Exchange. If our common stock was not traded on the NYSE MKT, it would be expected to trade on the OTCQX, an alternative regulated quotation service that provides quotes, sale prices and volume information in over-the-counter equity securities.

**Holdings**

As of March 15, 2013 there were approximately 100 stockholders of record of our common stock. Based in information we receive from brokerage firms in connection with proxy solicitations, we believe that there are approximately 5,000 beneficial owners of our common stock.

**Dividends**

We have not declared or paid any cash dividends on our common stock and we do not intend to declare or pay a dividend in the foreseeable future, as we are in our development stage and expect to sustain losses over the next several years. To the extent we do have earnings, we intend to retain any earnings to help provide funds for the development of our product candidates, the implementation of our business strategy and for our future growth.

**Recent Sales of Unregistered Securities**

During the years ended December 31, 2012 and 2011 we did not sell any unregistered securities.

**Table of Contents****Repurchases of Equity Securities**

During the year ended December 31, 2012, we did not repurchase any shares of our common stock, nor were any repurchases made on our behalf.

**Equity Compensation Plan Information**

The following table summarizes equity compensation plans approved by stockholders and equity compensation plans that were not approved by stockholders as of December 31, 2012.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders	3,170,000	\$ 1.62	2,491,169 <sup>1</sup>
Equity compensation plans not approved by stockholders		\$	
<b>Total</b>	<b>3,170,000</b>	<b>\$ 1.62</b>	<b>2,491,169</b>

<sup>1</sup> Under the terms of the plan in effect as of December 31, 2012, in addition to securities that may be issued upon the exercise of options, warrants or other rights granted under the plan, securities may also be issued under the plan in the form of shares of restricted stock of the Company issued with such restrictions on transfer, rights of first refusal, repurchase and/or forfeiture provisions and other provisions and conditions as the Board of Directors or the Compensation Committee may determine from time to time.

**ITEM 6. SELECTED FINANCIAL DATA**

Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION**

The following discussion and analysis is intended to help you understand our financial condition and results of operations for the last two years ended December 31, 2012. You should read the following discussion and analysis together with our audited consolidated financial statements and the notes to the consolidated financial statements included under Item 8 in this report. Statements in the following discussion that are not historical in nature are forward looking statements, and inherently subject to risk. Our future financial condition and results of operations will vary from our historical financial condition and results of operations described below based on a variety of factors. You should carefully review the risks described under Item 1A and elsewhere in this report, which identify certain important factors that could cause our future financial condition and results of operations to vary from our historical operations and from our current expectations of future results.

**Executive Overview**

*The following overview does not address all of the matters covered in the other sections of this Item 7 or other items in this report or contain all of the information that may be important to our stockholders or the investing public. This overview should be read in conjunction with the other sections of this Item 7 and this report.*





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We are a medical technology company primarily focused on the development and commercialization of novel products and devices for cardiovascular and ischemic disease, wound healing and tissue repair. Since we were initially funded in October 2005, we have made four strategic acquisitions and assembled a portfolio of innovative late-stage cardiovascular and regenerative medicine product candidates. We have established a pipeline of innovative products that are divided three operating units, Cardium Biologics, the Tissue Repair Company, and MedPodium Health Sciences, which acquired the products and assets of To Go Brands, Inc., a nutraceutical supplement business. We report our operations in a two operating segments.

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 having definable pathways to commercialization, and on partnering or other monetization following the achievement of corresponding development objectives. Consistent with our overall business strategy, as our product opportunities and businesses are advanced and corresponding valuations established, 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.

### **Recent Developments**

During 2012, we continued efforts to advance the development of Generx, began the commercialization of Excellagen, and acquired To Go Brands, Inc. to enhance our MedPodium Health Sciences nutraceutical supplement business. Recent highlights include the following:

#### ***Generx Development***

Generx<sup>®</sup> (alferminogene tadenovec/CardioNovo<sup>®</sup>) is an innovative DNA-based angiogenic therapy being developed for the potential treatment of myocardial ischemia due to advanced coronary artery disease. Generx is designed to stimulate and promote the growth of supplemental collateral vessels to enhance myocardial blood flow (perfusion) following a one-time intracoronary administration from a standard cardiac infusion catheter in patients who have insufficient blood flow due to atherosclerotic plaque build-up in the coronary arteries. Recent developments with respect to Generx include:

Initiated our Generx ASPIRE Phase 3/ registration study, a 100-patient, randomized and controlled multi-center study currently enrolling patients at up to nine leading cardiology centers in the Russian Federation for patients with myocardial ischemia due to coronary artery disease. The ASPIRE study is designed to further evaluate the safety and effectiveness of Cardium's Generx DNA-based angiogenic product candidate, which 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 efficacy of Generx is being quantitatively assessed using rest and stress SPECT (Single-Photon Emission Computed Tomography) myocardial imaging to measure improvements in microvascular cardiac perfusion following a one-time, non-surgical, catheter-based administration of Generx. The Cedars-Sinai Medical Center Nuclear Cardiology Core Laboratory in Los Angeles, California, is the central core lab for the study and is responsible for the analysis of SPECT myocardial imaging data electronically transmitted from the Russian medical centers participating in the ASPIRE study. The Russian Health Authority has assigned Generx the therapeutic drug trade name of Cardionovo<sup>®</sup> for marketing and sales in Russia.

Published important Generx findings in the peer-reviewed journal *Human Gene Therapy Methods* that demonstrate that Cardium's innovative technique employing transient cardiac ischemia can be used to dramatically enhance gene delivery and transfection efficiency after one-time intracoronary administration of adenovector in mammalian hearts. These findings have been incorporated into the treatment protocols of the Generx ASPIRE Phase 3 study.

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Presented at the 2013 Phacilitate Annual Cell & Gene Therapy Forum in Washington, DC., Optimizing Phase III Trial Design for Generx<sup>®</sup> (Ad5FGF-4) reporting on adaptive coronary collateral growth, the biological processes to be targeted by therapeutic angiogenesis, and discussed the lessons learned during the past decade of the Company's Generx clinical development program.

Won a patent decision in Europe and resolution of a long-standing competition between Cardium and its licensor the University of California, and Boston Scientific Corporation (NYSE: BSX) and its licensor Arch Development, over rights to key methods for the application of cardiovascular gene therapy to the treatment of coronary heart disease, as is employed in our Generx gene therapy candidate. Our patent portfolio now includes allowed and issued patents covering its gene therapy approach both in Europe and in the United States, with competing patent applications licensed and pursued by Boston Scientific having been successfully overcome in both Europe and the U.S. We have additional patents and patent applications directed to our methods of cardiovascular gene therapy in the U.S., Europe, Russia and elsewhere, and we recently filed new patent applications directed to certain improved techniques for the treatment of heart disease that are currently the subject of our ASPIRE study in Russia,

### ***Commercialization of Excellagen***

On October 3, 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<sup>®</sup> topical gel for wound healing of diabetic foot ulcers and other dermal wounds. 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. Recent developments with respect to Excellagen include:

Introduced FDA-cleared Excellagen<sup>®</sup> professional-use wound care product in March 2012 and entered into a logistics and cold chain services agreement with Smith Medical Partners, a subsidiary of H. D. Smith.

Awarded ISO 13485 Certification for Excellagen, State of California manufacturing license and state clearances to market and sell Excellagen in the U.S., and advancement of other international registrations for Excellagen, including CE Mark registration, which we expect to receive approval within the next several weeks.

Announced sales and distribution agreements with Academy Medical to market, sell and distribute Excellagen to U.S. government medical providers, including Veterans Administration and military hospitals.

Excellagen selected as one of the Top Ten Podiatry Innovations in 2012 by *Podiatry Today* publication, and awarded by the American Podiatric Medical Association's Seal of Approval for Excellagen's contributions to better foot health and mobility.

Formed the Excellagen Medical Advisory Board comprising leading practitioners, clinicians and researchers with diversified expertise in the field of advanced wound care, and Excellagen presentations and case studies at the Desert Foot 2012 High Risk Diabetic Foot Conference.

Entered into international agreements with (1) BL&H, Co. Ltd., an established pharmaceutical company, for the registration, marketing and distribution of Excellagen in the South Korean market; and (2) Advanced Biosciences Research, an affiliate of bioRASI, for the planned commercialization of Excellagen in the Russian Federation and the Commonwealth of Independent States.

Advanced applications to support the reimbursement process for Excellagen with the Centers for Medicare & Medicaid Services and private insurance providers, and broadened marketing and sales efforts into markets with established CPT<sup>®</sup> codes for surgical debridement procedures and in-hospital surgical markets covered under DRG reimbursement systems.



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### ***Commercialization of Cardium's Health Sciences Business***

Recent developments with respect to our Health Sciences business include the following:

We acquired To Go Brands® nutraceutical supplement business with over 25 products being developed and sold through established regional and national food, drug and mass channel retailers at over 10,000 nationwide storefronts. With a portfolio of over 25 products, To Go Brands' nutraceutical powder mixes, supplements and chews are being sold through mass, food and drug channel retailers and To Go Brands' web-based store. To Go Brands' experienced management team has key contacts and a track record of developing and placing new and innovative health and nutraceutical products into retail channels. To Go Brands has now assumed operational responsibility for Cardium's nutraceutical initiative, which includes the Company's strategic investment in SourceOne Global Partners, a leading supplier of science-based ingredients and proprietary formulas, and the MedPodium Nutra-Apps® product line.

Since 2007, To Go Brands has been making healthy, great tasting and anti-oxidant-rich phytonutrients and nutraceutical supplements in an array of easy use formats, including drink mixes, chews, powders and capsules, to empower busy lifestyles in today's fast-paced, tech-driven world. The Go Active! product line includes High Octane®, Green Tea Energy Fusion, Acai Natural Energy Boost, and Neo-Energy®. The Go Healthy! product line includes Greens to Go®, Extreme Berries to Go®, Healthy Belly®, VitaRocks®, and Neo-Chill. Go Trim! products include Smoothie Complete, Trim Green Coffee Bean, Trim Energy, and Neo-Carb Bloc. To Go Brands products are sold through mass, food and drug channels at retailers including Whole Foods, Kroger, GNC, Jewel-Osco, Ralph's Supermarkets, Meijer, and the Vitamin Shoppe, and from the company's web-based store.

We plan to (1) complete new packaging and message re-design to update the look of current products; (2) increase online customer acquisition and retention by introducing super affiliate programs and social media-based coupon offerings (Living Social, Groupon, etc.); (3) expand and leverage To Go Brands' VitaRocks children's product line; and (4) expand U.S. retail distribution and establish international distributors to leverage on the success of To Go Brands' lead product, Trim Green Coffee Bean dietary supplement.

### ***Planned Strategic Partner-Enabled Product Initiatives***

We recently announced the planned clinical development of Genedexa (previously referred to as the Excellerate product candidate) and our new in-house product development of LifeAgain, a survivable risk insurance product platform. We may use alternative independent private financings and strategic partners to finance the clinical development of Genedexa and to commercialize our LifeAgain platform. Details of these new planned initiatives include:

Planned partner-enabled pilot Phase 2b/3 clinical study for Genedexa (Ad5PDGF-B). Genedexa's initial clinical development's focus will be for the treatment of chronic, non-healing diabetic foot ulcers. The Company has completed the MATRIX-1 (Phase 1/2) and MATRIX-2 (Phase 2b) clinical studies and the planned Genedexa pilot study represents an important next step forward towards FDA registration of Cardium's advanced DNA biologic wound care product. Genedexa represents the first product candidate based on the Company's Excellagen product platform and is comprised of the FDA-cleared Excellagen collagen matrix gel (6%) topical gel and an adenovector gene therapy with DNA encoding for PDGF-B protein. PDGF-B is believed to promote wound healing by directly stimulating cells involved in wound repair and also by eliciting the production of other growth factors. Genedexa, a DNA-based biologic, requires data from clinical studies demonstrating patient safety and efficacy prior to filing for a Biologic License Application.

New in-house product development of LifeAgain, a partner-enabled medical analytics and social media-driven enabled e-commerce platform that is focused on the development, marketing and direct sales of new and innovative survivable risk, multi-year, non-convertible level term life insurance

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programs and other insurance products, that are currently non-accessible and unaffordable for certain sub-groups of highly motivated buyers considered uninsurable based on traditional underwriting standards by U.S. life insurance companies. Traditional life insurance has become over-optimized web-marketed, undifferentiated, low priced commodity largely marketed to healthy people. LifeAgain is being developed based on improvements in relative mortality in certain sub-group populations, including cancer patients and patients with chronic medical diseases, as a result of the success of early diagnostic screening, public education, the introduction of advanced drugs and biologics, improved and optimized therapies, and expanding access to healthcare.

### **Critical Accounting Policies and Estimates**

Our consolidated financial statements included under Item 8 in this report have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of our financial statements in accordance with GAAP requires that we make estimates and assumptions that affect the amounts reported in our financial statements and their accompanying notes.

We have identified certain policies such as derivative liabilities and stock option compensation expense that are calculated using the Binomial and Black-Scholes Option Model that we believe are important to the portrayal of our financial condition and results of operations. These policies require the application of significant judgment by our management. We base our estimates on our historical experience, industry standards, and various other assumptions that we believe are reasonable under the circumstances.

Actual results could differ from these estimates under different assumptions or conditions. An adverse effect on our financial condition, changes in financial condition, and results of operations could occur if circumstances change that alter the various assumptions or conditions used in such estimates or assumptions. If we were to undervalue our derivative liabilities or stock option compensation expense we would understate the expense recognized in our consolidated statements of operation. Conversely if we were to overvalue our derivative liabilities and stock option compensation expenses we would overstate the expense recognized in our consolidated statements of operations. Our significant accounting policies are described in the notes to our financial statements.

### **Results of Operations**

#### ***Fiscal 2012 Compared to Fiscal 2011***

Revenue for the year ended December 31, 2012 was \$785,318 compared to no revenue reported in the year ended December 31, 2011. The majority of revenue was comprised of sales from To Go Brands for the period from September 28, 2012 through December 31, 2012.

Costs of goods sold for the year ended December 31, 2012 was \$437,065 compared to no costs of goods sold reported in the year ended December 31, 2011. Gross margin for the year ended December 31, 2012 was 44%.

Research and development expenses for the year ended December 31, 2012 were \$2,621,321 compared to \$2,593,258 for the same period last year. The increase of \$28,063 was the result of increases in expenses related to our Generx Aspire study, offset by reductions in production costs for Excellagen which is now commercially ready for market.

Selling, general and administrative expenses for the year ended December 31, 2012 were \$6,116,746 compared to \$4,824,659 for the year ended December 31, 2011. The increase of \$1,292,087 was primarily due to increases in sales and marketing costs, employee benefits, and the inclusion of To Go Brands operations since September 28, 2012.

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Change in fair value of derivative liabilities was a gain of \$64,157 compared to a gain of \$283,142 for the prior year. The change in fair value was attributable to the decline in the value of derivative liability as a result of the expiration of price protection on outstanding warrants during the first quarter of 2012.

Interest income for the year ended December 31, 2012 was \$6,595 compared to \$11,189 for the same period last year. The \$4,594 decrease in interest income was related to the decrease in cash available for investment during the respective periods. Interest expense for the year ended December 31, 2012 was \$4,248 compared to \$5,506 for the year ended December 31, 2011 and primarily consisted of charges related to the financing of our annual insurance premiums.

Net loss for the year ended December 31, 2012 was \$8,323,310, compared to \$7,129,092, primarily as a result of the increase in selling, general and administrative expenses described above.

## **Liquidity and Capital Resources**

As of December 31, 2012, we had \$2,328,074 in cash and cash equivalents, and \$50,000 in restricted cash. Our working capital at December 31, 2012 was \$2,896,021.

Net cash used in operating activities was \$9,212,565 for the year ended December 31, 2012 compared to \$7,673,496 for the year ended December 31, 2011. The increase in net cash used in operating activities was due primarily to testing and process validation costs for the initial inventory of our Excellagen topical treatment gel. Since inception, our operations have consumed substantial amounts of cash and we have had only limited revenues. From inception (December 22, 2003) to December 31, 2012, net cash used in operating activities has been \$94,294,326.

Our primary source of liquidity has been cash flows from financing activities and in particular proceeds from sales of our debt and equity securities. Net cash provided by financing activities was \$6,547,075 for the year ended December 31, 2012. This included a registered direct equity financing with three institutional investors of 17.9 million shares of Cardium common stock priced at \$0.28 per share with no warrant coverage for net proceeds of \$4.5 million and the sale of 5.2 million shares of common stock in at-the-market transactions for net proceeds of \$1.9 million. From inception (December 22, 2003) to December 31, 2012 net cash provided by financing activities has been \$99,179,866.

Net cash provided by investing activities for the year ended December 31, 2012 was \$272,285. Net cash used in investing activities since inception has been \$2,557,466. At December 31, 2012 we did not have any significant capital expenditure requirements.

During the period since December 31, 2012, cash flows from financing activities include the sale of 343,749 shares of common stock in at the market transactions for net proceeds of \$65,743, and in April 2013, we entered into a securities purchase agreement with a current institutional investor pursuant to which we agreed to sell to the investor an aggregate of 4,012 shares of our newly authorized Series A Convertible Preferred Stock, for a total purchase price of \$4.0 million. No warrants are being issued in connection with this offering other than placement agent warrants. The securities purchase agreement provides for the sale of Series A Convertible Preferred Stock in two closings. Upon consummation of the financing, which is subject to exchange and other approvals, the initial closing under the securities purchase agreement would take place in April 2013. At that closing we would sell 2,356 shares of Series A Convertible Preferred Stock for an aggregate purchase of \$2,356,000. A second closing would take place promptly following shareholder approval of the offering of the Series A Convertible Preferred Stock and a reverse stock split.

We anticipate that negative cash flow from operations will continue for the foreseeable future. Although we believe that if we complete the second closing of the Series A Preferred Stock transaction we would expect to have sufficient capital to support our operations at least through September 2013, we are still a development

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stage company subject to all the risks and uncertainties that are typical in the lifecycle stage of our business. Our principal business objective is to complete an additional strategic licensing agreement to advance sales of the Excellagen product family and/or another corporate transaction. If we fail to enter into an additional strategic licensing arrangement or generate sufficient product sales, we will not generate sufficient cash flows to cover our operating expenses.

On September 28, 2010, we entered into a Sale Agreement with Brinson Patrick Securities Corporation which enables us to use Brinson Patrick as a sales manager to sell shares of our common stock on a best efforts basis from time to time in at-the-market transactions pursuant to our shelf registration statement. During the year ended December 31, 2012 we raised \$1.9 million under this agreement, the majority of which was raised during the first quarter of 2012.

We intend to secure additional working capital through sales of additional debt or equity securities. That could include the securities purchase agreement for the Series A Convertible Preferred Stock if we can obtain the necessary stockholder and other approvals to complete the second closing, the Sales Agreement with Brinson Patrick, or other financing we may seek. Over the past few years, we have raised capital under a shelf registration statement. Because our unaffiliated market capitalization has been less than \$75 million, we are limited in the dollar amount that we can raise under that registration statement in any 12 month period. The offering of the Series A Convertible Preferred Stock will use our current availability under the shelf registration statement for the next 12 months, unless the value of our unaffiliated public float rises from current levels. In connection with the offering of the Series A Convertible Preferred Stock we granted the investor certain rights of participation in future equity financings. As long as the Series A Convertible Preferred Stock is outstanding, we have also agreed not to incur specified indebtedness without the consent of the holders of the Series A Convertible Preferred Stock. These factors could restrict our ability to raise capital through equity offerings under our current registration statement or debt offerings in the future, which could require us to seek equity financing through a new registration statement, to sell, partner or otherwise monetize assets, to seek alternative sources of funding, or to further reduce expenses.

Our history of recurring losses and uncertainties as to whether our operations will become profitable raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments related to the recoverability of assets or classifications of liabilities that might be necessary should we be unable to continue as a going concern.

### **Off-Balance Sheet Arrangements**

As of December 31, 2012, we did not have any significant off-balance sheet debt nor did we have any transactions, arrangements, obligations (including contingent obligations) or other relationships with any unconsolidated entities or other persons that have or are reasonably likely to have a material current or future effect on financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenue or expenses material to investors.

### **Recent Accounting Pronouncements**

We do not believe that any recently issued accounting standards, if adopted, would have a material impact on our consolidated financial statements.



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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**  
**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Audit Committee of the  
  
Board of Directors and Shareholders of  
  
Cardium Therapeutics, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Cardium Therapeutics, Inc. and Subsidiaries (the "Company") (a development stage company) as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2012 and 2011 and for the period from December 22, 2003 (inception) through December 31, 2012. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cardium Therapeutics, Inc. and Subsidiaries (a development stage company) at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for the years ended December 31, 2012 and 2011 and for the period from December 22, 2003 (inception) through December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has had recurring operating losses since its inception and has historically been dependent on raising capital from external sources in order to fund its business. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans with regard to these matters are more fully described in Note 1. The consolidated financial statements do not include any adjustments to reflect the possible effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Marcum LLP

New York, New York

April 5, 2013

**Table of Contents****CARDIUM THERAPEUTICS, INC. AND SUBSIDIARIES****(a development stage company)****CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2012	2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,328,074	\$ 4,721,279
Restricted cash	50,000	150,000
Accounts receivable	328,953	0
Inventory, net	1,174,323	434,130
Prepaid expenses and other assets	407,389	68,204
Total current assets	4,288,739	5,373,613
Restricted cash	0	50,000
Property and equipment, net	97,582	135,581
Investment	435,000	435,000
Technology licenses, net	1,198,318	1,332,727
Intangible assets, net	1,019,692	0
Goodwill	584,711	0
Other long term assets	184,836	176,308
Total assets	\$ 7,808,878	\$ 7,503,229
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 777,861	\$ 749,586
Accrued liabilities	614,857	464,894
Derivative liabilities - fair value of warrants	0	85,506
Current liabilities	1,392,718	1,299,986
Deferred rent	50,370	118,313
Total liabilities	1,443,088	1,418,299
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; issued and outstanding 129,218,312 at December 31, 2012 and 96,585,834 at December 31, 2011	12,922	8,610
Additional paid-in capital	102,767,193	94,167,335
Deficit accumulated during development stage	(96,414,325)	(88,091,015)
Total stockholders' equity	6,365,790	6,084,930
Total liabilities and stockholders' equity	\$ 7,808,878	\$ 7,503,229

See accompanying notes, which are an integral part of these consolidated financial statements.



**Table of Contents****CARDIUM THERAPEUTICS, INC. AND SUBSIDIARIES****(a development stage company)****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended December 31,		Period from
	2012	2011	December 22, 2003 (Inception) to December 31, 2012
Revenues			
Product sales	\$ 785,318	\$ 0	\$ 785,318
Grant revenues	0	0	1,623,160
Total revenues	785,318	0	2,408,478
Cost of goods sold	437,065	0	437,065
Gross profit	348,253	0	1,971,413
Operating expenses			
Research and development	2,621,321	2,593,258	44,006,728
Selling, general and administrative	6,116,746	4,824,659	43,553,358
Total operating expenses	8,738,067	7,417,917	87,560,086
Loss from operations	(8,389,814)	(7,417,917)	(85,588,673)
Change in fair value of derivative liabilities	64,157	283,142	10,395,709
Gain on warrant exchange		0	473,872
Interest income	6,595	11,189	1,583,638
Interest expense	(4,248)	(5,506)	(7,126,254)
Net loss from continuing operations	\$ (8,323,310)	\$ (7,129,092)	\$ (80,261,708)
Net loss from discontinued operations		0	(22,561,220)
Gain on sale of business unit		0	6,408,603
Net loss	\$ (8,323,310)	\$ (7,129,092)	\$ (96,414,325)
Net loss per share basic and diluted	\$ (0.07)	\$ (0.08)	
Weighted average number of common shares outstanding	118,454,339	85,066,566	

See accompanying notes, which are an integral part of these consolidated financial statements.

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**CARDIUM THERAPEUTICS, INC. AND SUBSIDIARIES**

**(a development stage company)**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

**YEARS ENDED DECEMBER 31, 2012 AND 2011**

	Common Stock		Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount			
Balance January 1, 2011	83,097,967	\$ 8,310	\$ 88,381,852	\$ (80,961,923)	\$ 7,428,239
Stock option compensation expense			181,229		