

Cardium Therapeutics, Inc.  
Form 10-K  
April 15, 2011  
Table of Contents

**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, 2010

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 Amex

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

# Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

**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.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
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 as of the last business day of the registrant's most recently completed second quarter was 24.6 million based on the closing sale price of \$0.35 reported by AMEX on June 30, 2010. For this purpose all officers, directors and 10% stockholders of the registrant were assumed to be affiliates.

As of April 13, 2011, 83,097,967 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 held June 2, 2011 to be filed on or before April 30, 2011.

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS</u></b>	<b>1</b>
<b>PART I</b>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	10
Item 1B. <u>Unresolved Staff Comments</u>	25
Item 2. <u>Properties</u>	26
Item 3. <u>Legal Proceedings</u>	26
Item 4. <u>(Removed and Reserved)</u>	26
<b>PART II</b>	
Item 5. <u>Market for Our Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	27
Item 6. <u>Selected Financial Data</u>	27
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	28
Item 8. <u>Financial Statements and Supplementary Data</u>	34
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	58
Item 9A. <u>Controls and Procedures</u>	58
Item 9B. <u>Other Information</u>	58
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers, and Corporate Governance</u>	59
Item 11. <u>Executive Compensation</u>	59
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	59
Item 13. <u>Certain Relationships and Related Transactions and Director Independence</u>	59
Item 14. <u>Principal Accounting Fees and Services</u>	59
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	60
<b><u>SIGNATURES</u></b>	<b>66</b>

**Table of Contents**

**SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS**

**Special Note about Forward-Looking Statements**

Certain statements in this report, including information incorporated by reference, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as may, will, should, could, would, expects, plans, believes, anticipates, intends, estimates, ap projects, or the negative or other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results and the development of our products, are forward-looking statements. Forward-looking statements in this report may include statements about:

future financial and operating results;

our ability to fund operations and business plans, and the timing of any funding or corporate development transactions we may pursue;

the timing, conduct and outcome of discussions with regulatory agencies, regulatory submissions and clinical trials, including the timing for completion of enrollment in clinical studies;

our beliefs and opinions about the safety and efficacy of our products and product candidates and the 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 key product components, or to provide other services, of an acceptable quality on a timely and cost-effective basis;

our ability to enter into acceptable relationships with one or more development or commercialization partners to advance the commercialization of new products and product candidates and the timing of any product launches; our growth, expansion and acquisition strategies, the success of such strategies, and the benefits we believe can be derived from such strategies;

our ability to pursue and effectively develop new product opportunities and acquisitions and to obtain value from such product opportunities and acquisitions;

our ability to maintain the listing of our common stock on a national exchange;

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

the outcome of litigation matters;

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

our personnel, consultants and collaborators;

operations outside the United States;

current and future economic and political conditions;

overall industry and market performance;

the impact of accounting pronouncements;

management's goals and plans for future operations; and

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

## **Table of Contents**

The forward-looking statements in this report speak only as of the date of this report and caution should be taken not to place undue reliance on any such forward-looking statements. Forward-looking statements are subject to certain events, risks, and uncertainties that may be outside of our control. When considering forward-looking statements, you should carefully review the risks, uncertainties and other cautionary statements in this report as they identify certain important factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. These factors include, among others, the risks described under Item 1A and elsewhere in this report, as well as in other reports and documents we file with the United States Securities and Exchange Commission (SEC).

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

## **PART I**

### **ITEM 1. BUSINESS**

#### **Overview**

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

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

In March 2006, we acquired the technologies and products of Innercool Therapies, Inc., a medical technology company in the emerging field of therapeutic hypothermia or patient temperature modulation, whose systems and products are designed to rapidly and controllably cool the body to reduce cell death and damage following acute ischemic events. On July 24, 2009, after completing a strategic turn-around and expansion of Innercool's business and products, the business was acquired by Royal Philips Electronics (NYSE: PHG) for \$11.25 million (of which \$1,125,000 is still in escrow as security for certain indemnification obligations), as well as the assumption by Philips of approximately \$1.5 million in Innercool trade payables (the Philips Transaction). The operations of Innercool, which is now a part of Philips Healthcare, are shown as a discontinued operation in our consolidated statements of operations. After the closing, the name of Innercool Therapies, Inc. was changed to Post-Hypothermia Corporation.

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

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

## **Table of Contents**

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

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

#### ***Cardium Biologics***

The lead product candidate from our Cardium Biologics unit is Generx (alferminogene tadenovec, Ad5FGF-4), which is being developed as a potential treatment for myocardial ischemia (insufficient blood flow within the heart muscle) due to coronary heart disease. Generx represents a new therapeutic class of cardiovascular biologics designed to promote collateral angiogenesis, a natural process of blood vessel growth within the heart muscle, to increase blood supply to ischemic areas of the heart following a one-time intracoronary administration.

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

In 2010, we announced plans to conduct a follow-on clinical study of Generx in Russia, using SPECT imaging as a key clinical endpoint. If this program is successful, we plan to begin commercialization of Generx in Russia and associated CIS markets, most likely through a local pharmaceutical partner or joint venture, we believe that having additional clinical evidence confirming the safety and effectiveness of Generx for improving coronary collateral circulation in men and women with severe coronary artery disease could potentially be used to optimize and broaden commercial development pathways in the U.S. and other industrialized countries.

#### ***Tissue Repair Company***

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

On December 3, 2009 our Tissue Repair Company subsidiary has a pending a 510(k) premarket notification filing with the U.S. Food and Drug Administration (FDA) for its fibrillar collagen-based Excellagen topical gel for wound healing of diabetic foot ulcers and potentially other wounds. Our 510(k) filing covers ExcellagenXL and ExcellagenFX, advanced wound care management medical devices comprising customized protein-based gels designed 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

## **Table of Contents**

wounds, second degree burns, and other types of wounds. The 510(k) submission is based in part on positive findings from our Phase 2b Matrix clinical study, reported on October 14, 2009, demonstrating substantial improvements in wound healing responses in patients with non-healing diabetic foot ulcers following one or two applications of Excellagen, an enhanced, customized collagen-based gel matrix. ExcellagenXL is designed for use by health care professionals in a clinical setting and as an adjunct to standard of care topical wound therapy, which in the case of diabetic ulcers typically includes surgical debridement and off-loading. The ExcellagenFX kit is designed for use by health care providers in a clinical setting in the treatment of larger soft tissue or tunneling wounds that may occur with pressure, venous and diabetic ulcers, as well as surgical wounds. The ExcellagenFX flowable matrix product allows for deeper administration and direct intimate contact with the wound bed in these more complex, irregular and difficult to access wounds.

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

### ***Incidence of Chronic Wounds***

An estimated 12.5 million patients worldwide suffer from chronic wounds with the industrialized countries making up 8 million, of which the U.S. totals approximately 3.7 million.

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

Approximately 1.7 million patients suffer from pressure wounds, 1 million from diabetic foot ulcers and 1 million from venous status ulcers.

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

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

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

### ***Current Treatment Approaches for Chronic Wounds***

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

### ***Gene Activated Matrix (GAM) Technology***

We believe that patient compliance can be a major factor preventing or limiting improved medical outcomes, particularly when repeated administrations are required at a wound site. Tissue Repair Company's





## **Table of Contents**

Gene Activated Matrix technology is designed to provide a therapeutic level of protein synthesis at a particular site in the body and can be used in soft tissue such as skin, ligament, tendons and cartilage, as well as hard tissue such as bone. The technology is distinctive in that it is an immobilized form of local gene delivery that allows for control of gene uptake. GAM consists of a biocompatible matrix comprising a gene or DNA vector encoding a growth factor or other therapeutic protein.

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

### ***MedPodium***

Our MedPodium healthy lifestyle product line and web boutique, launched in November 2010, is expected to incorporate additional products and distribution channels, and to be developed into a portfolio of premium science-based, easy to use medicinals, neurologics, metabolics, nutraceuticals and aesthetics for promoting and managing personal health.

### **Business Strategy**

Given the limited nature of our revenues and the high costs we must incur to develop our product candidates, we have yet to generate positive cash flows or income from operations and do not anticipate doing so in the foreseeable future. As a result, we have been dependent on debt and equity funding to finance our operations. During the year ended December 31, 2010, we raised net proceeds of approximately \$10.8 million from the sale of common stock and warrants.

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

The key elements of our strategy are to:

complete an abbreviated FDA 510(k) registration process for Excellagen™ and complete commercial development; candidate Excellagen;

consider partnering opportunities to advance the clinical development of Excellerate™;

evaluate the potential of Generx™ to be a cost effective front-line therapy for patients with coronary artery disease in the large markets of newly-industrializing countries;

broaden and expand our MedPodium portfolio and our product base and financial resources through other corporate development transactions in an attempt to enhance stockholder value, which could include acquiring other medical-related companies or product opportunities and/or securing additional capital; and

monetize the economic value of our product portfolio by establishing strategic collaborations and selling businesses and assets at appropriate valuation inflection points.

### **Government Regulation**

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

New drugs, biologics, devices, and nutraceuticals, are subject to extensive regulation under the federal Food, Drug, and Cosmetic Act. In addition, biologics are also regulated under the Public Health Service Act. We

## **Table of Contents**

believe that the pharmaceutical products we are attempting to develop will be regulated either as biological products or as new drugs. Both statutes and their corresponding regulations govern, among other things, the testing, manufacturing, distribution, safety, efficacy, labeling, storage, record keeping, advertising and other promotional practices involving biologics or new drugs. FDA approval or other clearances must be obtained before clinical testing, and before manufacturing and marketing, of biologics and drugs. Obtaining FDA approval has historically been a costly and time-consuming process. Different regulatory regimes are applicable in other major markets.

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

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

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

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

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

## **Table of Contents**

manufacturing practices (GMPs), reporting of adverse effects, advertising, promotion and marketing. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

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

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

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

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

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

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

## **Competition**

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

## **Table of Contents**

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

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 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.

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

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

### **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 GMPs. 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.

## **Table of Contents**

### **Marketing and Sales**

Aside from our new MedPodium product line and web boutique, which is under development and does not account for substantial revenues at this time, our product candidates must generally undergo testing and development in clinical trials and pre-clinical studies, and we do not currently have any other products approved for marketing nor any present capacity to market and sell products that could be commercially developed based on our technology. If we should obtain any such marketing approvals, we expect that we would elect to engage in marketing or sales through or in collaboration with a commercialization partner, although we are not currently involved with such a partner.

### **Licensing and Intellectual Property**

Our overall business strategy is principally focused on the acquisition and development of a portfolio of product opportunities and is designed to create multiple opportunities for success while avoiding reliance on any single technology platform or product type. We also generally plan 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. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

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

In August 2006, we acquired the rights to various technologies and products now part of our Tissue Repair Company subsidiary, including Excellerate. In 2009, we reported that Excellagen, which contains the customized collagen-based gel matrix employed in Excellerate but does not contain the added growth factor DNA used in Excellerate, appeared to be substantially effective for wound healing of debrided diabetic foot ulcers and potentially other wounds, and Excellagen then became the subject of a 510(k) premarket notification filing with the U.S. Food and Drug Administration (FDA). 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 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.

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.

## **Table of Contents**

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, 2010 we employed 15 employees. We do not expect to hire additional employees during the next 12 months. 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 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 product candidates require regulatory approvals, and in some cases additional prior development or testing, before marketing. We may be unable to develop, obtain regulatory approval or market any of our product candidates or expand the market of our existing products and technology. If our product candidates are delayed or fail, 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 collagen-based product candidates are expected to be regulated under an FDA 510(k) premarketing notification procedure allowing the company or a commercialization partner to market and sell once 510(k) marketing clearance is obtained. There can be no assurance that marketing clearance will be achieved in a timely manner or at all, or that the FDA will not require additional studies or information to be provided for the 510(k) filing to be considered both complete and acceptable.



## **Table of Contents**

Our nutraceuticals, dietary supplements and other products within our MedPodium healthy lifestyle portfolio are also subject to numerous rules and regulations promulgated by the FDA and other food and health regulatory authorities, including regulations governing the sourcing, manufacture, labeling, handling, storage, marketing and use of such products. In 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. In addition, we have only limited experience and resources to apply to the marketing, distribution and commercialization of such products; and they face competition from organizations having product development, manufacturing, marketing and distribution resources that are far greater than ours or our collaborators, and these competitors may offer established and new products for addressing the same or similar conditions that could be safer, more effective or less costly than ours, or products that could be marketed or distributed more effectively and more efficiently than ours.

Our other product candidates require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, FDA has not yet approved any gene therapy or similar product and there can be no assurance that it will. There are many reasons that our products and product candidates may fail or not advance beyond clinical testing, including the possibility that:

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

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

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

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

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

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

others may develop equivalent, superior or less expensive products.

In addition, our product candidates are subject to the risks of failure inherent in the development of biologics, gene therapy and other products based on innovative technologies. As a result, we are not able to predict whether our research, development and testing activities will result in any commercially viable products or applications. If our product candidates are delayed or we fail to successfully develop and commercialize our product candidates, or if we are unable to 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



**Table of Contents**

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;

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

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

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

changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its results. Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable. If 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.***

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

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 products if and when they achieve FDA 510(k) marketing clearance, as well our Generx 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

## **Table of Contents**

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 sold all of the assets and business of our InnerCool Therapies, Inc. in July 2009 and may face claims for damages from the buyer if representations and warranties that we have made in connection with that sale have provided the buyer of those assets with certain indemnification rights.***

On July 10, 2009 we entered into an Asset Purchase Agreement with Phillips Electronics North America Corporation ( Phillips ), pursuant to which we sold to Phillips certain assets and liabilities of our Innercool Therapies, Inc. subsidiary. The sales closed on July 24, 2009. In connection with the transaction, Phillips assumed only certain specified liabilities relating to the business. We retained responsibility for all other liabilities of the business, including contingent and unknown claims that may have existed at the time of sale. Also, in connection with the sale we made certain representations and warranties to Phillips that are standard for such transactions, including representations regarding the condition of the Innercool Therapies assets and liabilities. We have agreed to indemnify Phillips for any damages arising from the breach of any of those representations and warranties, as well as any breach of any covenant under the Asset Purchase Agreement. Our liability for breach of certain representations is contractually capped at \$3.5 million; however, claims for damages arising out of certain Excepted Representations or any covenant under the Asset Purchase Agreement are not subject to the contractual limitation. At December 31, 2010 we are not aware of a breach of any of terms of this agreement. Under the terms of the Asset Purchase Agreement, we deposited \$1,125,000 of the proceeds from the sale into an escrow account to act as security for our indemnification obligations. We may, however, receive claims in excess of the funds in escrow. Any substantial indemnification claim under the Asset Purchase Agreement, or the defense of any such claim, could result in substantial costs, which would impair our financial condition and disrupt our ability to operate our remaining business.

***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, 2010, our accumulated deficit was approximately \$81 million, and our cash and cash equivalents were approximately \$6.6 million. To date, we have generated very limited revenues (mostly associated with our Innercool operations and a Tissue Repair Company grant, both of which have ended), 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 five years. Our ability to generate additional revenues and potential to become profitable will depend largely on our ability, alone or with potential collaborators, to efficiently and successfully complete the development of our product candidates, successfully complete pre-clinical and clinical tests, obtain necessary regulatory approvals, and manufacture and market our products. There can be no assurance that any such events will occur or that we will ever become profitable. Even if we do achieve profitability, we cannot predict the level of such profitability. If we sustain losses over an extended period of time, we may be unable to continue our business.

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

Since we have a relatively short operating history and our 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. These include,

## **Table of Contents**

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, 2010, 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.

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

On August 11, 2006, we acquired rights to develop the Excellerate product candidate of the Tissue Repair Company, a medical technology company focused on the development of growth factor therapeutics for the potential treatment of chronic wounds such as dermal ulcers. These businesses are subject to all of the operational risks that can affect medical technology companies, including those related to regulatory approvals

**Table of Contents**

and clinical studies, acceptance of technology, competing technology, intellectual property rights, profitability, suppliers and third party collaborators, adverse publicity, litigation, and retention of key personnel.

In the future, we may pursue additional acquisitions of other companies, technologies or products. Acquisitions of businesses or product rights, including Tissue Repair Company transactions, 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;

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 Tissue Repair transaction, 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

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

company's employees, products or operations successfully, our business, financial condition or results of operations could be harmed.

***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-



## **Table of Contents**

based gene transfer could potentially include viral or gene product toxicity resulting in inflammation or other injury to the heart or other parts of the body. In addition, the development or worsening of cancer in a patient could potentially be a perceived or actual side effect of gene therapy technologies such as our own. Furthermore, there is a possibility of side effects or decreased effectiveness associated with an immune response toward any viral vector or gene used in gene therapy. The possibility of such response may increase if there is a need to deliver the viral vector more than once.

***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 may not be able to successfully develop and effectively commercialize our new MedPodium portfolio of healthy lifestyle products.***

Our ability to develop and commercialize a portfolio of healthy lifestyle products is subject to numerous risks and uncertainties associated with the acquisition, development and commercialization of new products, including ensuring that they can be appropriately manufactured, labeled and shipped by third parties in a manner that complies with applicable regulations, that our sales and other commercialization efforts can be effectively developed and applied to these products, and that the products can be effectively marketed to and favorably received by potential consumers, and not regarded as less safe, less effective or more costly than actual or perceived competitive products.

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, marketing and distribution 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 or less costly than ours, or could be marketed more effectively and efficiently.

***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

## Table of Contents

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;

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

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

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

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

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

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

Our business strategy relies on third parties to manufacture and produce our products and product candidates and the catheters used to deliver the products in accordance with good manufacturing practices established by the FDA and other regulators. 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



## **Table of Contents**

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

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

We currently have limited sales, marketing and distribution capabilities. To commercialize our product candidates, if and when such products have been approved and are ready for marketing, we expect either to collaborate with third parties to perform these functions or develop them internally.

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

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

Our competitors and potential competitors include large pharmaceutical and medical device companies and more established biotechnology companies. These companies have significantly greater financial and other

## **Table of Contents**

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

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.***

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

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

## **Table of Contents**

***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.

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

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

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

We are currently conducting a follow on clinical study for our Generx product candidate in Russia, and may attempt to market and sell Generx in Russia and associated CIS markets.

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;

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

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.

## **Table of Contents**

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

### ***Risks Related to Our Intellectual Property and Potential Litigation***

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

The success of our operations will depend in part on our ability and that of our licensors to: obtain patent protection for our therapeutics, devices and procedures, and other methods or components on which we rely, both in the United States and in other countries with substantial markets; defend patents once obtained; maintain trade secrets and operate without infringing upon the patents and proprietary rights of others; and obtain appropriate licenses upon reasonable terms to patents or proprietary rights held by others that are necessary or useful to us in commercializing our technology, both in the United States and in other countries with substantial markets.

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

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

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

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



## **Table of Contents**

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 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.

## **Table of Contents**

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

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

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

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

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

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

***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.

## **Table of Contents**

*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 Amex could adversely affect the price of our common stock.*

On December 23, 2008, we received a notice from the staff of the NYSE AMEX noting that, based on their review of publicly available information, we did not meet certain of the Exchange's continued listing standards. On March 5, 2010, the exchange notified us that, based on its review of information provided by the Company, we made a reasonable demonstration of our ability to regain compliance with applicable listing requirements. Our ability to maintain our listing on the NYSE Amex is predicated on our continued compliance with the exchange's continued listing standards, including standards related to minimum shareholders' equity. If our common stock was delisted from the exchange, it would be traded on the OTC Bulletin Board, which could happen, adversely affecting the price of our common stock.

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

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

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;

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

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.

**Table of Contents**

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

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

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

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

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition 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**

Our principal executive office is listed below and we believe our facility is adequate to meet our operating requirements for the foreseeable future.

Location	Nature of Use	Square Feet	How Held	Monthly Base Rent	Lease Expiration Date
12255 El Camino Real, Suite 250 San Diego, CA USA	Principal executive office	11,184	Leased	\$ 48,650 <sup>1</sup>	July 31, 2013 <sup>2</sup>

<sup>1</sup> The monthly base rent increases to \$52,117 in April 2011 and is subject to an additional increase each year thereafter. 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.

<sup>2</sup> The lease contains an option for one five-year lease renewal.

**ITEM 3. LEGAL PROCEEDINGS**

As of December 31, 2010 and through the date of this report, 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, we could be compelled to seek licenses from one or more third parties who could be direct or indirect competitors and who might not make licenses available on terms that we find commercially reasonable or at all. In addition, 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.

**ITEM 4. (REMOVED AND RESERVED)**

**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 Amex 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, 2010 and 2009:

	2010		2009	
	High	Low	High	Low
First Quarter	\$ 0.81	\$ 0.44	\$ 1.63	\$ 0.40
Second Quarter	\$ 0.63	\$ 0.33	\$ 2.90	\$ 1.31
Third Quarter	\$ 0.66	\$ 0.30	\$ 2.05	\$ 1.61
Fourth Quarter	\$ 0.55	\$ 0.39	\$ 1.96	\$ 0.51

 **Holders**

As of April 13, 2011 there were approximately 108 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 5,700 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, 2010 and 2009 we did not sell any unregistered securities.

**Repurchases**

During the year ended December 31, 2010, we did not repurchase any shares of our common stock, nor were any repurchases made on our behalf.

**ITEM 6. SELECTED FINANCIAL DATA**

As a smaller reporting Company we are not required to provide disclosure under this item.

## **Table of Contents**

### **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, 2010. 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, 1B and 7A 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.*

We are a medical technology company primarily focused on the development and commercialization of novel therapeutics and medical devices for cardiovascular and ischemic disease, wound healing and tissue repair. Since we were initially funded in October 2005, we have made three strategic acquisitions and assembled a portfolio of innovative late-stage cardiovascular and regenerative medicine product candidates. We have established a pipeline of innovative products that are divided into two operating units, Cardium Biologics and the Tissue Repair Company. We report our operations in a single operating segment.

Our business is focused on the acquisition and strategic development of product opportunities or businesses having the potential to address significant unmet medical needs, and definable pathways to commercialization, partnering or other monetization following the achievement of corresponding development objectives. 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.

During 2009, we (i) completed the sale of all of the assets and liabilities of our wholly-owned subsidiary InnerCool Therapies, Inc. to Royal Philips Electronics, (ii) completed Tissue Repair Company's Matrix 2b clinical trial, (iii) submitted an FDA 510(k) application for the use of Excellagen™ in the potential treatment of diabetic and other chronic wounds, and (iv) announced the Company's new Orthobiologics initiative, designed to build on and extend the underlying technology developed by the Tissue Repair Company to hard tissue application such as bone.

We currently have limited products available for sale or use. Because of 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 are currently dependent on debt and equity funding to finance our operations. During the second half of 2009 we raised net proceeds of \$9.7 million from the sale of common stock and warrants in two registered direct offerings. During the year ended December 31, 2010, we raised additional net proceeds of approximately \$10.8 million from the sale of common stock and warrants.

During the second quarter of 2010 we entered into a Master Services Agreement with bioRASI, an international contract research organization, to assist us in conducting late-stage clinical studies and



---

## **Table of Contents**

commercialization activities for Cardium's Generx (Ad5FGF-4), in Russia and affiliated jurisdictions and other potential new markets. The Generx clinical study is expected to be initiated in the first half of 2011. We have budgeted approximately \$2 million for this product candidate to be paid over the term of the clinical studies and as certain milestones are met. The contract can be cancelled upon 90 days written notice.

We also entered into a multi-year supply agreement with Devro Medical Limited, part of Devro plc, a public limited company registered in Scotland, for the supply of highly-refined fibrillar bovine Type I collagen, an important component of our new Excellagen formulated collagen product candidate, which is pending FDA 510(k) clearance. Under this supply agreement, which does not require any minimum purchase, the collagen component of Excellagen will be manufactured at Devro's new cGMP manufacturing facility which has completed an accreditation audit for its ISO certifications and is now completing its final process validation activities. Devro also plans to establish a Device Master File with the FDA following completion of ISO certifications of other component manufacturing processes. In addition, we have also entered into a clinical manufacturing and supply agreement with a U.S.-based fill and finish contract manufacturer to provide final processing and assembly of the market ready Excellagen product.

On November 17, 2010 we entered into a custom technology access and product license agreement with BioZone Laboratories, Inc. ( BioZone ) for the co-development and strategic licensing of a portfolio of up to 20 aesthetics, advanced skin care formulations and other products for our MedPodium™ product line. The agreement grants us a royalty-free license of BioZone technology to develop a portfolio of 20 products, customized to our product specifications. We will have exclusive rights to the products developed to our specifications. The license is for a term of 10 years. In exchange for the technology access license we paid BioZone a fee of \$1.0 million. The license fee was paid with 2,000,000 shares of our unregistered common stock at a fair value \$0.50 per share. The common stock is subject to certain lock up restrictions and will be held in an escrow account, to be released to BioZone beginning six months following the closing date of the transaction with such shares being released in five equal monthly installments. Under the terms of the agreement, BioZone will provide manufacturing services to us. We have been granted a right of first refusal with respect to any potential sale of BioZone or BioZone assets, under which we would be entitled to acquire BioZone or BioZone assets as applicable on the same terms and conditions as negotiated to mutual acceptability with any third party.

On December 2, 2010 we filed a Tender Offer Statement to exchange (the **Warrant Exchange** ) certain outstanding warrants dated March 9, 2007, November 5, 2008 and November 10, 2008 that contain unlimited down round price protection (the **Eligible Warrants** ). The Eligible Warrants were exchanged for shares of our common stock, par value \$0.0001. The Warrant Exchange expired at 9:00 p.m., Pacific Time, on December 30, 2010. Pursuant to the Warrant Exchange, an aggregate of 6,931,805 Eligible Warrants to purchase common stock were tendered and accepted for cancellation, representing approximately 67.49% of the total Eligible Warrants outstanding and eligible for exchange in the Warrant Exchange. On December 31, 2010, we issued an aggregate of 2,310,613 shares of our common stock in exchange for the Eligible Warrants surrendered in the Warrant Exchange.

### **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.

---

**Table of Contents**

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 2010 Compared to Fiscal 2009***

For the year ended December 31, 2010 revenue was \$244,479 attributable to a one-time grant from the federal government for therapeutic discovery. That grant is complete, and we do not anticipate any further revenues from that grant. Revenue for the year ended December 31, 2009 was \$444,946 which was earned under a grant awarded by the National Institutes of Health, ( NIH ) specifically the National Heart, Lung & Blood Institute, a sponsored program by the federal government.

Research and development expenses for the year ended December 31, 2010 were \$2,313,839 compared to \$4,302,298 for the same period last year. The decrease of \$1,988,459 was primarily due to a reduction in expenses related to our Excellerate product candidate in its Phase 2b clinical trial. There were also reductions in Generx (AWARE) Phase 3 clinical trial costs partially offset by a performance bonus accrual of \$145,000 which was accrued during the second quarter of 2010 and covers 2007, 2008 and 2009. Half of the accrued performance bonus was paid in the third quarter of 2010. The remainder will be paid upon our receipt of FDA 510(k) clearance for our Excellagen product.

General and administrative expenses for the year ended December 31, 2010 were \$4,700,404 compared to \$4,855,582 for the year ended December 31, 2009. The decrease of \$155,178 was primarily the result of decreases in professional fees and stock option compensation expense, insurance costs and rent offset by a performance bonus accrual of \$440,000 which was accrued during the second quarter of 2010 and covers 2007, 2008 and 2009. Half of the accrued performance bonus was paid in the third quarter of 2010. The remainder will be paid upon our receipt of FDA 510(k) clearance for our Excellagen product.

Change in fair value of derivative liabilities was a gain of \$1,528,913, compared to a loss of \$1,118,120 for the prior year. The change in fair value was attributable to the decline in the value of derivative liability as a result of declines in the market value for our common stock during 2010.

Interest income for the year ended December 31, 2010 was \$33,687 compared to \$12,160 for the same last year. The \$21,527 increase in interest income for the period when compared to the same period last year was related to the increase in cash available for investment during the respective periods.

Interest expense for the year ended December 31, 2010 was \$2,999. Interest expense was \$6,339,523 for the year ended December 31, 2009, due to the interest associated with the notes we issued in November 2008, March 2009 and June 2009, all of which we paid off at the end of 2009.

We experienced a gain of \$473,872 in connection with the Warrant Exchange. The gain was the result of the cancellation of 6,931,805 of our outstanding warrants and the related derivative liability of \$1,419,761, offset by an expense of \$44,750 associated with our issuance of 2,310,613 shares of common stock in payment for the warrants. There was no comparable expense for the period ended December 31, 2009.

Net loss for the year ended December 31, 2010 was \$4,736,291 compared to a net loss from continuing operations of \$16,158,417 for the year ended December 31, 2009. The decline in net loss was attributable to a decrease in interest expense and a favorable adjustment in the change in the fair value of derivative liabilities.

**Table of Contents****Impact of Certain Non-Cash Charges**

The adoption of ASC 815 had a very substantial impact on our total liabilities, including certain non-cash derivative liabilities and corresponding reported net gains and losses arising from changes in the underlying market value of our common stock. To supplement our condensed consolidated financial statements, which statements are prepared and presented in accordance with accounting principles generally accepted in the United States of America (GAAP), our management uses a non-GAAP financial measure called non-GAAP earnings or loss per share. We define non-GAAP earnings or loss per share as net income or loss not including the impact of:

non-cash items (amortization of deferred financing costs and debt discount, stock-based compensation, and change in fair value of derivative liabilities); loss from discontinued operations and gain on sale of business unit.

It should be noted that basic and diluted weighted average shares are determined on a GAAP basis and the resulting share count is used for computing both GAAP and non-GAAP basic and diluted earnings per share.

Our management believes non-GAAP earnings or loss per share provides meaningful supplemental information regarding our performance by excluding certain expenses that may not be indicative of the core business operating results and may help in comparing current-period results with those of prior periods as well as with our peers. We use this information as an additional tool for evaluating our financial results in a manner that reflects ongoing operations and facilitates comparisons with operating results from prior periods. The presentation of this additional non-GAAP information is intended to provide investors with additional incremental tools for their review of our results and is not meant to be considered in isolation or as a substitute for financial information presented in accordance with GAAP.

**Reconciliation of Non-GAAP Measure****Net income (loss) to non-GAAP earnings or loss per share****For the three months and fiscal year ended December 31, 2010**

	Three months ended December 31,		Year ended December 31,	
	2010	2009	2010	2009
Net income (loss)	\$ 442,580	\$ 9,316,127	\$ (4,736,291)	\$ (11,680,450)
Add (subtract)				
Stock based compensation expense	75,139	414,422	390,268	909,142
Amortization of deferred financing cost and debt discount		344,806		4,563,434
Change in fair value of derivative liabilities	(1,458,633)	(11,391,398)	(1,528,913)	1,118,120
Gain on warrant exchange	(473,872)		(473,872)	
Income (loss) from discontinued operations				1,930,636
Gain on sale of business unit				(6,408,603)
Non-GAAP net loss	\$ (1,414,786)	\$ (1,306,033)	\$ (6,348,808)	\$ (9,567,721)
Non-GAAP net loss per common share basic and diluted	\$ (0.02)	\$ (0.02)	\$ (0.09)	\$ (0.20)
Weighted average common shares outstanding basic	79,477,951	54,207,761	73,852,167	48,976,917
Weighted average common shares outstanding diluted	79,477,951	54,374,522	73,852,167	48,976,917

---

**Table of Contents**

**Liquidity and Capital Resources**

As of December 31, 2010 we had \$6,644,054 in cash and cash equivalents and \$1,425,000 in restricted cash. Our working capital at December 31, 2010 was \$6,657,117 (excluding \$573,073 for the fair value of derivative liabilities).

Net cash used in operating activities was \$7,413,766 for the year ended December 31, 2010 compared to \$11,614,343 for the year ended December 31, 2009. The decrease in net cash used in operating activities for the year ended December 31, 2010 when compared to last year was a result of the decrease in companywide spending, the sale of all the assets of our InnerCool business in July 2009 and the completion of the MATRIX clinical study during the fourth quarter of 2009.

Our primary source of liquidity has been cash flows from financing activities and in particular proceeds from the sales of our debt and equity securities. On March 12, 2010, we completed a registered direct offering of 2,266,998 units, which were sold to institutional and retail investors, at a price of \$5.00 per unit. Each unit consisted of 10 shares of common stock and a warrant to purchase 5 shares of common stock. The warrants are exercisable at an exercise price of \$0.64 per share, at any time after six months from the date of closing and have a term of exercise equal to five years from the date the warrants are initially exercisable. In the aggregate 22,669,980 shares of common stock and warrants to purchase an additional 11,334,990 shares of common stock were issued in the offering. The offering resulted in gross proceeds to us of \$11.3 million, and net proceeds of approximately \$10.4 million after payment of offering fees and expenses.

On August 9, 2010 we filed a Form S-3 Registration Statement (declared effective by the securities and Exchange Commission on August 27, 2010) putting in place a universal shelf registration statement covering up to \$50 million of any combination of common stock, preferred stock, debt securities, warrants, or units we may offer through August 9, 2013, at which time we will provide the specific term of any offering in one or more supplements to the prospectus. This registration statement is intended to allow us to capitalize on strategic opportunities that may arise; we do not have any current commitments for shares to be registered under the registration. The registration statement replaced an existing universal shelf registration statement scheduled to expire.

On September 28, 2010, we entered into a Sales Agreement ( Sales Agreement ) with Brinson Patrick Securities Corporation to enable us to use Brinson Patrick as a sales manager to sell shares of our common stock from time to time in at-the-market transactions pursuant to our shelf registration statement on a best efforts basis. For the year ended December 31, 2010 we sold 935,200 shares under this agreement for net proceeds of \$418,303.

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, 2010, net cash used in operating activities has been \$77,408,265, net cash provided by financing activities was \$88,429,462, and net cash used in investing activities has been \$4,377,143.

We anticipate that the negative cash flow from operations will continue for 2011, although we believe that we have sufficient capital to support our operations through January 1, 2012. We are still a development stage company subject to all the risks and uncertainties that are typical in the lifecycle stage of our business. Our principal objective is to complete a strategic licensing agreement or secure the approval and future sales of the Excellagen product family and/or another corporate transaction. If we fail to enter into a strategic licensing arrangement or generate sufficient product sales, we will not generate sufficient cash flows to cover our operating expenses.

We do not have any credit facilities in place or unused sources of credit available to us at this time. Although we intend to secure additional working capital through sales of additional debt or equity securities we

**Table of Contents**

have not secured any financing at this time, and we cannot give any assurances about the availability or terms of any future financing.

Our history of recurring losses and uncertainties as to whether our operations might become profitable raise substantial doubt about our ability to continue as a going concern. The 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, 2010, 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.

**Contractual Obligations**

The following table summarizes our known contractual obligations and commercial commitments at December 31, 2010:

Contractual Obligations	Total	Payments Due By Period			
		Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-Term Debt	\$	\$	\$	\$	\$
Operating Leases	1,646,508	620,041	1,026,468		
			6		
Total Obligations	\$ 1,646,508	\$ 620,041	\$ 1,026,468	\$	\$

Our operating lease obligations relate to our facilities lease for our corporate headquarters.

**Recent Accounting Pronouncements**

In January 2010, the Financial Accounting Standards Board (FASB), issued new standards to update and amend existing standards on Fair Value Measurements and Disclosures. These standards require new disclosures on the amount and reason for transfers in and out of Level 1 and Level 2 fair value measurements. The standards also require disclosure of activities in Level 3 fair value measurements that use significant unobservable inputs, including purchases, sales, issuances, and settlements. The standards also clarify existing disclosure requirements on levels of disaggregation, which requires fair value measurement disclosure for each class of assets and liabilities, and disclosures about valuation techniques and inputs used to measure fair value of recurring and non-recurring fair value measurements that fall in either Level 2 or Level 3. The new disclosures and clarifications of existing disclosures are effective for our interim and annual reporting periods beginning January 1, 2010, except for the disclosures about purchases, sales, issuances and settlements in the roll forward activity in Level 3 fair value measurements. Those disclosures are effective for our fiscal year beginning January 1, 2011. As this guidance requires only expanded disclosures, the adoption did not and will not impact our consolidated financial condition and results of operations.

**Table of Contents**

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

To the Audit Committee of

The Board of Directors and Stockholders 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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2010 and for the period from December 22, 2003 (inception) through December 31, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. 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, 2010 and 2009, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2010 and for the period from December 22, 2003 (date of inception) through December 31, 2010 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that Cardium Therapeutics, Inc. and subsidiaries will continue as a going concern. As more fully described in Note 1, the Company has had recurring operating losses since its inception and is 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 also described in Note 1. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Marcum, LLP

Marcum, LLP

New York, New York

April 15, 2011

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

	December 31,	
	2010	2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,644,054	\$ 3,363,665
Restricted cash	1,225,000	562,500
Accounts receivable		115,138
Prepaid expenses and other assets	134,044	40,384
<b>Total current assets</b>	<b>8,003,098</b>	<b>4,081,687</b>
Restricted cash	200,000	862,500
Property and equipment, net	234,942	351,539
Deposits and other long term assets	1,074,035	179,938
<b>Total assets</b>	<b>\$ 9,512,075</b>	<b>\$ 5,475,664</b>
<b>Liabilities and Stockholders' Equity (Deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 597,868	\$ 2,300,786
Accrued liabilities	748,113	336,457
Derivative liabilities - fair value of warrants	573,073	4,802,882
<b>Current liabilities</b>	<b>1,919,054</b>	<b>7,440,125</b>
Deferred rent	164,782	190,114
<b>Total liabilities</b>	<b>2,083,836</b>	<b>7,630,239</b>
Commitments and contingencies		
Stockholders' equity (deficiency):		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; issued and outstanding 83,097,967 at December 31, 2010 and 55,182,174 at December 31, 2009	8,310	5,518
Additional paid-in capital	88,381,852	74,065,539
Deficit accumulated during development stage	(80,961,923)	(76,225,632)
<b>Total stockholders' equity (deficiency)</b>	<b>7,428,239</b>	<b>(2,154,575)</b>
<b>Total liabilities and stockholders' equity (deficiency)</b>	<b>\$ 9,512,075</b>	<b>\$ 5,475,664</b>

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
	2010	2009	December 22, 2003 (Inception) to December 31, 2010
<b>Revenues</b>			
Grant revenues	\$ 244,479	\$ 444,946	\$ 1,623,160
<b>Operating expenses</b>			
Research and development	2,313,839	4,302,298	38,792,149
General and administrative	4,700,404	4,855,582	32,611,953
Total operating expenses	7,014,243	9,157,880	71,404,102
Loss from operations	(6,769,764)	(8,712,934)	(69,780,942)
Change in fair value of derivative liabilities	1,528,913	(1,118,120)	10,048,410
Gain on warrant exchange	473,872		473,872
Interest income	33,687	12,160	1,565,854
Interest expense	(2,999)	(6,339,523)	(7,116,500)
Net loss from continuing operation	(4,736,291)	(16,158,417)	(64,809,306)
Loss from discontinued operation		(1,930,636)	(22,561,220)
Gain on sale of discontinued operation		6,408,603	6,408,603
Net Income (loss) from discontinued operation		4,477,967	(16,152,617)
Net loss	\$ (4,736,291)	\$ (11,680,450)	\$ (80,961,923)
Net loss from continuing operation	\$ (0.06)	\$ (0.33)	
Net income (loss) from discontinued operation		0.09	
Net loss	\$ (0.06)	\$ (0.24)	
Weighted average common shares outstanding basic and diluted	73,852,167	48,976,917	

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 STOCKHOLDERS EQUITY (DEFICIENCY)****YEARS ENDED DECEMBER 31, 2010 AND 2009**

	Common Stock		Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount			
Balance December 31, 2008	46,930,439	\$ 4,693	\$ 73,199,199	\$ (73,958,648)	\$ (754,756)
Cumulative effect of change in accounting principle (see note 6)			(12,982,785)	9,413,466	(3,569,319)
Balance January 1, 2009 as adjusted	46,930,439	\$ 4,693	\$ 60,216,414	\$ (64,545,182)	\$ (4,324,075)
Stock option compensation expense			909,142		909,142
Reclassification of derivative liabilities that no longer contain price protection provisions			2,538,793		2,538,793
Exercise of stock options and warrants	636,350	64	711,009		711,073
Additional listing fees for warrants issued with debt			(31,905)		(31,905)
Issuance of common stock for cash (September 16, 2009; \$1.50 per share)	3,000,000	300	4,161,876		4,162,176
Issuance of common stock for cash (October 15, 2009; \$1.30 per share)	4,615,385	461	5,560,210		5,560,671
Net Loss				(11,680,450)	(11,680,450)
Balance December 31, 2009	55,182,174	\$ 5,518	\$ 74,065,539	\$ (76,225,632)	\$ (2,154,575)
Reclassification of derivative liabilities that no longer contain price protection provisions			1,281,135		1,281,135
Stock option compensation expense			390,268		390,268
Issuance of common stock in exchange for cancelled warrants, less facilitation fee	2,310,613	231	900,908		901,139
Issuance of common stock in exchange for technology and product license fee, net of issuance costs	2,000,000	200	934,800		935,000
Issuance of common stock for cash (March 12, 2010; \$0.50 per share)	22,669,980	2,267	10,390,993		10,393,260
Issuance of common stock for cash, net of issuance costs	935,200	94	418,209		418,303
Net Loss				(4,736,291)	(4,736,291)
Balance December 31, 2010	83,097,967	\$ 8,310	\$ 88,381,852	\$ (80,961,923)	\$ 7,428,239

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 CASH FLOWS**

	<b>Years Ended December 31,</b>		<b>Period from December 22, 2003 (Inception) To December 31, 2010</b>
	<b>2010</b>	<b>2009</b>	
<b>Cash Flows From Operating Activities</b>			
Net loss	\$ (4,736,291)	\$ (11,680,450)	\$ (80,961,923)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of discontinued operation		(6,408,603)	(6,408,603)
Gain on warrant exchange	(518,622)		(518,622)
Loss on abandonment of leaseholds		135,344	135,344
Depreciation	169,005	476,792	1,899,536
Amortization intangibles		443,651	2,696,193
Amortization debt discount		4,563,434	5,291,019
Amortization deferred financing costs		738,893	925,859
Amortization technology and product license fee	11,364		11,364
Provision for obsolete inventory			200,000
Provision for doubtful accounts			
Change in fair value of warrants	(1,528,913)	1,118,120	(10,048,410)
Common stock and warrants issued for services and reimbursement of expenses			203,882
Stock based compensation expense	390,268	909,142	7,246,846
In-process purchased technology			2,027,529
Changes in operating assets and liabilities, excluding effects of acquisition:			
Accounts receivable	115,138	83,372	78,988
Inventories		297,562	(1,806,159)
Prepaid expenses and other assets	(2,751)	37,759	(155,725)
Deposits	3,630	(47,500)	(189,750)
Accounts payable	(1,702,918)	(1,259,383)	1,734,590
Accrued liabilities	411,656	(1,017,275)	64,995
Deferred rent	(25,332)	(5,201)	164,782
Net cash used in operating activities	(7,413,766)	(11,614,343)	(77,408,265)
<b>Cash Flows From Investing Activities</b>			
In-process technology purchased from Tissue Repair Company			(1,500,000)
Fee paid to list shares issued for technology and product license	(65,000)		(65,000)
Purchases of property and equipment	(52,408)		(2,812,143)
Net cash used in investing activities	(117,408)		(4,377,143)
<b>Cash Flows From Financing Activities</b>			
Proceeds from officer loan			62,882
Cash acquired in Aries merger and Innercool acquisition			1,551,800
Restricted cash collateral for letter of credit		100,000	(300,000)
Restricted cash proceeds placed in escrow from sale of discontinued operation		(1,125,000)	(1,125,000)
Proceeds from the exercise of warrants, net		711,073	1,258,448
Proceeds from debt financing agreement, net of deferred financing costs of \$251,901 and issuance cost of \$31,905 at December 31, 2009.		3,966,194	14,378,167
Proceeds from the sale business unit		11,250,000	11,250,000
Repayment of debt		(10,750,000)	(15,750,000)
Proceeds from the sale of common stock, net of issuance costs	10,811,563	9,722,847	77,103,165
Net cash provided by financing activities	10,811,563	13,875,114	88,429,462

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

Net (decrease) increase in cash	3,280,389	2,260,771	6,644,054
Cash and cash equivalents at beginning of period	3,363,665	1,102,894	
Cash and cash equivalents at end of period	\$ 6,644,054	\$ 3,363,665	\$ 6,644,054

### Supplemental Disclosures of Cash Flow Information:

Cash paid for interest	\$ 2,999	\$ 1,023,990	\$ 1,383,295
Cash paid for income taxes	\$ 2,400	\$ 2,400	\$ 24,562

### Non-Cash Activity:

Subscription receivable for common shares	\$	\$	\$ 17,000
Common stock issued for repayment of loans	\$	\$	\$ 62,882
Stock issued for technology and product license fee	\$ 1,000,000	\$	\$ 1,000,000
Net assets acquired for the issuance of common stock (exclusive of cash acquired)	\$	\$	\$ 5,824,000
Warrants exchanged for stock	\$ (901,139)	\$	\$ (901,139)
Reclassification of derivative liabilities with expired price protection provisions	\$ (1,281,135)	\$ (2,538,793)	\$ (3,819,928)
Issuance of note for accrued milestone payment	\$ 500,000	\$ 500,000	\$ 500,000

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)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 Organization and Liquidity**

**Organization**

Cardium Therapeutics, Inc. (the Company, Cardium, we, our and us ) was incorporated in Delaware in December 2003. Our business is focused on the acquisition and strategic development of product opportunities or businesses having the potential to address significant unmet medical needs, and definable pathways to commercialization, partnering or other monetization following the achievement of corresponding development objectives. 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. 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, Excellerate™ is initially being developed as a single administration for the treatment of non-healing, neuropathic diabetic foot ulcers. InnerCool Therapies and Tissue Repair Company are each operated as a wholly-owned subsidiary of Cardium.

On July 24, 2009, we closed a transaction for the sale of all of the assets and liabilities of our InnerCool Therapies business to Philips Electronics North America Corporation ( Philips ) for \$11.25 million, of which \$1,125,000 is held in escrow as security for certain indemnification obligations, as well as the transfer of approximately \$1.5 million in trade payables (the Philips Transaction ). We have agreed to indemnify Phillips for any damages arising from the breach of any of those representations and warranties, as well as any breach of any covenant under the Asset Purchase Agreement. Our liability for breach of certain representations is contractually capped at \$3.5 million; however, claims for damages arising out of certain Excepted Representations or any covenant under the Asset Purchase Agreement are not subject to the contractual limitation. As of December 31, 2010 we are not aware of a breach of any of the terms of this agreement. The operations of InnerCool are presented as a discontinued operation in our consolidated statements of operations. After the closing, the name of InnerCool Therapies, Inc. was changed to Post-Hypothermia Corporation.

We are a development stage company. We have yet to generate positive cash flows from operations, and are essentially dependent on debt and equity funding to finance our operations.

**Liquidity and Going Concern**

As of December 31, 2010 we had \$6,644,054 in cash and cash equivalents and \$1,425,000 in restricted cash. Our working capital at December 31, 2010 was \$6,657,117 (excluding \$573,073 for the fair value of derivative liabilities).

Net cash used in operating activities was \$7,413,766 for the year ended December 31, 2010 compared to \$11,614,343 for the year ended December 31, 2009. The decrease in net cash used in operating activities for the year ended December 31, 2010 when compared to last year was a result of the decrease in company-wide spending, the sale of all the assets of our InnerCool business in July 2009 and the completion of the MATRIX clinical study during the fourth quarter of 2009.

## **Table of Contents**

Our primary source of liquidity has been cash flows from financing activities and in particular proceeds from the sales of our debt and equity securities. On March 12, 2010, we completed a registered direct offering of 2,266,998 units, which were sold to institutional and retail investors, at a price of \$5.00 per unit. Each unit consisted of 10 shares of common stock and a warrant to purchase 5 shares of common stock. The warrants are exercisable at an exercise price of \$0.64 per share, at any time after six months from the date of closing and have a term of exercise equal to five years from the date the warrants are initially exercisable. In the aggregate 22,669,980 shares of common stock and warrants to purchase an additional 11,334,990 shares of common stock were issued in the offering. The offering resulted in gross proceeds to us of \$11.3 million, and net proceeds of approximately \$10.4 million after payment of offering fees and expenses.

On August 9, 2010 we filed a Form S-3 Registration Statement (declared effective by the securities and Exchange Commission on August 27, 2010) putting in place a universal shelf registration statement covering up to \$50 million of any combination of common stock, preferred stock, debt securities, warrants, or units we may offer through August 9, 2013, at which time we will provide the specific term of any offering in one or more supplements to the prospectus. This registration statement is intended to allow us to capitalize on strategic opportunities that may arise; we do not have any current commitments for shares to be registered under the registration. The registration statement replaced an existing universal shelf registration statement scheduled to expire.

On September 28, 2010, we entered into a Sales Agreement ( Sales Agreement ) with Brinson Patrick Securities Corporation to enable us to use Brinson Patrick as a sales manager to sell shares of our common stock from time to time in at-the-market transactions pursuant to our shelf registration statement on a best efforts basis. For the year ended December 31, 2010 we sold 935,200 shares under this agreement for net proceeds of \$418,303.

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, 2010, net cash used in operating activities has been \$77,408,265, net cash provided by financing activities was \$88,429,462, and net cash used in investing activities has been \$4,377,143.

We anticipate that the negative cash flow from operations will continue for 2011. Although we believe that we have sufficient capital to support our operations through January 1, 2012. We are still a development stage company subject to all the risks and uncertainties that are typical in the lifecycle stage of our business. Our principal objective is to complete a strategic licensing agreement or secure the approval and future sales of the Excellagen product family and/or another corporate transaction. If we fail to enter into a strategic licensing arrangement or generate sufficient product sales, we will not generate sufficient cash flows to cover our operating expenses. Although we intend to secure additional working capital through sales of additional debt or equity securities we have not secured any financing at this time, and we cannot give any assurances about the availability or terms of any future financing.

Our history of recurring losses and uncertainties as to whether our operations might become profitable raise substantial doubt about our ability to continue as a going concern. The 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.

## **Note 2 Summary of Significant Accounting Policies**

### **Basis of Presentation**

Our principal activities are expected to focus on the commercialization of our licensed technologies, other technologies and the expansion of our existing products. The accompanying financial statements have been prepared in accordance with ACS Topic 915 (formerly Statement of Financial Accounting Standard No. 7), Development Stage Enterprises.

## **Table of Contents**

### **FDIC Insured Limits**

Financial instruments that subject us to concentrations of credit risk consist primarily of cash and cash equivalents. We maintain all of our cash and cash equivalents in two financial institutions, although substantially all of the balance is within one institution. We perform periodic evaluations of the relative credit standing of the institutions. Our cash balances on deposit with this financial institution at December 31, 2010 exceeded the FDIC limits by \$5,997,416.

### **Fair Value of Financial Instruments**

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities approximate fair value due to the short term maturities of these instruments.

### **Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Principal estimates include valuing options and warrants using the Binomial and Black-Scholes Option Pricing Models.

### **Principles of Consolidation**

The accompanying consolidated financial statements include the financial statements of Cardium and its wholly-owned subsidiaries, Post-Hypothermia Corporation (a business that is presented as a discontinued operation as described in Note 3) and Tissue Repair Company. All inter-company balances and transactions have been eliminated in consolidation.

### **Restricted Cash**

We have a total of \$300,000 invested in a certificate of deposit that serves as collateral for an outstanding letter of credit, and is therefore restricted. The letter of credit is a security deposit towards tenant improvements for our office space and is reduced by \$100,000 every year on March 1. Therefore, \$200,000 is classified as non-current restricted cash and \$100,000 is classified as a cash equivalent. In addition under the terms of the Asset Purchase Agreement with Philips, we deposited \$1,125,000 of the proceeds from the sale into an escrow account to act as security for our indemnification obligations that may arise. At December 31, 2010 the escrow amount is scheduled to be released in the next few months, therefore \$1,125,000 is shown in current assets on our balance sheet.

### **Accounts Receivable**

Accounts receivable represents amounts due for the services provided under the grant that we record on an as earned basis.

### **Deferred Financing Costs**

The costs incurred in connection with the issuance of certain indebtedness were capitalized as deferred costs and were amortized over the term of the related indebtedness as a financing cost over the period of future benefit. We incurred related amortization expense of \$738,893 for the year ended December 31, 2009. The notes were paid off in the fourth quarter of 2009 and therefore there is no interest expense recorded in connection with this debt for the year ended December 31, 2010. Amortization of the deferred costs is included as interest expense in the accompanying consolidated statements of operations. For the period December 22, 2003 (inception) to December 31, 2010 was \$925,859.

## **Table of Contents**

### **Accounting for Debt/Proceeds Allocations**

In accordance with ASC Topic 740 we recorded a discount on notes payable based on the relative fair values of the notes and the common stock purchase warrants issued in connection with the notes and amortized the discount over the terms of the notes through the date of repayment. We recorded non-cash interest expense for the accretion of the discount on the notes of \$4,563,434 for the year ended December 31, 2009. Amortization of debt discount is included as interest expense in the accompanying consolidated statements of operations for the period December 22, 2003 (inception) to December 31, 2010 was \$5,291,019.

### **Impairment of Long-Lived Assets**

Long-lived assets to be held and used, including property, plant and equipment as well as intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable such as:

a significant decline in the observable market value of an asset;

a significant change in the extent or manner in which an asset is used; or

a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable.

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell. We do not believe there was any impairment of long-lived assets at December 31, 2010.

### **Property and Equipment**

Property and equipment are stated at cost, net of accumulated depreciation. Property and equipment are depreciated on a straight-line basis over the estimated useful lives of the assets (three years for computer equipment and five years for furniture and fixtures). Leasehold improvements are being amortized on a straight-line basis over a period of six years.

### **Common Stock Purchase Warrants**

We account for the issuance of common stock purchase warrants issued in connection with capital financing transactions in accordance with the provisions of ASC Topic 815. Based upon the provisions of ASC Topic 815, we classify as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). We classify as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

As more fully described in Note 7, we classified certain common stock purchase warrants with contingent exercise features as derivative liabilities in the accompanying consolidated balance sheet as of December 31, 2010 and 2009.

### **Revenue Recognition**

Revenue is recognized on the grant when the services are provided and direct costs are incurred. Grant revenues are received by the Company to further advance its research and development activities associated with

## **Table of Contents**

product development. As of December 31, 2009, the grant had concluded and all revenue had been recorded. The Grant was awarded by the National Institutes of Health, ( NIH ) specifically the National Heart, Lung & Blood Institute, a sponsored program by the federal government and provided 100% of our revenues for the year ended December 31, 2009.

For the year ended December 31, 2010 we received a one-time Qualifying Therapeutic Discovery Grant from the federal government. In order to receive the grant funds we applied for a credit with the Internal Revenue Service. Based on expenditures made during the year ended December 31, 2009 we were awarded \$244,479. We recognized the revenue on this grant when the funds were made available.

### **Reclassification**

Certain prior year amounts have been reclassified to conform to the current year presentation. The reclassification did not have any effect on reported consolidated net losses for any periods presented.

### **Research and Development**

In accordance with ASC Topic 730 research and development costs are expensed as incurred. Research and development expenses consist of purchased technology, purchased research and development rights and outside services for research and development activities associated with product development. In accordance with ASC Topic 730, the cost to purchase such technology and research and development rights are required to be charged to expense if there is currently no alternative future use for this technology and, therefore, no separate economic value.

### **Income Taxes**

In accordance with ASC Topic 740 we account for deferred income taxes under the liability method. Under this method, we recognize deferred tax assets and liabilities based on the tax effects of temporary differences between the financial statement and tax bases of assets and liabilities, as measured by current enacted tax rates. A valuation allowance is recorded to reduce deferred tax assets when necessary.

### **Loss Per Common Share**

We compute loss per share, in accordance with ASC Topic 260 which requires dual presentation of basic and diluted earnings per share.

Basic income or loss per common share for continuing operations and discontinued operation is computed by dividing net income or loss by the weighted average number of common shares outstanding during the period. Diluted income or loss per common share is computed by dividing net income or loss by the weighted average number of common shares outstanding, plus the issuance of common shares, if dilutive, resulting from the exercise of outstanding stock options and warrants. These potentially dilutive securities were not included in the calculation of loss per common share for the years ended December 31, 2010 and 2009 because, due to the loss we incurred during such periods, their inclusion would have been anti-dilutive. Accordingly, basic and diluted loss per common share are the same for all periods presented.

Potentially dilutive securities consisted of outstanding stock options and warrants to acquire 35,254,835 shares as of December 31, 2010. As of December 31, 2009, potentially dilutive securities consisted of outstanding stock options and warrants to acquire 27,586,356 shares.

### **Stock-Based Compensation**

In accordance with ASC 718 stock-based compensation costs are recognized on a straight-line basis over the requisite service period of the award, which is generally the vesting term of the award.



**Table of Contents**

Total stock-based compensation expense included in the consolidated statements of operations was allocated as follows to research and development and general and administrative expenses as follows:

	December 31,	
	2010	2009
Research and development	\$ 122,891	\$ 240,095
General and administrative	267,377	669,047
<b>Total stock-based compensation</b>	<b>\$ 390,268</b>	<b>\$ 909,142</b>

**Recent Accounting Pronouncements**

In January 2010, the Financial Accounting Standards Board (FASB), issued new standards to update and amend existing standards on Fair Value Measurements and Disclosures. These standards require new disclosures on the amount and reason for transfers in and out of Level 1 and Level 2 fair value measurements. The standards also require disclosure of activities in Level 3 fair value measurements that use significant unobservable inputs, including purchases, sales, issuances, and settlements. The standards also clarify existing disclosure requirements on levels of disaggregation, which requires fair value measurement disclosure for each class of assets and liabilities, and disclosures about valuation techniques and inputs used to measure fair value of recurring and non-recurring fair value measurements that fall in either Level 2 or Level 3. The new disclosures and clarifications of existing disclosures are effective for our interim and annual reporting periods beginning January 1, 2010, except for the disclosures about purchases, sales, issuances and settlements in the roll forward activity in Level 3 fair value measurements. Those disclosures are effective for our fiscal year beginning January 1, 2011. As this guidance requires only expanded disclosures, the adoption did not and will not impact our consolidated financial condition and results of operations.

**Note 3 Disposal of Long-Lived Assets**

In accordance with the provisions of ASC topic 360 the disposal of our Innercool business segment as a discontinued operation in the accompanying consolidated financial statements.

The following results of operations of Innercool Therapies, Inc.:

	For the years ended December 31, 2009	Period from December 22, 2003 (Inception) to December 31, 2009
<b>Revenues</b>		
Product sales	\$ 793,770	\$ 4,620,076
Cost of goods sold	579,895	4,313,998
Gross profit	213,875	306,078
<b>Operating expenses</b>		
Research and development	324,020	5,965,833
Selling, general and administrative	1,357,249	13,681,733
Amortization intangibles	443,651	2,696,193
Total operating expenses	2,124,920	22,343,759
Loss from operation	(1,911,045)	(22,037,681)
Interest, net	(19,591)	(523,539)

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

Net loss from discontinued operation	\$ (1,930,636)	\$ (22,561,220)
--------------------------------------	----------------	-----------------

On July 24, 2009, we closed the sale of our Innercool business unit to Philips. The purchase price was \$11,250,000 net of a working capital adjustment of \$7,148.

**Table of Contents**

The following is the calculation of the gain on the sale of Innercool.

Selling price	\$ 11,250,000
Less working capital adjustment	(7,148)
Net cash received	11,242,852
Net assets sold:	
Accounts receivable	97,606
Prepaid expenses and other current assets	131,137
Inventory, net	1,702,823
Property and equipment, net	742,390
Intangible assets, net	3,533,023
Other long term assets	40,103
Accounts payable	(1,185,152)
Other liabilities	(227,681)
Subtotal	4,834,249
Gain on sale of discontinued operation	\$ 6,408,603

**Note 4 Property and Equipment**

Property and equipment consisted of the following:

	December 31,	
	2010	2009
Computer and telecommunication equipment	\$ 517,617	\$ 466,329
Machinery and equipment	31,779	31,779
Office equipment	53,050	53,050
Instrumentation	115,421	115,421
Office furniture and equipment	474,772	473,652
Leasehold improvements	152,774	152,774
	1,345,413	1,293,005
Accumulated depreciation and amortization	(1,110,471)	(941,466)
Property and equipment, net	\$ 234,942	\$ 351,539

Depreciation and amortization of property and equipment from continuing operations totaled \$169,005 and \$259,286 for the years ended December 31, 2010 and 2009. For the period from December 22, 2003 (inception) through December 31, 2010 depreciation and amortization of property and equipment from continuing operations totaled \$1,166,197.

**Table of Contents****Note 5 Intangible assets**

On November 17, 2010 we entered into a custom technology access and product license agreement with BioZone Laboratories, Inc. ( BioZone ) for the co-development and strategic licensing of a portfolio of up to 20 aesthetics, advanced skin care formulations and other products for our MedPodium product line. The agreement grants us a royalty-free license of BioZone technology to develop a portfolio of 20 products, customized to our product specifications. We will have exclusive rights to the products developed to its specifications. The license is for a term of 10 years with an automatic 1 year renewal. In exchange for the technology access license we have agreed to pay BioZone a fee of \$1.0 million.

		<b>December 31, 2010</b>	
	<b>Cost</b>	<b>Accumulated Amortization</b>	<b>Net Asset</b>
Technology and product license fee	\$ 1,000,000	\$ 11,364	\$ 988,636

**Note 6 Accrued Liabilities**

Accrued Liabilities consisted of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Payroll and benefits	\$ 624,412	\$ 311,849
Other	123,701	24,608
<b>Total</b>	<b>\$ 748,113</b>	<b>\$ 336,457</b>

**Note 7 Derivative Liabilities**

The adoption of ASC 815, as described under Note 2, can affect the accounting for warrants and convertible instruments with provisions that protect holders from a decline in the stock price (or down-round provisions). Down-round provisions reduce the exercise price or increase the number of shares underlying the common stock equivalents the Company issues, new equity or equity linked securities at prices or with exercise prices that are more favorable than the security that features price protection. We evaluated whether warrants to acquire stock of the Company contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price under the respective warrant agreements.

	<b>Number of Warrants (in shares)</b>	<b>Fair Value</b>
Balance outstanding, January 1, 2009	15,854,279	\$ 4,806,150
Warrants issued	2,730,832	1,417,405
Warrants expired or cancelled	(4,591,927)	(2,538,793)
Fair value adjustment		1,118,120
<b>Balance outstanding, December 31, 2009</b>	<b>13,993,184</b>	<b>\$ 4,802,882</b>
Warrants issued due to price protection provisions	2,838,777	
Warrants exchanged for stock	(6,931,805)	(1,419,761)
Warrants cancelled	(6,560,481)	(1,281,135)
Fair value adjustment		(1,528,913)
<b>Balance outstanding, December 31, 2010</b>	<b>3,339,675</b>	<b>\$ 573,073</b>

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

We had 15,854,279 warrants outstanding that contain anti-dilution or price protection on January 1, 2009, the date in which ASC 815 became effective. The aggregate fair value of all such warrants as of their original

**Table of Contents**

issue dates amounted to \$14,443,766. We calculated the fair value of these warrants using the Binomial Option Pricing Model with the following weighted average assumptions: exercise price \$1.96, fair value of common stock \$0.75, risk free interest rate of 1.16%, dividend yield of 0%, volatility of 82% and remaining contractual term of 4.17 years. We recorded an issuance date liability for these warrants by reducing additional paid in capital by \$12,982,785, and increasing the discount of certain related indebtedness by an additional \$1,460,981. The aggregate fair value of these warrants amounted to \$4,806,150 as of January 1, 2009. Accordingly, we reduced the issuance date fair value of the warrant liability by \$9,637,617 and the accumulated deficit for the cumulative change in fair value of the warrants through January 1, 2009. We then decreased the debt discount by \$224,151 for amortization that would have been recorded from the dates of original issuance to the January 1, 2009. The net effect of reducing the liability to fair value and amortization of the debt discount as of January 1, 2009 is reflected in the accompanying statement of stockholders' equity (deficiency) as a \$9,413,466 reduction of the accumulated deficit.

During the year ended December 31, 2009, we issued an additional 2,730,832 warrants that contain anti-dilution or price protection. The aggregate fair value of all such warrants issued during the year ended December 31, 2009 amounted to \$1,417,405. We calculated the fair value of these warrants using the Binomial Option Pricing Model with the following weighted average assumptions: exercise price \$1.87, fair value of common stock \$1.15, risk free interest rate of 1.9%, dividend yield of 0%, volatility of 92% and remaining contractual term of 4.69 years.

Included in the above table are 3,198,410 warrants which expired or no longer contain price protection that requires them to be recorded as derivative liabilities. Accordingly, we reduced derivative liabilities \$2,583,793 with respect to these warrants. Warrants to purchase 1,393,517 shares of common stock were cancelled during the year ended December 31, 2009. As a result, we had 13,993,184 warrants outstanding that contain anti-dilution price protection as of December 31, 2009. The aggregate fair value of all such warrants amounted to \$4,802,882. We calculated the fair value of these warrants using the Binomial Option Pricing Model with the following weighted average assumptions: exercise price \$1.30, fair value of common stock \$0.68, risk free interest rate of 1.27%, dividend yield of 0%, volatility of 98% and a remaining contractual term of 3.36 years. We recorded a \$1,118,120 charge in the statement of operations during the year ended December 31, 2009 to increase the amount of the derivative liability to fair value as of December 31, 2009.

During the year ended December 31, 2010 we issued warrants to purchase 2,838,777 shares of our common stock when down-round provisions were triggered on March 12, 2010 as a result of the registered direct offering. During the year ended December 31, 2010 we cancelled warrants to purchase 6,560,481 shares of our common stock as their down-round provisions were no longer in effect. The fair value of the warrants we cancelled amounted to \$1,281,135 and were recorded as an increase in paid in capital and a reduction of derivative liabilities. In addition 6,931,805 warrants were exchanged for 2,310,613 shares of our common stock. As a result, we had warrants to purchase 3,339,675 shares of our common stock outstanding that contain down-round provisions as of December 31, 2010. The aggregate fair value at such date of all such warrants amounted to \$573,073. We calculated the fair value of these warrants using the Binomial Option Pricing Model with the following weighted average assumptions: exercise price \$0.50, closing price of common stock \$0.39, risk free interest rate of 0.54%, dividend yield of 0%, volatility of 95% and a remaining contractual term of 1.79 years. We recorded a change in fair value of \$1,528,913 for the year ended December 31, 2010 which is shown as change in fair value of derivative liabilities in our consolidated statement of operations.

The fair value hierarchy distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The hierarchy consists of three levels:

Level one Quoted market prices in active markets for identical assets or liabilities;

Level two Inputs other than level one inputs that are either directly or indirectly observable; and

Level three Unobservable inputs developed using estimates and assumptions, which are developed by the reporting entity and reflect those assumptions that a market participant would use.

**Table of Contents**

Determining which category an asset or liability falls within the hierarchy requires significant judgment. We evaluate our hierarchy disclosures each quarter. Assets and liabilities measured at fair value on a recurring basis are summarized as follows:

Assets	Level 1	Level 2	Level 3	December 31, 2010
None	\$	\$	\$	\$

Liabilities	Level 1	Level 2	Level 3	December 31, 2010
Fair value of common stock warrants (derivative liabilities)	\$	\$	\$ 573,073	\$ 573,073
Total	\$	\$	\$ 573,073	\$ 573,073

Assets	Level 1	Level 2	Level 3	December 31, 2009
None	\$	\$	\$	\$

Liabilities	Level 1	Level 2	Level 3	December 31, 2009
Fair value of common stock warrants (derivative liabilities)	\$	\$	\$ 2,300,786	\$ 2,300,786
Total	\$	\$	\$ 2,300,786	\$ 2,300,786

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of December 31, 2010:

	Fair Value Measurements at December 31, 2010			
	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Derivative liabilities	\$ 573,073	\$	\$	\$ 573,073

**Note 8 Commitments and Contingencies****Lease Commitments**

Effective November 1, 2005, we entered into a two year lease for our principal executive offices. The lease contained two options, the first for an additional term of one year and the second for an additional term of two years. The second option was subject to a third party right of first refusal. During the first year of the lease, the monthly installment of base rent was approximately \$21,500, which increased to approximately \$22,335 in November 2006. In addition to base rent, we also were required to pay our proportionate share of operating and tax expenses for the office park in which our space was located. We chose not to exercise our option for an additional term and the lease expired in the fourth quarter of 2008.

On December 20, 2006, we entered into a six year lease for our technology center, which housed the operations of Innercool Therapies Inc. and Tissue Repair Company until Innercool was sold In July 2009. At the time of the sale, Philips assumed the lease for the technology center.

On November 19, 2007 we entered into a lease for approximately 11,184 square feet of office space in San Diego, California to be used as Cardium's corporate headquarters. The lease commenced in April 2008 once substantial improvements were completed and has a term of 64

## Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

months from the commencement date with an option to renew for an additional five years. Monthly base rent was approximately \$46,972 during the first year of the lease and increases to \$48,650, \$50,328, \$52,117, \$53,907 and \$55,808 each year thereafter. In addition to monthly base rent, we are also required to pay our proportionate share of any building operating expenses in excess of 2008 levels. In connection with entering into the lease, we paid a security deposit of \$55,808 and



**Table of Contents**

delivered a \$500,000 letter of credit to the landlord. The letter of credit is subject to annual reductions of \$100,000 during the original term of the lease. At December 31, 2010 the letter of credit has a remaining balance of \$300,000.

Future annual minimum rental payments under the leases are as follows:

Year Ending December 31,	Facilities (Operating Lease)
2011	620,041
2012	641,514
2013	384,953
Total	\$ 1,646,508

Rent expense included in continuing operations was \$593,756 and \$661,983, for the years ended December 31, 2010 and 2009, respectively.

**Purchase of Technology from Schering AG**

In October 2005, we completed a transaction with Schering AG Group, Germany (now part of Bayer AG) and related licensors, including the University of California, New York University and Yale University, for the transfer or license of certain assets and technology for potential use in treating ischemic and other cardiovascular conditions. Under the terms of the transaction, we paid Schering a \$4 million fee, and would be required to pay a \$10 million milestone payment upon the first commercial sale of each resulting product. We also may be obligated to pay the following future royalties to Schering: (i) 5% on net sales of an FGF-4 based product such as Generx, or (ii) 4% on net sales of other products developed based on technology transferred to Cardium by Schering. As part of the Schering transaction, we acquired rights and corresponding obligations under the Regents of the University of California (Regents) September 1995 agreement, as amended. The agreement as amended may be canceled by us at any time on 60 days' notice, following which we would continue to be responsible only for obligations and liabilities accrued before termination. Under the agreement, we are obligated to pay (1) an annual royalty fee of 2% based on net sales of products incorporating the technology licensed under the agreement, and (2) a minimum annual royalty fee (which may be offset against the net sales-based royalty fee) \$100,000 for 2010, \$100,000 for 2011, \$150,000 for 2012, \$150,000 for 2013 and \$200,000 for 2014 and thereafter, payable on February 28 of the following year. The royalty fee for 2010 was paid in February 2011.

**Legal Proceedings**

From time to time, we may become involved in various investigations, claims and legal proceedings that arise in the ordinary course of our business. These matters may relate to intellectual property, product liability, employment, tax, regulation, contract or other matters. The resolution of these matters as they arise will be subject to various uncertainties and, even if such claims are without merit, could result in the expenditure of significant financial and managerial resources.

**Note 9 Income Taxes**

We file income tax returns in the United States (federal) and California. In most instances, we are no longer subject to federal, state and local income tax examinations by tax authorities for years prior to 2007.

We adopted the provisions of FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes*, on January 1, 2007. This Interpretation clarifies the accounting and reporting for uncertainties in income tax law. It prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions. Differences between a tax position taken or expected to be taken in the Company's tax returns and the amount of benefit recognized and measured in the financial statements result in

**Table of Contents**

unrecognized tax benefits, which are recorded in the balance sheet as either a liability for unrecognized tax benefits or reductions to recorded tax assets, as applicable. As of December 31, 2010 and 2009, no liability for unrecognized tax benefits was required to be recorded.

As of December 31, 2010, we recognized deferred tax assets of \$31.7 million which are primarily comprised of net operating loss carryovers. We had net operating loss carryovers of \$77 million and \$70.6 million as of December 31, 2010 and 2009, respectively. These net operating losses are subject to Internal Revenue Code Section 382, which could result in limitations on the amount of such losses that could be utilized during any taxable year. The net operating losses begin to expire in 2023 for federal income purposes and in 2013 for state income tax purposes.

The ultimate realization of deferred tax assets depends on the generation of future taxable income during the periods in which those net operating losses are available. The Company considers projected future taxable income and tax planning strategies in making its assessment. At present, the Company does not have a sufficient history of income to conclude that it is more-likely-than-not that the Company will be able to realize all of its tax benefits in the near future and therefore a valuation allowance was established for the full value of the deferred tax asset.

A valuation allowance will be maintained until sufficient positive evidence exists to support the reversal of any portion or all of the valuation. Should the Company become profitable in future periods with supportable trends, the valuation allowance will be reversed accordingly. For the years ended December 31, 2010 and 2009 the change in the valuation allowance was \$2,377,926 and 4,035,034, respectively.

The Company's net deferred tax asset consisted of the following at December 31, 2010 and 2009:

	December 31,	
	2010	2009
Deferred tax asset:		
Net operating loss carryforwards	\$ 30,356,352	\$ 28,430,918
Deferred compensation	704,851	656,270
True up	301,444	
Deferred rent	65,640	75,730
Accrued expenses	248,731	124,223
Other	13,676	25,627
Total deferred tax assets	31,690,694	29,312,768
Less: Valuation allowance	(31,690,694)	(29,312,768)
Net deferred tax asset	\$	\$

**Table of Contents**

The income tax provision (benefit) from income taxes consists of the following at December 31, 2010 and 2009:

	Years Ended December 31,	
	2010	2009
Federal		
Current	\$	\$
Deferred	(2,029,640)	(3,444,037)
State		
Current		
Deferred	(348,286)	(590,997)
<b>Total</b>	<b>\$ (2,377,926)</b>	<b>\$ (4,035,034)</b>
Change in valuation allowance	2,377,926	4,035,034
<b>Income tax provision (benefit)</b>	<b>\$</b>	<b>\$</b>

As a result of the Company's significant operating loss carryforwards and the corresponding valuation allowance, no income tax benefit was recorded at December 31, 2010 or 2009. The provision for income taxes using the statutory federal tax rate as compared to the Company's effective tax rate is summarized as follows:

	December 31,	
	2010	2009
Expected federal statutory rate	(34.0)%	(34.0)%
State income taxes, net of federal benefits	(5.8)%	(5.8)%
Discontinued operation		11.0%
True up of net operating loss deferred tax asset	6.4%	
Change in fair value of derivative liabilities	(12.9)%	2.8%
Other permanent differences	(3.9)%	1.1%
	(50.2)%	(25.0)%
Change in valuation allowance	50.2%	25.0%
<b>Totals</b>	<b>%</b>	<b>%</b>

**Note 10 Stockholders' Equity (Deficiency)****Common Stock**

On January 31, 2008, we completed a registered direct offering of our common stock that resulted in the sale of 2,655,000 shares, in the aggregate, of our common stock at a purchase price of \$2.00 per share. We received gross proceeds of approximately \$5,300,000, before placement agent fees and offering expenses of approximately \$400,000. At December 31, 2010 warrants to purchase 1,028,550 shares of our common stock remain outstanding. The warrants have an exercise price of \$2.00 and are scheduled to expire in January of 2013.

On June 27, 2008, we completed a follow-on registered direct offering of our common stock that resulted in the sale of 1,625,000 shares, in the aggregate, of our common stock at a purchase price of \$2.00 per share. We received gross proceeds of approximately \$3,250,000, before placement agent fees and offering expenses of approximately \$224,000. At December 31, 2010 warrants to purchase 2,371,500 shares of our common stock remain outstanding. 2,275,000 of these warrants have an exercise price of \$0.50 and 96,500 have an exercise price of \$2.29. The warrants are scheduled to expire in June of 2013.

On July 18, 2008, we completed a second follow-on registered direct offering of our common stock that resulted in the sale of 1,670,000 shares, in the aggregate, of our common stock at a purchase price of \$2.00 per



---

**Table of Contents**

share. We received gross proceeds of approximately \$3,340,000, before placement agent fees, offering expenses and expense reimbursements of approximately \$330,000. At December 31, 2010 warrants to purchase 2,428,999 shares of our common stock remain outstanding. 2,337,999 of these warrants have an exercise price of \$0.50 and 91,000 have an exercise price of \$2.20. The warrants are scheduled to expire in June of 2013.

On November 5, 2008, we completed a secured debt financing pursuant to the terms of a Note and Warrant Purchase Agreement entered into with certain accredited investors. Under the terms of the purchase agreement we issued notes in the aggregate principal amount of \$6 million to the investors, and five year warrants to purchase an additional 9,386,625 shares of our common stock, in the aggregate, at an exercise price of \$2.00 per share. The warrants are subject to price protection provisions pursuant to the purchase agreement. At December 31, 2010 warrants to purchase 2,862,525 shares of our common stock remain outstanding. The warrants have an exercise price of \$0.50 and are scheduled to expire in November of 2013.

On March 5, 2009 we completed a \$3.5 million financing in the form of senior subordinated secured debt with accompanying warrants to purchase 1,505,000 shares of our common stock. The warrants were fully exercisable when issued, have a five year term and an exercise price of \$2.00. We received gross proceeds of approximately \$3.5 million, less placement agent fees and offering expenses of approximately \$252,000. In addition, we issued warrants to purchase 90,300 shares of common stock to the placement agent on the same terms as the warrants issued to the lenders. At December 31, 2010 all warrants issued in this transaction remain outstanding.

On June 23, 2009 we completed a \$750,000 unsecured debt financing with accompanying warrants to purchase 502,500 shares of our common stock. The warrants were fully exercisable when issued, have a five year term and have an exercise price of \$1.30. We received aggregate gross proceeds of approximately \$750,000 before placement agent fees and offering expenses of approximately \$50,000. In addition, we issued warrants to purchase 12,060 shares of common stock to the placement agent on the same terms as the warrants issued to the lenders. At December 31, 2010 all warrants issued in this transaction remain outstanding.

In September 16, 2009, we sold an aggregate of 3,000,000 at a price of \$1.50 per share of our common stock and 2,250,000 warrants to common stock to certain institutional investors in exchange for gross proceeds of \$4.2 million, net of issuance costs. Each investor received warrants to purchase a number of shares equal to 75% of the number of shares of common stock purchased by the investor in the offering. The exercise price of the warrants is \$1.77. In addition, the placement agent for the September financing received 150,000 warrants to purchase common stock at an exercise price of \$1.87 on substantially identical terms; provided, however that the warrants to the placement agent expire on December 19, 2012. At December 31, 2010 all warrants issued in this transaction remain outstanding.

On October 15, 2009, we sold an aggregate of 4,615,385 shares of our common stock and 3,000,000 warrants to common stock to certain institutional investors in exchange for gross proceeds of \$5.6 million, net of issuance costs. Each investor received warrants to purchase a number of shares equal to 75% of the number of shares of common stock purchased by the investor in the offering. The units were sold at a price of \$1.30 per unit. The exercise price of the warrants is \$1.40. In addition, the placement agent for the October financing received 230,769 warrants to purchase common stock at an exercise price of \$1.63 on substantially identical terms; provided, however that the warrants to the placement agent expire on December 19, 2012. At December 31, 2010 all warrants issued in this transaction remain outstanding.

During 2009, 270,590 shares of common stock were issued when warrants to purchase 1,097,207 shares of common stock were exercised in cashless transactions, whereby a portion of the respective warrants representing the right to purchase 826,617 shares of common stock, in the aggregate, were cancelled as the method of payment for the exercise of the warrants. We paid \$15 to various warrant holders for fractional shares resulting from the cashless exercises. Also during 2009, 356,310 shares of common stock were issued upon the exercise of warrants for which we received \$707,620 as payment of the exercise price.

## Table of Contents

On March 12, 2010, we completed a registered direct offering of 2,266,998 units, which were sold to institutional and retail investors, at a price of \$5.00 per unit. The offering resulted in gross proceeds to us of \$11.3 million and net proceeds of approximately \$10.4 million after payment of offering fees and expenses. Each unit consisted of 10 shares of common stock and a warrant to purchase 5 shares of common stock. In the aggregate 22,669,980 shares of common stock and warrants to purchase an additional 11,334,990 shares of common stock were issued in the offering. Dawson James received placement agent fees of \$793,449 and a warrant to purchase an aggregate of 1,133,499 shares of common stock, exercisable at \$0.64 per share. The placement agent's warrants expire on December 9, 2012. At December 31, 2010 all warrants issued in this transaction remain outstanding.

On August 9, 2010 we filed a Form S-3 Registration Statement (declared effective by the securities and Exchange Commission on August 27, 2010) putting in place a universal shelf registration statement covering up to \$50 million of any combination of common stock, preferred stock, debt securities, warrants, or units we may offer through August 9 2013, at which time we will provide the specific term of any offering in one or more supplements to the prospectus. This registration statement is intended to allow us to capitalize on strategic opportunities that may arise; we do not have any current commitments for shares to be registered under the registration. The registration statement replaced an existing universal shelf registration statement scheduled to expire.

On September 28, 2010, we entered into a Sales Agreement ( Sales Agreement ) with Brinson Patrick Securities Corporation to enable us to use Brinson Patrick as a sales manager to sell shares of our common stock from time to time in at-the-market transactions pursuant to our shelf registration statement on a best efforts basis. For the year ended December 31, 2010 we sold 935,200 shares under this agreement for net proceeds of \$418,303.

On November 17, 2010 we entered into a custom technology access and product license agreement with BioZone Laboratories, Inc. ( BioZone ) for the co-development and strategic licensing of a portfolio of up to 20 aesthetics, advanced skin care formulations and other products for our MedPodium™ product line. The agreement grants us a royalty-free license of BioZone technology to develop a portfolio of 20 products, customized to our product specifications. We will have exclusive rights to the products developed to its specifications. The license is for a term of 10 years plus a one year automatic renewal. In exchange for the technology access license we have agreed to pay BioZone a fee of \$1.0 million. The license fee was paid with 2,000,000 shares of our unregistered common stock at a fair value \$0.50 per share. The common stock is subject to certain lock up restrictions and will be held in an escrow account, to be released to BioZone beginning six months following the closing date of the transaction with such shares being released in five equal monthly installments. Under the terms of the agreement, BioZone will provide manufacturing services to us. We have been granted a right of first refusal with respect to any potential sale of BioZone or BioZone assets, under which we would be entitled to acquire BioZone or BioZone assets as applicable on the same terms and conditions as negotiated to mutual acceptability with any third party.

On December 2, 2010 we filed a Tender Offer Statement to exchange (the **Warrant Exchange** ) certain outstanding warrants dated March 9, 2007, November 5, 2008 and November 10, 2008 that contain unlimited down round price protection (the **Eligible Warrants** ). The Eligible Warrants were exchanged for shares of our common stock, par value \$0.0001. The Option Exchange expired at 9:00 p.m., Pacific Time, on December 30, 2010. Pursuant to the Warrant Exchange, an aggregate of 6,931,805 Eligible Warrants to purchase common stock were tendered and accepted for cancellation, representing approximately 67.49% of the total Eligible Warrants outstanding and eligible for exchange in the Warrant Exchange. On December 31, 2010, we issued an aggregate of 2,310,613 shares of our common stock in exchange for the eligible warrants surrendered in the Warrant Exchange. The gain on sale was calculated by taking the current fair value of the warrants, \$1,419,761 and reducing this by the current market value of the shares issued of \$901,139, resulting in a gain of \$518,622. This gain was then reduced by a facilitation fee paid to Empire Asset management in the amount of \$44,750.

**Table of Contents****Stockholder Rights Plan**

On July 10, 2006, Cardium's Board of Directors approved the adoption of a Stockholder Rights Plan ( Rights Plan ). Pursuant to the Rights Plan, Cardium issued a dividend of one right for each share of its common stock held by stockholders of record as of the close of business on July 21, 2006. The rights are not immediately exercisable and will become exercisable only upon the occurrence of certain events. In general, if a person or group acquires, or announces a tender or exchange offer that would result in the acquisition of, 15% or more of Cardium's common stock while the Rights Plan remains in place, then, unless the rights are redeemed by Cardium for \$0.001 per right, the rights will become exercisable by all rights holders except the acquiring person or group, for 0.001 of a share of newly created Series A Preferred Stock of the Company at an exercise price of \$40.00. Until the rights become exercisable, the rights will be represented by, and will automatically trade with, the Company's common stock certificates.

The Rights Plan was reviewed in 2009 and will be evaluated every three years by a committee of independent directors of Cardium's Board of Directors to consider whether the plan continues to be in the best interests of Cardium and its stockholders. The Rights Plan may be amended or revoked by Cardium at any time and unless earlier terminated or amended, the rights will expire on July 10, 2016.

**Stock Options and Other Equity Compensation Plans**

We have an equity incentive plan that was established in 2005 under which 5,665,856 shares of our common stock have been reserved for issuance to employees, non-employee directors and consultants of the Company. In addition we have one other equity compensation plan, Warrants Tissue Repair. The equity compensation plans, Warrants for Common Stock, Innercool Incentive Warrant Plan, terminated 90 days after the sale of Innercool.

At December 31, 2010 the following shares were outstanding and available for future issuance:

Plan	Shares Outstanding	Shares Available for Issuance
2005 Equity Incentive Plan	3,220,000	2,445,856
Warrants Tissue Repair	385,000	
<b>Total all plans</b>	<b>3,605,000</b>	<b>2,445,856</b>

A summary of stock options and warrants that we granted during the years December 31, 2009 and 2010 are as follows:

Grant Date	Quantity Issued	Expected Life (Years)	Strike Price	Volatility	Dividend Yield	Risk-Free Interest Rate	Grant Date Fair Value Per Option	Aggregate Fair Value
03/09/09	1,542,500	5.25	\$ 0.74	88%	0%	1.82%	\$ 0.52	\$ 802,100
08/09/10	30,000	6.03	\$ 0.74	88%	0%	1.95%	\$ 0.55	\$ 16,500
11/01/10	50,000	6.05	\$ 0.74	95%	0%	1.62%	\$ 0.39	\$ 19,500

As of December 31, 2010, the Company had \$508,396 of unvested stock-based compensation at fair value remaining to be expensed ratably over the period January 2010 through October 2014. During the year ended December 31, 2010 the company recognized \$390,268 of stock option compensation expense.

During the year ended December 31, 2009 and 2010, the options and warrants granted had a contractual term of seven years, and vest over approximately four years.





**Table of Contents**

We calculate the fair value of stock options using the Black-Scholes option-pricing model. In determining the expected term, we separate groups of employees that have historically exhibited similar behavior with regard to option exercises and post-vesting cancellations. The option-pricing model requires the input of subjective assumptions, such as those included in the table above. The volatility rates are based principally on our historical stock prices and expectations of the future volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The total expense to be recorded in future periods will depend on several variables, including the number of share-based awards and expected vesting.

The following is a summary of stock option and warrant activity under our equity incentive plan and warrants issued outside of the plan to employees and consultants, during the years ended December 31, 2009 and 2010:

	Number of Options or Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Balance outstanding, December 31, 2008	5,360,406	2.22	6.2
Granted	1,542,500	0.74	6.2
Exercised	(4,687)	0.74	6.2
Cancelled	(732,344)	2.17	5.2
Expired	(2,140,875)	2.21	2.9
Balance outstanding, December 31, 2009	4,025,000	1.67	3.4
Granted	80,000	0.74	6.0
Exercised			
Cancelled	(164,617)	.90	4.9
Expired	(335,383)	1.92	3.0
Balance outstanding, December 31, 2010	3,605,000	\$ 1.67	4.8
Balance exercisable, December 31, 2010	2,738,176	\$ 1.91	4.6

As of December 31, 2010 there was no intrinsic value to the outstanding and exercisable options.

**Table of Contents****Warrants**

The following table summarizes warrant activity for the years ended December 31, 2009 and 2010:

	Number of Warrants	Exercise Price	Weighted Average Remaining Contractual Life (in years)
Balance outstanding, December 31, 2008	16,663,472	2.03	4.2
Warrants issued	8,361,601	1.62	5.1
Warrants exercised	(626,900)	1.55	1.9
Warrants expired			
Warrants cancelled	(836,817)	1.51	1.4
Balance outstanding, December 31, 2009	23,561,356	1.52	4.0
Warrants issued	15,307,266	.61	4.5
Warrants exercised			
Warrants expired	(286,982)	1.50	
Warrants cancelled	(6,931,805)	.50	2.7
Balance outstanding, December 31, 2010	31,649,835	\$ 1.02	3.8
Warrants exercisable at December 31, 2010	31,649,835	\$ 1.02	3.8

As of December 31, 2010 there was no intrinsic value to the outstanding and exercisable options.

The table above does not include warrants issued to employees and consultants as they are included under Option Activity above.

**Table of Contents****Note 11 Supplemental Financial Data (unaudited)**

The following table presents selected unaudited financial results for each of the eight quarters during the two-year period ended December 31, 2010. In the opinion of management, this unaudited information has been prepared on the same basis as the audited information and includes all adjustments (consisting of only normal recurring adjustments) necessary for the fair statement of the financial information for the periods presented.

<b>Year Ended December 31, 2010</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Revenues	\$	\$	\$	\$ 244,479
Loss from operations	\$ (1,480,587)	\$ (1,972,069)	\$ (1,821,080)	\$ (1,496,028)
Net (loss) income	\$ (1,039,816)	\$ (690,324)	\$ (3,448,731)	\$ 442,580
Net loss per common share basic and diluted	\$ (0.01)	\$ (0.01)	\$ (0.04)	\$ 0.01
Weighted average shares outstanding basic and diluted	59,968,059	77,852,154	77,852,154	79,477,951
<b>Year Ended December 31, 2009 (1)</b>	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Revenues	\$ 18,636	\$ 6,996	\$ 235,917	\$ 183,397
Loss from operations	\$ (2,513,248)	\$ (2,322,568)	\$ (2,250,357)	\$ (1,626,761)
(Loss) income from continuing operations	\$ (13,743,176)	\$ (10,110,163)	\$ (1,621,205)	\$ 9,316,127
(Loss) income from discontinued operation	\$ (993,701)	\$ (1,032,511)	\$ 95,576	\$
Gain on discontinued operation	\$	\$	\$ 6,408,603	\$
Net (loss) income	\$ (14,736,877)	\$ (11,142,674)	\$ 4,882,974	\$ 9,316,127
Net (loss) income per common share basic	\$ (0.31)	\$ (0.24)	\$ 0.10	\$ 0.17
Net (loss) income per common share diluted	\$ (0.31)	\$ (0.24)	\$ 0.10	\$ 0.17
Weighted average shares outstanding basic	46,960,439	46,931,134	47,771,609	54,207,761
Weighted average shares outstanding diluted	46,960,439	46,931,134	49,620,079	54,374,522

(1) On July 24, 2009 we sold our Innercool business unit. Results of the Innercool business unit are included as a discontinued operation for all periods presented.

---

**Table of Contents**

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

We maintain certain disclosure controls and procedures. They are designed to ensure that material information is: (1) gathered and communicated to our management, including our principal executive and financial officers, on a timely basis; and (2) recorded, processed, summarized, reported and filed with the SEC as required under the Securities Exchange Act of 1934, as amended.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2010. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective for their intended purpose described above.

**Internal Control Over Financial Reporting**

***Management's Annual Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes policies and procedures for maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for the preparation of our financial statements; providing reasonable assurance that receipts and expenditures of the Company are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of Company assets that could have a material effect on our financial statements would be prevented or detected on a timely basis. Because of inherent limitations in all control systems, internal control over financial reporting is intended to provide only reasonable assurance, not absolute assurance, that a misstatement of our financial statements would be prevented or detected.

Under the supervision, and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective at that reasonable assurance level as of December 31, 2010.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to SEC rules applicable to smaller reporting companies.

***Changes in Internal Control Over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**Table of Contents**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

The information for this item is incorporated by reference to the sections Our Board of Directors, Our Executive Officers, Section 16(a) Beneficial Ownership Reporting Compliance, and Code of Ethics in our definitive proxy statement for our Annual Meeting of Stockholders to be held on June 2, 2011, to be filed on or before April 30, 2011.

**ITEM 11. EXECUTIVE COMPENSATION**

The information for this item is incorporated by reference to the sections Director Compensation and Executive Officer Compensation in our definitive proxy statement for our Annual Meeting of Stockholders to be held on June 2, 2011, to be filed on or before April 30, 2011.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information for this item is incorporated by reference to the sections Stock Holdings of Certain Owners and Management and Securities Authorized for Issuance Under Equity Compensation Plans in our definitive proxy statement for our Annual Meeting of Stockholders to be held on June 2, 2011, to be filed on or before April 30, 2011.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

The information for this item is incorporated by reference to the sections Certain Relationships and Related Transactions and Our Board of Directors in our definitive proxy statement for our Annual Meeting of Stockholders to be held on June 2, 2011, to be filed on or before April 30, 2011.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information for this item is incorporated by reference to the sections Audit Fees, Audit-Related Fees, Tax Fees, All Other Fees and Pre-Approval Policies and Procedures in our definitive proxy statement for our Annual Meeting of Stockholders to be held on June 2, 2011, to be filed on or before April 30, 2011.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

The following documents are filed as part of this report:

(1) **Financial Statements.** The financial statements listed below are included under Item 8 of this report:

Consolidated Balance Sheets as of December 31, 2010 and 2009;

Consolidated Statements of Operations for the years ended December 31, 2010 and 2009 and for the period from December 22, 2003 (inception) to December 31, 2010;

Consolidated Statements of Stockholders' Equity (Deficiency) for the years ended December 31, 2010 and 2009;

Consolidated Statements of Cash Flows for the years ended December 31, 2010 and 2009 and for the period from December 22, 2003 (inception) to December 31, 2010; and

Notes to Consolidated Financial Statements.

(2) **Financial Statement Schedules.** The following financial statement schedules are included under Item 8 of this report: None.

(3) **Exhibits.** The following exhibit index shows those exhibits filed with this report and those incorporated by reference:

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
3.1	Second Amended and Restated Certificate of Incorporation of Cardium Therapeutics, Inc. as filed with the Delaware Secretary of State on January 13, 2006	Exhibit 3(i) of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the commission on January 18, 2006
3.2	Amended and Restated Bylaws of Cardium Therapeutics, Inc. as adopted on January 12, 2006	Exhibit 3(ii) of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the Commission on January 18, 2006
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock	Exhibit 3.2 of our Registration Statement on Form 8-A, filed with the Commission on July 11, 2006
4.1	Form of Warrant issued to employees and consultants of Innercool Therapies, Inc.	Exhibit 4.1 of our Current Report on Form 8-K dated March 8, 2006, filed with the Commission on March 14, 2006
4.2	Form of Common Stock Certificate for Cardium Therapeutics, Inc.	Exhibit 4.5 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the Commission on March 31, 2006
4.3	Form of Rights Agreement dated as of July 10, 2006, between Cardium Therapeutics, Inc. and Computershare Trust	Exhibit 4.1 of our Registration Statement on Form 8-A, filed with the Commission on July 11, 2006



**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
4.4	Form of Rights Certificate	Exhibit 4.2 of our Registration Statement on Form 8-A, filed with the Commission on July 11, 2006
4.5	Form of Warrant issued to purchasers in 2007 private financing	Exhibit 4.1 of our Current Report on Form 8-K dated March 6, 2007, filed with the Commission on March 6, 2007
4.6	Form of Warrant issued to Oppenheimer & Co. Inc. as Placement Agent in 2007 private financing	Exhibit 4.7 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
4.7	Form of Warrant issued to purchasers in January 2008 registered direct offering	Exhibit 4.1 of our Current Report on Form 8-K dated January 30, 2008, filed with the Commission on January 31, 2008
4.8	Form of Warrant issued to purchasers in June 2008 registered direct offering	Exhibit 4.1 of our Current Report on Form 8-K dated June 27, 2008, filed with the Commission on June 30, 2008
4.9	Form of Warrant issued to Empire Asset Management Company in June 2008 registered direct offering	Exhibit 4.2 of our Current Report on Form 8-K dated June 27, 2008, filed with the Commission on June 30, 2008
4.10	Form of Warrant issued to purchasers in July 2008 registered direct offering	Exhibit 4.1 of our Current Report on Form 8-K dated July 18, 2008, filed with the Commission on July 21, 2008
4.11	Form of Warrant issued to Empire Asset Management Company in July 2008 registered direct offering	Exhibit 4.2 of our Current Report on Form 8-K dated July 18, 2008, filed with the Commission on July 21, 2008
4.12	Form of Senior Secured Promissory Note issued to investors in the November 2008 debt financing	Exhibit 4.1 of our Current Report on Form 8-K dated November 5, 2008, filed with the Commission on November 13, 2008
4.13	Form of Common Stock Purchase Warrant issued to investors and the placement agent in the November 2008 debt financing	Exhibit 4.2 of our Current Report on Form 8-K dated November 5, 2008, filed with the Commission on November 13, 2008
4.14	Convertible Promissory Note dated February 23, 2009 made by Cardium for the benefit of TRC Royalty Company, LLC in the principal amount of \$500,000	Exhibit 4.1 of our Current Report on Form 8-K dated February 23, 2009, filed with the Commission on February 26, 2009
4.15	Form of Senior Subordinated Secured Promissory Note issued to investors in the February 2009 debt financing	Exhibit 4.1 of our Current Report on Form 8-K dated February 27, 2009, filed with the Commission on March 5, 2009
4.16	Form of Common Stock Purchase Warrant issued to investors and the placement agent in the February 2009 debt financing	Exhibit 4.2 of our Current Report on Form 8-K dated February 27, 2009, filed with the Commission on March 5, 2009
4.17	Form of Promissory Note issued to investors in the June 2009 debt financing	Exhibit 4.1 of our Current Report on Form 8-K dated June 11, 2009, filed with the Commission on June 16, 2009



**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
4.18	Form of Common Stock Purchase Warrant issued to investors and the placement agent in the June 2009 debt financing	Exhibit 4.2 of our Current Report on Form 8-K dated June 11, 2009, filed with the Commission on June 16, 2009
4.19	Form of Common Stock Purchase Warrant issued to investors in the September 2009 registered direct offering	Exhibit 4.1 of our Current Report on Form 8-K dated September 14, 2009, filed with the Commission on September 15, 2009
4.20	Form of Common Stock Purchase Warrant issued to investors in the October 2009 registered direct offering	Exhibit 4.1 of our Current Report on Form 8-K dated October 15, 2009, filed with the Commission on October 15, 2009
4.21	Form of Warrant Agreement between Cardium Therapeutics, Inc. and Computershare Trust Company, NA.	Exhibit 4.1 of our Current Report on Form 8-K dated March 15, 2010, filed with the Commission on March 15, 2010.
4.22	Form of Warrant issued to Life Sciences Capital LLC	Exhibit 10.42 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, filed with the Commission on November 14, 2007
10.1	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of August 31, 2005, by and among New York University, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.1 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.2	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of August 31, 2005, by and among Yale University, Schering Aktiengesellschaft and Cardium Therapeutics, Inc.	Exhibit 10.2 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.3	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of July 31, 2005, by and among the Regents of the University of California, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.3 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.4	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of July 31, 2005, by and among the Regents of the University of California, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.4 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.5	Technology Transfer Agreement effective as of October 13, 2005, by and among Schering AG, Berlex, Inc., Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.5 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.6	Amendment to the Exclusive License Agreement for Angiogenesis Gene Therapy effective as of October 20, 2005, between the Regents of the University of California and Cardium Therapeutics, Inc.	Exhibit 10.6 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
10.7	Amendment to License Agreement effective as of October 20, 2005, by and between New York University and Cardium Therapeutics, Inc.	Exhibit 10.7 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.8	Second Amendment to Exclusive License Agreement effective as of October 20, 2005, by and between Yale University and Cardium Therapeutics, Inc.	Exhibit 10.8 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.9	2005 Equity Incentive Plan as adopted effective as of October 20, 2005*	Exhibit 10.9 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.10	Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Christopher Reinhard*	Exhibit 10.10 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.11	First Amendment dated March 16, 2007 to Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Tyler Dylan*	Exhibit 10.39 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed with the Commission on May 15, 2007.
10.12	Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Tyler Dylan*	Exhibit 10.11 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.13	First Amendment dated March 16, 2007 to Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Christopher Reinhard*	Exhibit 10.38 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed with the Commission on May 15, 2007.
10.14	Yale Exclusive License Agreement between Yale University and Schering Aktiengesellschaft dated September 8, 2000	Exhibit 10.13 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the Commission on December 22, 2005
10.15	Research and License Agreement between New York University and Collateral Therapeutics, Inc. dated March 24, 1997 (with amendments dated April 28, 1998 and March 24, 2000)	Exhibit 10.14 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the Commission on December 22, 2005
10.16	Exclusive License Agreement for Angiogenesis Gene Therapy between the Regents of the University of California and Collateral Therapeutics, Inc. dated as of September 27, 1995 (with amendments dated September 19, 1996, June 30, 1997, March 11, 1999 and February 8, 2000)	Exhibit 10.15 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the Commission on December 22, 2005
10.17	Michigan License agreement between the Regents of the University of Michigan and Matrigen, Inc. dated July 13, 1995	Exhibit 10.33 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
10.18	Amendment to License agreement between the Regents of the University of Michigan and Matrigen, Inc. dated August 10, 1995	Exhibit 10.34 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
10.19	Second Amendment to the Michigan License agreement between the Regents of the University of Michigan and Selective Genetics, Inc. dated February 1, 2004	Exhibit 10.35 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
10.20	Third Amendment to Michigan License Agreement between the Regents of the University of Michigan, and Tissue Repair Company, and Cardium Biologics Inc. dated August 10, 2006	Exhibit 10.36 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
10.21	Office Lease by and between Paseo Del Mar CA LLC and Cardium Therapeutics, Inc., effective as of November 19, 2007	Exhibit 10.43 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, filed with the Commission on November 14, 2007
10.22	Form of Securities Purchase Agreement dated January 30, 2008, by and between Cardium Therapeutics, Inc. and each purchaser in the January 2008 registered direct offering (an agreement on substantially this form was signed by each purchaser in the offering)	Exhibit 10.1 of our Current Report on Form 8-K dated January 30, 2008, filed with the Commission on January 31, 2008
10.23	Form of Securities Purchase Agreement dated June 27, 2008, by and between Cardium Therapeutics, Inc. and each purchaser in the June 2008 registered direct offering (an agreement on substantially this form was signed by each purchaser in the offering)	Exhibit 10.1 of our Current Report on Form 8-K dated June 27, 2008, filed with the Commission on June 30, 2008
10.24	Form of Note and Warrant Purchase Agreement, dated as of November 5, 2008, by and among Cardium, Innercool Therapies, Inc., Tissue Repair Company and each investor in the November 2008 debt financing	Exhibit 10.1 of our Current Report on Form 8-K dated November 5, 2008, filed with the Commission on November 13, 2008
10.25	Security Agreement dated as of November 5, 2008, by and among Cardium, Innercool Therapies, Inc., Tissue Repair Company and Robert Marvin as collateral agent	Exhibit 10.2 of our Current Report on Form 8-K dated November 5, 2008, filed with the Commission on November 13, 2008
10.26	Form of Note and Warrant Purchase Agreement, dated as of February 27, 2009, by and among Cardium, Innercool Therapies, Inc., Tissue Repair Company and each investor in the February 2009 debt financing	Exhibit 10.1 of our Current Report on Form 8-K dated February 27, 2009, filed with the Commission on March 5, 2009
10.27	Security Agreement dated as of February 27, 2009, by and among Cardium, Innercool Therapies, Inc., Tissue Repair Company and Dr. Robert Marshall as collateral agent	Exhibit 10.2 of our Current Report on Form 8-K dated February 27, 2009, filed with the Commission on March 5, 2009

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
10.28	Placement Agency Agreement dated February 27, 2009, by and among Cardium, Innercool Therapies, Inc., Tissue Repair Company and Empire Asset Management Company	Exhibit 10.3 of our Current Report on Form 8-K dated February 27, 2009, filed with the Commission on March 5, 2009
10.29	Asset Purchase Agreement dated July 10, 2009, by and among Innercool Therapies, Inc., Cardium Therapeutics, Inc., and Philips Electronics North America Corporation	Exhibit 10.1 of our Current Report on Form 8-K dated July 10, 2009, filed with the Commission on July 15, 2009.
10.30	Letter Agreement dated September 10, 2009, by and between Cardium and Dawson James Securities Inc.	Exhibit 10.2 of our Current Report on Form 8-K dated September 14, 2009, filed with the Commission on September 15, 2009
10.31	Securities Purchase Agreement dated September 14, 2009, by and among Cardium and the investors named therein with respect to the September 2009 registered direct offering.	Exhibit 10.1 of our Current Report on Form 8-K dated September 14, 2009, filed with the Commission on September 15, 2009
10.32	First Amendment to Letter Agreement dated October 15, 2009, by and between Cardium and Dawson James Securities Inc.	Exhibit 10.3 of our Current Report on Form 8-K dated October 15, 2009, filed with the Commission on October 15, 2009
10.33	Securities Purchase Agreement dated October 15, 2009, by and among Cardium and the investors named therein with respect to the October 2009 registered direct offering.	Exhibit 10.1 of our Current Report on Form 8-K dated October 15, 2009, filed with the Commission on October 15, 2009
10.34	Placement Agency Agreement dated February 16, 2010, between Cardium Therapeutics Inc. and Dawson James Securities, Inc.	Exhibit 10.1 of our Current Report on Form 8-K dated February 16, 2010, filed with the Commission on February 18, 2010.
10.35	Sales Agreement September 28, 2010, by and between Cardium Therapeutics Inc. and Brinson Patrick Securities Corporation	Exhibit 10.1 of our Current Report on Form 8-K dated September 28, 2010, filed with the Commission on September 29, 2010.
21	Subsidiaries of the registrant	Filed herewith
23.1	Consent of Marcum LLP	Filed herewith
24.1	Power of Attorney	Included on signature page of this report
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32	Section 1350 Certification	Filed herewith

\* Indicates management contract or compensatory plan or arrangement.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Cardium Therapeutics, Inc., the registrant, has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 15, 2011

CARDIUM THERAPEUTICS, INC.

By: /s/ CHRISTOPHER J. REINHARD  
**Christopher J. Reinhard,**

**Chief Executive Officer**

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby severally constitutes and appoints Christopher J. Reinhard and Tyle Dylan-Hyde, and each of them, his true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Commission, granting unto said attorney-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each said attorneys-in-fact and agents or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of Cardium Therapeutics, Inc., in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CHRISTOPHER J. REINHARD  (Christopher J. Reinhard)	Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	April 15, 2011
/s/ DENNIS M. MULROY  (Dennis M. Mulroy)	Chief Financial Officer (principal financial officer and principal accounting officer)	April 15, 2011
/s/ TYLER M. DYLAN-HYDE  (Tyler M. Dylan-Hyde)	Director	April 15, 2011
/s/ EDWARD W. GABRIELSON	Director	April 15, 2011

Edgar Filing: Cardium Therapeutics, Inc. - Form 10-K

(Edward W. Gabrielson)

/s/ MURRAY H. HUTCHISON

Director

April 15, 2011

(Murray H. Hutchison)

/s/ ANDREW M. LEITCH

Director

April 15, 2011

(Andrew M. Leitch)

/s/ GERALD J. LEWIS

Director

April 15, 2011

(Gerald J. Lewis)

/s/ LON E. OTREMBIA

Director

April 15, 2011

(Lon E. Otremba)