

Cardium Therapeutics, Inc.
Form 10-K
March 16, 2010
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009

Or

**** TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE**
SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File No. 001-33635

CARDIUM THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

12255 El Camino Real, Suite 250

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

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

27-0075787
(IRS Employer Identification No.)

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

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

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

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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 voting and non-voting common equity held by non-affiliates computed as of the last business day of the registrant's most recently completed second quarter was approximately \$73,000,000 (based on the closing sale price of \$1.85 reported by AMEX on June 30, 2009). For this purpose, all of Cardium's officers and directors and each person who owned 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 15, 2010, 77,852,154 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 3, 2010 to be filed on or before April 30, 2010.

Table of Contents

TABLE OF CONTENTS

	Page
<u>SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS</u>	1
<u>PART I</u>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	9
Item 1B. <u>Unresolved Staff Comments</u>	24
Item 2. <u>Properties</u>	24
Item 3. <u>Legal Proceedings</u>	25
Item 4. <u>(Removed and Reserved)</u>	25
<u>PART II</u>	
Item 5. <u>Market for Our Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	26
Item 6. <u>Selected Financial Data</u>	27
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	29
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
Item 8. <u>Financial Statements and Supplementary Data</u>	36
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	63
Item 9A. <u>Controls and Procedures</u>	63
Item 9B. <u>Other Information</u>	66
<u>PART III</u>	
Item 10. <u>Directors, Executive Officers, and Corporate Governance</u>	67
Item 11. <u>Executive Compensation</u>	67
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	67
Item 13. <u>Certain Relationships and Related Transactions and Director Independence</u>	67
Item 14. <u>Principal Accounting Fees and Services</u>	67
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	68
<u>SIGNATURES</u>	75

Table of Contents

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.

Special Note about Forward-Looking Statements

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

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 or key product components, or to provide other services, of an acceptable quality on a 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 intellectual property rights and those of others, including actual or potential competitors;

the outcome of litigation matters;

our personnel, consultants and collaborators;

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

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

1

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).

PART I

ITEM 1. BUSINESS

Overview

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

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, we sold the business to 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 included with this report. After the closing, the name of our Innercool Therapies, Inc. subsidiary 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 Excellagen™ and Excellarate™ product candidates are initially being developed for the potential treatment of chronically non-healing diabetic foot ulcers. Tissue Repair Company is operated as a wholly-owned subsidiary of Cardium.

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

Table of Contents

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 (Journal of American College of 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. We also believe that having such 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

Our 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 filed 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 ExcellagenFXTM, 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 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

Table of Contents

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

Gene Activated Matrix (GAM) Technology

We believe that patient compliance can be a major factor preventing or limiting improved medical outcomes, particularly when repeated administrations are required at a wound site. Tissue Repair Company's Gene Activated Matrix technology is designed to provide a therapeutic level of protein synthesis at a particular site in the body 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).

Table of Contents

Other Biologics Growth Factors for Regenerative Medicine

Biologics and Stem Cells for Regenerative Medicine

A complementary approach to the development of therapeutics for regenerative medicine involves the use of stem cells that can be incorporated into injured tissue like the heart as a means of preventing further damage and promoting healing of the affected organ. In that regard, filings by Cardium related to Ad5IGF-1 also described the potential use of stem cells, such as mesenchymal stem cells or MSCs transfected with an Ad5IGF-1 vector (such as that used in Corgentin), for addressing coronary syndromes such as heart disease or heart attack.

In March 2009, Cardium reported that studies conducted by independent researchers at the University of Cincinnati showed in a preclinical model of heart attack that MSCs transfected with Ad5IGF-1 were effective at promoting angiogenesis within the heart and that the zone of heart attack related tissue damage (the infarct zone) was significantly reduced, and contractile function significantly improved, following administration of Ad5IGF-1 transfected MSCs highlighting the potential value of these therapeutic approaches.

Business Strategy

Strategic Goals

Since December 31, 2008, we (i) completed the sale of Innercool Therapies 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 ExcellagenTM 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.

Following the sale of our Innercool Therapies business, we do not currently have any 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 have been dependent on debt and equity funding to finance our operations. During September and October 2009, we raised net proceeds of approximately \$9.7 million from the sale of common stock and warrants in two registered direct offerings. After year ended December 31, 2009, we raised additional net proceeds of approximately \$10.4 from an additional registered direct offering 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 ExcellagenTM and complete commercial development; candidate Excellagen;

advance the clinical development of ExcellerateTM;

evaluate the potential of GenerxTM to be a cost effective front-line therapy for patients with coronary artery disease in the large markets of newly-industrializing countries, and evaluate partnering opportunities designed to support the potential commercialization;

broaden and expand 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

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

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

Table of Contents

Government Regulation

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

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

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

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

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

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

Table of Contents

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

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

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

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 and medical device 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. Many of these organizations have financial, technical, research, clinical, manufacturing and marketing resources that are greater than ours. If a competing company develops or acquires rights to a more efficient, more effective, or safer competitive therapy for treatment of the same or similar diseases we have targeted, or one that offers significantly lower costs of treatment, our business, financial condition and results of

Table of Contents

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.

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 Good Manufacturing Practice regulations promulgated by the FDA. We may also seek to refine the current manufacturing process and final product formulation to achieve improvements in storage temperatures and the like.

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

Marketing and Sales

Our product candidates must generally undergo testing and development in clinical trials and pre-clinical studies. We do not currently have any 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.

Table of Contents

Intellectual Property

As part of our acquisition of Schering's portfolio of cardiovascular growth factor therapeutic assets, pursuant to a Technology Transfer Agreement entered into between Cardium and Schering, we acquired from Schering a portfolio of methods and compositions directed at the treatment of cardiovascular diseases. In August 2006, we acquired the rights to various technologies and products now part of our Tissue Repair Company subsidiary, including Excellerate. There can be no assurance that our intellectual property assets will 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, 2009 we employed 13 full-time employees and one part-time employee. 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. 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 us 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 other product candidates require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, the 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 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;

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

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;

Table of Contents

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.

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 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

Table of Contents

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. 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, 2009, our accumulated deficit was approximately \$76.2 million, and our cash and cash equivalents were approximately \$3.4 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, 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

Table of Contents

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. The audit opinion accompanying our consolidated financial statements for the year ended December 31, 2009, 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 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;

Table of Contents

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 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-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

Table of Contents

unproven and there is no guarantee that health care providers or patients will be interested in our products even if they are approved for use. Our success will depend in part on our ability to demonstrate sufficient clinical benefits, reliability, safety and cost effectiveness of our product candidates and technology relative to other approaches, as well as on our ability to continue to develop our product candidates to respond to competitive and technological changes. If the market does not accept our products or product candidates, when and if we are able to commercialize them, then we may never become profitable. It is difficult to predict the future growth of our business, if any, and the size of the market for our product candidates because the market and technology are continually evolving. There can be no assurance that our technologies and product candidates will prove superior to technologies and products that may currently be available or may become available in the future or that our technologies or research and development activities will result in any commercially profitable products.

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

Our strategy for the development, testing, manufacturing and commercialization of our product candidates generally relies on establishing and maintaining collaborations with licensors and other third parties. For example, we have various licenses from third parties relating to the use and delivery of our Generx product candidates. We may not be able to maintain or expand these or other licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

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

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

we do not achieve our objectives under our collaboration agreements;

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

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.

Table of Contents

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 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.

Table of Contents

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 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.

Table of Contents

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.

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

Our future success depends on our ability to attract, retain and motivate highly qualified management and scientific and regulatory personnel and advisors. The loss of any of our senior management team, in particular Christopher J. Reinhard, our Chairman of the Board, Chief Executive Officer, President and Treasurer, Tyler M. Dylan-Hyde, our director, Chief Business Officer, General Counsel, Executive Vice President and Secretary, and Dennis M. Mulroy, our Chief Financial Officer, or our vice presidents, or the operating officers of our subsidiaries, could harm our business. We do not maintain any key man life insurance on any of our executive officers.

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

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

Our headquarters are in San Diego, California, and our third party manufacturing and storage facilities in Carlsbad, California, are both located in or near seismic zones, and there is a constant possibility that an earthquake or other natural disaster or resource shortage could be disruptive to our operations and result in delays in our research and development efforts. In the event of a natural or other disaster such as an earthquake, fire, flood or terrorist attack, if our facilities or the equipment in our facilities, or our clinical supplies, are significantly damaged or destroyed, we may not be able to rebuild or relocate our facility or replace any damaged equipment, records or clinical supplies in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

Table of Contents

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

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

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

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

changes and limits in import and export controls;

increases in custom duties and tariffs;

changes in currency exchange rates;

economic and political instability;

changes in government regulations and laws;

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

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

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

Risks Related to Our Intellectual Property and Potential Litigation

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

The success of our operations will depend in part on our ability and that of our licensors 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.

Table of Contents

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

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

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

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

Patents issued and patent applications filed internationally relating to gene therapy 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.

Table of Contents

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.

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.

Table of Contents

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.

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

We have a substantial number of warrants to purchase common stock outstanding. Some of these warrants contain antidilution purchase price protection such that the exercise price is reduced if we issue common stock or common stock equivalents to third parties at a purchase price that is less than the exercise price of the warrants. 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.

Our common stock is currently listed on the NYSE Amex (the Exchange). To maintain that listing, we must continue to comply with various listing standards of the Exchange, as set forth in Part 10 of the Exchange's Company Guide. In December 2008, we received a notice from the staff of the Exchange noting that, based on their review of publicly available information, we did not meet certain of the Exchange's continued listing standards related to the maintenance of a minimum level of stockholders' equity and losses from ongoing

Table of Contents

operations. In January 2009, we submitted a plan of compliance (the Plan) advising the Exchange of the actions taken or to be taken to regain compliance with the Company Guide. In February 2009, our Plan was accepted and in July 2009, following completion of the Philips Transaction, we were informed that Cardium was considered to have regained compliance with the Exchange's requirements, in advance of the June 23, 2010 deadline. On December 28, 2009, the Exchange noted that we were not considered to be in compliance with Section 1003(a)(iv) of the Company Guide because we reported stockholders' equity of less than \$4,000,000 and losses from continuing operations and net losses in three of our most recent fiscal years. With losses from continuing operations and net losses in five of our most recent fiscal years, the stockholders' equity threshold would increase to \$6,000,000. The Exchange asked us to supplement our previously-filed Plan advising the Exchange of the actions we have taken or will take to regain compliance with the Company Guide by June 23, 2010. Prior to the January 27, 2010 deadline, we provided a supplement to the Plan to the Exchange. That supplement was accepted; however, if we are not in compliance with the continued listing standards at the end of the Plan period, or we do not make progress consistent with the Plan during such period, then the Exchange could initiate delisting proceedings. If our common stock was ultimately delisted from the exchange, it would be expected to trade on the OTC Bulletin Board, a regulated quotation service that provides quotes, sale prices and volume information in over-the-counter equity securities which may reduce the liquidity of, and may adversely affect the price of, our common stock. Our common stock was traded on the OTC Bulletin Board until July 2007, when we elected to instead list our shares on the Exchange.

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;

Table of Contents

additions or departures of key personnel;

sales or other transactions involving our common stock; and

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

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

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

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

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

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

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 ¹	July 31, 2013 ²

¹ The monthly base rent increases to \$50,328 in April 2010 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.

² The lease contains an option for one five-year lease renewal.

Table of Contents

ITEM 3. 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, 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.

As of March 16, 2010, 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 sale prices of our common stock as reported by the NYSE Amex for each quarter of the years ended December 31, 2009 and 2008:

	2009		2008	
	High	Low	High	Low
First Quarter	\$ 1.63	\$ 0.40	\$ 2.63	\$ 2.10
Second Quarter	\$ 2.90	\$ 1.31	\$ 2.50	\$ 2.03
Third Quarter	\$ 2.05	\$ 1.61	\$ 2.24	\$ 1.65
Fourth Quarter	\$ 1.96	\$ 0.51	\$ 1.70	\$ 0.48

 Holders

As of March 11, 2010 there were approximately 119 stockholders of record of our common stock. Based on information we receive from brokerage firms in connection with proxy solicitations, we believe that there are approximately 2,800 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, 2009, 2008 and 2007, we did not sell any unregistered securities.

Repurchases

During the year ended December 31, 2009, we did not repurchase any shares of our common stock, nor were any repurchases made on our behalf.

Table of Contents

Performance Graph

The graph below provides a comparison of cumulative total returns for our common stock, the Nasdaq Composite Index, the Nasdaq Biotechnology Index, and the RDG MicroCap Biotechnology Index for the five year period ended December 31, 2009. Please note that the information used to calculate the returns for periods before December 2005 is based on the share price of Aries Ventures Inc. On October 20, 2005, Cardium completed a reverse merger whereby it merged with a wholly-owned subsidiary of Aries. Thereafter, Aries was merged with and into Cardium with Cardium as the surviving entity and successor issuer to Aries. For the period from December 31, 2002 until October 20, 2005, Aries had no business operations. The graph below assumes an investment of \$100 on December 31, 2004 in each of our common stock, and the stock comprising each of the indices shown. Each of the indices assumes that all dividends were reinvested. The graph lines merely connect the prices on the dates indicated and do not reflect fluctuations between those dates.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN

Among Cardium Therapeutics, The NASDAQ Composite Index,
The NASDAQ Biotechnology Index And The RDG MicroCap Biotechnology Index

The stock performance shown above is not indicative of future performance.

The performance information above is not deemed to be filed with the SEC or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed incorporated by reference by any general statement incorporating by reference this report into any filing with the SEC, except to the extent we specifically incorporate this information by reference.

ITEM 6. SELECTED FINANCIAL DATA

The following tables contain certain financial information about the Company, including its subsidiaries. You should review this information together with our audited consolidated financial statements and the notes to the consolidated financial statements included under Item 8 in this report. Our future financial condition and results of operations will vary from our historical financial information below based on a variety of factors. You should carefully review the risks described under Items 1A 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 historical or anticipated results.

Table of Contents**Annual Financial Data**

	Years Ended December 31,				
	2009 ⁽¹⁾	2008 ⁽¹⁾	2007 ⁽¹⁾	2006 ⁽¹⁾	2005
Consolidated Statements of Operations Data:					
Revenues	\$ 444,946	\$ 416,912	\$ 445,958	\$ 71,225	\$
Loss from continuing operations	\$ (16,158,417)	\$ (17,601,990)	\$ (16,885,355)	\$ (13,395,064)	\$ (5,588,288)
Loss from discontinued operation	\$ (1,930,636)	\$ (6,996,068)	\$ (8,436,415)	\$ (5,198,101)	\$
Gain on sale of discontinued operation	\$ (6,408,603)	\$	\$	\$	\$
Net loss	\$ (11,680,450)	\$ (24,598,058)	\$ (25,321,770)	\$ (18,593,165)	\$ (5,441,694)
Net loss per common share basic and diluted					
Net loss from continuing operations	\$ (0.33)	\$ (0.39)	\$ (0.43)	\$ (0.43)	\$ (0.54)
Net income (loss) from discontinued operation	\$ 0.09	\$ (0.16)	\$ (0.21)	\$ (0.16)	\$
Net loss per common share basic and diluted	\$ (0.24)	\$ (0.55)	\$ (0.64)	\$ (0.59)	\$ (0.54)
Weighted average shares outstanding basic and diluted					
	48,976,917	44,978,169	39,311,359	31,308,650	9,992,426

⁽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.

	Years Ended December 31,				
	2009	2008	2007	2006	2005
Consolidated Balance Sheets Data:					
Current assets, net of current liabilities	\$ (3,363,730)	\$ (6,814,721)	\$ 4,592,268	\$ 4,754,127	\$ 21,344,443
Total assets	\$ 5,475,664	\$ 10,296,921	\$ 16,925,689	\$ 14,117,423	\$ 22,351,624
Long-term liabilities, less current portion	\$ 190,114	\$ 195,315	\$ 3,241,992	\$	\$
Total stockholders (deficiency) equity	\$ (2,154,575)	\$ (754,756)	\$ 8,428,305	\$ 11,153,355	\$ 21,738,116

Quarterly Consolidated Financial Data Unaudited

	Year Ended December 31, 2009 ⁽¹⁾	Years Ended December 31,			
		First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues		\$ 18,636	\$ 6,996	\$ 235,917	\$ 183,397
(Loss) income 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 sale of 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

Table of Contents

Year Ended December 31, 2008 ⁽¹⁾	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	\$ 112,203	\$ 262,430	\$ 42,279	\$ 42,279
Loss from operations	\$ (4,666,040)	\$ (4,639,798)	\$ (4,290,914)	\$ (3,557,612)
Loss from continuing operations	\$ (4,593,851)	\$ (4,624,351)	\$ (4,282,886)	\$ (4,100,902)
Loss from discontinued operation	\$ (2,140,277)	\$ (2,010,111)	\$ (1,868,629)	\$ (977,051)
Net loss	\$ (6,734,128)	\$ (6,634,462)	\$ (6,151,515)	\$ (5,077,953)
Net loss per common share basic and diluted	\$ (0.17)	\$ (0.15)	\$ (0.13)	\$ (0.11)
Weighted average shares outstanding basic and diluted	40,709,247	43,629,975	46,603,700	46,930,439

⁽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.

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 three years ended December 31, 2009. 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. Our future financial condition and results of operations will vary from our historical financial condition and results of operations described below based on a variety of factors. You should carefully review the risks described under Item 1A and 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 historical or anticipated 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.

Since December 31, 2008, we (i) completed the sale of Innercool Therapies 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 ExcellaGelTM 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.

Table of Contents

Following the sale of our Innercool Therapies business, we do not currently have any 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. After year ended December 31, 2009, we raised additional net proceeds of approximately \$10.4 from an additional registered direct offering of common stock and warrants.

More detailed information about our products, product candidates, our intended efforts to develop our products and our business strategy is included under Item 1 of this report.

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 Black-Scholes Option Model that we believe are important to the portrayal of our financial condition and results of operations. For the year ended December 31, 2009 expenses related to derivative liabilities were calculated at \$4,563,434 and expenses for stock based compensation was \$909,142. These policies require the application of significant judgment by our management. We base our estimates on our historical experience, industry standards, and various other assumptions that we believe are reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions. An adverse effect on our financial condition, changes in financial condition, and results of operations could occur if circumstances change that alter the various assumptions or conditions used in such estimates or assumptions. If we were to undervalue of 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 or 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 2009 Compared to Fiscal 2008

Tissue Repair Company generated \$444,946 in grant revenue during the year ended December 31, 2009, compared to \$416,912, for the year ended December 31, 2008. The \$28,034 increase was directly attributable to the level of activity expended on the grant until November 2009 when the grant ended.

Research and development expenses for the year ended December 31, 2009 were \$4,302,298 compared to \$11,041,930 for the year ended December 31, 2008. The decrease of \$6,739,632 was primarily due to reductions in Generx (AWARE) Phase 3 clinical trial costs and related clinical support staff reductions as we chose to focus our resources on the MATRIX Phase 2b clinical trial, and costs related to our Excellerate (MATRIX) product candidate which substantially completed its Phase 2b clinical trial prior to fiscal year end.

For the year ended December 31, 2009, general and administrative expenses were \$4,855,582 compared to \$6,529,346 for the year ended December 31, 2008. The \$1,673,764 decrease in general and administrative expenses was mainly due to decreases in payroll related costs, consulting fees, stock option compensation and legal fees.

We derive interest income from the investment of our available cash in various short-term obligations, such as certificates of deposit, commercial paper and money market funds. Interest income for the year ended December 31, 2009 was \$12,160 compared to \$102,201 for the same period last year. The \$90,041 decrease in

Table of Contents

interest income for the year when compared to the same period last year was directly related to the decrease in cash available for investment as we used the proceeds from our equity financings and debt financing to fund operations.

Interest expense for the year ended December 31, 2009 was \$6,339,523 compared to \$549,827 for the year ended December 31, 2008. The \$5,789,696 increase is as a result of the senior secured note financing from November 2008, senior subordinated secured note financing from March 2009 and unsecured note financing from June 2009. For the year ended December 31, 2009 interest expense consisted of \$1,037,196 of interest paid or accrued, \$738,893 of amortization of debt costs, and \$4,563,434 of amortization of warrant value in connection with warrants issued with the debt financings.

Fiscal 2008 Compared to Fiscal 2007

Tissue Repair Company generated \$416,912 in grant revenue during the year ended December 31, 2008, compared to \$445,958, for the year ended December 31, 2007. The \$29,046 decrease was directly attributable to the level of activity expended on the grant. During 2008 the primary focus was on the Excellerate clinical research study.

Research and development expenses for the year ended December 31, 2008 were \$11,041,930 compared to \$10,644,142 for the year ended December 31, 2007. The increase of \$397,788 was primarily due to increased expenses in our efforts to advance our Excellerate product candidate in its Phase 2b clinical trial, offset by reductions in Generx (AWARE) Phase 3 clinical trial costs as spending in the year ended December 31, 2007 included product material and initial start-up costs not required in 2008. In addition we recorded a \$500,000 reversal of research and development bonuses that were accrued at the end of 2007 and not paid. As of December 31, 2007, the Company recorded a liability for discretionary employee and officer bonuses for past performance. The payment of such bonuses was expected to take place sometime in 2008. Given the ongoing difficulties in the financial markets, which made it more challenging and expensive for companies to raise funds, the Compensation Committee of our Board of Directors felt it appropriate to forego the planned payment of these bonuses.

For the year ended December 31, 2008, selling, general and administrative expenses were \$6,529,346 compared to \$7,242,743 for the year ended December 31, 2007. The \$713,397 decrease in selling, general and administrative expenses was mainly due to decreases in professional fees, payroll and payroll related cost with the reversal of \$700,000 in administrative bonuses that were accrued at the end of 2007 and not paid, as noted above, and a significant reduction in our head count in the fourth quarter of 2008 as we moved towards strategic distribution relationships.

We derive interest income from the investment of our available cash in various short-term obligations, such as certificates of deposit, commercial paper and money market funds. Interest income for the year ended December 31, 2008 was \$102,201 compared to \$555,572 for the same period last year. The \$453,371 decrease in interest income for the year when compared to the same period last year was directly related to the decrease in cash available for investment as we used the proceeds from our commercial credit facility, equity financings and debt financing to fund operations.

Interest expense for the year ended December 31, 2008 was \$549,827. There was no interest expense for the year ended December 31, 2007. The increase was a result of our secured debt financing in November 2008.

Liquidity and Capital Resources

Liquidity

As of December 31, 2009 we had \$3,363,665 in cash and cash equivalents. We did not have any accounts receivable, inventory or other assets on our balance sheet at December 31, 2009 that provided us with liquidity. Our working capital was a deficit of \$3,358,458 at December 31, 2009, compared to a deficit of \$1,838,048 at

Table of Contents

December 31, 2008. However, our working capital deficit at December 31, 2009 included \$4,802,882 in derivative liabilities for warrants which we will not have to pay in cash. Excluding the effect of the derivative liabilities our working capital at December 31, 2009 would have been \$1,444,444.

Net cash used in operating activities was \$11,614,343 for the year ended December 31, 2009 compared to \$16,613,779 for the same period last year. The decrease in net cash used in operating activities for the year ended December 31, 2009 was a result of the decrease in company wide spending as we focused on resources on the completion of near-term milestones including the MATRIX clinical study and advancement of Innercool's portfolio of products, each of which provides partnering opportunities.

Our primary source of liquidity has been cash flows from financing activities and in particular proceeds from the sale of our common stock and our debt financing. Net cash provided by financing activities was \$13,875,114 for the year ended December 31, 2009, and was primarily derived from proceeds we received from the sale of our common stock and debt financing, net of issuance costs and the sales of our Innercool business unit, offset by principal debt repayments in the amount of \$10,750,000 during the year. On March 5, 2009 we completed a subordinated secured debt financing for which we received gross proceeds of approximately \$3.5 million before placement agent fees and offering expenses of approximately \$252,000. In June 2009 we completed an unsecured debt financing for which we received aggregate gross proceeds of approximately \$750,000 before placement agent fees and offering expenses of approximately \$50,000. During the third quarter of 2009 we closed the Philips transaction and received net proceeds of approximately \$10.1 million (excluding \$1,125,000 being held in an escrow account). In addition on September 16, 2009 we closed a securities purchase agreement for the sale of 3,000,000 shares of our common stock and 1,500,000 warrants to purchase our common stock in exchange for proceeds of approximately \$4.1 million, net of issuance costs. On October 15, 2009, we sold an aggregate of 4,615,385 shares of our common stock and 3,000,000 warrants to purchase our common stock to certain institutional investors in exchange for proceeds of \$5.6 million, net of issuance costs.

There was no net cash used in investing activities during the year ended December 31, 2009 compared to \$1,681,604 for investing activities during the year ended December 31, 2008.

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, 2009, net cash used in operating activities has been \$69,994,499, net cash provided by financing activities was \$77,617,899, and net cash used in investing activities has been \$4,259,735.

Subsequent to the year ended December 31, 2009 we entered into a financing transaction. 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 common stock purchase 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 initial exercise date. In the aggregate 22,669,980 shares of common stock and warrants to purchase an additional 11,334,990 shares were issued in the offering. The offering resulted in gross proceeds of \$11.3 million, and net proceeds of approximately \$10.4 million after deduction of offering fees and expenses.

Capital Resources

Our primary source of capital is the cash that we generate from the sale of debt or equity securities. We do not currently have any line of credit or other source of capital available to us.

We have generated significant losses from operation to date and anticipate that the negative cash flow from operations will continue for 2010. We raised in excess of \$10 million in capital following the year ended December 31, 2010. We expect that capital will support our operations for at least the next twelve months, during

Table of Contents

which time we hope to complete a strategic licensing agreement or secure the approval and future sales of the Excellagen product family and/or other corporate transaction.

However, if we fail to enter into a significant licensing arrangement or generate sufficient product sales, we will not generate sufficient cash flows to cover our operating expenses. If needed, we intend to secure additional working capital through the sale of additional debt or equity securities. No arrangements or commitments for any such financing are in place at this time, and we cannot give any assurances about the availability or terms of any future financing.

Because of our historic net losses, and our working capital deficit, these conditions raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements contained in this report 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, 2009, 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, 2009:

Contractual Obligations	Total	Payments Due By Period			More than 5 Years
		Less Than 1 Year	1-3 Years	3-5 Years	
Long-Term Debt	\$	\$	\$	\$	\$
Operating Leases	2,245,411	598,903	1,646,508		
Total Obligations	\$ 2,245,411	\$ 598,903	\$ 1,646,508	\$	\$

Recent Accounting Pronouncements

In September 2006, the FASB issued ASC topic 820 (formerly SFAS No. 157), Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value and expands disclosure of fair value measurements. ASC topic 820 is applicable to other accounting pronouncements that require or permit fair value measurements, except those relating to lease accounting, and accordingly does not require any new fair value measurements. Our adoption of the provisions of ASC topic 820 on January 1, 2008, with respect to financial assets and liabilities measured at fair value, did not have an effect on our financial statements for the year ended December 31, 2008.

In December 2007, the FASB issued ASC topic 805 (formerly SFAS No. 141 (revised 2007)), Business Combinations. ASC topic 805 retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. ASC topic 805 is effective for acquisitions occurring in fiscal periods beginning after December 15, 2008 and was required to be adopted by the Company in its first quarter of fiscal 2009. The adoption of ASC topic 805 could have an impact on the accounting for any future acquisition, if one were to occur.

Table of Contents

In December 2007, the FASB issued ASC topic 810 (formerly SFAS No. 160), Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51, Consolidated Financial Statements. ASC topic 810 requires (i) that non-controlling (minority) interests be reported as a component of stockholders' equity, (ii) that net income attributable to the parent and to the non-controlling interest be separately identified in the consolidated statement of operations, (iii) that changes in a parent's ownership interest while the parent retains its controlling interest be accounted for as equity transactions, (iv) that any retained non-controlling equity investment upon the deconsolidation of a subsidiary be initially measured at fair value, and (v) that sufficient disclosures are provided that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. ASC topic 810 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We adopted ASC topic 810 for our fiscal year beginning January 1, 2009, and the adoption did not have any impact on our consolidated financial position, results of operations and cash flows.

In March 2008, the FASB issued ASC topic 815, Statement of Financial Accounting Standards (formerly SFAS No. 161), Disclosures about Derivative Instruments and Hedging Activities. ASC topic 818 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance and cash flows. The adoption of this pronouncement on January 1, 2009 did not have a material impact on our consolidated financial statements.

In April 2008, the FASB issued ASC topic 815, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock and provided guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception and was effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of this pronouncement had a material impact on our consolidated financial statements (See note 6).

Effective January 1, 2009 we adopted ASC topic 820 (formerly FSP FAS 157-3), Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active which clarifies the application in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. ASC topic 820 became effective immediately upon issuance, and its adoption did not have an effect on our financial statements. We currently determine the fair value of our property and equipment when assessing long-lived asset impairments and ASC topic 820 was effective for these fair value assessments as of January 1, 2009.

In April 2009, the FASB issued ASC topic 820 Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly which provides additional guidance for estimating fair value when the volume and level of activity for the asset or liability have significantly decreased. ASC topic 820 also includes guidance on identifying circumstances that indicate a transaction is not orderly and emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. ASC topic 820 was effective for interim and annual reporting periods ending after June 15, 2009, and is applied prospectively. The adoption of this pronouncement had a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued ASC topic 825 (formerly SFAS 107), Interim Disclosures about Fair Value of Financial Instruments, which require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies, as well as in annual financial statements. The adoption of ASC

Table of Contents

topic 825 did not have a material impact on our consolidated financial position, results of operations and cash flows. The carrying value of our cash and cash equivalents approximates fair value because these instruments have original maturities of three months or less. The carrying value of our short-term debt approximates fair value because these instruments now have maturities of less than six months.

In May 2009, the FASB issued ASC topic 855 (formerly SFAS No. 165), *Subsequent Events*. The objective of ASC topic 855 is to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, ASC topic 855 sets forth the period after the balance sheet date during which management should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The requirements of ASC topic 855 should be applied to interim or annual financial periods ending after June 15, 2009. Accordingly, we adopted ASC topic 855 in the second quarter of 2009. Management has evaluated subsequent events through the date of this report.

In June 2009, the FASB issued ASC topic 105 (formerly SFAS No. 168), *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* establishes the FASB Accounting Standards Codification (the *Codification*) to become the source of authoritative accounting principles generally accepted in the United States of America (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of ASC topic 105, the Codification superseded all then-existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become non-authoritative. ASC topic 105 became effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of ASC topic 105 did not have a material impact on our consolidated financial statements and results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to a limited level of market risk, which is the potential loss arising from adverse changes in market rates and prices, such as interest rates, due to the investment of our available cash in various instruments.

The goal of our investment activities is to preserve principal while seeking to increase income received on our investments without significantly increasing risk. In the normal course of business, we employ established policies and procedures to manage our exposure to changes in the fair value of our investments. We generally do not, however, enter into derivatives or other financial instruments for trading or speculative purposes or to otherwise manage our exposure to interest rate changes. Generally, we seek to limit our exposure to risk by investing substantially in short-term, investment grade securities, such as commercial paper, certificates of deposit and money market funds. The amount of interest income we receive on our investments will vary with changes in the general level of interest rates in the United States, generally decreasing as interest rates decrease and increasing as interest rates increase.

While we cannot predict with any certainty our future exposure to fluctuations in interest rates or other market risks or the impact, if any, such fluctuations may have on our future business, consolidated financial condition, results of operations or cash flows, due to the short-term, investment grade nature of our investments, we do not believe our exposure to market risk from our investments is material.

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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2009 and for the period from December 22, 2003 (inception) through December 31, 2009. 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, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2009 and for the period from December 22, 2003 (date of inception) through December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for certain convertible debt and equity instruments (Note 6) effective January 1, 2009.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As more fully described in Note 1, the Company has had recurring operating losses since its inception and must raise additional capital from external sources in order to sustain the 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cardium Therapeutics, Inc. and subsidiaries' internal control over financial reporting as December 31, 2009, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report, dated March 16, 2010, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Marcum LLP

Marcum LLP

March 16, 2010

New York, New York

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

	December 31,	
	2009	2008
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,363,665	\$ 1,102,894
Accounts receivable	115,138	42,279
Deferred financing costs, net		432,966
Prepaid expenses and other assets	40,384	76,202
Restricted cash	562,500	
Current assets of business held for sale		7,363,973
Total current assets	4,081,687	9,018,314
Restricted cash	862,500	400,000
Property and equipment, net	351,539	746,169
Deposits and other long term assets	179,938	132,438
Total assets	\$ 5,475,664	\$ 10,296,921
Liabilities and Stockholders Deficiency		
Current liabilities:		
Accounts payable	\$ 2,300,786	\$ 3,359,152
Accrued liabilities	336,457	1,332,448
Current liabilities of business held for sale		2,127,986
Derivative liabilities fair value of warrants	4,802,882	
Short-term debt, net of debt discount of \$1,963,224 at December 31, 2008		4,036,776
Current liabilities	7,440,125	10,856,362
Deferred rent	190,114	195,315
Total liabilities	7,630,239	11,051,677
Commitments and contingencies		
Stockholders deficiency:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; issued and outstanding 55,182,174 at December 31, 2009 and 46,930,439 at December 31, 2008	5,518	4,693
Additional paid-in capital	74,065,539	73,199,199
Deficit accumulated during development stage	(76,225,632)	(73,958,648)
Total stockholders deficiency	(2,154,575)	(754,756)
Total liabilities and stockholders deficiency	\$ 5,475,664	\$ 10,296,921

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 December 22, 2003 (Inception) to December 31, 2009
	2009	2008	2007	
Revenues				
Grant revenues	\$ 444,946	\$ 416,912	\$ 445,958	\$ 1,378,681
Operating expenses				
Research and development	4,302,298	11,041,930	10,644,142	36,478,310
General and administrative	4,855,582	6,529,346	7,242,743	27,911,549
Total operating expenses	9,157,880	17,571,276	17,886,885	