

Taxus Cardium Pharmaceuticals Group Inc.  
Form 10-K  
April 15, 2014  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

001-33635

(Commission file number)

**TAXUS CARDIUM PHARMACEUTICALS GROUP INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State of incorporation)

11750 Sorrento Valley Rd., Suite 250

San Diego, California 92121  
(Address of principal executive offices)

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

None

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

Common Stock, par value \$0.0001 per share

27-0075787  
(IRS Employer Identification No.)

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

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

## Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

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

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

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

The aggregate market value of common equity held by non-affiliates, computed on the basis of the closing sale price for the common stock as reported on the NYSE MKT on June 28, 2013, was \$8.7 million. Shares of common stock held by executive officers, directors and by persons who own 10% or more of the outstanding common stock of the registrant have been excluded for purposes of the foregoing calculation in that such persons may be deemed to be affiliates. This does not reflect a determination that such persons are affiliates for any other purpose.

As of March 30, 2014, 9,652,710 shares of the registrant's common stock were outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K incorporates by reference portions of the registrant's definitive proxy statement for its Annual Meeting of Stockholders to be filed on or before April 30, 2014.

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>EXPLANATORY NOTE</u>	1
<u>SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS</u>	1
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	16
Item 1B. <u>Unresolved Staff Comments</u>	30
Item 2. <u>Properties</u>	30
Item 3. <u>Legal Proceedings</u>	30
Item 4. <u>Mine Safety Disclosures</u>	30
<b><u>PART II</u></b>	
Item 5. <u>Market for Our Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	31
Item 6. <u>Selected Financial Data</u>	32
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	32
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	38
Item 8. <u>Financial Statements and Supplementary Data</u>	39
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	65
Item 9A. <u>Controls and Procedures</u>	65
Item 9B. <u>Other Information</u>	66
<b><u>PART III</u></b>	
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
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	68
<b><u>SIGNATURES</u></b>	73

**Table of Contents**

**EXPLANATORY NOTE**

Unless the context requires otherwise, all references in this report to the Company, Taxus Cardium, Cardium, we, our, and us refer to Taxus Cardium Pharmaceuticals Group Inc. (formerly Cardium Therapeutics, Inc.) and, as applicable, its wholly-owned subsidiaries Tissue Repair Company, To Go Brands, Inc. and LifeAgain Insurance Solutions, Inc.

Effective July 18, 2013 we effected a reverse split of our outstanding common stock, par value \$0.0001 per share, in a ratio of 1 for 20. All common stock and per share amounts included in this report have been retroactively adjusted to reflect a 1 for 20 reverse stock split, as if such split had been effective at the beginning of the period reported.

**SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS**

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

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

planned development pathways and potential commercialization activities or opportunities;

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

our ability to increase revenues, and raise sufficient financing to meet our working capital requirements;

our beliefs and opinions about the safety and efficacy of our products and product candidates and the anticipated results of our clinical studies and trials;

our ability to enter into acceptable relationships with one or more contract manufacturers or other service providers on which we may depend, and the ability of such contract manufacturers or other service providers to manufacture biologics, devices, nutraceuticals or other key products or components, or to provide other services, of an acceptable quality on a timely and cost-effective basis;

our ability to enter into acceptable relationships with one or more development or commercialization partners to advance the commercialization of new products and product candidates and the timing of any product launches;

our growth, expansion and acquisition strategies, the success of such strategies, and the benefits we believe can be derived from such strategies;

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

**Table of Contents**

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

the outcome of litigation matters;

the anticipated activities of our personnel, consultants and collaborators;

expectations concerning our operations outside the United States;

current and future economic and political conditions;

overall industry and market performance;

the impact of new accounting pronouncements;

management's goals and plans for future operations; and

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

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

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Taxus Cardium Pharmaceuticals Group is a development-stage regenerative medicine biotechnology company. We are focused on the development of advanced regenerative therapeutics designed to promote the activation and growth of (1) microvascular circulation to enhance perfusion of ischemic cardiac tissue as a potential treatment for heart disease; and (2) granulation tissue as a treatment for chronic non-healing wounds. We have a commercial FDA-cleared wound care product, a late clinical stage cardiovascular gene therapy product candidate and corresponding technology platforms as outlined below. We also own non-core interests in the Healthy Brands Collective, a health products company, and LifeAgain Insurance Solutions, Inc., an advanced medical data analytics business.

<b>Lead Product</b>	<b>Technology Platform</b>	<b>Formulation</b>	<b>Status</b>
Excellagen®	Advanced Tissue Regeneration for Wounds &	Aseptic Pharmaceutically- Formulated Fibrillar	Initial Product FDA-Cleared
Commercial			

## Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

Product	Biologics Delivery Platform	Collagen	
Generx®	Gene Therapy		
Product	Cardiovascular	Ad5FGF-4 DNA Construct	Phase 3 Registration Study
Candidate	Growth Factor Therapeutics		

Our business model is designed to create a portfolio of multiple opportunities for success while avoiding reliance on any single technology platform or product type, and to leverage our skills in late-stage product development in order to bridge the critical gap between promising new technologies and product opportunities that are ready for commercialization. Consistent with our long-term strategy, we intend to consider various corporate development transactions designed to place our products or product candidates into larger organizations or with

## **Table of Contents**

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.

Based on our recent sale of the Company's non-core health sciences business To Go Brands® and the commercial market launch of the first program under the LifeAgain® advanced medical data analytics platform, we now plan to primarily focus on the clinical and commercial development of our core biotechnology assets and technology platforms as described above. Our business strategy focuses on achieving key milestones with the potential to offer significant valuation inflection points of our core technology assets, as well as asset sales or other monetizations of Cardium's non-core investments. The key elements of our strategy include:

The advancement of our ASPIRE international Phase 3 registration clinical study for Generx® which is currently underway in the Russian Federation, and the release of findings from interim data analysis in mid-2014. With clinical success, the Company plans to meet with the U.S. FDA to seek harmonization between the international clinical study with Cardium's already FDA-cleared Generx Phase 3 clinical study in an effort to advance U.S.-based clinical studies supported by a strategic partner.

Strategically partner and monetize our FDA-cleared pharmaceutically formulated collagen commercial wound care product Excellagen® for select U.S.-based vertical market channels, and build on Cardium's capabilities and resources to leverage Excellagen as an advanced regenerative medicine delivery platform by identifying innovative product extensions for tissue regeneration based on stem cells, biologics, peptides and/or small molecule drugs for future development. Consistent with the Company's long-term business strategy, as previously reported, Taxus Cardium does not plan to establish an internal marketing and sales force to directly support the commercialization of Excellagen, but continues to credentialize Excellagen in preparation for the completion of strategic partnerings for various vertical channel market opportunities or asset monetization. The Company has continued to pursue a CE mark certification for Excellagen, has fully responded to all information requested by the notified body, and looks forward to completing this process. The Excellagen website is [www.excellagen.com](http://www.excellagen.com).

Advance the commercialization of our non-core LifeAgain advanced medical data analytics business investment, which is focused on the development, marketing and sale of survivable risk term life insurance for cancer survivors or others with medical conditions who are currently considered uninsurable based on traditional underwriting standards. We may seek to support the growth and development of this non-core business and technology platform through the sale of a minority stake in our LifeAgain business to a strategic partner or financial investors. The LifeAgain website address is [www.lifeagain.com](http://www.lifeagain.com).

Monetize our equity stake in Cardium's non-core Healthy Brands Collective Cell-nique Corporation investment. We acquired this investment through the recent sale of our To Go Brands® health sciences business through an asset exchange for a preferred equity position in Healthy Brands. Healthy Brands has been making significant acquisitions and has previously reported plans to move forward as a public company as its current businesses advance and grow through further acquisition. The Healthy Brands Collective website address is [www.healthybrandsco.com](http://www.healthybrandsco.com).

Advance our strategic cooperation agreement with Shanxi Taxus Pharmaceuticals Ltd., a strategic Chinese investor, which includes the evaluation of opportunities to distribute our Excellagen product and Generx product candidate in China, and distribution of Shanxi Taxus Pharmaceutical Ltd.'s oncology related products in the United States.

Deploy capital strategically to develop our portfolio of product candidates and create shareholder value.



## **Table of Contents**

### **Core Biotechnology Focus**

#### **Generx® [Ad5FGF-4]**

The Company's Cardium Therapeutics operating unit is a leader in the field of cardiovascular gene therapy. Generx (alferminogene tadenovec), Cardium's lead Phase 3 clinical study product candidate, is a transformative disease-modifying angiogenic gene therapy growth factor therapeutic that is being developed to promote the growth of cardiac microvascular circulation to enhance perfusion (blood flow) for patients with advanced coronary artery disease.

Generx is designed for the potential treatment of patients with Cardiac Microvascular Insufficiency or CMI due to advanced coronary artery disease. CMI is a principal cause of Coronary Microvascular Dysfunction (CMD), a well-recognized clinical condition characterized by functional and structural abnormalities of the microvasculature (smaller blood vessels of the heart), which leads to myocardial ischemia and angina pectoris in the absence of large artery/obstructive disease. CMD, which is also sometimes referred to as microvascular angina, frequently cannot be addressed using traditional surgical approaches such as coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI, i.e. angioplasty and stents). In particular, many patients (1) have coronary artery disease that is not limited or localized to large vessels, (2) continue to experience angina after CABG or PCI, and/or (3) are not suitable candidates for surgical interventions.

Generx represents a new class of therapeutic designed to address a large and unmet medical need among patients with heart disease. It is estimated that 12% of patients with obstructive coronary artery disease continue to experience angina because their underlying medical condition is not fully addressed or cannot be resolved by chronic drugs or surgical/mechanical interventions. In addition, a recent meta-analysis reported that approximately 20% of patients who have a coronary angiography due to ongoing angina do not have obvious large vessel disease, a condition generally referred to as Cardiac Syndrome X, many of whom are presumed to have coronary disease that is diffuse and/or affects smaller vessels within the heart that are not reachable through surgical intervention. Generx is designed to be a one-time non-surgical treatment that may help many of such patients by directly addressing their underlying microvascular angina, as well as providing a non-surgical option for patients in whom coronary intervention is either contraindicated or not desirable.

Myocardial ischemia, including that associated with CMI, can be effectively diagnosed and its potential treatment quantified using SPECT imaging (Single-photon emission computed tomography). SPECT has both diagnostic and prognostic value in the management of patients with coronary artery disease because it identifies and quantitatively measures regions of the heart muscle that are at greatest risk during periods of ischemia, such as that brought on during exertion. Cardium believes that other catheter-based diagnostic techniques including catheter-based imaging diagnostics to measure fractional flow reserve and washout collaterometry will be further developed, which may enhance and broaden clinical adoption of non-surgical Generx angiogenesis therapy following initial Generx registration. Cardium believes that Generx therapy may also apply to patients with Cardiac Syndrome X, which is also characterized by microvascular dysfunction.

Based on the data from four completed clinical studies, Generx appears to be safe and well tolerated and capable of improving myocardial perfusion, as measured by validated diagnostic Single-Photon Emission Computed Tomography or SPECT imaging, in patients with Reversible Perfusion Defect Size or RPDS of greater than 9%. Generx also improved exercise tolerance time or ETT, based on an analysis of pre-specified patient sub-groups with stable angina pectoris due to advanced coronary artery disease who were unresponsive to optimal medical therapy and are not considered suitable candidates for traditional coronary artery by-pass surgery, angioplasty and/or stenting.

Upon completion of the current ASPIRE international clinical study, data from the our five Generx clinical studies will represent one of the largest clinical and regulatory dossiers for a cardiac gene therapy product candidate in the world covering the treatment of over 750 patients in the United States, Canada, South America Western Europe and the Russian Federation at over 100 medical centers.

## **Table of Contents**

In December 2013, we reported encouraging initial positive findings from our ASPIRE international clinical study, which is consistent with the results obtained in our AGENT Phase 2a clinical study which showed that Generx appeared to be safe and well tolerated and that observed effects for patients with advanced coronary artery disease receiving Generx were similar in magnitude to those reported in the medical literature for patients undergoing surgical revascularization procedures such as cardiac by-pass surgery, or angioplasty and stenting, as measured by improvements of reversible perfusion defects of comparable size following such procedures. We expect to be in a position to provide findings from an interim data analysis in mid-2014, to support the advancement and completion of the Generx international clinical study in Russia, which could then support advancement of other studies and product development efforts in the U.S. and elsewhere.

### ***Coronary Artery Disease Market Data and Potential Economic Opportunity***

According to the Centers for Disease Control and Prevention, heart disease is the leading cause of death for both men and women in the U.S. and the industrialized world. In the U.S. the American Heart Association (AHA) reports that there are approximately 15.4 million patients with coronary artery disease, and that the lifetime risk of developing the coronary heart disease after 40 years of age is 49% for men and 32% for women. The AHA reports there are currently 7.8 million Americans that have been diagnosed with angina pectoris due to coronary artery disease, and it is estimated that approximately 12% of patients with angina are unresponsive to optimal medical therapy and are considered not suitable for coronary artery bypass surgery and angioplasty and stenting. In addition, the AHA reports that each year there are over 2.4 million percutaneous interventional procedures, inpatient cardiac by-pass surgeries and diagnostic cardiac catheterizations in the U.S. Likewise, cardiovascular disease is the leading cause of death in the Russian Federation and other countries in the Commonwealth of Independent States (CIS). However, comparative health statistics show that in the Russian Federation there is an early onset of heart disease in the general population, and the mortality rate is even more severe than in the U.S. For example, the current average life expectancy for males in the U.S. is 76 years of age in comparison to 64 years of age in Russia. The U.S. cardiovascular death rate for males is 80 per 100,000 in the general population compared to almost 300 per 100,000 in the Russian Federation. The cardiovascular death rates in certain countries of the CIS are even more severe than in the Russian Federation and are reported to exceed 400 per 100,000 in the general population, over five times the U.S. cardiovascular death rate.

Of the approximately 7.7 million Americans with symptomatic angina pectoris, the Cleveland Clinic Foundation reports that approximately 12% (i.e. more than 900,000 patients) are relatively unresponsive to optimal medical therapy and are considered not suitable for coronary artery bypass surgery and angioplasty and stenting. If the safety and effectiveness of Generx continue to be demonstrated in clinical trials, it could potentially be labeled for the treatment of this very significant patient population. Overall, we project that this patient population could represent a \$3.0 billion addressable market opportunity in the United States, and is significantly larger when considered on a global basis given the large and increasing number of patients worldwide who are affected by coronary artery disease.

Cardium's commercialization program has also established a six year shelf life for Generx based on validated real time cGMP studies validated studies conducted by Cardium researchers. As a result, Cardium anticipates that Generx would be campaign-manufactured in large quantity and held for marketing, sale and distribution during the six year stability period by SAFC, our cGMP contract manufacturer which is located in Carlsbad, California. This facility has the capacity to scale the manufacture of Generx to larger batch quantities (up to approximately 2.0 million doses annually) without the need for significant additional capital investment or major process technology engineering. This flexibility allows Cardium to manufacture Generx at a highly economical direct cost, which could potentially yield economic gross margins that would be approximately equivalent to a small molecule drug model, as opposed to many traditional biologic products having much higher costs of manufacture. This would represent a significant commercial advantage in the market, since cost per dose could be many fold lower than that typically associated with the manufacture of complex donor-based autologous cell therapies and similar approaches currently under development by other biotechnology companies for cardiovascular applications.

## **Table of Contents**

### ***How Does Generx Work?***

Generx is designed to be administered to patients as a single non-surgical treatment during a standard catheter-based procedure by an interventional cardiologist in an out-patient setting using well established diagnostic angiography. Generx is an adenovector (serotype 5) DNA-based gene therapy construct that encodes the Fibroblast Growth Factor-4 (FGF-4) gene. Following administration by a catheter into the three major coronary arteries of the heart, Generx is designed to allow the cellular expression of FGF-4 protein which has been shown to stimulate the release and action of other angiogenic growth factors including Platelet-Derived Growth Factor (PDGF), Hepatocyte Growth Factor (HGF) and Vascular Endothelial Growth Factor (VEGF). This process is believed to orchestrate and promote the growth of cardiac microvascular circulation (a functional collateral network) in ischemic cardiac tissue. Cardium's methods of gene therapy utilize an intra-coronary angioplasty balloon catheter that produces transient myocardial ischemia. The induction of transient ischemia during intra-coronary Generx administration, together with the introduction of nitroglycerin, significantly facilitate the transfection of Generx into heart cells, apparently via enhanced penetration through microvessel endothelium and upregulation of Cocksackie-Adenovirus Receptor or CAR. Company-sponsored research demonstrates that Generx has the capacity to promote and enhance cardiac microvascular circulation through the formation of new capillary vessels, a process referred to as angiogenesis, as well as enlargement of pre-existing collateral arterioles, a process referred to as arteriogenesis.

### ***Generx Clinical Development Strategy***

Generx has been cleared by the U.S. FDA for a Phase 3 clinical study, and has also been cleared for a Phase 3 registration study in the Russian Federation, the international clinical study called ASPIRE. In 2012, Cardium initiated the ASPIRE study, which is expected to involve up to 100 patients with myocardial ischemia, defined as patients with a reversible perfusion defect of 9% or greater based on SPECT imaging. The international study is a randomized, multi-center study with two parallel arms conducted at leading medical centers in Moscow and Novosibirsk to supplement previously-obtained data from the four prior clinical studies. The study's primary efficacy endpoint is improvement in Reversible Perfusion Defect Size or RPDS, as measured by SPECT imaging eight weeks following Generx administration

In December 2013, we reported encouraging initial positive findings from the ASPIRE international clinical study, which is consistent with the results obtained in the AGENT Phase 2a clinical study which showed that Generx appeared to be safe and well tolerated and that observed effects for patients with advanced coronary artery disease receiving Generx were similar in magnitude to those reported in the medical literature for patients undergoing surgical revascularization procedures such as cardiac by-pass surgery, or angioplasty and stenting, as measured by improvements of reversible perfusion defects of comparable size following such procedures. We expect to be in a position to provide findings from an interim data analysis in mid-2014, which could then support completion of the ASPIRE registration study in Russia, as well as other studies and product development efforts in the U.S. and elsewhere.

If we achieve clinical success in the current international clinical study, we plan to secure initial regulatory approval and enter into a strategic partnership to have Generx marketed and sold in the Russian Federation, as well as other countries in the CIS. We also plan to pursue the registration of Generx in other international markets based on the extensive Generx clinical database and regulatory dossier which includes the safety and efficacy data derived from the five clinical studies in nine countries. In addition, we plan to meet with the U.S. FDA to discuss the Generx registration in the Russian Federation and seek to harmonize the clinical study design of the international clinical study with the U.S. clinical study in concert with a strategic partner.

### ***Generx Clinical Study Data Summary***

Upon completion of the international clinical study, Generx will have been the subject of five randomized and controlled multi-center clinical studies involving approximately 750 patients with advanced coronary artery disease at over 100 medical centers in the United States, Canada, Western Europe, South America and the

## **Table of Contents**

Russian Federation. The study results from each of the completed AGENT clinical studies have been published in peer-reviewed journals and have supported, from a safety and preliminary efficacy perspective, the clearances by the U.S. FDA and the Russian Federation Health Ministry for Cardium to conduct two Phase 3 clinical studies. With completion of the current international clinical study, data from the five clinical studies will represent one of the largest clinical and regulatory dossiers in the world. In summary, based on the clinical data from the four completed clinical studies, Generx appears to be safe and well tolerated and capable of improving myocardial perfusion, as measured by SPECT imaging, in patients with myocardial ischemia due to advanced coronary artery disease. Generx also improves ETT based on an analysis of pre-specified patient sub-groups with stable angina pectoris due to advanced coronary artery disease who are not optimal candidates for traditional coronary artery by-pass surgery, angioplasty and/or stenting.

The international clinical study was designed based on positive results from the prior Generx Phase 2a clinical study (Grines et al., J Am Coll Cardiol 2003; 42:1339-47) showing that Generx improved myocardial blood flow in the ischemic region of the hearts of men and women following a single intracoronary infusion as measured by the objective efficacy endpoint of SPECT imaging. As noted in the publication, the mean change observed in Generx-treated patients was a 4.2% absolute reduction (which represents a 20% relative reduction) in the reversible perfusion defect size from baseline at eight weeks ( $p < 0.001$ ), while the placebo group showed only a 1.6% absolute reduction from baseline (not significant) at eight weeks following treatment. The observed treatment effect for patients receiving Generx was similar in magnitude to that reported in the literature for patients undergoing angioplasty/stent or revascularization procedures with reversible perfusion defects of comparable size at one year following these procedures.

An independent long-term prospective study published in Circulation (Meier et al, Circ. 2007; 116:975-983) provided key evidence indicating that men and women with more recruitable collateral circulation have a better chance of surviving a heart attack than patients who have less developed collateral circulation. This important study quantitatively evaluated coronary collateral blood flow in 845 patients with coronary artery disease during a 10-year follow-up period and showed that long-term cardiac mortality was approximately 66% lower in patients with a highly developed collateral vessel blood supply ( $p = 0.019$ ). For the first time, this study showed the importance of collateral circulation beyond simply the relief of angina and provided further support of the potential for long term benefits from angiogenic therapy, the primary premise behind Generx's therapeutic potential.

Cedars-Sinai Medical Center Nuclear Cardiology Core Laboratory is the core lab responsible for data collection and quality control of SPECT data from the Russian-based clinical study sites. This Center is considered to be one of the world's leading core laboratories for SPECT imaging. It has operated as an independent core laboratory for over 20 years and has participated in numerous multi-center clinical trials, including the recent COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) clinical study enrolling over 3,200 patients at over 60 clinical study sites. The scope of work performed by the Cedars-Sinai Core Laboratory includes imaging protocol design, quality assurance and control, interpretation, and data analysis of nuclear myocardial perfusion studies. The Core Laboratory is led by Daniel S. Berman, M.D., who has been the head of Nuclear Cardiology at Cedars-Sinai Medical Center for over 30 years, and is the Associate Director for Cardiac Imaging at the Cedars-Sinai Heart Institute. Dr. Berman is considered a leader in the field of SPECT myocardial perfusion imaging and has authored over 300 original peer-reviewed manuscripts dealing with non-invasive cardiac imaging.

### ***Generx Technological Advances Supporting the Enhanced Delivery of Cardiovascular Therapy***

Cardium researchers have developed an enhanced method of delivering Generx and potentially other agents to the heart, which has been tested in preclinical studies conducted at Emory University and is now being employed in the ASPIRE human clinical study. Cardium's innovative technique employs transient cardiac ischemia, which has been found to dramatically enhance gene delivery and transfection efficiency after one-time intracoronary administration of adenovector in mammalian hearts. Two consecutive but brief periods of coronary

## **Table of Contents**

artery occlusion combined with co-administration of nitroglycerin increased both adenovector presence (measured by PCR) and transgene expression (assessed by luciferase activity) by over two orders of magnitude (>100 fold) in the heart, as compared to prior intracoronary artery delivery methods. Preclinical testing using Cardium's new approach, which was published in 2012 (Shi et al., *Human Gene Therapy*, 23(3): 204-212), effectively confirmed that the new technique for adenovector gene delivery in the heart can be used to dramatically boost vector delivery and therefore gene transfer. By enhancing uptake even in patients with less severe forms of disease and ischemia, it would be expected to reduce response variability and allow for the potential treatment of patients with a broader range of associated coronary artery disease. The new treatment protocols for Cardium's international clinical study have been developed to use this improved knowledge about induced transient ischemia techniques to enhance the non-surgical, catheter-based delivery of Generx to the heart.

### ***Generx Manufacturing Capabilities and Simplified Product Handling***

Cardium has also been actively advancing its Generx product candidate's engineering and process technology in preparation for potential commercialization. The Company has successfully transferred a refined, improved and fully-validated manufacturing process from Schering AG (now part of Bayer AG) to SAFC, the custom manufacturing and services business unit of Sigma-Aldrich Corporation, a global specialty chemicals and biologics supplier, located in Carlsbad, California. As a result of the rigorous technical transfer process, important process improvements were achieved enabling much higher manufacturing process yields.

Generx's long-term product stability (at the current storage temperature of -70°C) has been established and validated at a minimum of six years making it possible to manufacture Generx in large, cost effective batch sizes. Based on the current Generx validated cGMP manufacturing processes, and a recommended dosage of  $6 \times 10^9$  viral particles per treatment, Cardium believes that it has the capacity to scale the manufacture of Generx to larger batch quantities (up to approximately 2.0 million doses annually) without the need for significant additional capital investment or major process technology engineering. Due to the validated six year stability of Generx, Cardium anticipates Generx can be campaign manufactured in large quantity and held for marketing, sale and distribution during the stability period. This flexibility will allow Cardium to manufacture Generx at a highly economical direct cost, which could potentially yield economic gross margins that would be approximately equivalent to a favorable classic small molecule drug model.

In addition, the dose preparation process for Generx has been simplified through the integration of a fully-validated, closed-system drug transfer process incorporating the use of the Becton Dickinson PhaSeal® System passive safety technology to streamline and simplify the cath-lab preparation process and eliminating the need to prepare Generx in a sterile, biological safety hood. The use of the PhaSeal system has now been integrated into the international clinical study and will be utilized for Generx commercialization. The Company has also developed a new and unique, fully-validated bio-activity performance-based, quality release assay to measure and evaluate the pro-angiogenic potency of each newly manufactured batch of Generx.

### **Excellagen®**

Excellagen is an FDA-cleared, pharmaceutically-formulated acellular biological modulator that has been engineered to activate and promote wound healing through the growth of granulation tissue in chronic non-healing diabetic foot, pressure and venous ulcers, as well as other dermal wounds (including traumatic and surgical wounds). We believe that Excellagen is a cost-effective, easy to use professional product that has now been classified for reimbursement purposes by the U.S. Centers for Medicare and Medicaid Services as a unique skin substitute - a designation which is consistent with other forms of skin substitutes including living skin equivalents Dermagraft® and Apligraf® and human dermal and amnion placental tissue-based products including Graftjacket® and EpiFix®.

## **Table of Contents**

Excellagen is prepared as a sterile professional-use syringe, physiologically formulated homogenate of purified atelopeptide bovine dermal collagen (Type I) in its native 3-dimensional fibrillar configuration, providing a structural scaffold for chemotaxis, cellular adhesion, migration and proliferation to promote wound healing. Cardium research and published scientific literature also support Excellagen's capability to activate blood platelets to release growth factors, including Platelet-Derived Growth Factor (PDGF), an important endogenous wound healing mediator.

In a U.S.-based, multi-center, randomized and controlled clinical study (the Matrix study), a single protocol specified application of Excellagen was found to accelerate the rate of tissue granulation at one week by 204% compared to standard of care ( $p=0.018$ ), and this accelerated healing response continued for two weeks (104%;  $p=0.032$ ). While Excellagen is FDA-cleared for use in a broad array of dermal wounds, initial clinical focus has been on the treatment of chronic non-healing diabetic foot, pressure and venous ulcers. In December 2013, the Centers for Medicare and Medicaid Services (CMS) made a final determination to assign Excellagen a unique, product-specific Q code, classifying Excellagen as a skin substitute, after reviewing Cardium's HCPCS Level II Code Modification Request and subsequent supporting information for Excellagen as a wound care product indicated for the treatment of hard to heal wounds such as diabetic foot ulcers and pressure ulcers as well as other dermal wounds. This new reimbursement code took effect January 1, 2014, although a reimbursement rate has not yet been determined.

In addition to its application for dermal wounds, Excellagen's pharmaceutically formulated collagen has been engineered to serve as a biologics delivery platform, potentially enabling multiple device, tissue scaffolding and therapeutic product extensions for tissue regeneration based on stem cells, biologics, peptides and small molecule drugs. This technological attribute of Excellagen is expected to enable product extensions, which could be co-developed for commercialization with a variety of different strategic partners.

Excellagen is Cardium's initial commercial product developed based on technology through its acquisition of the Tissue Repair Company. Consistent with Cardium's business strategy, Excellagen has been substantially credentialized and we are now seeking strategic partners to market and sell Excellagen in the United States and elsewhere through multiple marketing channels. Consistent with the Company's long-term business strategy, as previously reported, Taxus Cardium does not plan to establish an internal marketing and sales force to directly support the commercialization of Excellagen, but continues to credentialize Excellagen in preparation for the completion of strategic partnerships for various vertical channel market opportunities or asset monetization. The Company has continued to pursue a CE mark certification for Excellagen, has fully responded to all information requested by the notified body, and looks forward to completing this process.

### ***Recent Excellagen Wound Healing Case Studies***

We have recently completed two clinical evaluation studies in collaboration with wound care practitioners to assess the use of Excellagen to treat chronic pressure ulcers in elderly patients in residence at long-term care facilities. The wounds studied in these patients were of over 18 months in duration and located in hard to treat areas, including the buttocks or coccyx, the most prevalent locations for pressure ulcers. Following weekly treatment regimens consisting of sharp debridement immediately followed by application of Excellagen, the three case study patients exhibited robust formation of new granulation tissue within their previously non-healing pressure ulcers, which led to either complete wound closure or substantial wound reduction after only 5 to 6 weeks of treatment. The results of this study, entitled "Serial Sharp Debridement and Formulated Collagen Gel to Treat Pressure Ulcers in Elderly Long-term Care Patients", was published in the November 2013 issue of the peer-reviewed journal *Ostomy Wound Management* (*Ostomy Wound Manage.* 2013;59(11):43-49). The second case study involved elderly long-term care facility patients with chronic (>12 months duration) pressure ulcers located on the heel, the second most prevalent location for pressure ulcers. The weekly treatment regimen consisted of sharp debridement immediately followed by application of Excellagen. The study period was eight weeks in duration and all three case study patients exhibited rapid and robust formation of new granulation tissue within their previously non-healing heel pressure ulcers (decrease in wound volume of 93-100%). The patients

## **Table of Contents**

were monitored for four weeks following the official eight week study period, and all three heel ulcers continued to improve, with one going to complete closure. The results of this study have been submitted for publication in the peer-reviewed journal, *Advances in Skin and Wound Care*.

### ***Excellagen Stem Cell Delivery Platform Studies***

We believe that Excellagen can also be useful for the delivery of stem cells to promote the growth of an engineered tissue graft using autologous mesenchymal fetal stem cells, and to promote diabetic wound healing using allogeneic stem cells, respectively. Ongoing collaborations are designed to confirm the opportunity to develop product line extensions using Excellagen as a delivery vehicle in combination with stem cells and other biologics for the development of new and innovative advanced regenerative therapeutics.

Researchers at Boston Children's Hospital are evaluating the use of Excellagen® as a delivery scaffold to seed autologous mesenchymal fetal stem cells for ex-vivo engineering of tissue grafts for transplantation into infants to repair prenatally diagnosed birth defects. Autologous mesenchymal fetal stem cells are derived prenatally from infants with a medical defect requiring life-saving tissue repairs. These stem cells are sourced from amniotic fluid, the placenta or umbilical cord blood. The stem cells are then seeded into a scaffold to promote the growth of an engineered tissue graft. These grafts will potentially be used to surgically repair, either in the fetus or immediately following birth, certain prenatally diagnosed birth defects that could include congenital diaphragmatic hernia, tracheal and chest wall defects, bladder extrophy and various cardiac anomalies. Preliminary pre-clinical research has confirmed that Excellagen collagen homogenate maintains mesenchymal fetal stem cell viability. Additional proof-of-concept studies are currently underway.

The Company is also engaged in a collaboration with Orbsen Therapeutics in a European study that is designed to confirm the role of Excellagen in a diabetic wound model, with and without stem cells. The study is being conducted by researchers led by Professor Timothy O'Brien at the National University of Ireland, in Galway and Orbsen Therapeutics Ltd., to evaluate the medical utility of Excellagen as a delivery agent for Orbsen's human mesenchymal stem cells (MSC) for the potential treatment of diabetic wounds. The research is sponsored by the European-funded ReddStar initiative.

### ***Excellagen U.S. Market Opportunity***

The U.S. advanced wound care market exceeds \$5 billion annually with seven million Americans suffering from chronic wounds. The skin substitutes market segment, which includes Excellagen, as well as Dermagraft®, Apligraf®, EpiFix® and Graftjacket®, represents a \$500 million annual market opportunity. This market is expected to grow due to the aging population and the rise in diabetes, obesity and the increased number of seniors living in long-term care facilities now and in the coming decade. According to the National Diabetes Fact Sheet (2011), over 25 million Americans are living with diabetes. Annually healthcare professionals treat approximately 900,000 diabetic foot ulcers. The National Institutes of Health estimates that 15% of people with diabetes will develop a foot ulcer. In addition, approximately 68,000 non-traumatic lower-limb amputations are performed annually in those with diabetes.

### **Cardium Business Strategy**

With the recent preclinical, clinical and regulatory advances of our key products Generx® and Excellagen®, we are committed to applying our first-mover scientific leadership position in the field of regenerative medicine for the development and commercialization of these products in collaboration with strategic partners. The key elements of our business strategy include:

The advancement of our ASPIRE international Phase 3 registration clinical study for Generx® which is currently underway in the Russia Federation, and release of findings from interim data analysis in mid-2014. Upon clinical success, the Company plans to meet with the U.S. FDA to seek harmonization between the international ASPIRE study with Cardium's already FDA-cleared Generx Phase 3 clinical study and advance U.S.-based clinical studies supported by a strategic partner;

---

## **Table of Contents**

Strategically partner and monetize our FDA-cleared pharmaceutically formulated collagen commercial wound care product Excellagen<sup>®</sup>, for selected U.S.-based vertical market channels and build on Cardium's capabilities and resources to leverage Excellagen's advanced regenerative medicine delivery platform by identifying innovative product extensions for tissue regeneration based on stem cells, biologics, peptides and/or small molecule drugs for future development and commercialization with one or more strategic partners. Consistent with the Company's long-term business strategy, as previously reported, Taxus Cardium does not plan to establish an internal marketing and sales force to directly support the commercialization of Excellagen, but continues to credentialize Excellagen in preparation for the completion of strategic partnerships for various vertical channel market opportunities or asset monetization. The Company has continued to pursue a CE mark certification for Excellagen, has fully responded to all information requested by the notified body, and looks forward to completing this process;

Advance the commercialization of our non-core LifeAgain Insurance Solutions advanced medical analytics business, which is focused on the development, marketing and sale of survivable risk term life insurance for cancer survivors or others with medical conditions who are currently considered uninsurable based on traditional underwriting standards. The Company plans to potentially support the growth and development of this non-core business and technology platform through the sale of a minority stake in our LifeAgain business to a strategic partner or financial investors;

Monetize our equity stake in Cardium's non-core Healthy Brands Collective Cell-nique Corporation investment. We acquired this investment through the recent sale of our To Go Brands<sup>®</sup> health sciences business through an asset exchange for a preferred equity position in Healthy Brands. Healthy Brands has been making significant acquisitions and has previously reported plans to move forward as a public company as its current businesses advance and growth through further acquisition;

Leverage our recent cooperation agreement with Shanxi Taxus Pharmaceuticals Ltd. to distribute our Excellagen product and Generx product candidate in China, and distribute Shanxi Taxus Pharmaceuticals Ltd.'s oncology related products in the United States; and

Deploy capital strategically to develop our portfolio of product candidates and create shareholder value.

### **Government Regulation**

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

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

To commercialize our product candidates, we must sponsor and file an investigational new drug (IND) application and be responsible for initiating and overseeing the human clinical trials to demonstrate the safety and efficacy and, for a biologic product, the potency, which are necessary to obtain FDA approval of any such



## **Table of Contents**

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 clinical trials 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, the approval process can take more than two years.

Notwithstanding the submission of relevant data, the FDA may ultimately decide that the new drug application or biologic license application does not satisfy its regulatory criteria for approval and may require additional studies. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness. Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to compliance with current good manufacturing practices (GMPs), reporting of adverse effects, advertising, promotion and marketing. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

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

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

## **Table of Contents**

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

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

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

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

## **Competition**

The pharmaceutical, biotechnology, medical device and nutraceutical industries are intensely competitive. Our products and any product candidates developed by us would compete with existing drugs, therapies, devices or procedures and with others under development. There are many pharmaceutical, biotechnology and medical device companies, public and private universities and research organizations actively engaged in research and development of products for the treatment of cardiovascular and related diseases, and/or products for the healing of chronic wounds. Many of these organizations have financial, technical, research, clinical, manufacturing and marketing resources that are greater than ours. If a competing company develops or acquires rights to a more efficient, more effective, or safer competitive approach for treatment of the same or similar diseases or conditions we have targeted, or one that offers significantly lower costs of treatment, our business, financial condition and results of operations could be materially adversely affected.

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

In the areas of tissue repair and wound healing, such as Excellagen and others being developed by our Tissue Repair subsidiary, there are a number of approaches being employed, including other collagen-based products, living skin equivalents, negative pressure wound therapy devices and other devices, and biologics and small molecule drugs designed to promote repair and healing. Competing products include Dermagraft®, Apligraf®, EpiFix® and Graftjacket®, and others.

## **Table of Contents**

We believe that the most significant competitive factor in the field of new therapeutics and devices is the effectiveness of a product candidate, as well as its relative safety and cost as compared to other products, product candidates or approaches that may be useful for treating a particular disease condition. If validated and commercialized we expect that our Generex product will provide an effective and safe alternative for cardiac patients are no longer responsive to medical therapy, and are considered not suitable candidates for traditional percutaneous or surgical revascularization procedures such as cardiac by-pass surgery, or angioplasty and stenting. We also anticipate that treatment by Generex will cost substantially less than surgical procedures.

We believe that our product development programs will be subject to significant competition from companies using alternative technologies, some of which are described above, as well as to increasing competition from companies that develop and apply technologies similar to ours. Other companies may succeed in developing products earlier than we do, obtaining approvals for these products from the FDA more rapidly than we do or developing products that are safer, more effective or less expensive than those under development or proposed to be developed by us. We cannot assure you that research and development by others will not render our technology or product candidates obsolete or non-competitive or result in treatments superior to any product candidate developed by us, or that any product candidate developed by us will be preferred to any existing or newly developed technologies.

## **Manufacturing Strategy**

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

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

## **Marketing and Sales**

The Company's key skill set is focused on the discovery, manufacturing process, engineering, clinical, and commercial development of new and innovative products. Taxus Cardium does not currently have the financial resources and internal capabilities to market and sell current core products and product candidates under development. Consistent with this long-term business strategy, Taxus Cardium does not plan to develop a direct internal marketing and sale force for Excellagen or the Generx product candidate, and plans to rely on strategic partnerships and alliances for the United States and international marketing and sales for these products. Our marketing and sales strategies will vary by product line. Our product candidates, such as Generx must undergo clinical trials before any marketing and sales can begin. If we should obtain marketing approvals, we expect to engage in marketing and sales efforts through or in collaboration with a partner that specializes in commercialization, marketing and sales of drugs and therapeutics.

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

## **Table of Contents**

long-term business strategy, as previously reported, Taxus Cardium does not plan to establish an internal marketing and sales force to directly support the commercialization of Excellagen, but continues to credentialize Excellagen in preparation for the completion of strategic partnerships for various vertical channel market opportunities or asset monetization. The Company has continued to pursue a CE mark certification for Excellagen, has fully responded to all information requested by the notified body, and looks forward to completing this process. We do not expect to generate meaningful levels of sales for Excellagen until strategic partnerships are established as appropriate.

### **Licensing and Intellectual Property**

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

As part of our acquisition of a portfolio of cardiovascular growth factor therapeutic assets pursuant to a Technology Transfer Agreement entered into between Cardium and the Schering AG Group (now part of Bayer AG), we acquired from Schering a portfolio of methods and compositions directed at the treatment of cardiovascular diseases, including Generx. In connection with that portfolio we acquired the rights to certain patents owned by the University of California and New York University, which would require us to pay royalties on products developed on the basis of those patents. Information related to our purchase from Schering AG Group is provided under Notes to Consolidated Financial Statements, Note 8 Commitments and Contingencies. Our patent portfolio includes allowed and issued patents covering our gene therapy approach both in Europe and in the United States. We have additional patents and patent applications directed to methods of cardiovascular gene therapy in the U.S., Europe, Russia and elsewhere, and we recently filed new patent applications directed to certain improved techniques for the treatment of heart disease that are currently the subject of Cardium's ASPIRE study in Russia.

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

We expect to continue evaluations of the safety, efficacy and possible commercialization of our product candidates and technologies as they advance in development. On the basis of such evaluations, we may alter our current research and development programs, clinical studies, partnering or other development or commercialization activities. Accordingly, we may elect to amend or cancel, from time to time, one or more of our arrangements with third parties, subject to any applicable accrued liabilities and fees. Alternatively, the other parties to such arrangements may, in certain circumstances, be entitled to terminate the arrangements. Further, the amounts payable under certain of our arrangements may depend on the number of products or indications for which any particular technology licensed under such arrangement is used by us. Thus, any statement of potential fees payable by us under each agreement is subject to a high degree of potential variation from the amounts indicated.

Although we or our licensors may file and prosecute patent applications related to various technologies under license or development, or seek to protect some technologies in other ways such as through the maintenance of trade secrets, our product candidates are based on complex and rapidly evolving technologies, and none of our biologic product candidates have completed clinical development. There are also a number of additional uncertainties affecting our ability to enforce any of our intellectual property rights as described below

## **Table of Contents**

under Risks Related to Our Intellectual Property and Potential Litigation. There can be no assurance that any intellectual property assets, or other approaches to marketing exclusivity or priority, would be sufficient to protect our commercialization opportunities, nor that our planned commercialization activities will not infringe any intellectual property rights held or developed by third parties.

### **Employees**

As of December 31, 2013 we had 11 full-time employees. We do not expect that employee headcount to increase significantly during the next 12 months while our products and product candidates advance. Our employees are not represented by a collective bargaining agreement and we have not experienced any work stoppages as a result of labor disputes. We believe our relationship with our employees is good. We also rely on various consultants and advisors to provide services to us.

### **Available Information**

Our website address is [www.cardiumthx.com](http://www.cardiumthx.com). We make available, free of charge, through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments 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. The information on our website is not part of this or any other report we file with, or furnish 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. Information about our products are available through the additional website addresses, [www.excellagen.com](http://www.excellagen.com); [www.lifeagain.com](http://www.lifeagain.com); and [www.healthbrandsco.com](http://www.healthbrandsco.com).

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

***Our products and product candidates are subject to ongoing regulatory requirements or require regulatory approvals, and in some cases additional prior development or testing, before marketing. We may be unable to develop, obtain or maintain regulatory approval or market any of our product candidates or expand the market of our existing products and technology. If our product candidates are delayed or fail, we will not be able to generate revenues and cash flows from operations, and we may have to curtail or cease our operations.***

Our Excellagen<sup>®</sup> collagen-based product and other wound care and biologics products are subject to numerous rules and regulations promulgated by the FDA and other food and health regulatory authorities, including regulations governing the sourcing, manufacture, labeling, handling, storage, marketing and use of such products. In most cases, we will rely on third parties to perform many of these activities, which may not be performed in an effective or timely manner.

## **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, FDA has not yet approved any gene therapy like that contained in our Generx product candidate, or similar product and there can be no assurance that it will. There are many reasons that our products and product candidates may fail or not advance beyond clinical testing, including the possibility that:

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

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

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

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

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

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

others may develop equivalent, superior or less expensive products.

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

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

To obtain regulatory approvals for new products, we must, among other things, initiate and successfully complete multiple clinical trials demonstrating to the satisfaction of the FDA that our product candidates are sufficiently safe and effective for a particular indication. We currently rely on third party clinical research organizations to assist us in designing, administering and assessing the results of those trials. In relying on those third parties, we are dependent upon them to timely and accurately perform their services. We have experienced, and in the future may experience, delays in our clinical trials. Any such delay will result in additional costs, and defer any prospective opportunities to monetize the product candidate. Product development costs to us and our potential collaborators will increase, and our business may be negatively impacted, if we experience delays in testing or approvals or if we need to perform more or larger clinical trials than planned, for reasons such as the following:

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

## Edgar Filing: Taxus Cardium Pharmaceuticals Group 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;

## **Table of Contents**

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

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

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

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

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

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

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

changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its results. Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable. If third party organizations do not accurately collect and assess the trial data we may discontinue development of viable product candidates or continue allocating resources to the development and marketing of product candidates that are not efficacious. Either outcome could result in significant financial harm to our company and damage to our reputation.

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

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, 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 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

## **Table of Contents**

our product candidates, cannot be offset by our limited revenues during our development stage. As of December 31, 2013, our accumulated deficit was approximately \$105 million, and our cash and cash equivalents were approximately \$22,000. To date, we have generated very limited revenues and a large portion of our expenses are fixed, including expenses related to facilities, equipment, contractual commitments and personnel. As a result, we expect our net losses from operations to continue for at least the next few years. Our ability to generate additional revenues and potential to become profitable will depend largely on our ability, alone or with potential collaborators, to efficiently and successfully complete the development of our product candidates, successfully complete pre-clinical and clinical tests, obtain necessary regulatory approvals, and manufacture and market our products. There can be no assurance that any such events will occur or that we will ever become profitable. Even if we do achieve profitability, we cannot predict the level of such profitability. If we sustain losses over an extended period of time, we may be unable to continue our business.

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

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

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

Conducting the costly and time consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our products to market will require a commitment of substantial funds in excess of our current capital. Our future capital requirements will depend on many factors, including, among others: the progress of our current and new product development programs; the progress, scope and results of our pre-clinical and clinical testing; the time and cost involved in obtaining regulatory approvals; the cost of manufacturing our products and product candidates; the cost of prosecuting, enforcing and defending against patent claims and other intellectual property rights; competing technological and market developments; and our ability and costs to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market and/or to monetize the economic value of our product portfolio. We expect we will need to raise additional funds in the future. The audit opinion accompanying our consolidated financial statements for the year ended December 31, 2013, 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

## **Table of Contents**

assets. Fluctuating interest rates could also increase the costs of any debt financing we may obtain. Raising capital through a licensing or other transaction involving our intellectual property could require us to relinquish valuable intellectual property rights and thereby sacrifice long term value for short-term liquidity.

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

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

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

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

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

### ***We may pursue acquisitions of other companies or product rights that, if not successful, could adversely affect our business, financial condition and results of operations.***

As part of our business strategy, we may pursue acquisitions of other companies, technologies or products. Acquisitions of businesses or product rights involve numerous risks, including:

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

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

**Table of Contents**

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

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

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

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

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

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

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

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

potential loss of key employees of the acquired company; and

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

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

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

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

We expect to rely at least in part on third party service providers and collaborators to perform a number of activities relating to the development and commercialization of our product candidates, including the manufacture of product materials, the design and conduct of clinical trials, and

## Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

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

## Table of Contents

programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate. In addition, if any of these collaborators withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

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

we do not achieve our objectives under our collaboration agreements;

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

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

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

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

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

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

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

Our business strategy relies on third parties to manufacture and produce our products and product candidates and the catheters used to deliver the products in accordance with Good Manufacturing Practices established by the FDA and other regulators. These third party manufacturers are subject to extensive government regulation and must receive FDA approval before they can produce clinical material or commercial product.

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

If any manufacturing agreement is terminated or any third party service provider or collaborator experiences a significant problem that could result in a delay or interruption in the supply of product materials to us, there are very few contract manufacturers who currently have the capability to produce our product candidates. There can be no assurance that manufacturers on whom we depend will be able to successfully produce our products or



## **Table of Contents**

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.

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

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

Our industry is characterized by extensive research and development, rapid technological change, frequent innovations and new product introductions, and evolving industry standards. Existing products and therapies to treat vascular and cardiovascular disease, including drugs and surgical procedures, as well as competitive approaches to wound healing and tissue repair, will compete directly or indirectly with the products that we are seeking to develop and market. In addition, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization and market penetration than us. As these competitors develop their technologies, they may develop proprietary positions that prevent us from successfully commercializing our future products. To be successful, we must be able to adapt to rapidly changing technologies by continually enhancing our products and introducing new products. If we are unable to adapt, products and technologies developed by our competitors may render our products and product candidates uneconomical or obsolete, and we may not be successful in marketing our products and product candidates against competitors. We may never be able to capture and maintain the market share necessary for growth and profitability and there is no guarantee we will be able to compete successfully against current or future competitors.



## **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.***

Our ability to earn sufficient returns on our products and future products will depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other third-party payers. If we fail to obtain appropriate reimbursement, it could prevent us from successfully commercializing and marketing our products and future products.

There have been and will continue to be efforts by governmental and third-party payers to contain or reduce the costs of health care through various means, including limiting coverage and the level of reimbursement. We expect that there will continue to be a number of legislative proposals to implement government controls and 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.

***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.

## **Table of Contents**

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

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

changes and limits in import and export controls;

increases in custom duties and tariffs;

changes in currency exchange rates;

economic and political instability;

changes in government regulations and laws;

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

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

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

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

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

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

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



## **Table of Contents**

***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.

***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.

## **Table of Contents**

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.

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

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

Product liability may result from harm to patients using our products, such as a complication that was either not communicated as a potential side effect or was more extreme than communicated. We will require all patients enrolled in our clinical trials to sign consents, which explain various risks involved with participating in the trial. However, patient consents provide only a limited level of protection, and it may be alleged that the consent did not address or did not adequately address a risk that the patient suffered from. Additionally, we will generally be

## **Table of Contents**

required to indemnify the clinical product manufacturers, clinical trial centers, medical professionals and other parties conducting related activities in connection with losses they may incur through their involvement in the clinical trials. We may not be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities.

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

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

On April 4, 2013 we entered into a securities purchase agreement with an institutional investor to purchase up to 4,012 shares of our newly authorized Series A Convertible Preferred Stock for maximum proceeds of \$4.0 million. The Series A Convertible Preferred Stock is convertible into shares of our common stock at a current conversion price of \$0.70 per share. In addition, the conversion price is subject to downward adjustment if we issue common stock or common stock equivalents at a price less than the then effective conversion price. In connection with the offering of the Series A Convertible Preferred Stock we granted the investor certain rights of participation in future equity financings. At December 31, 2013, there were 1,500 shares of Series A Convertible Preferred Stock outstanding. As long as the Series A Convertible Preferred Stock is outstanding, we have also agreed not to incur specified indebtedness without the consent of the holders of the Series A Convertible Preferred Stock. These factors may restrict our ability to raise capital through equity or debt offerings in the future.

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

We will need to raise substantial additional capital to fund our future operations. To the extent we raise additional capital through the sale of equity securities or we issue securities in connection with another transaction, our stock price can be adversely affected and the ownership position of existing stockholders could be substantially diluted. Anti-dilution adjustments to our securities currently outstanding would cause further dilution. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in our assets. Fluctuating interest rates could also increase the costs of any debt financing we may obtain. Raising capital through a licensing or other transaction involving our intellectual property could require us to relinquish valuable intellectual property rights and thereby sacrifice long term value for short-term liquidity.

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

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

***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;

**Table of Contents**

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;

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

regulatory developments in the United States and other countries;

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

additions or departures of key personnel;

sales or other transactions involving our common stock; and

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

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

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

Our board of directors has adopted a stockholder rights plan in which preferred stock purchase rights were distributed as a dividend. These provisions may make it more difficult for stockholders to take corporate actions and may have the effect of delaying or preventing a change in control. These provisions also could deter or prevent transactions that stockholders deem to be in their interests. In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Subject to specified exceptions, this section provides that a

## Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

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.



**Table of Contents**

*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**

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

Location	Nature of Use	Square Feet	Monthly Base Rent	Lease Expiration Date
11750 Sorrento Valley Road, Suite 250 San Diego, CA USA	Corporate Headquarters Principal executive office	4,419	\$ 9,678 <sup>1</sup>	Aug. 31, 2016
8505 Commerce Avenue San Diego, CA USA	Office and Warehouse for To Go Brands	7,216	\$ 6,594	May 31, 2014

<sup>1</sup> The monthly base rent increases to \$10,016 in September 2014, and \$10,367 in September 2015. In addition to base rent, we are also required to pay our proportionate share of any increase in operating expenses from 2014 levels for the office park in which our space is located.

**ITEM 3. LEGAL PROCEEDINGS**

As of December 31, 2013, neither Cardium nor its subsidiaries were a party to any material pending legal proceeding nor was any of their property the subject of any material pending legal proceeding. In the course of our business, however, we could become engaged in various intellectual property, product-related, and other matters in connection with the technology we develop or license and the products we develop or sell. To the extent we are not successful in defending against any adverse claims concerning our technology, business relationships or products, we could be compelled to seek licenses from one or more third parties who could be direct or indirect competitors and who might not make licenses available on terms that we find commercially reasonable or at all, or to pay other forms of compensation or expenses. In addition, any such proceedings, even if decided in our favor, involve lengthy processes, are subject to appeals, and typically result in substantial costs and diversion of resources. In the course of our business, we are also routinely involved in proceedings such as disputes involving goods or services provided by various third parties to Cardium or its subsidiaries, which we do not consider likely to be material to Cardium, but which can nevertheless result in costs and diversions of resources to pursue and resolve.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.



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

Our common stock currently trades on OTC QB under the symbol CRXM. Prior to January 24, 2014, our common stock traded on the NYSE MKT market. Below are the high and low closing prices of our common stock for the time it has traded on the OTC QB and the high and low closing prices for the time it traded on the NYSE MKT, for each quarter of the years ended December 31, 2013 and 2012:

	2013		2012	
	High	Low	High	Low
First Quarter	\$ 4.00	\$ 3.20	\$ 8.00	\$ 5.40
Second Quarter	\$ 3.40	\$ 1.40	\$ 5.60	\$ 4.40
Third Quarter	\$ 1.60	\$ 0.69	\$ 5.00	\$ 3.60
Fourth Quarter	\$ 1.07	\$ 0.70	\$ 4.60	\$ 3.60

 **Holders**

As of March 15, 2014 there were approximately 100 stockholders of record of our common stock. Based in information we receive from brokerage firms in connection with proxy solicitations, we believe that there are approximately 5,000 beneficial owners of our common stock.

**Dividends**

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

**Recent Sales of Unregistered Securities**

During the years ended December 31, 2013 and 2012 we did not sell any unregistered securities.

**Repurchases of Equity Securities**

During the year ended December 31, 2013, we did not repurchase any shares of our common stock, nor were any repurchases made on our behalf.

**Table of Contents****Equity Compensation Plan Information**

The following table summarizes equity compensation plans approved by stockholders and equity compensation plans that were not approved by stockholders as of December 31, 2013.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders	144,000	\$ 31.74	139,058 <sup>1</sup>
Equity compensation plans not approved by stockholders		\$	
<b>Total</b>	<b>144,000</b>	<b>\$ 31.74</b>	<b>139,058</b>

<sup>1</sup> Under the terms of the plan in effect as of December 31, 2013, in addition to securities that may be issued upon the exercise of options, warrants or other rights granted under the plan, securities may also be issued under the plan in the form of shares of restricted stock of the Company issued with such restrictions on transfer, rights of first refusal, repurchase and/or forfeiture provisions and other provisions and conditions as the Board of Directors or the Compensation Committee may determine from time to time.

**ITEM 6. SELECTED FINANCIAL DATA**

As a smaller reporting company, we are not required to provide the information required by this item.

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

The following discussion and analysis is intended to help you understand our financial condition and results of operations for the last two years ended December 31, 2013. You should read the following discussion and analysis together with our audited consolidated financial statements and the notes to the consolidated financial statements included under Item 8 in this report. Statements in the following discussion that are not historical in nature are forward looking statements, and inherently subject to risk. Our future financial condition and results of operations will vary from our historical financial condition and results of operations described below based on a variety of factors. You should carefully review the risks described under Item 1A and elsewhere in this report, which identify certain important factors that could cause our future financial condition and results of operations to vary from our historical operations and from our current expectations of future results.

**Executive Overview**

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

We are a development-stage regenerative medicine biotechnology company. We are focused on the development of advanced regenerative therapeutics designed to promote the activation and growth of (1) microvascular circulation to enhance perfusion of ischemic cardiac tissue as a potential treatment for heart disease; and (2) granulation tissue as a treatment for chronic non-healing wounds. We have a commercial FDA-cleared wound care product, a late clinical stage cardiovascular gene therapy product candidate and corresponding technology platforms as outlined below. We also own non-core interests in the Healthy Brands Collective, a health products company, and LifeAgain Insurance

Solutions, Inc., an advanced medical data analytics business.

---

## **Table of Contents**

Our business is focused on the acquisition and strategic development of product opportunities or businesses having the potential to address significant unmet medical needs, and having definable pathways to commercialization, and on partnering or other monetization following the achievement of corresponding development objectives. Consistent with the Company's long-term business strategy, as previously reported, Taxus Cardium does not plan to establish an internal marketing and sales force to directly support the commercialization of Excellagen, but continues to credentialize Excellagen in preparation for the completion of strategic partnerings for various vertical channel market opportunities or asset monetization. The Company has continued to pursue a CE mark certification for Excellagen, has fully responded to all information requested by the notified body, and looks forward to completing this process. Consistent with our overall business strategy, as our product opportunities and businesses are advanced and corresponding valuations established, we intend to consider various corporate development transactions designed to place our product candidates into larger organizations or with partners having existing commercialization, sales and marketing resources, and a need for innovative products. Such transactions could involve the sale, partnering or other monetization of particular product opportunities or businesses.

### **Recent Developments**

During 2013, we continued efforts to advance the development of Generx, continued the commercialization of Excellagen, sold To Go Brands, Inc. and completed development of our first LifeAgain product offering. Subsequent to the year ended December 31, 2013, we entered into a strategic cooperation agreement and financing arrangement with Shanxi Taxus Pharmaceuticals Ltd. Recent highlights include the following:

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

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

Initiated our Generx ASPIRE Phase 3/ registration study, a 100-patient, randomized and controlled multi-center study currently enrolling patients at up to nine leading cardiology centers in the Russian Federation for patients with myocardial ischemia due to coronary artery disease. The ASPIRE study is designed to further evaluate the safety and effectiveness of Cardium's Generx DNA-based angiogenic product candidate, which has already been tested in clinical studies involving 650 patients at more than one hundred medical centers in the U.S., Europe and elsewhere. The efficacy of Generx is being quantitatively assessed using rest and stress SPECT (Single-Photon Emission Computed Tomography) myocardial imaging to measure improvements in microvascular cardiac perfusion following a one-time, non-surgical, catheter-based administration of Generx. The Cedars-Sinai Medical Center Nuclear Cardiology Core Laboratory in Los Angeles, California, is the central core lab for the study and is responsible for the analysis of SPECT myocardial imaging data electronically transmitted from the Russian medical centers participating in the ASPIRE study. The Russian Health Authority has assigned Generx the therapeutic drug trade name of Cardionovo<sup>®</sup> for marketing and sales in Russia.

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

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

---

## **Table of Contents**

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

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

On October 3, 2011, our Tissue Repair Company subsidiary received a 510(k) premarket notification from the U.S. Food and Drug Administration (FDA) for its fibrillar collagen-based Excellagen® topical gel for wound healing of diabetic foot ulcers and other dermal wounds. Our 510(k) filing covers Excellagen's use as a wound care management medical device for topical application by health care professionals for patients with dermal wounds, which can include diabetic ulcers, pressure ulcers, venous ulcers, tunneled/undermined wounds, surgical and trauma wounds, second degree burns, and other types of wounds. Developments with respect to Excellagen include:

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

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

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

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

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

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

## **Table of Contents**

### ***Sale of To-Go Brands, Inc.***

On November 15, 2013, we sold our To Go Brands® business to Healthy Brands Collective® in exchange for an equity stake in Healthy Brands preferred stock which, at the time of the transaction, was convertible into approximately 4% of their fully-diluted common stock, and Healthy Brands Collective's assumption of approximately \$370,000 of liabilities. Healthy Brands Collective® is a fast growing private company that has acquired a portfolio of eight independent brand product platforms (prior to To Go Brands) including Cell-nique®, Cherrybrook Kitchen®, Yumnuts®, Living Harvest/Tempt®, Bites of Bliss®, High Country Kombucha® drinks and Organics European Gourmet Bakery (formerly Dr. Oetker) natural and organic baking mixes. Healthy Brands expects to make additional brand acquisitions and has previously reported plans to move forward as a public company as its business advances. As a result of the sale, management determined it appropriate to discontinue the nutraceutical operations which led to the sale of To Go Brands Inc., and to write off the unamortized balance of our technology licenses which was focused on that product line. Accordingly, the activities of To Go Brands, Inc. are reflected in the accompanying financial statements as discontinued operations.

### ***LifeAgain Insurance Solutions***

During 2013, we completed the initial product development of LifeAgain, a medical analytics and social media-driven enabled e-commerce platform that is focused on the development, marketing and direct sales of new and innovative survivable risk, multi-year, non-convertible level term life insurance programs and other insurance products, that are currently non-accessible and unaffordable for certain sub-groups of highly motivated buyers considered uninsurable based on traditional underwriting standards by U.S. life insurance companies. Traditional life insurance has become over-optimized web-marketed, undifferentiated, low priced commodity largely marketed to healthy people. LifeAgain is being developed based on improvements in relative mortality in certain sub-group populations, including cancer patients and patients with chronic medical diseases, as a result of the success of early diagnostic screening, public education, the introduction of advanced drugs and biologics, improved and optimized therapies, and expanding access to healthcare. We released the first product aimed at individuals with prostate cancer in 2013. The Company plans to potentially support the growth and development of this non-core business and technology platform through the sale of a minority stake in our LifeAgain business to a strategic partner or financial investors;

### ***Cooperation Agreement with Shanxi Taxus Pharmaceuticals Ltd.***

On February 28, 2014, after the period covered by this report, we entered into a collaboration and financing arrangement with Shanxi Taxus Pharmaceuticals Co., Ltd. (Shanxi Taxus), a strategic corporate investor based in China, pursuant to which the parties agreed to collaborate on the advancement of the Company's product opportunities in China, and the investor's product opportunities in the United States. The arrangement is reflected in two definitive agreements, each dated as of February 21, 2014, which were concluded and delivered on February 28, 2014, in connection with the first tranche of funding under the financing arrangement. Under the terms of a collaboration agreement, Shanxi Taxus agreed to apply commercially reasonable efforts to assist Cardium to develop and refine a plan or plans pursuant to which Cardium products, particularly its Generx® and Excellagen® product opportunities, could be commercialized in China; and Cardium agreed that it will, upon request, apply commercially reasonable efforts to assist Shanxi Taxus to develop and refine a plan or plans pursuant to which Shanxi Taxus oncology-related products and product opportunities could be commercialized in the United States. As part of the agreement the Company changed its name to Taxus Cardium Pharmaceuticals Group, Inc. In addition, the Company agreed to grant Shanxi Taxus certain board rights based on the level of its financing pursuant to the financing arrangement discussed below.

### ***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



## **Table of Contents**

financial statements in accordance with GAAP requires that we make estimates and assumptions that affect the amounts reported in our financial statements and their accompanying notes.

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

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

## **Results of Operations**

### ***Fiscal 2013 Compared to Fiscal 2012***

Revenue for the year ended December 31, 2013 was \$109,200 compared to \$59,409 of revenue reported in the year ended December 31, 2012. The majority of revenue was comprised of sales from Excellagen.

Costs of goods sold for the year ended December 31, 2013 was \$69,160 compared to \$54,151 for costs of goods sold reported in the year ended December 31, 2012. Gross margin for the year ended December 31, 2013 was 37% compared to 9% in 2012 as the result of an increase in the selling price of 36%.

Research and development expenses for the year ended December 31, 2013 were \$2,037,370 compared to \$2,581,094 for the same period in 2012. The decrease of \$544,000 was the result of decreases in expenses related to our Generx Aspire study and reductions in production costs for Excellagen which is now commercially ready for market.

Selling, general and administrative expenses for the year ended December 31, 2013 were \$4,908,919 compared to \$5,717,985 for the year ended December 31, 2012. The decrease of \$809,000 was primarily due to cost reductions implemented in the second half of the year which included an overall 29% headcount reduction and salary reductions as well as savings in facility costs associated with the relocation of our corporate headquarters.

Interest income for the year ended December 31, 2013 was \$217 compared to \$6,592 for the same period last year. The \$6,375 decrease in interest income was related to the decrease in cash available for investment during the respective periods.

Net loss from continuing operations for the year ended December 31, 2013 was \$6,906,803 compared to \$8,227,114 for the same period last year primarily as a result of the decrease in operating expenses described above.

Net loss from discontinued operations for the year ended December 31, 2013 was \$2,007,490 compared to \$96,196 for the same period last year. Management determined it appropriate to discontinue the nutraceutical operations which led to the sale of To Go Brands Inc., and to write off the unamortized balance of our technology licenses which was focused on that product line. The 2013 loss represents the net loss from To Go Brands Inc. of \$909,979 in 2013 and \$1,097,511 from the technology write off compared to the net loss of \$96,196 in the period October December 2012 while we owned To Go Brands Inc.

## **Table of Contents**

Net loss for the year ended December 31, 2013 was \$8,914,293 compared to \$8,323,310 for the same period of 2012.

### **Liquidity and Capital Resources**

As of December 31, 2013, we had \$22,000 in cash and cash equivalents. Our working capital deficit at December 31, 2013 was approximately \$1,110,000.

During the period subsequent to December 31, 2013, cash flows from financing activities include the sale of 714,286 shares of common stock in transactions for net proceeds of \$492,500.

Net cash used in operating activities was \$6 million for the year ended December 31, 2013 compared to \$9.2 million for the year ended December 31, 2012. The decrease in net cash used in operating activities was due primarily to reduced operating expenses as a result of reductions in testing and process validation costs for the initial inventory of our Excellagen topical treatment gel. Since inception, our operations have consumed substantial amounts of cash and we have had only limited revenues. From inception (December 22, 2003) to December 31, 2013, net cash used in operating activities has been \$100.3 million.

Our primary source of liquidity has been cash from financing activities and in particular proceeds from sales of our debt and equity securities. Net cash provided by financing activities was \$3.7 million for the year ended December 31, 2013. This included a preferred stock equity financing with one institutional investor of 4,012 shares of Cardium Series A Convertible Preferred Stock priced at \$1,000 per share with no warrant coverage for net proceeds of \$3.7 million. From inception (December 22, 2003) to December 31, 2013 net cash provided by financing activities has been \$102.9 million.

Net cash used in investing activities for the year ended December 31, 2013 was \$23,000. Net cash used in investing activities since inception has been approximately \$2.6 million. At December 31, 2013 we did not have any significant capital expenditure requirements.

On September 28, 2010, we entered into a Sale Agreement with Brinson Patrick Securities Corporation which enables us to use Brinson Patrick as a sales manager to sell shares of our common stock on a best efforts basis from time to time in at-the-market transactions pursuant to our shelf registration statement. During the year ended December 31, 2013 we raised \$65,744 under this agreement, the majority of which was raised during the first quarter of 2013. The Sale Agreement required that we register the sale of our shares to Brinson Patrick Securities Corporation on a shelf registration statement on Form S-3. Because our common stock is no longer listed on a national exchange, we are not eligible to use a Form S-3 registration statement. Accordingly we do not anticipate additional sales under the Sales Agreement unless and until we regain listing on a national exchange.

On February 28, 2014, we entered into a collaboration and financing arrangement with Shanxi Taxus Pharmaceuticals Co., Ltd. ( Shanxi Taxus ), a strategic corporate investor based in China, pursuant to which the parties agreed to collaborate on the advancement of the Company's product opportunities in China, and the investor's product opportunities in the United States. The arrangement is reflected in two definitive agreements, each dated as of February 21, 2014, which were concluded and delivered on February 28, 2014, in connection with the first tranche of funding under the financing arrangement.

Under the terms of a Stock Purchase Agreement, Shanxi Taxus agreed to purchase up to \$5 million of shares of the Company's unregistered common stock in multiple tranches, each at a 10% premium to the then-current trailing average market prices of the Company's common stock at the time of each closing. We closed the initial \$500,000 tranche of funding on February 28, 2014, by selling 714,286 shares of common stock at \$0.70 per share, based on a trailing average price.

The purchase price for each subsequent tranche would be equal to one hundred ten percent (110%) of the then-current volume-weighted average price for sales of the Company's common stock over the thirty

## **Table of Contents**

(30) calendar day period prior to each closing. Additional shares would be placed during an exclusive financing period ending on June 30, 2014, in up to four additional tranches, as follows: *Tranche 2*, in the amount One Million Five Hundred Thousand Dollars (\$1,500,000) would be placed on or around March 31, 2014; *Tranche 3*, in the amount of One Million Dollars (\$1,000,000) would be placed on or around April 30, 2014, provided that if the purchaser elected to not proceed with the full amount of Tranche 3, it would provide notice of such election to the Company on or before April 15, 2014, following which election, the amount of Tranche 3 would be reduced to a minimum of Three Hundred Thousand Dollars (\$300,000), and the exclusive financing period with the purchaser would be terminated as of April 30, 2014; *Tranche 4*, in the amount of One Million Dollars (\$1,000,000) would be placed on or around May 30, 2014, provided that if the purchaser elected to not proceed with the full amount of Tranche 4, it would provide notice of such election to the Company on or before May 15, 2014, following which election, the amount of Tranche 4 would be reduced to a minimum of Three Hundred Thousand Dollars (\$300,000), and the exclusive financing period would be terminated as of May 30, 2014; and *Tranche 5*, in the amount of One Million Dollars (\$1,000,000) would be placed on or around June 30, 2014, provided that if the purchaser elected to not proceed with the full amount of Tranche 5, it would provide notice of such election to the Company on or before June 16, 2014, following which election, the amount of Tranche 5 would be reduced to a minimum of Three Hundred Thousand Dollars (\$300,000).

We believe that if we complete the full \$5.0 million funding under this financing arrangement we will have sufficient capital to fund our operations until December 31, 2014.

We anticipate that negative cash flow from operations will continue for the foreseeable future. We do not have any unused credit facilities. As long as any shares of our Series A Convertible Preferred Stock are outstanding, we have agreed that we will not, without the consent of the holders of two-thirds of the Series A Convertible Preferred Stock, incur indebtedness other than specified Permitted Indebtedness, incur any liens other than specified Permitted Liens. We intend to secure additional working capital through sales of additional debt or equity securities to finance our operations. Our principal business objective is to complete an additional strategic licensing agreement to advance sales of the Excellagen product family and/or another corporate transaction. If we fail to enter into an additional strategic licensing arrangement or generate sufficient product sales, we will not generate sufficient cash flows to cover our operating expenses

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

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

As of December 31, 2013, we did not have any significant off-balance sheet debt nor did we have any transactions, arrangements, obligations (including contingent obligations) or other relationships with any unconsolidated entities or other persons that have or are reasonably likely to have a material current or future effect on financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenue or expenses material to investors.

### **Recent Accounting Pronouncements**

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

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As a smaller reporting company, we are not required to provide the information required by this item.

**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 Shareholders of

Taxus Cardium Pharmaceuticals Group, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Taxus Cardium Pharmaceuticals Group, Inc. and Subsidiaries (the Company) (a development stage company) as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2013 and 2012 and for the period from December 22, 2003 (inception) through December 31, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Taxus Cardium Pharmaceuticals Group, Inc. and Subsidiaries (a development stage company) at December 31, 2013 and 2012, and the consolidated results of their operations and their cash flows for the years ended December 31, 2013 and 2012 and for the period from December 22, 2003 (inception) through December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

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

Marcum LLP

New York, New York

April 15, 2014

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

	December 31,	
	2013	2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 22,489	\$ 2,328,074
Accounts receivable	0	22,320
Inventory, net	159,831	682,094
Current assets of discontinued operations	0	852,546
Prepaid expenses and other assets	309,200	403,705
Total current assets	491,520	4,288,739
Property and equipment, net	30,196	52,115
Investment	1,699,672	0
Deposit on investment option	435,000	435,000
Technology licenses, net	0	1,198,318
Other long term assets	129,989	175,808
Assets of discontinued operations	0	1,658,898
Total assets	\$ 2,786,377	\$ 7,808,878
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 990,279	\$ 374,126
Accrued liabilities	611,007	376,512
Current liabilities of discontinued operations	0	642,080
Total current liabilities	1,601,286	1,392,718
Deferred rent	0	50,370
Total liabilities	1,601,286	1,443,088
Commitments and contingencies		
Stockholders equity:		
Series A Convertible Preferred stock, \$0.0001 par value; 40,000,000 shares authorized; issued and outstanding 1,500 at December 31, 2013 and 0 at December 31, 2012, with liquidation preferences of \$1,000	0	0
Common stock, \$0.0001 par value; 200,000,000 shares authorized; issued and outstanding 8,810,624 at December 31, 2013 and 6,460,586 at December 31, 2012	12,956	12,922
Additional paid-in capital	106,500,753	102,767,193
Deficit accumulated during development stage	(105,328,618)	(96,414,325)
Total stockholders equity	1,185,091	6,365,790
Total liabilities and stockholders equity	\$ 2,786,377	\$ 7,808,878

Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

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

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

	Years Ended December 31,		Period from
	2013	2012	December 22, 2003 (Inception) to December 31, 2013
Revenues			
Product sales	\$ 109,200	\$ 59,409	\$ 894,518
Grant revenues	0	0	1,623,160
Total revenues	109,200	59,409	2,517,678
Cost of goods sold	(69,160)	(54,151)	(506,225)
Gross profit	40,040	5,258	2,011,453
Operating expenses			
Research and development	(2,037,370)	(2,581,094)	(46,044,098)
Selling, general and administrative	(4,908,919)	(5,717,985)	(48,462,277)
Total operating expenses	(6,946,289)	(8,299,079)	(94,506,375)
Loss from operations	(6,906,249)	(8,293,821)	(92,494,922)
Change in fair value of derivative liabilities	0	64,157	10,395,709
Gain on warrant exchange	0	0	473,872
Interest income	217	6,592	1,583,855
Interest expense	(771)	(4,042)	(7,127,025)
Net loss from continuing operations	\$ (6,906,803)	\$ (8,227,114)	\$ (87,168,511)
Net loss from discontinued operations	(2,007,490)	(96,196)	(24,568,710)
Gain on sale of business unit	0	0	6,408,603
Net loss	\$ (8,914,293)	\$ (8,323,310)	\$ (105,328,618)
Deemed dividend on preferred stock	\$ (405,872)	\$ (0)	\$
Net loss applicable to common stockholders	\$ (9,320,165)	\$ (8,323,310)	\$
Net loss per share basic and diluted			
Net loss from continued operations	\$ (1.04)	\$ (1.39)	
Net Loss from discontinued operations	(0.29)	(0.02)	
Net loss per share basic and diluted	\$ (1.33)	\$ (1.41)	
Weighted average number of common shares outstanding	6,995,676	5,922,717	

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





**Table of Contents****TAXUS CARDIUM PHARMACEUTICALS GROUP, INC. AND SUBSIDIARIES****(a development stage company)****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY****YEARS ENDED DECEMBER 31, 2013 AND 2012**

	Common Stock		Series A Convertible Preferred Stock		Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount	Shares	Amount			
Balance January 1, 2012	4,828,963	\$ 8,610	0	\$ 0	\$ 94,167,335	\$ (88,091,015)	\$ 6,084,930
Reclassification of derivative liabilities that no longer contain price protection provisions					21,349		21,349
Stock option compensation					169,746		169,746
Issuance of common stock for acquisition of To Go Brands	480,000	960	0	0	2,015,040		2,016,000
Issuance of common stock for cash, net of issuance costs	1,151,487	3,352	0	0	6,392,959		6,396,311
Exercise of warrants	136		0		764		764
Net Loss						(8,323,310)	(8,323,310)
Balance December 31, 2012	6,460,586	12,922	0	0	102,767,193	(96,414,325)	6,365,790
Issuance of common stock for cash, net of issuance costs	17,187	34			65,709		65,743
Stock option compensation					40,750		40,750
Issuance of Series A preferred stock for cash, net of issuance costs	0	0	4,012		3,627,101		3,627,101
Issuance of common stock on conversion of preferred stock	2,332,851	0	(2,512)	0	0		0
Net Loss						(8,914,293)	(8,914,293)
Balance December 31, 2013	8,810,624	\$ 12,956	1,500	\$ 0	\$ 106,500,753	\$ (105,328,618)	\$ 1,185,091

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

**Table of Contents****TAXUS CARDIUM PHARMACEUTICALS GROUP, INC. AND SUBSIDIARIES****(a development stage company)****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		December 22, 2003 (Inception ) To December 31, 2013
	2013	2012	
<b>Cash Flows From Operating Activities</b>			
Net loss	\$ (8,914,293)	\$ (8,323,310)	\$ (105,328,618)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of discontinued operation	0	0	(6,408,603)
Gain on sale of warrants	0	0	(518,622)
Loss on abandonment of leaseholds	0	0	135,344
Depreciation	72,357	107,823	2,183,485
Amortization intangibles	123,280	38,308	2,857,781
Amortization debt discount	0	0	5,291,019
Amortization deferred financing costs	0	0	925,859
Amortization and write-off technology and licenses	100,807	134,409	337,489
Write-off of technology licenses	1,097,511	0	1,097,511
Provision for obsolete inventory	(62,482)	(40,852)	96,666
Reserve for product returns	(76,000)	76,000	0
Change in fair value of warrants	(0)	(64,157)	(10,395,709)
Common stock and warrants issued for services and reimbursement of expenses	0	0	203,882
Stock based compensation expense	40,750	169,746	7,638,571
In-process purchased technology	0	0	2,027,529
Deferred rent	(50,370)	(67,943)	(0)
Changes in operating assets and liabilities			
Accounts receivable	222,110	(182,675)	118,423
Inventories	620,698	(305,603)	(1,925,194)
Prepaid expenses and other assets	90,130	(332,465)	(423,129)
Deposits	54,847	4,770	(130,133)
Accounts payable	517,490	(181,812)	2,221,986
Accrued liabilities	137,789	(244,804)	(325,239)
Net cash used in operating activities	(6,025,376)	(9,212,565)	(100,319,702)
<b>Cash Flows From Investing Activities</b>			
In-process technology purchased from Tissue Repair Company	0	0	(1,500,000)
Fee paid to list shares issued for technology and product license	0	0	(65,000)
Purchases of property and equipment	(23,053)	(15,866)	(2,855,470)
Cash acquired in acquisitions	0	288,151	1,839,951
Net cash provided by (used in) investing activities	(23,053)	272,285	(2,580,519)
<b>Cash Flows From Financing Activities</b>			
Proceeds from officer loan	0	0	62,882
Restricted cash collateral for letter of credit	50,000	150,000	0
Proceeds from the exercise of warrants, net	0	764	1,259,212
Proceeds from debt financing agreement, net of debt issuance costs of \$871,833	0	0	14,378,167

Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

Proceeds from the sale of business unit	0	0	11,250,000
Repayment of debt	0	0	(15,750,000)
Proceeds from sales of preferred and common stock, net of issuance costs of \$67,386	3,692,844	6,396,311	91,722,449
Net cash provided by financing activities	3,742,844	6,547,075	102,922,710
Net increase (decrease) in cash	(2,305,585)	(2,393,205)	22,489
Cash and cash equivalents at beginning of period	2,328,074	4,721,279	0
Cash and cash equivalents at end of period	\$ 22,489	\$ 2,328,074	\$ 22,489

**Table of Contents**

	Years Ended December 31,		December 22, 2003 (Inception ) To December 31, 2013
	2013	2012	
<b>Supplemental Disclosures of Cash Flow Information:</b>			
Cash paid for interest	\$ 1,438	\$ 4,248	\$ 1,394,487
Cash paid for income taxes	\$ 3,200	\$ 2,400	\$ 31,762
<b>Non-Cash Activity:</b>			
Subscription receivable for common shares	\$ 0	\$ 0	\$ 17,000
Common stock issued for repayment of loans	\$ 0	\$ 0	\$ 62,882
Stock issued for technology license fee	\$ 0	\$ 0	\$ 1,870,000
Net assets acquired for the issuance of common stock (exclusive of cash acquired)	\$ 0	\$ 1,727,849	\$ 7,551,849
Warrants exchanged for stock	\$ 0	\$ 0	\$ (901,139)
Reclassification of derivative liabilities with expired price protection provisions	\$ 0	\$ (21,349)	\$ (4,045,702)
Issuance of note for accrued milestone payment	\$ 0	\$ 0	\$ 500,000
Sale of To Go Brands for preferred stock	\$ 1,699,672	\$ 0	\$ 1,699,672

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

**Table of Contents**

**TAXUS CARDIUM PHARMACEUTICALS GROUP, INC. AND SUBSIDIARIES**

**(a development stage company)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Organization and Liquidity**

**Organization**

Taxus Cardium Pharmaceuticals Group, Inc. (the Company, Cardium, we, our and us ) was incorporated in Delaware in December 2003. We are a development-stage regenerative medicine biotechnology company. We are focused on the development of advanced regenerative therapeutics designed to promote the activation and growth of (1) microvascular circulation to enhance perfusion of ischemic cardiac tissue as a potential treatment for heart disease; and (2) granulation tissue as a treatment for chronic non-healing wounds. We have a commercial FDA-cleared wound care product, a late clinical stage cardiovascular gene therapy product candidate and corresponding technology platforms as outlined below. We also own non-core interests in the Healthy Brands Collective, a health products company, and LifeAgain Insurance Solutions, Inc., a medical analytics business.

In October 2005, we acquired a portfolio of biologic growth factors and related delivery techniques from the Schering AG Group (now part of Bayer AG) for potential use in treating ischemic and other cardiovascular conditions.

In March 2006, we acquired the technologies and products of InnerCool Therapies, Inc., a medical technology company in the emerging field of therapeutic hypothermia, or patient temperature modulation, whose systems and products are designed to rapidly and controllably cool the body to reduce cell death and damage following acute ischemic events such as cardiac arrest and stroke, and to potentially lessen or prevent associated injuries such as adverse neurologic outcomes.

In August 2006, we acquired rights to assets and technologies of Tissue Repair Company, a company focused on the development of growth factor therapeutics for the potential treatment of tissue wounds such as chronic diabetic wounds, and whose product candidate, Excellagen is initially being developed as a single administration therapeutic for the treatment of non-healing, neuropathic diabetic foot ulcers. Tissue Repair Company is operated as a wholly-owned subsidiary of Cardium.

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

On September 28, 2012 we acquired substantially all of the business assets and product portfolio of privately-held To Go Brands, Inc. To Go Brands develops, markets and sells a portfolio of products, including nutraceutical powder mixes, supplements and chews intended to support healthy lifestyles. These products are sold through food, drug and mass channels at retailers including Whole Foods®, CVS®, Kroger®, GNC®, Jewel-Osco®, Ralph's Supermarkets®, Meijer®, and the Vitamin Shoppe® and from the Company's web-based store.

On November 15, 2013, the Company sold its To Go Brands® business to Healthy Brands Collective® in exchange for an equity stake in Healthy Brands preferred stock which, at the time of the transaction, was convertible into approximately 4% of their fully-diluted common stock, and the assumption of approximately \$370,000 of liabilities. Healthy Brands Collective® is a fast growing private company that has acquired a portfolio of eight independent brand product platforms (prior to To Go Brands).

Our business is focused on the acquisition and strategic development of product opportunities or businesses having the potential to address significant unmet medical needs, and having definable pathways to

## **Table of Contents**

commercialization. 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.

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

### **Reverse Stock Split**

On July 17, 2013, pursuant to board and stockholder approval, we filed a Certificate of Amendment to our Restated Certificate of Incorporation with the State of Delaware to affect a reverse split of our outstanding common stock, par value \$0.0001 per share, in a ratio of 1:20. The effective date of the reverse stock split was July 18, 2013.

On that date, every 20 shares of outstanding common stock were reclassified and combined into one share of common stock. No fractional shares were issued as a result of the reverse stock split. Instead, each resulting fractional share of common stock was rounded down to one whole share. The reverse stock split reduced the number of shares of common stock outstanding from 134,366,340 to 6,718,317.

All common stock and per share amounts contained in the consolidated financial statements included in this report have been retroactively adjusted to reflect the 1 for 20 reverse stock split, as if such split had been effective at the beginning of the earliest period reported.

### **Liquidity and Capital Resources**

As of December 31, 2013, we had \$22,000 in cash and cash equivalents. Our working capital deficit at December 31, 2013 was approximately \$1,110,000.

During the period subsequent to December 31, 2013, cash flows from financing activities include the sale of 714,286 shares of common stock in transactions for net proceeds of \$492,500.

Net cash used in operating activities was \$6.0 million for the year ended December 31, 2013 compared to \$9.2 million for the year ended December 31, 2012. The increase in net cash used in operating activities was due primarily to testing and process validation costs for the initial inventory of our Excellagen topical treatment gel. Since inception, our operations have consumed substantial amounts of cash and we have had only limited revenues. From inception (December 22, 2003) to December 31, 2013, net cash used in operating activities has been \$100.3 million.

Our primary source of liquidity has been cash from financing activities and in particular proceeds from sales of our debt and equity securities. Net cash provided by financing activities was \$3.7 million for the year ended December 31, 2013. This included a preferred stock equity financing with one institutional investor of 4,012 shares of Cardium Series A Convertible Preferred Stock priced at \$1,000 per share with no warrant coverage for net proceeds of \$3.7 million. From inception (December 22, 2003) to December 31, 2013 net cash provided by financing activities has been \$102.9 million.

Net cash used in investing activities for the year ended December 31, 2013 was \$23,000. Net cash used in investing activities since inception has been approximately \$2.6 million. At December 31, 2013 we did not have any significant capital expenditure requirements.

We anticipate that negative cash flow from operations will continue for the foreseeable future. We do not have any unused credit facilities. As long as any shares of our Series A Convertible Preferred Stock are

## **Table of Contents**

outstanding, we have agreed that we will not, without the consent of the holders of two-thirds of the Series A Convertible Preferred Stock, incur indebtedness other than specified Permitted Indebtedness, incur any liens other than specified Permitted Liens. We intend to secure additional working capital through sales of additional debt or equity securities to finance our operations. Our principal business objective is to complete an additional strategic licensing agreement to advance sales of the Excellagen product family and/or another corporate transaction. If we fail to enter into an additional strategic licensing arrangement or generate sufficient product sales, we will not generate sufficient cash flows to cover our operating expenses.

On September 28, 2010, we entered into a Sale Agreement with Brinson Patrick Securities Corporation which enables us to use Brinson Patrick as a sales manager to sell shares of our common stock on a best efforts basis from time to time in at-the-market transactions pursuant to our shelf registration statement. During the year ended December 31, 2013 we raised \$65,743 under this agreement, the majority of which was raised during the first quarter of 2013. The Sale Agreement required that we register the sale of our shares to Brinson Patrick Securities Corporation on a shelf registration statement on Form S-3. Because our common stock is no longer listed on a national exchange, we are not eligible to use a Form S-3 registration statement. Accordingly we do not anticipate additional sales under the Sales Agreement unless and until we regain listing on a national exchange.

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

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

### **Basis of Presentation**

The accompanying financial statements have been prepared in accordance with authoritative guidance for development stage enterprises.

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

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

### **Estimates**

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

### **Principles of Consolidation**

The consolidated financial statements include the accounts of Taxus Cardium Pharmaceuticals Group, Inc. and its wholly-owned subsidiaries, Tissue Repair Company, To Go Brands, Inc. (a business that is presented as a discontinued operation as described in Note 3) and LifeAgain Insurance Solutions, Inc. (collectively, the Company). All significant inter-company transactions and balances have been eliminated in consolidation.

### **Business Acquisitions.**

Business combinations are accounted for using the acquisition method of accounting in accordance with ASC 850 Business Combinations. The cost of an acquisition is measured as the fair value of the consideration

## **Table of Contents**

transferred on the acquisition date. When the Company acquires a business, it assesses the acquired assets and liabilities assumed for the appropriate classification and designation in accordance with the contractual terms, economic circumstances and pertinent conditions at the acquisition date. The excess of the total consideration transferred over the net identifiable assets acquired and liabilities assumed is recognized as goodwill. If this consideration is lower than the fair value of the identifiable net assets acquired, the difference is recognized as a gain on business acquisition. Acquisition costs are expensed as incurred and included in general and administrative expenses in our consolidated statements of operations.

### **Cash and Cash Equivalents**

We consider all highly liquid investments with maturities of three months or less when purchased to be cash equivalents.

### **Concentration of Credit Risk**

Financial instruments that potentially subject us to significant concentrations of credit risk consist of cash and cash equivalents. At times, our cash and cash equivalents may be uninsured or in deposit accounts that exceed the Federal Deposit Insurance Corporation ( FDIC ) insurance limits. As of December 31, 2013, we had no cash and cash equivalent balances in excess of the federally insured limit of \$250,000.

### **Accounts Receivable**

Accounts receivable are stated at cost less an allowance for doubtful accounts, which reflects our estimate of balances that will be not collected. The allowance is based on the history of past write-offs, the aging of balances, collections experience and current credit conditions. Additions to the allowance for doubtful accounts include provisions for bad debt and deductions to the allowance for doubtful accounts including customer write-offs. The Company has a low occurrence of credit losses and therefore does not believe an allowance for doubtful accounts in necessary.

### **Inventory**

Inventories are stated at lower of cost or market and consist of raw materials associated with the Excellagen product. Inventories are valued on a first-in, first-out (FIFO) basis. The Company records reserves for inventories that are obsolete or exceed anticipated demand or carried at an amount that exceeds management's estimate of net realizable. In establishing such reserves, management considers historical sales of identical and/or similar goods, product development plans and expected market demand.

### **Property and Equipment**

Property and equipment are stated at cost and include equipment, installation costs and materials. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the useful lives or the term of the respective lease.

Expenditures for maintenance and repairs, which do not extend the useful life of the assets, are charged to expense as incurred. Gains or losses on disposal of property and equipment are reflected in general and administrative expenses in the statement of operations.

### **Technology Licenses**

Technology licenses represent two distinct licenses that we acquired for the use of fully developed product formulas that we planned to use as part of our initiative to create a portfolio of nutraceutical products. We planned to market these products to consumers principally through convenience stores, pharmacy chains, and



## **Table of Contents**

wholesale clubs that we gained access to as a result of our acquisition of To Go Brands (Note 3). These licenses were initially recorded at cost and were being amortized over the fixed term of the underlying agreements, which we believed was approximately equal to the useful lives of the underlying product formulas. We periodically tested the carrying amounts of these licenses for possible impairment in accordance with the guidelines enumerated under Accounting Standards Codification (ASC) 350 Intangibles-Goodwill and Other. Under ASC 350, intangible assets with definite lives are periodically tested for impairment based on an analysis of undiscounted cash flows (as described below). Management has determined it appropriate to discontinue the nutraceutical operations which led to the sale of To Go Brands Inc., and the write-off of the unamortized balance of \$1.1 million of our technology licenses associated with that product line.

### **Long-Lived Assets**

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

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

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

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

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell. We do not believe there was any impairment of long-lived assets at December 31, 2013 but determined it appropriate to discontinue the nutraceutical operations which led to the sale of To Go Brands Inc., and to fully reserve the unamortized balance of \$1.1 million of our technology licenses which was focused on that product line.

### **Preferred Stock**

We apply the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of our preferred stock. Shares that are subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. We classify conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

### **Revenue Recognition**

The Company's revenues principally consist of sales of Excellagen product. The Company applies the revenue recognition principles set forth under the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) 104. Accordingly, revenue from product sales is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred, (iii) the sales price is fixed or determinable, and (iv) collectability is reasonably assured. These criteria are met when the risk of ownership and title passes to the Company's customers.

### **Research and Development**

In accordance with ASC Topic 730 research and development costs are expensed as incurred. Research and development expenses consist of purchased technology, purchased research and development rights and outside

## **Table of Contents**

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

### **Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period enacted. A valuation allowance is provided when it is more likely than not that a portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which related temporary differences become deductible. The benefit of tax positions taken or expected to be taken in the Company's income tax returns are recognized in the consolidated financial statements if such positions are more likely than not to be sustained upon examination.

### **Common Stock Purchase Warrants**

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

### **Loss Per Common Share**

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

Basic income or loss per common share is computed by dividing net income or loss by the weighted average number of common shares outstanding during the period. Diluted income or loss per common share is computed by dividing net income or loss by the weighted average number of common shares outstanding, plus the issuance of common shares, if dilutive, that could result from the exercise of outstanding stock options and warrants. These potentially dilutive securities were not included in the calculation of loss per common share for the years ended December 31, 2013 or 2012 because their effect would be anti-dilutive.

As of December 31, 2013 potentially dilutive securities consist of outstanding stock options and warrants to acquire 1,122,830 shares of our common stock. As of December 31, 2012, potentially dilutive securities consisted of outstanding stock options and warrants to acquire 1,547,071 shares of our common stock.

### **Stock-Based Compensation**

Stock-based compensation costs are recognized on a straight-line basis over the requisite service period of the award, which is generally the vesting term of the award.

**Table of Contents**

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

	December 31,	
	2013	2012
Research and development	\$ 5,997	\$ 23,883
General and administrative	34,753	145,863
<b>Total stock-based compensation</b>	<b>\$ 40,750</b>	<b>\$ 169,746</b>

**Deferred Rent**

Rent expense is recorded on the straight-line method based on the total minimum rent payments required over the term of the lease. The cumulative difference between the lease expense recorded under this method and the contractual lease payment terms is recorded as deferred rent.

**Recent Accounting Pronouncements**

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

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

In accordance with the provisions of ASC topic 360 (formerly SFAS No. 144), Accounting for the Impairment or Disposal of Long-Lived Assets, the disposal of our To Go Brands Inc. business segment is presented as assets and liabilities held for sale and as a discontinued operation in the accompanying consolidated financial statements.

**Assets and liabilities of discontinued operations**

The major categories of assets and liabilities of discontinued operations included in the consolidated balance sheet at December 31, 2012 were as follows:

<b>Assets of discontinued operations:</b>	
Accounts receivable	306,633
Inventories, net	492,229
Prepaid expenses and other current assets	53,684
Property, plant and equipment, net	45,467
Goodwill	584,711
Intangibles, net	1,019,692
Long term assets	9,028
<b>Total assets of discontinued operations</b>	<b>\$ 2,511,444</b>
<b>Liabilities of discontinued operations:</b>	
Accounts payable	\$ 403,735
Accrued liabilities	238,345
<b>Total liabilities of discontinued operations</b>	<b>\$ 642,080</b>



**Table of Contents**

The following results of operations of To Go Brands, Inc. and the expense associated with the write-off of the remaining recorded value of the technology licenses associated with the nutraceutical business are presented as a loss from a discontinued operation in the consolidated statements of operations:

	For the years ended December 31,		Period from December 22, 2003 (Inception) to December 31, 2009
	2013	2012	
Revenues			
Product sales	\$ 1,728,177	\$ 725,909	\$ 2,454,086
Cost of goods sold	1,002,064	382,914	1,384,978
Gross profit	726,113	342,995	1,069,108
Operating expenses			
Research and development	128,215	40,227	168,442
Selling, general and administrative	1,507,210	398,761	1,905,971
Total operating expenses	1,635,425	438,988	2,074,413
Loss from operation	(909,312)	(95,993)	(1,005,305)
Interest, net	(667)	(203)	(870)
Net loss from discontinued operations of To Go Brands, Inc.	\$ (909,979)	\$ (96,196)	\$ (1,006,175)
Write-off of technology licenses associated with the nutraceutical product lines	(1,097,511)	0	(1,097,511)
Net loss from discontinued operations	\$ (2,007,490)	\$ (96,196)	\$ (2,103,686)

On November 15, 2013, we closed the sale of our To Go Brands, Inc. business unit to Healthy Brands Collective. The purchase price was 33,441 shares of preferred stock of Cell-nique (parent company of Healthy Brands). Since Cell-nique Corporation is a private company we have recorded the value of those shares of preferred stock on our balance sheet as an investment in Cell-nique Corporation, at the net asset value of the assets transferred and liabilities assumed by Cell-nique Corporation. The Company has elected to defer recognition of any gain on the sale of the To Go Brands business until such time that the realization of the gain is reasonably assured. Accordingly, the Company is accounting for its investment in Cell-nique using the cost method of accounting, in which the cost is equal to the carrying amount of the net assets sold to Cell-nique as of the date that the transaction closed. The Company will periodically review the carrying amount of its investment in Cell-nique to determine whether the value is impaired or a write down may be necessary for an other than temporary decline in value.

The Cell-nique preferred shares are convertible into Cell-nique common stock at the option of the Company which would currently represent approximately 4% of the fully-diluted voting interests of Cell-nique. These shares also accrue dividends at the rate of 8% per annum, are mandatorily convertible into common shares under certain circumstances, and feature customary rights of priority and a liquidation preference in the event of a dissolution or winding up Cell-nique's affairs or upon the occurrence of other deemed liquidation events described in Cell-nique's articles of incorporation.

The following is the calculation of the net assets on the sale of To Go Brands, Inc.

Net assets sold:	
Accounts receivable	106,843
Prepaid expenses and other current assets	8,059
Inventory, net	456,276
Property and equipment, net	18,082
Intangible assets, net	1,481,123

Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

Other long term assets	0
Accounts payable	(305,072)
Other liabilities	(65,639)
Net Assets of To Go Brands, Inc. sold	1,699,672

**Table of Contents****Note 4 Inventories**

Inventories consisted of the following:

	December 31, 2013	December 31, 2012
Raw materials	\$ 183,398	\$ 430,825
Finished goods	0	313,700
	183,398	744,525
Less provision for obsolete inventory	(23,567)	(62,431)
Inventories, net	\$ 159,831	\$ 682,094

**Note 5 Property and Equipment**

Property and equipment consisted of the following:

	December 31,	
	2013	2012
Computer and telecommunication equipment	\$ 425,331	\$ 532,069
Machinery and equipment	31,779	31,779
Office equipment	11,490	53,050
Instrumentation	0	115,421
Office furniture and equipment	223,206	480,594
Leasehold improvements	23,053	152,774
	714,859	1,365,687
Accumulated depreciation and amortization	(684,663)	(1,313,572)
Property and equipment, net	\$ 30,196	\$ 52,115

Depreciation and amortization of property and equipment from continuing operations totaled \$44,973 and \$99,332 for the years ended December 31, 2013 and 2012, respectively. For the period from December 22, 2003 (inception) through December 31, 2013 depreciation and amortization of property and equipment from continuing operations totaled \$1,414,271.

**Note 6 Intangible assets and strategic investment**

On November 17, 2010 we entered into a custom technology access and product license agreement with BioZone Laboratories, Inc. ( BioZone ) for the co-development and strategic licensing of a portfolio of up to 20 aesthetics, advanced skin care formulations and other products for our MedPodium product line. The agreement grants us a royalty-free license of BioZone s technology to develop a portfolio of 20 products, customized to our product specifications. We have exclusive rights to the products developed to our specifications. The license is for a term of 10 years with an automatic 1 year renewal at our option, without any material restrictions or additional consideration. In exchange for the technology access license we paid BioZone a fee of \$1.0 million. The license fee was paid through the issuance of 100,000 shares of our unregistered common stock. The license fee was being amortized over 11 years on a straight line basis; however, the Company is now primarily focused on the development of advanced regenerative medicine therapeutics and determined it appropriate to discontinue the nutraceutical operations which led to the sale of To Go Brands Inc., and to the write-off of the unamortized balance of \$738,636 of this technology license which was focused on that product line.

On December 20, 2011 we received a license for a portfolio of nutraceutical, pharmaceutical and medical food product opportunities with SourceOne Global Partners, LLC ( SourceOne ). In exchange for the license we





**Table of Contents**

issued 75,000 restricted shares of our common stock valued at \$5.80 per share. The shares were deposited in escrow for nine months and subject to release at future dates thereafter based on our advancement of certain jointly-developed products. Under terms of the licensing arrangement, we received a fully-paid-up license to commercialize formulations of various SourceOne ingredients to be marketed as nutraceuticals, pharmaceuticals and/or medical foods. In addition, we obtained the right to designate up to ten products to be jointly developed by the parties, with cash and other resources to be contributed jointly under a profit-share arrangement. The license fee was being amortized over 10 years on a straight line basis; however, the Company is now primarily focused on the development of advanced regenerative medicine therapeutics and determined it appropriate to discontinue the nutraceutical operations which led to the sale of To Go Brands Inc., and to the write-off of the unamortized balance of \$358,875 of this technology license which was focused on that product line.

Under the SourceOne agreement, we also made a deposit on a potential equity investment in the form of unregistered, restricted shares of our common stock to acquire an option to purchase up to a 15% ownership interest in SourceOne Global Partners. The seven year option was acquired through the issuance into escrow of 75,000 shares of our common stock which were recorded at a value of \$5.80 per share based on the closing price of our stock on December 19, 2011, and is exercisable for an exercise fee of \$10,000. The shares of our common stock issued for the option are being held in escrow and are subject to release in four allotments at 6, 9, 12 and 18 months following the closing date. During the year ended December 31, 2012, 50,000 shares were released from the escrow account and the balance of 25,000 was released in 2013. We also have certain rights to maintain our proportionate ownership interest in SourceOne, and a right of first refusal to acquire SourceOne on the terms that SourceOne were to offer a third-party acquirer. The company has over five years remaining to determine if it will exercise this option. In the event the Company chooses not to proceed with making the investment in Source One, the non-refundable deposit would be recorded as a charge to operations.

**Note 7 Accrued Liabilities**

Accrued Liabilities consisted of the following:

	December 31,	
	2013	2012
Payroll and benefits	\$ 511,098	\$ 376,512
Other	99,909	0
<b>Total</b>	<b>\$ 611,007</b>	<b>\$ 376,512</b>

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

On September 28, 2012 with the acquisition of To Go Brands, we assumed the office for approximately 4,745 square feet of office and warehouse space in San Diego, California to be used as To Go Brands operating headquarters. The lease originally commenced in June 2012 and has a two year term. Monthly base rent is \$4,270 during the first year of the lease and increases to \$4,441 for the second year of the lease. In addition to monthly base rent, we are also required to pay \$300 to cover the Association monthly fees. In connection with entering into this lease, the landlord holds a security deposit of \$4,441 on this lease.

On January 30, 2013 we entered into a lease for approximately 2,471 square feet of additional warehouse space in San Diego, California to be used for To Go Brands. Monthly base rent is \$1,853. In connection with entering into the lease, we paid a security deposit of \$1,853.

On August 15, 2013 we entered into a lease for approximately 4,419 square feet of office space in San Diego, California to be used as our corporate headquarters. The lease commenced on September 1, 2013 once improvements were completed and has a term of 36 months from the commencement date. In addition to

**Table of Contents**

monthly base rent, we are also required to pay our proportionate share of any building operating expenses in excess of 2014 levels. In connection with entering into the lease, we paid a security deposit of \$9,231. Monthly base rent is \$9,678 during the first year of the lease and increases to \$10,016 in year two and \$10,367 in year three.

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

Year Ending December 31,	Facilities (Operating Lease)
2014	150,458
2015	121,596
2016	82,936
Total	\$ 354,990

Rent expense included in continuing operations was \$435,573, and \$582,146 for the years ended December 31, 2013 and 2012 respectively.

**License Fees**

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

**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.

**Note 9 Income Taxes**

We file income tax returns in the United States (federal) and California. In most instances, we are no longer subject to federal, state and local income tax examinations by tax authorities for years prior to 2010.

ASC 740 clarifies the accounting and reporting for uncertainties in income tax law. It prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions. Differences between a tax position taken or expected to be taken in the Company's tax

**Table of Contents**

returns and the amount of benefit recognized and measured in the financial statements result in unrecognized tax benefits, which are recorded in the balance sheet as either a liability for unrecognized tax benefits or reductions to recorded tax assets, as applicable. As of December 31, 2013 and 2012, no liability for unrecognized tax benefits was required to be recorded.

Interest costs related to unrecognized tax benefits are required to be calculated and would be classified as interest expense in the consolidated statement of operations. Penalties would be recognized as a component of general and administrative expenses. No interest and penalties were recorded during the years ended December 31, 2013 and December 31, 2012.

We had U.S. federal and state net operating loss carryovers of \$92.5 million and \$88.2 million as of December 31, 2013 and 2012, respectively. These net operating losses are subject to Internal Revenue Code Section 382, which could result in limitations on the amount of such losses that could be utilized during any taxable year. The net operating losses begin to expire in 2023 for federal income purposes and in 2013 for state income tax purposes.

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

A valuation allowance will be maintained until sufficient positive evidence exists to support the reversal of any portion or all of the valuation. For the years ended December 31, 2013 and 2012 the change in the valuation allowance was \$1,530,946 and \$4,417,362, respectively.

Our net deferred tax asset consisted of the following at December 31, 2013 and 2012:

	December 31,	
	2013	2012
Deferred tax asset:		
Net operating loss carryforwards	\$ 36,837,171	\$ 35,135,946
Deferred compensation	881,025	881,025
Depreciation and amortization	886,149	944,369
License impairment	437,187	0
Deferred rent	0	20,065
Research and development credit	194,132	0
Accrued expenses	97,326	100,936
Other	137,611	57,643
Total deferred tax assets	39,470,601	37,139,984
Less: Valuation allowance	(39,470,601)	(37,139,984)
Net deferred tax asset		

The income tax provision (benefit) from income taxes consists of the following at December 31, 2013 and 2012:

	Years Ended December 31,	
	2013	2012
Federal		
Current	\$	\$
Deferred	(1,306,714)	(3,770,936)
State		
Current		
Deferred	(224,232)	(646,426)

Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

Total	\$ (1,530,946)	\$ (4,417,362)
Change in valuation allowance	1,530,946	4,417,362
Income tax provision (benefit)	\$	\$

**Table of Contents**

As a result of our significant operating loss carryforwards and the corresponding valuation allowance, no income tax benefit was recorded at December 31, 2013 or 2012. The provision for income taxes using the statutory federal tax rate as compared to our effective tax rate is summarized as follows:

	December 31,	
	2013	2012
Expected U.S. federal statutory rate	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(5.8)%	(5.8)%
Deferred tax true-up	18.7%	(13.5)%
R&D credit	(1.4)%	0%
Other permanent differences	0.3%	0.3%
	(22.2)%	(53.0)%
Change in valuation allowance	22.2%	53.0%
Totals	0%	0%

**Note 10 Stockholders Equity****Common Stock**

Cardium was incorporated in Delaware on December 22, 2003. On December 31, 2003, we sold 85,000 shares of our common stock to our founders and executives for \$17,000. On April 1, 2005, we issued an additional 190,000 shares of our common stock (of which 182,500 shares were issued to our co-founders and the remainder was issued to another employee of Cardium), in exchange for services and reimbursement of expenses valued at \$38,000.

On May 19, 2005, our Board of Directors and stockholders approved an increase in our authorized shares of common stock from 5,500,000 shares to 100,000,000 shares and a change in the par value of our shares of common stock from \$0.001 to \$0.0001.

On May 20, 2005, we issued 17,500 shares of our common stock to our co-founders in exchange for services and reimbursement of expenses valued at \$3,500. On July 1, 2005, we sold 100,000 shares of our common stock for \$20,000 to one of our founders.

On October 20, 2005, we completed a reverse merger with Aries Ventures Inc., a publicly-traded shell company, whereby a newly formed and wholly-owned subsidiary of Aries was merged with and into Cardium. At the time of the reverse merger, Cardium had 392,500 shares of its common stock outstanding and Aries had 101,611 shares of its common stock outstanding.

In connection with the reverse merger, a three year warrant to purchase 20,000 shares of our common stock at an exercise price of \$35.00 per share was issued to an Aries stockholder who held of record or beneficially more than 45% of the outstanding common stock of Aries before the reverse merger, as consideration for such stockholder's agreement not to sell any of such stockholder's shares for a specified period of time. These warrants expired in October 2008.

Concurrently with the reverse merger, we closed a private placement of 966,282 shares of common stock at a purchase price of \$30.00 per share and received net proceeds of \$25,542,389. Investors who invested at least \$1,000,000 in shares of common stock received a three-year warrant to buy 10% of the number of shares of common stock purchased in the private placement, at an exercise price of \$35.00 per share. Warrants to purchase 21,213 shares of common stock, in the aggregate, were issued to such investors. These warrants expired in October 2008.

On March 8, 2006, as described in Note 3 above, we acquired substantially all of the assets of Innercool Therapies, Inc. As partial consideration, we issued to the seller 125,000 shares of our common stock.

## **Table of Contents**

On March 9, 2007, we closed a private placement of 431,800 shares of common stock at a purchase price of \$50.00 per share and received net proceeds of approximately \$20 million. Investors received five-year warrants to buy up to 35% of the number of shares of common stock purchased in the private placement, at an exercise price of \$75.00 per share. Warrants to purchase approximately 151,130 shares of common stock, in the aggregate, were issued to such investors. These warrants had a price protection provision which was triggered on January 31, 2008 and therefore were reduced to an exercise price of \$40.00.

In connection with the private placement, we incurred selling commissions, and expenses payable to the placement agent, totaling approximately \$1,480,300, and legal, accounting and other fees and expenses totaling approximately \$100,000. In addition, a five-year warrant to purchase 25,908 shares of our common stock was issued to the placement agent at an exercise price of \$75.60 per share.

In November 2007, we entered into a Loan and Security Agreement with Life Sciences Capital, LLC whereby we obtained debt financing in the principal amount of \$5 million to be used for general working capital purposes. The proceeds were immediately made available to us under this credit agreement. In connection with this financing, we issued a warrant to Life Sciences Capital, LLC to purchase 4,666 shares of our common stock at an exercise price of \$75.00. We also recorded deferred financing costs in the amount of \$108,500 in connection with this debt financing.

On January 31, 2008, we completed a registered direct offering of our common stock that resulted in the sale of 132,750 shares, in the aggregate, of our common stock at a purchase price of \$40.00 per share. We received gross proceeds of approximately \$5,300,000, before placement agent fees and offering expenses of approximately \$400,000. At December 31, 2012 warrants to purchase 51,428 shares of our common stock remain outstanding. The warrants had an exercise price of \$40.00 and expired in January of 2013.

On June 27, 2008, we completed a follow-on registered direct offering of our common stock that resulted in the sale of 81,250 shares, in the aggregate, of our common stock at a purchase price of \$40.00 per share. We received gross proceeds of approximately \$3,250,000, before placement agent fees and offering expenses of approximately \$224,000. Warrants to purchase 118,575 shares of our common stock were issued with this transaction. 113,750 of these warrants had an exercise price of \$10.00 and 4,825 had an exercise price of \$45.80. The warrants expired in June of 2013.

On July 18, 2008, we completed a second follow-on registered direct offering of our common stock that resulted in the sale of 83,500 shares, in the aggregate, of our common stock at a purchase price of \$40.00 per share. We received gross proceeds of approximately \$3,340,000, before placement agent fees, offering expenses and expense reimbursements of approximately \$330,000. Warrants to purchase 121,450 shares of our common stock were issued with this transaction. 116,900 had an exercise price of \$10.00 and 4,550 had an exercise price of \$44.00. The warrants expired in June of 2013.

On November 5, 2008, we completed a secured debt financing pursuant to the terms of a Note and Warrant Purchase Agreement entered into with certain accredited investors. Under the terms of the purchase agreement we issued notes in the aggregate principal amount of \$6 million to the investors, and five year warrants to purchase an additional 469,331 shares of our common stock, in the aggregate, at an exercise price of \$40.00 per share. These warrants expired in November of 2013.

On March 5, 2009 we completed a \$3.5 million financing in the form of senior subordinated secured debt with accompanying warrants to purchase 75,250 shares of our common stock. The warrants were fully exercisable when issued, have a five year term and an exercise price of \$40.00. We received gross proceeds of approximately \$3.5 million, less placement agent fees and offering expenses of approximately \$252,000. In addition, we issued warrants to purchase 4,515 shares of common stock to the placement agent on the same terms as the warrants issued to the lenders. At December 31, 2013 all warrants issued in this transaction remain outstanding.

---

**Table of Contents**

On June 23, 2009 we completed a \$750,000 unsecured debt financing with accompanying warrants to purchase 25,125 shares of our common stock. The warrants were fully exercisable when issued, have a five year term and an exercise price of \$40.00. These warrants have subsequently been repriced to \$10.00. We received aggregate gross proceeds of approximately \$750,000 before placement agent fees and offering expenses of approximately \$50,000. In addition, we issued warrants to purchase 603 shares of common stock to the placement agent on the same terms as the warrants issued to the lenders. At December 31, 2013 all warrants issued in this transaction remain outstanding.

In September 16, 2009, we sold an aggregate of 150,000 at a price of \$30.00 per share of our common stock and 112,500 warrants to common stock to certain institutional investors in exchange for gross proceeds of \$4.2 million, net of issuance costs. Each investor received warrants to purchase a number of shares equal to 75% of the number of shares of common stock purchased by the investor in the offering. The exercise price of the warrants is \$35.40. In addition, the placement agent for the September financing received 7,500 warrants to purchase common stock at an exercise price of \$37.40 on substantially identical terms; provided, however that the warrants to the placement agent expired on December 19, 2012. At December 31, 2013, 112,500 of the warrants issued in this transaction remain outstanding.

On October 15, 2009, we sold an aggregate of 230,769 shares of our common stock and 150,000 warrants to common stock to certain institutional investors in exchange for gross proceeds of \$5.6 million, net of issuance costs. Each investor received warrants to purchase a number of shares equal to 75% of the number of shares of common stock purchased by the investor in the offering. The units were sold at a price of \$26.00 per unit. The exercise price of the warrants is \$28.00. In addition, the placement agent for the October financing received 11,538 warrants to purchase common stock at an exercise price of \$32.60 on substantially identical terms; provided, however that the warrants to the placement agent expired on December 19, 2012. At December 31, 2013, 150,000 of the warrants issued in this transaction remain outstanding.

On March 12, 2010, we completed a registered direct offering of 2,266,998 units, which were sold to institutional and retail investors, at a price of \$5.00 per unit. The offering resulted in gross proceeds to us of \$11.3 million and net proceeds of approximately \$10.4 million after payment of offering fees and expenses. Each unit consisted of .5 share of common stock and a warrant to purchase .25 share of common stock. In the aggregate 1,133,500 shares of common stock and warrants to purchase an additional 566,750 shares of common stock were issued in the offering. Dawson James received placement agent fees of \$793,449 and a warrant to purchase an aggregate of 56,675 shares of common stock, exercisable at \$12.80 per share. The placement agent's warrants expired on December 9, 2012. At December 31, 2013, 566,750 of the warrants issued in this transaction remain outstanding.

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

On September 28, 2010, we entered into a Sales Agreement ( Sales Agreement ) with Brinson Patrick Securities Corporation to enable us to use Brinson Patrick as a sales manager to sell shares of our common stock from time to time in at-the-market transactions pursuant to our shelf registration statement on a best efforts basis. For the year ended December 31, 2011 we sold 524,393 shares under this agreement for net proceeds of \$4,530,129.

On November 17, 2010 we entered into a custom technology access and product license agreement with BioZone Laboratories, Inc. ( BioZone ) for the co-development and strategic licensing of a portfolio of up to

## **Table of Contents**

20 aesthetics, advanced skin care formulations and other products for our MedPodium™ product line. The agreement grants us a royalty-free license of BioZone technology to develop a portfolio of 20 products, customized to our product specifications, and exclusive rights to the products developed to its specifications. The license is for a term of 10 years plus a one year automatic renewal. In exchange for the technology access license we paid BioZone a fee of \$1.0 million. The license fee was paid with 100,000 shares of our unregistered common stock at a fair value \$10.00 per share.

On December 2, 2010 we filed a Tender Offer Statement to exchange (the Warrant Exchange ) certain outstanding warrants dated March 9, 2007, November 5, 2008 and November 10, 2008 that contain unlimited down round price protection (the Eligible Warrants ). The Eligible Warrants were exchanged for shares of our common stock, par value \$0.0001. The Warrant Exchange expired at 9:00 p.m., Pacific Time, on December 30, 2010. Pursuant to the Warrant Exchange, an aggregate of 346,590 Eligible Warrants to purchase common stock were tendered and accepted for cancellation, representing approximately 67.49% of the total Eligible Warrants outstanding and eligible for exchange in the Warrant Exchange. On December 31, 2010, we issued an aggregate of 115,530 shares of our common stock in exchange for the eligible warrants surrendered in the Warrant Exchange. The gain on sale was calculated by taking the current fair value of the warrants, \$1,419,761 and reducing this by the current market value of the shares issued of \$901,139, resulting in a gain of \$518,622. This gain was then reduced by a facilitation fee paid to Empire Asset Management in the amount of \$44,750.

On December 20, 2011 we made a \$0.75 million equity investment in the form of unregistered, restricted Cardium shares to acquire rights to a 15% ownership interest in SourceOne Global Partners. Our ownership interest was acquired through the issuance into escrow of 75,000 shares of our common stock based on a \$10.00 per share value representing a 70% premium above the closing price of our stock on December 19, 2011. We also have certain rights to maintain our proportionate ownership interest in SourceOne, and a right of first refusal to acquire SourceOne on the terms that SourceOne were to offer a third-party acquirer.

In parallel with the cross-equity investment and acquisition of an ownership interest in SourceOne, we also received a license for a portfolio of nutraceutical, pharmaceutical and medical food product opportunities for a licensing fee of \$0.75 million, which SourceOne applied to the purchase of 75,000 restricted shares of our common stock at \$10.00 per share.

During 2012, we raised net proceeds of \$6.4 million through the completion of a registered direct equity financing with three institutional and accredited investors of 895,000 shares of Cardium common stock priced at \$5.60 per share with no warrant coverage for net proceeds of approximately \$4.5 million and through the sale of 260,000 shares of common stock under at-the-market transactions for net proceeds of \$1.9 million.

During the first quarter of 2013, we raised net proceeds of \$65,743 through the sale of 17,187 shares of common stock under at-the-market transactions under our sales agreement with Brinson Patrick Securities Corporation.

## **Preferred Stock**

In April 2013, we entered into a securities purchase agreement with one of our institutional investors pursuant to which we agreed to sell to the investor an aggregate of 4,012 shares of our newly authorized Series A Convertible Preferred Stock, for a total purchase price of \$4.0 million. No warrants were issued in connection with this offering, other than 44,087 placement agent warrants with an exercise price of \$2.275 per share and an expiration date of August 27, 2015. The securities purchase agreement provided for the sale of Series A Convertible Preferred Stock in two closings. The initial closing under the securities purchase agreement took place in April 2013, at which we sold 2,356 shares of Series A Convertible Preferred Stock for aggregate net proceeds of \$2,160,000. A second closing for the remaining 1,656 shares of Series A Convertible Preferred Stock for aggregate net proceeds of \$1,532,000 took place promptly after shareholder approval of the offering of the



## **Table of Contents**

Series A Convertible Preferred Stock and the 1 for 20 reverse stock split of our outstanding common stock. That closing took place on July 18, 2013. Prior to December 31, 2013 the investor had converted 2,512 shares of Series A Convertible Preferred Stock into 2,332,851 shares of common stock. As a result of the conversion, 1,500 shares of Series A Convertible Preferred Stock were outstanding at December 31, 2013.

The holders of our Series A Convertible Preferred Stock are entitled, on an as-converted basis, to dividends equal to and in the same form as any dividends declared and issued on our common stock. Except as required by law, holders of Series A Convertible Preferred Stock are not entitled to voting rights. Upon any liquidation, dissolution or winding up, holders of the Series A Convertible Preferred Stock will be entitled to a liquidation preference above the holders of common stock or any other junior stock in an amount equal to the original purchase price of \$1,000, plus any fees, damages or dividends arising. The Series A Convertible Preferred Stock is convertible into shares of our common stock at the option of the holder, subject to a beneficial ownership limitation of 9.99%. The initial conversion price was \$1.82 per share after giving effect to the reverse stock split, but was subsequently reset to \$1.02 per share; the conversion price is subject to downward adjustment if we issue common stock or common stock equivalents at a price less than the then effective conversion price. We have the right to force conversion if the volume weighted average price for our common stock exceeds \$12.00 per share for 25 trading days during a 30 consecutive trading day period and certain other equity conditions are met.

As long as any shares of Series A Convertible Preferred Stock are outstanding, we have agreed that we will not, without the consent of the holders of two-thirds of the Series A Convertible Preferred Stock, incur indebtedness other than specified Permitted Indebtedness, incur any liens other than specified Permitted Liens, amend our Certificate of Incorporation in any manner that adversely affects the Series A Convertible Preferred Stock, repurchase or redeem any common stock or common stock equivalents, pay dividends on our common stock, or enter into any related party transactions.

In connection with the convertible preferred stock, the Company determined the instrument contained a beneficial conversion feature at the date of issuance. This beneficial conversion feature amounted to \$233,011 for the April transaction and was recorded as a deemed preferred dividend in April 2013. The beneficial conversion feature on the July transaction amounted to \$172,861 and was recorded as a deemed preferred dividend in July 2013.

## **Stockholder Rights Plan**

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

The Rights Plan was reviewed in 2012 and will be evaluated every three years by a committee of independent directors of our Board of Directors to consider whether the plan continues to be in the best interests of Cardium and its stockholders. The Rights Plan may be amended or revoked by our Board of Directors at any time and unless earlier terminated or amended, the rights will expire on July 10, 2016.

## **Stock Options and Other Equity Compensation Plans**

We have an equity incentive plan that was established in 2005 under which 283,292 shares of our common stock have been reserved for issuance to employees, non-employee directors and consultants of the Company.

**Table of Contents**

At December 31, 2013 the following shares were outstanding and available for future issuance:

Plan	Shares Outstanding	Shares Available for Issuance
2005 Equity Incentive Plan	144,000	139,058

There were no new grants during the year ended December 31, 2013. The following table summarizes the stock options and warrants that we granted during the year ended December 31, 2012:

Grant Date	Quantity Issued	Expected Life (Years)	Strike Price	Volatility	Dividend Yield	Risk-Free Interest Rate	Grant Date Fair Value Per Option	Aggregate Fair Value
03/12/12	2,500	4.58	\$ 14.80	99%	0%	0.85%	\$ 0.16	\$ 8,000
11/05/12	2,500	4.40	\$ 14.80	98%	0%	0.64%	\$ 0.09	\$ 4,500

As of December 31, 2013, we had no unvested stock-based compensation at fair value remaining to be expensed. During the year ended December 31, 2013 we recognized \$40,750 of stock option compensation expense.

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

The following is a summary of stock option and warrant activity under our equity incentive plan and warrants issued outside of the plan to employees and consultants, during the years ended December 31, 2013 and 2012:

	Number of Options or Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Balance outstanding, December 31, 2011	179,234	\$ 33.40	3.8
Granted	5,000	\$ 14.80	4.5
Exercised			
Cancelled	(2,500)	\$ 14.80	0
Cancelled (unvested)	(3,984)	\$ 18.80	0
Expired (vested)			
Balance outstanding, December 31, 2012	177,750	\$ 33.40	2.8
Granted	0	\$ 0.0	0
Exercised			
Cancelled (unvested)	(2,844)	\$ 14.80	0
Expired (vested)	(30,906)	\$ 41.70	0
Balance outstanding, December 31, 2013	144,000	\$ 31.74	2.1

## Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

Balance exercisable, December 31, 2013	144,000	\$ 31.80	2.1
--	---------	----------	-----

As of December 31, 2013 there was no intrinsic value to the outstanding and exercisable options.

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

The following table summarizes warrant activity for the years ended December 31, 2013 and 2012:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Balance outstanding, December 31, 2011	1,582,492	\$ 20.40	3.8
Warrants issued			
Warrants exercised	(137)	\$ 5.60	
Warrants expired	(213,034)	\$ 19.80	
Warrants cancelled			
Balance outstanding, December 31, 2012	1,369,321	\$ 19.00	2.1
Warrants issued	44,088	2.28	
Warrants exercised	(0)	\$ 0.0	
Warrants expired	(434,579)	\$ 15.72	
Warrants cancelled			
Balance outstanding, December 31, 2013	978,830	\$ 19.82	1.9
Warrants exercisable at December 31, 2013	978,830	\$ 19.82	1.9

As of December 31, 2013 there was no intrinsic value to the outstanding and exercisable options.

**Note 11 Segment Information**

Effective October 1, 2012, we commenced reporting the results our operations in two segments; Pharmaceutical Products and Health Sciences ( Nutraceutical ) Products. We established these two segments following our acquisition of To Go Brands, which presented us with a turn-key opportunity to acquire a limited but established portfolio of nutritional supplement products. We managed these two segments separately due to inherent differences in the nature of pharmaceutical and nutraceutical products. Pharmaceutical products are subject to significantly more stringent regulatory approval standards than nutraceutical products; there are material differences in the cost, time and effort we must expend to develop and test pharmaceutical products, each of these product categories have distinctly different marketing channels and the initial sales ramp is much slower for our products in the Pharmaceutical segment.

The Nutraceutical segment of our business included the purchasing, packaging, selling and distribution of the To Go Brands portfolio of products that we acquired on September 28, 2012. The Pharmaceutical segment of our business, which is our core and planned principal operation, includes the development, testing and clinical trials of Generx and Excellagen products. The Company does not have an internal sales force for its pharmaceutical products and will rely on strategic partnerships and distribution agreements in the U.S. and internationally. We have distributed samples and made initial sales of Excellagen and have entered into distribution agreements for future sales growth. With the sale of our To Go Brands business as described in Note 3 we no longer have the Nutraceutical segment and therefore only have one reporting segment. Currently LifeAgain s expenditures are immaterial and therefore doesn t warrant a separate segment.

**Note 12 Subsequent Events**

On February 28, 2014, the Company entered into a collaboration and financing arrangement with Shanxi Taxus Pharmaceuticals Co., Ltd. ( Shanxi Taxus ), a strategic corporate investor based in China, pursuant to which the parties agreed to collaborate on the advancement of the Company s product opportunities in China, and the investor s product opportunities in the United States. The arrangement is reflected in two definitive agreements, each dated as of February 21, 2014, which were concluded and delivered on February 28, 2014, in connection with the first tranche of funding under the financing arrangement.



## Table of Contents

Under the terms of a Collaboration Agreement, Shanxi Taxus agreed to apply commercially reasonable efforts to assist Cardium to develop and refine a plan or plans pursuant to which Cardium products, particularly its Generx<sup>®</sup> and Excellagen<sup>®</sup> product opportunities, could be commercialized in China; and Cardium agreed that it will, upon request, apply commercially reasonable efforts to assist Shanxi Taxus to develop and refine a plan or plans pursuant to which Shanxi Taxus oncology-related products and product opportunities could be commercialized in the United States. In connection with the collaboration agreement, the Company changed its name to Taxus Cardium Pharmaceuticals Group, Inc. In addition, the Company agreed that following the closing of \$2.0 million in financing under the Stock Purchase Agreement (described below) it will increase the size of its board of directors by two members and appoint Mr. Jiayue Zhang, who is the Chairman of Shanxi Taxus, and an additional individual with U.S. corporate and financial experience to Cardium's Board of Directors, and following the closing of \$5.0 million of financing under the Stock Purchase Agreement, the Company will increase the size of its Board of Directors by one additional member and appoint a third individual designated by Shanxi Taxus to the Board of Directors.

Under the terms of a Stock Purchase Agreement, Shanxi Taxus agreed to purchase up to \$5 million of shares of the Company's unregistered common stock in multiple tranches, each at a 10% premium to the then-current trailing average market prices of the Company's common stock at the time of each closing.

Cardium closed the initial tranche of funding by selling 714,286 shares of common stock at \$0.70 per share, based on a trailing average price. The purchase price for each subsequent tranche would be equal to one hundred ten percent (110%) of the then-current volume-weighted average price for sales of the Company's common stock over the thirty (30) calendar day period prior to each closing. Additional shares would be placed during an exclusive financing period ending on June 30, 2014, in up to four additional tranches, as follows: *Tranche 2*, in the amount One Million Five Hundred Thousand Dollars (\$1,500,000) would be placed on or around March 31, 2014; *Tranche 3*, in the amount of One Million Dollars (\$1,000,000) would be placed on or around April 30, 2014, provided that if the purchaser elected to not proceed with the full amount of Tranche 3, it would provide notice of such election to the Company on or before April 15, 2014, following which election, the amount of Tranche 3 would be reduced to a minimum of Three Hundred Thousand Dollars (\$300,000), and the exclusive financing period with the purchaser would be terminated as of April 30, 2014; *Tranche 4*, in the amount of One Million Dollars (\$1,000,000) would be placed on or around May 30, 2014, provided that if the purchaser elected to not proceed with the full amount of Tranche 4, it would provide notice of such election to the Company on or before May 15, 2014, following which election, the amount of Tranche 4 would be reduced to a minimum of Three Hundred Thousand Dollars (\$300,000), and the exclusive financing period would be terminated as of May 30, 2014; and *Tranche 5*, in the amount of One Million Dollars (\$1,000,000) would be placed on or around June 30, 2014, provided that if the purchaser elected to not proceed with the full amount of Tranche 5, it would provide notice of such election to the Company on or before June 16, 2014, following which election, the amount of Tranche 5 would be reduced to a minimum of Three Hundred Thousand Dollars (\$300,000).

The common stock purchased by the investor is unregistered but in the event that the Company files a registration statement for other shares of common stock after the exclusive financing period with the strategic investor ends, then the Company agreed to supplement such registration statement to provide piggyback registration rights for the shares purchased by the Shanxi Taxus. No warrants were issued to the strategic investor in connection with the transaction.

On February 28, 2014 the Company issued 1,457,100 common stock warrants to directors, officers and our chief medical advisor. The warrants were approved by the Board of Directors, have a ten year term and an exercise price of \$0.80 per share, which represents a 57% premium to the closing stock price on the date of issuance.

The Company has evaluated events that occurred subsequent to December 31, 2013 and through the date the financial statements were issued.

---

**Table of Contents**

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2013. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective for their intended purpose described above.

**Internal Control Over Financial Reporting**

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

Under the supervision, and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992). Based on this evaluation, management concluded that our internal control over financial reporting was effective for their intended purposes described above as of December 31, 2013.

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

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

During the fourth quarter of 2013, we sold our To Go Brands business to Health Brands Collective. In connection with that sale, we transferred assets, equipment and personnel to Healthy Brands Collective. In connection with the sale, management determined to discontinue our nutraceuticals business. The discontinuance of our nutraceuticals business has resulted in a simplification of our product lines, accounting systems, and

**Table of Contents**

personnel. We have correspondingly experienced changes to our internal controls related to the elimination of some accounting functions and personnel, and the focus on our core biologics business.

**ITEM 9B. OTHER INFORMATION**

None.



**Table of Contents**

**PART III**

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

The information for this item is incorporated by reference to the sections Our Board of Directors, Our Executive Officers, Section 16(a) Beneficial Ownership Reporting Compliance, and Code of Ethics in our definitive proxy statement for our Annual Meeting of Stockholders to be filed on or before April 30, 2014.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item will be included in our definitive proxy statement for our Annual Meeting of Stockholders to be filed on or before April 30, 2014, which is incorporated by reference herein.

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

The information required by this item will be included in our definitive proxy statement for our Annual Meeting of Stockholders to be filed on or before April 30, 2014, which is incorporated by reference herein.

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

The information required by this item will be included in our definitive proxy statement for our Annual Meeting of Stockholders to be filed on or before April 30, 2014, which is incorporated by reference herein.

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

The information required by this item will be included in our definitive proxy statement for our Annual Meeting of Stockholders to be filed on or before April 30, 2014, which is incorporated by reference herein.

**Table of Contents**

**PART IV**

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

The following documents are filed as part of this report:

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

Consolidated Balance Sheets as of December 31, 2013 and 2012;

Consolidated Statements of Operations for the years ended December 31, 2013 and 2012 and for the period from December 22, 2003 (inception) to December 31, 2013;

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013 and 2012;

Consolidated Statements of Cash Flows for the years ended December 31, 2013 and 2012 and for the period from December 22, 2003 (inception) to December 31, 2013; and

Notes to Consolidated Financial Statements.

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

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

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
3.1	Second Amended and Restated Certificate of Incorporation of Cardium Therapeutics, Inc. as filed with the Delaware Secretary of State on January 13, 2006	Exhibit 3(i) of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the commission on January 18, 2006
3.2	Certificate of Ownership and Merger as filed with the Delaware Secretary of State on March 14, 2014	Exhibit 3.1 of our Current report on Form 8-K, filed with the Commission on March 18, 2014.
3.2	Amended and Restated Bylaws of Cardium Therapeutics, Inc. as adopted on January 12, 2006	Exhibit 3(ii) of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the Commission on January 18, 2006
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock	Exhibit 3.2 of our Registration Statement on Form 8-A, filed with the Commission on July 11, 2006
3.4		

## Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

	Certificate of Designation for Series A Convertible Preferred Stock	Exhibit 3.1 of our Current Report on Form 8-K, filed with the Commission on April 5, 2013.
4.1	Form of Warrant issued to employees and consultants of Innercool Therapies, Inc.	Exhibit 4.1 of our Current Report on Form 8-K dated March 8, 2006, filed with the Commission on March 14, 2006
4.2	Form of Common Stock Certificate for Cardium Therapeutics, Inc.	Exhibit 4.5 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the Commission on March 31, 2006

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
4.3	Form of Rights Agreement dated as of July 10, 2006, between Cardium Therapeutics, Inc. and  Computershare Trust Company, Inc., as Rights Agent	Exhibit 4.1 of our Registration Statement on Form 8-A, filed with the Commission on July 11, 2006
4.4	Form of Rights Certificate	Exhibit 4.2 of our Registration Statement on Form 8-A, filed with the Commission on July 11, 2006
4.5	Form of Common Stock Purchase Warrant issued to investors and the placement agent in the February 2009 debt financing	Exhibit 4.2 of our Current Report on Form 8-K dated February 27, 2009, filed with the Commission on March 5, 2009
4.6	Form of Common Stock Purchase Warrant issued to investors and the placement agent in the June 2009 debt financing	Exhibit 4.2 of our Current Report on Form 8-K dated June 11, 2009, filed with the Commission on June 16, 2009
4.7	Form of Common Stock Purchase Warrant issued to investors in the September 2009 registered direct offering	Exhibit 4.1 of our Current Report on Form 8-K dated September 14, 2009, filed with the Commission on September 15, 2009
4.8	Form of Common Stock Purchase Warrant issued to investors in the October 2009 registered direct offering	Exhibit 4.1 of our Current Report on Form 8-K dated October 15, 2009, filed with the Commission on October 15, 2009
4.9	Form of Warrant Agreement between Cardium Therapeutics, Inc. and Computershare Trust Company, NA.	Exhibit 4.1 of our Current Report on Form 8-K dated March 15, 2010, filed with the Commission on March 15, 2010.
10.1	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of August 31, 2005, by and among New York University, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.1 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.2	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of August 31, 2005, by and among Yale University, Schering Aktiengesellschaft and Cardium Therapeutics, Inc.	Exhibit 10.2 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.3	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of July 31, 2005, by and among the Regents of the University of California, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.3 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.4	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of July 31, 2005, by and among the Regents of the University of California, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.4 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
10.5	Technology Transfer Agreement effective as of October 13, 2005, by and among Schering AG, Berlex, Inc., Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.5 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.6	Amendment to the Exclusive License Agreement for Angiogenesis Gene Therapy effective as of October 20, 2005, between the Regents of the University of California and Cardium Therapeutics, Inc.	Exhibit 10.6 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.7	Amendment to License Agreement effective as of October 20, 2005, by and between New York University and Cardium Therapeutics, Inc.	Exhibit 10.7 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.8	Second Amendment to Exclusive License Agreement effective as of October 20, 2005, by and between Yale University and Cardium Therapeutics, Inc.	Exhibit 10.8 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.9	2005 Equity Incentive Plan as adopted effective as of October 20, 2005*	Exhibit 10.9 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.10	Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Christopher Reinhard*	Exhibit 10.10 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.11	First Amendment dated March 16, 2007 to Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Tyler Dylan*	Exhibit 10.39 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed with the Commission on May 15, 2007.
10.12	Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Tyler Dylan*	Exhibit 10.11 of our Current Report on Form 8-K dated October 20, 2005, filed with the Commission on October 26, 2005
10.13	First Amendment dated March 16, 2007 to Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Christopher Reinhard*	Exhibit 10.38 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed with the Commission on May 15, 2007.
10.14	Yale Exclusive License Agreement between Yale University and Schering Aktiengesellschaft dated September 8, 2000	Exhibit 10.13 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the Commission on December 22, 2005
10.15	Research and License Agreement between New York University and Collateral Therapeutics, Inc. dated March 24, 1997 (with amendments dated April 28, 1998 and March 24, 2000)	Exhibit 10.14 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the Commission on December 22, 2005

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
10.16	Exclusive License Agreement for Angiogenesis Gene Therapy between the Regents of the University of California and Collateral Therapeutics, Inc. dated as of September 27, 1995 (with amendments dated September 19, 1996, June 30, 1997, March 11, 1999 and February 8, 2000)	Exhibit 10.15 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the Commission on December 22, 2005
10.17	Michigan License agreement between the Regents of the University of Michigan and Matrigen, Inc. dated July 13, 1995	Exhibit 10.33 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
10.18	Amendment to License agreement between the Regents of the University of Michigan and Matrigen, Inc. dated August 10, 1995	Exhibit 10.34 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
10.19	Second Amendment to the Michigan License agreement between the Regents of the University of Michigan and Selective Genetics, Inc. dated February 1, 2004	Exhibit 10.35 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
10.20	Third Amendment to Michigan License Agreement between the Regents of the University of Michigan, and Tissue Repair Company, and Cardium Biologics Inc. dated August 10, 2006	Exhibit 10.36 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006, filed with the Commission on March 15, 2007
10.21	Office Lease by and between Paseo Del Mar CA LLC and Cardium Therapeutics, Inc., effective as of November 19, 2007	Exhibit 10.43 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, filed with the Commission on November 14, 2007
10.23	Sales Agreement September 28, 2010, by and between Cardium Therapeutics Inc. and Brinson Patrick Securities Corporation	Exhibit 10.1 of our Current Report on Form 8-K dated September 28, 2010, filed with the Commission on September 29, 2010.
10.24	Placement Agent Agreement dated April 4, 2013, between Cardium Therapeutics, Inc. and Ladenburg Thalman & Co. Inc.	Exhibit 10.3 of our Current Report on Form 8-K, filed with the Commission on April 5, 2013.
10.25	Securities Purchase Agreement dated April 4, 2013 for the purchase of Series A Convertible Preferred Stock.	Exhibit 10.1 of our Current Report on Form 8-K, filed with the Commission on April 5, 2013.
10.26	Asset Acquisition Agreement dated November 15, 2013 between To Go Brands, Inc. and Cell-nique Corporation	Exhibit 10.1 of our Current Report on Form 8-K, filed with the Commission on November 21, 2013

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
10.27	Strategic Cooperation Agreement dated February 21, 2014 between Cardium Therapeutics, Inc. and Shanxi Taxus Pharmaceuticals Co., Ltd.	Exhibit 10.1 of our Current Report on Form 8-K, filed with the Commission on March 4, 2014
10.27	Securities Purchase Agreement dated February 21, 2014 between Cardium Therapeutics, Inc. and Shanxi Taxus Pharmaceuticals Co., Ltd.	Exhibit 10.2 of our Current Report on Form 8-K, filed with the Commission on March 4, 2014
21.1	Subsidiaries of the registrant	Filed herewith
23.1	Consent of Marcum LLP	Filed herewith
24.1	Power of Attorney	Included on signature page of this report
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32	Section 1350 Certification	Filed herewith
101	The following financial statements and footnotes from the Cardium Therapeutics, Inc. Annual Report on Form 10-K for the year ended December 31, 2013 formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) the Notes to Consolidated Financial Statements.	

\* Indicates management contract or compensatory plan or arrangement.

**Table of Contents**

**SIGNATURES**

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

Date: April 15, 2014

TAXUS CARDIUM PHARMACEUTICALS

GROUP, INC.

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

**Chief Executive Officer**

**POWER OF ATTORNEY**

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

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

Signature	Title	Date
/s/ CHRISTOPHER J. REINHARD  (Christopher J. Reinhard)	Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	April 15, 2014
/s/ DENNIS M. MULROY  (Dennis M. Mulroy)	Chief Financial Officer (principal financial officer and principal accounting officer)	April 15, 2014
/s/ TYLER M. DYLAN-HYDE  (Tyler M. Dylan-Hyde)	Director	April 15, 2014
/s/ EDWARD W. GABRIELSON  (Edward W. Gabrielson)	Director	April 15, 2014
/s/ MURRAY H. HUTCHISON  (Murray H. Hutchison)	Director	April 15, 2014
/s/ ANDREW M. LEITCH  (Andrew M. Leitch)	Director	April 15, 2014



Edgar Filing: Taxus Cardium Pharmaceuticals Group Inc. - Form 10-K

<i>/s/</i> GERALD J. LEWIS	Director	April 15, 2014
<b>(Gerald J. Lewis)</b>		
<i>/s/</i> LON E. OTREMBBA	Director	April 15, 2014
<b>(Lon E. Otremba)</b>		