Taxus Cardium Pharmaceuticals Group Inc. Form 10-K May 22, 2015 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, 2014

001-33635

(Commission file number)

# TAXUS CARDIUM PHARMACEUTICALS GROUP INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State of incorporation)

 ${\bf 27\text{-}0075787} \\ \textbf{(IRS Employer Identification No.)}$ 

11750 Sorrento Valley Rd., Suite 250

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant sknowledge, 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 x Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). "Yes x No

The aggregate market value of common equity held by non-affiliates, computed on the basis of the closing sale price for the common stock as reported on the OTC QB on June 30, 2014, was \$5.2 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 May 22, 2015, 12,775,044 shares of the registrant s common stock were outstanding.

#### TABLE OF CONTENTS

EXPLANATORY NOTE SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS		
PART I		
Item 1.	Business	2
Item 1A.	Risk Factors	17
Item 1B.	<u>Unresolved Staff Comments</u>	31
Item 2.	<u>Properties</u>	31
Item 3.	Legal Proceedings	31
Item 4.	Mine Safety Disclosures	31
PART II		
Item 5.	Market for Our Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	32
Item 6.	Selected Financial Data	33
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	33
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	40
Item 8.	Financial Statements and Supplementary Data	41
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	62
Item 9A.	Controls and Procedures	62
Item 9B.	Other Information	63
PART III		
Item 10.	Directors, Executive Officers, and Corporate Governance	64
Item 11.	Executive Compensation	69
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	72
Item 13.	Certain Relationships and Related Transactions and Director Independence	74
Item 14.	Principal Accounting Fees and Services	74
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	76
<u>SIGNATURES</u>		

#### EXPLANATORY NOTE

Unless the context requires otherwise, all references in this report to the Company, Taxus Cardium, Cardium, we, our, and us refer to Tax Cardium Pharmaceuticals Group Inc. and, as applicable, our wholly-owned subsidiaries Angionetics Inc., Activation Therapeutics, Inc. (formerly 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, 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;

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

1

our intellectual property rights and those of others, including actual or potential competitors;
the outcome of any pending or threatened 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

We are a regenerative medicine biotechnology company 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:

Lead Product	Technology Platform	Formulation	Status
Product	riauoriii	rormulation	Status
Excellagen ®	Advanced Tissue Regeneration	Aseptic	Initial Product
	for Wounds &	Pharmaceutically-	FDA-Cleared
Commercial		Formulated Fibrillar	
	Biologics Delivery Platform	Collagen	
Product			

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Generx <sup>®</sup> Gene Therapy Ad5FGF-4 Phase 3
DNA Construct Registration Study

Product Cardiovascular

Candidate Growth Factor Therapeutics

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.

Our business model is designed to create a portfolio of opportunities for success, avoiding reliance on any single technology platform or product type. We focus on late-stage product development bridging 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

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 where we identify the potential for strong value enhancement.

Our current business are established in four subsidiaries: Angionetics Inc., Activation Therapeutics, Inc., To Go Brands, Inc. and LifeAgain Insurance Solutions, Inc. We formed the Angionetics Inc. subsidiary in 2015 to continue the late-stage clinical development and commercialization of the Company s Gener® angiogenic gene therapy product candidate. Activation Therapeutics, Inc. (formerly known as Tissue Repair Company) is focused on the commercialization of our Excellagen ® FDA-cleared wound care product and the joint clinical development of Excellagen product line extensions as an advanced biologic delivery platform for new and innovative wound healing therapeutics. During 2013 we completed the sale of our To Go Brands health sciences business in exchange for a minority stake in Healthy Brands Collective. Our LifeAgain® Insurance Solutions, Inc. subsidiary uses proprietary medical data analytics to develop unique survivable risk insurance products.

For 2015, we plan to focus on achieving key milestones with the potential to offer significant valuation inflection points of our core biotechnology assets, while evaluating option for sales or other monetizations of our non-core investments. The key elements of our business strategy include:

Advance our ASPIRE international Phase 3 registration clinical study for Generx ® which is currently underway in the Russian Federation. With clinical success in the Russian Federation, we plan to meet with the U.S. Food & Drug Administration (FDA) to seek harmonization between the ASPIRE 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 evaluate opportunities to leverage Excellagen into 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. The Excellagen website is <a href="https://www.excellagen.com">www.excellagen.com</a>

Entered into a binding term sheet with Shenzhen Qianhai Taxus Industry Capital Management Co., Ltd (Shenzhen Qianhai Taxus), as lead investor, to purchase an equity stake in Angionetics Inc., Under the terms of the agreement, Shenzhen Qianhai Taxus agreed to acquire 15% of Angionetics—outstanding common stock for an aggregate purchase price of \$3,000,000, payable in three tranches to be completed by May 30, 2015. On completion of the purchase, Taxus Cardium has agreed to grant Shenzhen Qianhai Taxus a right of first negotiation for exclusive license agreements for certain Asian markets to fund local country registrations, market and sell the Generx® product candidate, Excellagen®, an FDA-cleared dermal matrix product for advanced wound healing and a delivery platform for biologics and stem cells, and LifeAgain®, an advanced medical data analytics product technology platform. The agreement contemplates that this initial funding is a bridge equity investment to a separate larger financing to be conducted by Angionetics Inc., including a potential registration and public offering of securities. The terms provide for Taxus Cardium to gross up Shenzhen Qianhai Taxus—shares to equate to a 15% interest in Angionetics following any such public offering. It also provides for certain registration rights for the shares purchased by Shenzhen Qianhai Taxus.

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. The LifeAgain website address is <a href="https://www.lifeagain.com">www.lifeagain.com</a>.

Monetize our equity stake in Cardium s non-core Healthy Brands Collective investment. We acquired this investment through the 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 grow through further acquisition. The Healthy Brands Collective website address is <a href="https://www.healthybrandsco.com">www.healthybrandsco.com</a>.

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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.

3

#### **Core Biotechnology Focus**

#### Angionetics Inc. Gener® [Ad5FGF-4]

Angionetics Inc. is a leader in the field of cardiovascular gene therapy. Generx (*alferminogene tadenovec*), Angionetics 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 represents a new class of therapeutic designed to address a large and unmet medical need among patients with heart disease. Generx is targeted for the potential treatment of patients with Cardiac Microvascular Insufficiency or CMI due to advanced coronary artery disease. CMI is a principal cause of microvascular angina or coronary microvascular dysfunction, 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. 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. Observed results from our Phase 2 clinical trial demonstrated effects that 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.

CMI 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 have coronary artery disease that is not limited or localized to large vessels, continue to experience angina after CABG or PCI, and/or are not suitable candidates for surgical interventions. 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 study 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.

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. We believe 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 Genery angiogenesis therapy following initial Genery registration.

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 SPECT imaging, in patients with reversible perfusion defect size of greater than 9%. Generx also improved exercise tolerance time, 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 Phase 3 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.

4

In December 2013, we reported encouraging initial positive findings from our ASPIRE international clinical study. The results were consistent with those obtained in our AGENT Phase 2a clinical study which showed that Generx appeared to be safe and well tolerated. The AGENT study also 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.

In March 2015 we announced our entry into a binding term sheet with Dr. Reddy s Laboratories, Inc. (NYSE: [RDY]) covering the co-development, marketing and sales of the Generx [Ad5FGF-4] angiogenic microvascular gene therapy Phase 3 product candidate for patients with refractory angina and myocardial ischemia due to cardiac microvascular insufficiency. The terms sheet outlines the principle agreements between the parties and is binding, but is expected to be superseded by a definitive agreement with more detailed terms. The term sheet grants Dr. Reddy s Laboratories an exclusive license to market and sell Generx in Russia, the Commonwealth of Independent States (CIS), Venezuela, Vietnam and Myanmar (the Licensed Territories) for a period of ten years with two five-year renewal options. Dr. Reddy s Laboratories Russian-based business unit currently markets and sells prescription products in Russia. The term sheet grants Dr. Reddy s Laboratories a right of first negotiation for the license rights to market and sell Generx in up to 32 other countries in Latin America and the Association of Southeast Asian Nations. Taxus Cardium retains full commercialization rights for North America, Europe, Japan, China, the Middle East, and Africa. Taxus Cardium has established a wholly-owned operating unit Angionetics to manage for the worldwide commercialization of the Generx. If we achieve clinical success in the Russian Federation, we plan to meet with the U.S. FDA to seek harmonization between the ASPIRE 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.

#### 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, angioplasty or 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. 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, angioplasty or 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 that are affected by coronary artery disease.

5

#### How Does Generx Work?

Generx is designed to be administrated 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 activate and promote the growth of cardiac microvascular circulation (a functional collateral network) in ischemic cardiac tissue.

Generx is delivered through an intra-coronary angioplasty balloon catheter that produces transient myocardial ischemia. The induction of transient ischemia, together with the introduction of nitroglycerin, significantly facilitates the transfection of Generx into heart cells, apparently via enhanced penetration through microvessel endothelium and upregulation of Coxsackie-Adenovirus Receptor or CAR. Company-sponsored research demonstrates that Generx has the capacity to promote and enhance cardiac microvascular circulation through both angiogenesis (the formation of new capillary vessels) and arteriogenesis (enlargement of pre-existing collateral arterioles).

#### Generx Clinical Development Strategy

Generx is currently being evaluated in a Phase 3 registration study in the Russian Federation, conducted under the name ASPIRE. Generx has also been cleared by the U.S. FDA for a Phase 3 clinical study in the United States.

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.

In March 2015 we announced our entry into a binding term sheet with Dr. Reddy s Laboratories, Inc. (NYSE: [RDY]) covering the co-development, marketing and sales of the Generx [Ad5FGF-4] angiogenic microvascular gene therapy Phase 3 product candidate for patients with refractory angina and myocardial ischemia due to cardiac microvascular insufficiency. The terms sheet outlines the principle agreements between the parties and is binding, but is expected to be superseded by a definitive agreement with more detailed terms. The term sheet grants Dr. Reddy s Laboratories an exclusive license to market and sell Generx in Russia, the Commonwealth of Independent States (CIS), Venezuela, Vietnam and Myanmar (the Licensed Territories) for a period of ten years with two five-year renewal options. Dr. Reddy s Laboratories Russian-based business unit currently markets and sells prescription productsin Russia. The term sheet grants Dr. Reddy s Laboratories a right of first negotiation for the license rights to market and sell Generx in up to 32 other countries in Latin America and the Association of Southeast Asian Nations. Taxus Cardium retains full commercialization rights for North America, Europe, Japan, China, the Middle East, and Africa. Taxus Cardium has established a wholly-owned operating unit Angionetics to manage for the worldwide commercialization of the Generx.

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

6

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 us 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 exercise tolerance time 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. 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

Our 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. Our 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

7

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 our ASPIRE 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

Angionetics has also been actively advancing its Generx product candidate s engineering and process technology in preparation for potential commercialization. We have 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 x 10 9 viral particles per treatment, Angionetics 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 us 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 <sup>®</sup> 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.

#### Activation Therapeutics, Inc. 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 <sup>®</sup> and Apligraf <sup>®</sup> and human dermal and amnion placental tissue-based products including Graftjacket <sup>®</sup> and EpiFix <sup>®</sup>.

8

Excellagen is prepared as a sterile professional-use syringe, containing a physiologically formulated homogenate of purified atelopeptide bovine dermal collagen (Type I) in its native 3-dimensional fibrillar configuration. Excellagen is designed to provide a structural scaffold for chemotaxis, cellular adhesion, migration and proliferation to promote wound healing. Company-funded 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 our 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.

Consistent with our 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. The Company has continued to pursue a CE mark certification for Excellagen.

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

We 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 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

9

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 collaborating 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**

For 2015, we plan to focus on achieving key milestones with the potential to offer significant valuation inflection points of our core biotechnology assets, while evaluating option for sales or other monetizations of our non-core investments. The key elements of our business strategy include:

Advance our ASPIRE international Phase 3 registration clinical study for Generx <sup>®</sup> which is currently underway in the Russia Federation. Upon clinical success, the Company plans to meet with the U.S. FDA to seek harmonization between the international ASPIRE study with our FDA-cleared Generx Phase 3 clinical study and advance U.S.-based clinical studies supported by a strategic partner;

10

Strategically partner and monetize our FDA-cleared pharmaceutically formulated collagen commercial wound care product Excellagen ®, for selected U.S.-based vertical market channels and 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. 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 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;

Monetize our equity stake in Cardium s Healthy Brands Collective investment. We acquired this investment through the 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 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

11

products. For any 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, 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.

12

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

#### Competition

The pharmaceutical, biotechnology and medical device industries are intensely competitive. Our products and any product candidates developed by us would compete with existing drugs, therapies, bio-therapies, stem cell therapies, medical devices or procedures and with others under development that are designed to enhance cardiac perfusion in patients with coronary artery disease and other medical conditions that result in chronic myocardial ischemia and persistent angina pectoris. 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. 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 candidate. These include biological 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; NeoVasc is developing a catheter based product, similar to a stent, intended as a treatment for refractory angina; Juventas Therapeutics is developing Stromal Cell-Derived Factor-1 (SDF-1), a naturally-occurring chemokine, to induce neovascularization and angiogenesis to treat ischemic cardiovascular disease; and Neostem is developing a chemotactic hematopoietic stem cell product comprised of autologous bone marrow derived CD34/CXCR4 cells selected to treat damaged heart muscle following a heart attack. We will also face competition from entities using other traditional methods, including new drugs and mechanical therapies, to treat cardiovascular and vascular disease.

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 patients with CMI.

Our Generx® alferminogene tadenovec [Ad5FGF-4] Phase 3 product candidate is a first in class, single-dose, disease altering therapeutic specifically targeted for the cardiac micro-vasculature, that is designed to endogenously initiate the formation of new biologic structures in the heart to increase the level of micro-vascularity and enhance cardiac perfusion, and improve cardiac performance, as measured by exercise tolerance and the occurrence and severity of myocardial ischemia-driven angina. Current pharmacologic therapies for patients with CMI are limited to anti-anginal medications to relieve angina chest pain, which are dosed daily or episodically and carry physiologic side effects, and surgical and percutaneous interventions to address large vessel coronary artery disease. Angionetics product candidates are designed to easily fit within the current practice of medicine, as single-dose treatments, which are administered by interventional cardiologists using standard cardiac catheters, during an approximately one-hour, out-patient, angiogram-like procedure which is conducted in a hospital or medical center.

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.

In the areas of tissue repair and wound healing, such as Excellagen and others being developed by our Activation Therapeutics, Inc. 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.

14

We believe that the most significant competitive factors in the field of new therapeutics and devices are the effectiveness, 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**

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. We plan 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 <sup>®</sup> wound care product, we expect to engage in sales principally through or in collaboration with a sales and distribution partner and/or strategic partners. 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.

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, some of which are included in 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 our ASPIRE study in Russia.

15

In August 2006, we acquired the rights to various technologies and products now part of our Activation Therapeutics 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. 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 is used. 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. There are a number of additional uncertainties affecting our ability to enforce any of our intellectual property rights as described below

16

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**

During the fourth quarter of 2014 we implemented significant reductions in headcount, and as of December 31, 2014 we had 3 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 rely on various consultants and advisors to provide services to us.

#### **Available Information**

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

#### 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 ® 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.

17

Our Generx® and other product candidates require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, the FDA has not yet approved any gene therapy 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 or other regulatory authority 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;

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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;

18

patients die during a clinical study for a variety of reasons that may or may not be related to our product candidates, 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.

We have entered into agreements with third parties to market our Excellagen product and to market our Generx product in certain territories if approved by relevant regulatory authorities, 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.

We are a development stage company. We have incurred losses since our inception in December 2003 and expect to incur significant net losses in the foreseeable future and may never become profitable.

We have sustained operating losses to date and will likely continue to sustain losses as we seek to develop our products and product candidates. We expect these losses to be substantial because our product development and other costs, including significant amounts we expect to spend on development activities and clinical trials for

our product candidates, cannot be offset by our limited revenues during our development stage. As of December 31, 2014, our accumulated deficit was approximately \$111 million, and our cash and cash equivalents were approximately \$217,000. 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. Whether we will generate additional revenues and 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.

We need substantial additional capital to develop our products and for our 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 need to raise additional working capital to fund our operations. The audit opinion accompanying our consolidated financial statements for the year ended December 31, 2014, included under Item 8 of this report, includes an explanatory paragraph indicating substantial doubt about our ability to continue as a going concern.

We 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. 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

20

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 gene transfer like that contained in Generx could 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;

21

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 business strategy relies on establishing and maintaining collaborations with licensors and other third parties for the development, testing, manufacturing and commercialization of our product candidates. For example, we have various licenses from third parties relating to the development, marketing and sale of our Generx product candidate. We have also entered into collaboration agreements with third parties to assist in the completion of the clinical trials and regulatory filings to secure approval to market the products, as well as agreements to distribute the products on regulatory approval.

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.

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

We expect to rely 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, 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

22

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 significant process development changes may 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 delay or interrupt the supply of product to us, there are very few contract manufacturers who currently have the capability to produce our product candidates. There can be no assurance that manufacturers on whom we depend will be able to successfully produce our products or

product candidates on acceptable terms, or on a timely or cost-effective basis, or in accordance with our product specifications and applicable FDA or other governmental regulations. We must have sufficient and acceptable quantities of our product materials to conduct our clinical trials and to market our product candidates, if and when such products have been approved by the FDA for marketing. If we are unable to obtain sufficient and acceptable quantities of our product material, we may be required to delay the clinical testing and marketing of our products, which would negatively impact our business.

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.

24

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. We currently rely on Christopher J. Reinhard, our Chairman of the Board, Chief Executive Officer, President and Treasurer, as our sole executive officer. The loss of Mr. Reinhards services would significantly disrupt our operations. We do not maintain any key man life insurance on 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.

25

To the extent that 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 any business operations that we conduct 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 that we do not have exclusive rights, others may license the same technology and may develop the technology more successfully or may develop products similar to ours and that compete with our products. Even if we are provided with exclusive rights, the scope of our rights under our licenses may be subject to dispute and termination or reduction by our licensors or third parties. Our licenses also contain milestones that we must meet and/or minimum royalty or other payments that we must make to maintain the licenses. There is no assurance that we will be able to meet such milestones and/or make such payments. Our licenses may be terminated if we fail to meet applicable milestones or make applicable payments.

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

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

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

Patents issued and patent applications filed internationally relating to gene therapy and biologics, collagen-based products, and other of our technologies are numerous, and we cannot assure you that current and potential competitors or other third parties have not filed or received, or will not file or receive applications in the future for patents or obtain additional proprietary rights relating to products or processes used or proposed to be used by us.

Additionally, there is certain subject matter that is patentable in the United States but not generally patentable outside of the United States. Differences in what constitutes patentable subject matter in various countries may limit the protection we can obtain outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may prevent us from obtaining patent protection outside of the United States, which would have a material adverse effect on our business, financial condition and results of operations.

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 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. 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.

27

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.

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.

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

28

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 \$0.6437 per post-split 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, 2014, there were 1,176 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. We may raise that capital through the sale of additional debt or equity securities the Cardium parent level, or through direct investment into any of our subsidiaries. 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 and stock options will significantly dilute the ownership interest of existing stockholders.

At December 31, 2014 we had an aggregate of 2,788,242 stock options and warrants outstanding at exercise prices ranging from \$0.80 to \$55.00. 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, limited resources, and dependence on relatively few products or product candidates, 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, 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;

29

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

provides that a corporation may not engage in any business combination with any interested stockholder during the three-year period following the time that such stockholder becomes an interested stockholder. This provision could have the effect of delaying or preventing a change of control of our company. The foregoing factors could reduce the price that investors or an acquirer might be willing to pay in the future for shares of our common stock.

30

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

We have never paid 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	Corporate Headquarters			
San Diego, CA USA	Principal executive office	4,419	\$ 10,0161	Aug. 31, 2016

The monthly base rent increases to \$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, 2014 neither Cardium nor its subsidiaries were a party to 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 for commercialization. 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 the technology we develop or license, or the products we develop for commercialization, but which can nevertheless result in costs and diversions of resources to pursue and resolve. For example, in October 2014 we received a complaint filed by Biorasi LLC in Broward County, Florida, seeking payments of approximately \$0.5 million related to its activities in connection with the Company s ASPIRE clinical trial conducted in the Russian Federation. We plan to defend the action and are awaiting a ruling on our request to dismiss; we have not recorded a liability for this contingency as we believe that the probability of an adverse outcome is remote.

# ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

#### PART II

# ITEM 5. MARKET FOR OUR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EOUITY 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, 2014 and 2013:

	20	2015		2014		13
	High	Low	High	Low	High	Low
First Quarter	\$ 0.21	\$ 0.15	\$ 0.80	\$ 0.50	\$ 4.00	\$ 3.20
Second Quarter	\$	\$	\$ 0.70	\$ 0.46	\$ 3.40	\$ 1.40
Third Quarter	\$	\$	\$ 0.65	\$ 0.36	\$ 1.60	\$ 0.69
Fourth Quarter	\$	\$	\$ 0.39	\$ 0.18	\$ 1.07	\$ 0.70

#### **Holders**

As of May 22, 2015 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 never 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**

On February 28, 2014, we entered into a strategic collaboration and funding arrangement with Shanxi Taxus Pharmaceuticals Co., Ltd., which is based in the Peoples Republic of China (PRC) and is affiliated with Shenzhen Forntsea Taxus Industry Capital Management (Shanxi Taxus), to support the worldwide clinical and commercial development of Cardium s advanced regenerative medicine therapeutics products, including the Generx product candidate and Excellagen. In connection with the agreement, Shanxi Taxus acquired an initial tranche of \$0.5 million by purchasing 714,286 shares of common stock at \$0.70 per share.

On May 12, 2014, Shanxi Taxus acquired a second tranche of \$1.5 million by purchasing 2,330,278 shares of common stock at \$0.6437 per share. The common stock issued to Shanxi Taxus is unregistered, but under the terms of the Stock Purchase Agreement, we agreed to grant the investor piggyback registration rights in the event that the Company files a registration statement for other shares of common stock. No warrants were issued in connection with the transaction. Under the terms of the securities purchase with Shanxi Taxus, the strategic investor agreed to purchase an additional tranche of securities in the amount of \$300,000, priced at a 10% premium to the market price of our common stock.

Following the completion of these three investment tranches, at year-end 2014, Shanxi Taxus had invested \$2.3 million in Taxus Cardium and owned 3,510,620 shares or 27.5% of the Company s common stock.

# **Repurchases of Equity Securities**

During the year ended December 31, 2014, we did not repurchase any shares of our common stock, nor were any repurchases made on our behalf.

# **Equity Compensation Plan Information**

The following table summarizes equity compensation plans approved by stockholders and equity compensation plans that were not approved by stockholders as of December 31, 2014.

Plan Category	(a)  Number of securities to be issued upon exercise of outstanding options, warrants and rights	exer outstand war	(b) ted-average cise price of ding options, rants 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	, and the second				
stockholders	104,000	\$	31.03	179,058	
Equity compensation plans not approved by					
stockholders		\$			
Total	104,000	\$	31.03	179,058	

# 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, 2014. 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 regenerative medicine biotechnology company 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 LifeAgain Insurance Solutions, Inc., an advanced medical data analytics business and hold an investment interest in Healthy Brands Collective, a health products company.

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. Our business model is designed to create a portfolio of opportunities for success, avoiding reliance on any single technology platform or product type. We focus on late-stage product development bridging the critical gap between promising new technologies and product opportunities that are ready for commercialization. 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.

33

# **Recent Developments**

During 2014, 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. During the twelve months ending December 31, 2014, we continued to support the clinical advancement of our Generx <sup>®</sup> angiogenic therapy product candidate, continued activities to commercialize our Excellagen <sup>®</sup> dermal matrix wound care product, and entered into a strategic cooperation agreement and financing arrangement with Shanxi Taxus Pharmaceuticals Ltd. a strategic investor based in the People s Republic of China (PRC) and affiliated with Shenzhen Forntsea Taxus Industry Capital Management (Shanxi Taxus).

For 2015, we are focusing our efforts on the development of our core Generx ® product candidate and our Excellagen ® platform. As described in more detail below, preliminary results from our Phase 3 clinical study for Generx have been positive, demonstrating potential efficacy of the product in treating myocardial ischemia due to coronary artery disease. Generx is administered in a one-time intracoronary administration from a standard cardiac infusion catheter. Interim study results demonstrate effectiveness similar to that of bypass surgery or stents, but in a significantly less costly and less invasive procedure.

Our Excellagen product has been approved by the FDA for use in wound healing applications such as diabetic foot ulcers. We are aggressively pursuing distribution arrangements and opportunities for the commercialization of Excellagen. In addition, we believe that Excellagen can have significant commercial value as a platform for tissue regeneration based on stem cells, biologics, peptides and/or small molecule drugs therapeutics and are commencing strategic partnering arrangements to evaluate those opportunities.

Our principal business objective is to complete additional strategic licensing agreements to advance sales of the Excellagen ® product family and/or another corporate transaction in order to fund our operations to further advance the Excellagen ® platform and complete the development and commercialization of Generx ® . If we fail to enter into an additional strategic licensing arrangements or generate sufficient product sales, we will not generate sufficient cash flows to cover our operating expenses.

Based on our business strategy of partnering or otherwise monetizing products and product candidates with third party commercialization partners, two business units have been formed to coordinate the independent monetization and funding activities of our core products and technologies. Our Angionetics business unit is focused on the late-stage clinical development and commercialization of the Company s Gener® angiogenic gene therapy product candidate, and the Activation Therapeutics unit is focused on the commercialization of the Excellagen <sup>®</sup> FDA-cleared wound care product and the joint clinical development of Excellagen product line extensions as an advanced biologic delivery platform for new and innovative wound healing therapeutics.

Recent highlights include the following:

# Generx Development

Generx ® (alferminogene tadenovec/CardioNovo ® ) 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 refractory angina or other medical conditions such as Cardiac Syndrome X. Developments with respect to Generx include:

Announced positive interim Phase 3 data from Cardium s international ASPIRE clinical study showing apparently significant efficacy of Generx <sup>®</sup> angiogenic gene therapy for myocardial ischemia due to coronary artery disease. The interim results demonstrated statistically significant improvement, as measured by changes after eight weeks in the reversible perfusion defect size (RPDS), determined using rest/stress single-photon emission computed tomography (SPECT) imaging. This improvement in RPDS was consistent with the RPDS improvement previously reported in the Generx AGENT Phase 2 clinical study, and of a magnitude similar to that observed following large vessel revascularization procedures, such as by-pass surgery or percutaneous coronary intervention.

Presented the positive interim Phase 3 primary efficacy data and an overview of the Generx clinical development program at the 2014 Biotechnology Industry Organization International Convention, and presented corporate development activities and plans at the annual 2014 Marcum Microcap Conference, covering the Company s strategic focus on its core advanced regenerative therapeutics and technology platforms.

Reported publication of a scientific article, entitled Identifying and Overcoming Obstacles in Angiogenic Gene Therapy for Myocardial Ischemia, by Gabor M. Rubanyi, M.D., Ph.D., Cardium s Chief Scientific Officer, in the August 2014 issue of the *Journal of Cardiovascular Pharmacology*. The publication outlines advances in scientific and medical knowledge pioneered by Cardium and

34

others in therapeutic angiogenesis for myocardial ischemia, including mechanistic and biological insights, optimization of clinical trial design, and selection of target patient populations and meaningful efficacy endpoints. The publication also reports, for the first time, the results of studies performed by Cardium researchers and collaborators, demonstrating a synergistic interaction between Generx-expressed fibroblast growth factor-4 (FGF-4) and vascular endothelial growth factor (VEGF) in the promotion of neovessel formation, with evidence that FGF controls angiogenesis upstream of VEGF.

Completed the pilot phase of our Generx ASPIRE Phase 3 / registration study, a 100-patient, randomized and controlled multi-center study at leading cardiology centers in the Russian Federation for patients with myocardial ischemia due to coronary artery disease, and engaged a new clinical research organization to support continuation of the study in coordination with a planned strategic partner. 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 ® 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 finding have been incorporated into the treatment protocols of the Generx ASPIRE Phase 3 study.

Presented at the 2014 Phacilitate Annual Cell & Gene Therapy Forum in Washington, DC, Optimizing Phase III Trial Design for Generx ® (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.

#### Commercialization of Excellagen

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

Consistent with the Company s long-term business strategy, as previously reported, Taxus Cardium does not plan to build inventory or 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 and looks forward to completing this process. Developments with respect to Excellagen include:

Excellagen ® flowable dermal matrix in combination with Orbsen Therapeutics mesenchymal stromal stem cell therapy Cyndacel-M has been selected for clinical evaluation in a Phase 1b safety study for the potential treatment of chronic diabetic wounds to be funded by the European Union under EU Framework 7 (FP7). The project, known by the acronym REDDSTAR (Repair of Diabetic Damage by Stromal Cell Administration), is being coordinated by Professor Timothy O Brien, Dean of Medicine and Director of Ireland s Regenerative Medicine Institute (REMEDI) at National University of Ireland Galway (NUI). The REDDSTAR preclinical studies evaluated the use of Excellagen ® and an alternative collagen-based product to promote the maintenance of stem cell viability. The combination of Cyndacel-M and Excellagen® improved wound closure and neo-vascularization in a diabetic dermal wound healing model. Based on those results, Excellagen® was selected to be used with Cyndacel-M in a human clinical study.

Continued activities relating to the strategic partnering process and monetization Excellagen <sup>®</sup> flowable dermal matrix wound care product for select U.S.-based vertical market channels and geographic markets. Activities have also continued to leverage Excellagen as an advanced regenerative medicine delivery platform by identifying innovative potential future product extensions for tissue regeneration based on stem cells, biologics, peptides and/or small molecule drugs.

Continue to pursue an application for CE Mark registration for Excellagen <sup>®</sup> flowable dermal matrix would care product, which is designed to support the potential commercialization of Excellagen in Europe.

Consistent with the Company s long-term business strategy, as previously reported, Taxus Cardium does not plan to build inventory or 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 and looks forward to completing this process.

# Sale of To-Go Brands, Inc.

On November 15, 2013, the Company sold its To Go Brands ® business to Healthy Brands Collective ® in exchange for 33,441 shares of preferred stock in Cell-nique Corporation (the parent company of Healthy Brands Collective) 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 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.

The 33,441 shares of preferred stock represented approximately 4% of the outstanding shares of common stock of Cell-nique Corporation on a fully diluted basis at the time of the transaction. 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 net assets transferred (cost) to Cell-nique Corporation. The Company periodically reviews 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. A non-cash impairment charge of approximately \$1,400,000 was recorded during the year ended December 31, 2014.

36

On December 20, 2011, the Company 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 the Company issued 75,000 restricted shares of its 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 advancement of certain jointly-developed products. Under terms of the licensing arrangement, the Company 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, the Company 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, the Company also made an equity investment in the form of unregistered, restricted shares of its common stock to acquire an option to purchase to a 15% ownership interest in SourceOne Global Partners. The option was acquired through the issuance into escrow of 75,000 shares of the Company s common stock which were recorded at a value of \$5.80 per share based on the closing price of the Company s 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 were released in 2013. The Company also has certain rights to maintain its 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. During the year ended December 31, 2014, the Company believed there were certain impairment triggering events and circumstances that warranted an evaluation of its SourceOne agreement and as a result a non-cash impairment charge of \$435,000 was recorded.

# 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, we entered into a collaboration and financing arrangement with 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.

In connection with the agreement, Shanxi Taxus acquired an initial tranche of \$0.5 million by purchasing 714,286 shares of common stock at \$0.70 per share.

On May 12, 2014, Shanxi Taxus acquired a second tranche of \$1.5 million by purchasing 2,330,278 shares of common stock at \$0.6437 per share. The common stock issued to Shanxi Taxus is unregistered, but under the terms of the Stock Purchase Agreement, we agreed to grant the investor piggyback registration rights in the event that the Company files a registration statement for other shares of common stock. No warrants were issued in connection with the transaction. Under the terms of the securities purchase with Shanxi Taxus, the strategic investor agreed to purchase an additional tranche of securities in the amount of \$300,000, priced at a 10% premium to the market price of our common stock.

Following the completion of these three investment tranches, at year-end 2014, Shanxi Taxus had invested \$2.3 million in Taxus Cardium and owned 3,510,620 shares or 27.5% of the Company s common stock.

In addition 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 our Generx ® and Excellagen ® product opportunities, could be commercialized in China; and we agreed, upon request, to 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 we changed our name to Taxus Cardium Pharmaceuticals Group, Inc. In addition, we agreed to grant Shanxi Taxus certain board rights based on the level of its financing pursuant to the financing arrangement discussed below.

Cardium and Shanxi Taxus are moving forward with plans to explore the commercialization of Cardium s advanced regenerative medicine therapeutic products for the emerging and rapidly growing advanced healthcare market in China, and Shanxi Taxus oncology-focused product opportunities for the U.S. market; and for Mr. Jiayue Zhang, who is the Chairman of Shanxi Taxus, and an additional individual with U.S. corporate and financial experience, to join Cardium s Board of Directors.

37

# **Critical Accounting Policies and Estimates**

Our consolidated financial statements included under Item 1 in this report have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of our financial statements in accordance with GAAP requires that we make estimates and assumptions that affect the amounts reported in our financial statements and their accompanying notes.

We have identified certain policies that we believe are important to the portrayal of our financial condition and results of operations, including obsolescence reserve for inventory, valuation of equity instruments and impairment of long-lived assets. These significant accounting estimates or assumptions bear the risk of change due to the fact that there are uncertainties attached to these estimates or assumptions, and certain estimates or assumptions are difficult to measure or value. 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.

We records reserves for inventories that are obsolete or exceed anticipated demand or carried at an amount that exceeds management s estimate of net realizable value. In establishing such reserves, management considers historical sales of identical and/or similar goods, product development plans and expected market demand. For the year ended December 31, 2014, we recorded a provision for obsolete inventory of approximately \$160,000 related to our Excellagen product.

We calculate the value of equity compensation expense associated with the issuance of warrants and stock options using the Binomial and Black-Scholes Option Model. Determining the appropriate fair value model and calculating the fair value of equity based payment awards requires the input of a number of subjective assumptions including the expected stock volatility, the risk free interest rate, the option s expected life, the dividend yield on the underlying stock. The assumptions used in calculating the fair value of equity based payment awards represent management s best estimates, which involve inherent uncertainties and the application of management s judgment. As a result, if factors change and the Company uses different assumptions, equity based compensation could be materially different in the future. In addition, the Company is required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If actual forfeiture rate is materially different from the estimates, the equity based compensation could be significantly different from what the Company has recorded in the current period. If we were to undervalue our derivative liabilities or stock option compensation expense we would understate the expense recognized in our consolidated statements of operations. Conversely if we were to overvalue our warrant and stock option compensation expenses we would overstate the expense recognized in our consolidated statements of operations.

We periodically review the carrying amount of our long lived assets to determine whether the value is impaired or a write down may be necessary for an other than temporary decline in value. On November 15, 2013, we sold the assets of our To Go Brands business to Cell-nique Corporation (the owner of Healthy Brands Collective) in exchange for 33,441 shares of preferred stock (representing approximately 4% of the outstanding shares of common stock on a fully diluted basis) and the assumption of certain liabilities. 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 net assets transferred (cost) to Cell-nique Corporation. During the year ended December 31, 2014, we believe there were certain impairment triggering events and circumstances which warranted an evaluation of investment and as such a non-cash impairment charge of \$1,400,000 was recorded during the year ended December 31, 2014.

Under the SourceOne agreement, the Company also made an equity investment in the form of unregistered, restricted shares of its common stock to acquire an option to purchase to a 15% ownership interest in SourceOne Global Partners. The option was acquired through the issuance into escrow of 75,000 shares of the Company s common stock which were recorded at a value of \$5.80 per share based on the closing price of the Company s 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 were released in 2013. The Company also has certain rights to maintain its 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. During the year ended December 31, 2014, the Company believed there were certain impairment triggering events and circumstances that warranted an evaluation of its SourceOne agreement and as a result a non-cash impairment charge of \$435,000 was recorded.

Other significant accounting policies are described in the notes to our financial statements.

**Results of Operations** 

Fiscal 2014 Compared to Fiscal 2013

We generated \$109,200 in revenue from the sale of Excellagen products associated with the introduction of the product to the market in the year ended December 31, 2013, but did record any revenue for 2014. We do not plan to build inventory or establish an internal marketing and sales force to directly support the commercialization of Excellagen, but continue to credentialize Excellagen in preparation for the completion of strategic partnerings for various vertical channel market opportunities or asset monetization.

There were no costs of goods sold for the year ended December 31, 2014. Costs of Excellagen product sold in the year ended December 31, 2013 was \$69,160.

Research and development expenses for the year ended December 31, 2014 were \$640,425 compared to \$2,037,370 for the same period in 2013. The decrease of \$1,396,945 was the result of \$399,000 decreased costs related to our Generx ASPIRE study, reductions in production and testing costs of \$370,000 for Excellagen, and \$628,000 reduction in personnel costs.

Selling, general and administrative expenses for the year ended December 31, 2014 were \$2,935,863 compared to \$4,908,919 for the year ended December 31, 2013. We implemented a number of cash savings initiatives during the second

38

half of each of 2013 and 2014 which decreased certain expenses by approximately \$2,000,000 on an annual basis, including a reduction in personnel costs of approximately \$1.2 million through headcount and salary reductions, as well as savings in facility costs of approximately \$314,000 associated with the relocation of our corporate headquarters, \$394,000 reduction in sales and marketing costs and \$511,000 reduction in professional services and other costs. These expense reductions were offset in the first quarter of 2014 by a non-cash, stock based compensation expense of \$454,756 associated with warrants issued during the period. Total stock-based compensation expense for all stock options and warrants for the year ended December 31, 2014 was \$508,629.

Interest expense for the year ended December 31, 2014 was \$94,576 and represents interest costs incurred by a Company officer in connection with advances for payables to be reimbursed by the Company.

Other expense of \$1,834,672 for the year ended December 31, 2014 includes non-cash impairment charges of \$1,399,672 associated with a write down of our investment in Healthy Brands Collective and \$435,000 associated with the write down of our investment in SourceOne Global Partners LLC.

Net loss from continuing operations for the year ended December 31, 2014 was \$5,505,536, which included \$508,628 of non-cash stock based compensation expense (\$457,220 of which was included in selling, general and administrative, and \$51,408 of which was included in research and development expense) and non-cash impairment charges of \$1,834,672 as described above. Net loss from continuing operations for the year ended December 31, 2013 was \$6,906,803 (which included only \$40,750 of non-cash stock based compensation expense). The decrease in net loss was primarily 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, which was comprised of a \$909,979 loss on the sale of our To Go Brands Inc. business of \$909,979 and a \$1,097,511 write off of the unamortized balance of certain technology licenses which was focused on that product line. There were no discontinued operations for the year ended December 31, 2014.

Net loss for the year ended December 31, 2014 was \$5,505,536 (including the \$508,628 non-cash stock based compensation expense) compared to a net loss of \$8,914,293 for the same period of 2013.

# **Liquidity and Capital Resources**

As of December 31, 2014, we had approximately \$217,000 in cash and cash equivalents. Our working capital deficit at December 31, 2014 was approximately \$2,008,000. We have incurred recurring losses and as of December 31, 2014, we had accumulated deficit of approximately \$111 million.

Net cash used in operating activities was \$2.5 million for the year ended December 31, 2014 compared to \$6 million for the year ended December 31, 2013. The decrease in net cash used in operating activities was due primarily to spending and headcount reductions in the second half of both 2013 and 2014.

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 \$2.7 million for the year ended December 31, 2014 consisting of approximately \$2.1 million in net proceeds from the sale of common stock to a strategic investor and cash advances from our Chief Executive Officer of approximately \$527,000 to cover certain company expenses incurred in the ordinary course of business.

On February 28, 2014, we entered into a strategic collaboration and funding arrangement with Shanxi Taxus. The stock purchase agreement granted Shanxi Taxus the right to purchase up to \$5.0 million of our common stock. The purchases were to occur in up to five tranches, each at a 10% premium to the then-current trailing average market prices of our common stock at the time of each closing. In February 2014, the Company closed the initial tranche of funding by selling 714,286 shares of common stock at \$0.70 per share. On May 12, 2014, Shanxi Taxus acquired a second tranche of \$1.5 million by purchasing 2,330,278 shares of common stock at \$0.6437 per share a mutually agreed upon price. In December 2014, Shanxi Taxus acquired a portion of the third tranche of \$300,000 by purchasing 466,056 shares of common stock at \$0.6437 per share a mutually agreed upon price. The common stock issued to Shanxi Taxus is unregistered, but under the terms of the Stock Purchase Agreement, we agreed to grant the investor piggyback registration rights in the event that the Company files a registration statement for other shares of common stock. No warrants were issued in connection with the transaction.

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.

On April 4, 2015, after the period covered by this report, we entered into a binding term sheet with Shenzhen Qianhai Taxus Industry Capital Management Co., Ltd (Shenzhen Qianhai Taxus), as lead investor, to purchase an equity stake in Angionetics Inc., Under the terms of the agreement, Shenzhen Qianhai Taxus agreed to acquire 15% of Angionetics outstanding common stock for an aggregate purchase price of \$3,000,000 or 600,000 shares at \$5 per share, payable in three tranches to be completed by May 30, 2015. On completion of the purchase, Taxus Cardium has agreed to grant Shenzhen Qianhai Taxus a right of first negotiation for exclusive license agreements for certain Asian markets to fund local country registrations, market and sell

39

the Generx® product candidate, Excellagen®, an FDA-cleared dermal matrix product for advanced wound healing and a delivery platform for biologics and stem cells, and LifeAgain®, an advanced medical data analytics product technology platform. The agreement contemplates that this initial funding is a bridge equity investment to a separate larger financing to be conducted by Angionetics Inc., including a potential registration and public offering of securities. The terms provide for Taxus Cardium to gross up Shenzhen Qianhai Taxus shares to equate to a 15% interest in Angionetics following any such public offering. It also provides for certain registration rights for the shares purchased by Shenzhen Qianhai Taxus. We expect that the proceeds of this offering, if received in full, will be sufficient to fund our operations through December 31, 2015.

Our principal business objectives are to advance the independent monetization and funding activities of our core products and technologies, with our Angionetics Inc. subsidiary being focused on the Generx <sup>®</sup> angiogenic gene therapy product candidate, and our Activation Therapeutics, Inc. subsidiary being focused on the Excellagen <sup>®</sup> FDA-cleared wound care product and the joint clinical development of Excellagen product line extensions as an advanced biologic delivery platform for new and innovative wound healing therapeutics, and/or to complete alterative corporate transactions. If we fail to conclude such transaction in a timely manner or alternatively fail to generate sufficient cash from financing activities, 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, 2014, 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**

The Financial Accounting Standards Board has issued a number of new Accounting Standards Update which will or may impact the Company s consolidated financial statements, including Accounting Standards Update 2014 08, Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity; Accounting Standards Update 2014 09, Revenue from Contracts with Customers; Accounting Standards Update 2014 12, Compensation Stock Compensation (Topic 718); Accounting Standards Update 2014 15, Presentation of Financial Statements Going Concern; Accounting Standards Update 2014 16, Derivatives and Hedging; Accounting Standards Update 2014 Business Combinations (Topic 805): Pushdown Accounting. The Company will implement the changes required by Accounting Standards Update 2014-08, Reporting Discontinued Operations and Disclosures of Disposal of Components of an Entity in future financial statements and is currently evaluating the effects of the other Accounting Standards Update listed above on the consolidated financial statements. Additional information concerning the nature of requirements of these Accounting Standards Updates is contained in Note 2 of the Notes to Consolidated Financial Statements contained in this report.

# 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.

40

# 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) as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders (deficit)/equity and cash flows for the years ended December 31, 2014 and 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 audits 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 audits 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 at December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for the years ended December 31, 2014 and 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.

/s/ Marcum LLP

Marcum LLP

New York, New York

May 22, 2015

# $TAXUS\ CARDIUM\ PHARMACEUTICALS\ GROUP, INC.\ AND\ SUBSIDIARIES$

# CONSOLIDATED BALANCE SHEETS

	December 31,			
		2014		2013
Assets				
Current assets:	Ф	016 700	ф	22 400
Cash and cash equivalents	\$	216,733	\$	22,489
Inventories, net		202075		159,831
Prepaid expenses and other assets		202,957		309,200
Total current assets		419,690		491,520
Property and equipment, net		16,414		30,196
Investment		300,000		1,699,672
Deposit on investment option				435,000
Other long term assets		9,989		129,989
Total other assets		326,403		2,294,857
Total assets	\$	746,093	\$	2,786,377
Liabilities and Stockholders (Deficit)/Equity				
Current liabilities:				
Accounts payable	\$	1,204,302	\$	990,279
Accrued liabilities		535,251		611,007
Advances from officer		688,433		
		2 427 006		1 (01 20)
Current liabilities		2,427,986		1,601,286
Total liabilities		2,427,986		1,601,286
Commitments and contingencies				
Stockholders (deficit)/equity:				
Series A Convertible Preferred stock, \$0.0001 par value; 40,000,000 shares authorized; issued and outstanding 1,176 at December 31, 2014 and 1,500 at December 31, 2013, with liquidation preferences of \$1,000				
Common stock, \$0.0001 par value; 200,000,000 shares authorized; issued and outstanding				
12,775,044 at December 31, 2014 and 8,810,624 at December 31, 2013		1,278		881
Additional paid-in capital		109,150,983	1	06,512,828
Accumulated deficit		110,834,154)		05,328,618)
. accumumos dellos	(	110,00 1,10 1)	(1	00,020,010)
Total stockholders (deficit)/equity		(1,681,893)		1,185,091
Total liabilities and stockholders (deficit) equity	\$	746,093	\$	2,786,377

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

Table of Contents 63

42

# $TAXUS\ CARDIUM\ PHARMACEUTICALS\ GROUP, INC.\ AND\ SUBSIDIARIES$

# CONSOLIDATED STATEMENTS OF OPERATIONS

		Years Ended 2014	December 31, 2013	
Revenues				
Product sales		\$	\$ 109,20	0
Grant revenues				
			400.00	
Total revenues			109,20	
Cost of goods sold			(69,16	(0)
Gross profit			40,04	Ю
Operating expenses				
Research and development		(640,425)	(2,037,37	
Selling, general and administrative		(2,935,863)	(4,908,91	9)
Total operating expenses		(3,576,288)	(6,946,28	(9)
Loss from operations		(3,576,288)	(6,906,24	19)
•			, , ,	
Other income (expenses):				
Impairment loss on investment		(1,834,672)		
Interest income			21	.7
Interest expense		(94,576)	(77	1)
Total other expenses		(1,929,248)	(55	54)
Net loss from continuing operations		(5,505,536)	(6,906,80	13)
Net loss from discontinued operations		(3,303,330)	(2,007,49	
1 to 1000 from discontinued operations			(2,007,1)	0)
Net loss		(5,505,536)	(8,914,29	03)
Deemed dividend on preferred stock			(405,87	
No. 1. 1. 1.		Φ (5.505.526)	Φ (0.220.16	· <b>(</b> )
Net loss applicable to common stockholders		\$ (5,505,536)	\$ (9,320,16	(Ci
Not less manches thesis and diluted				
Net loss per share basic and diluted Net loss from continued operations		\$ (0.50)	\$ (1.0	14)
Net Loss from discontinued operations  Net Loss from discontinued operations		, ,	(0.2)	
Net Loss from discontinued operations		(0.00)	(0.2	, <b>7</b> )
Net loss per share basic and diluted		\$ (0.50)	\$ (1.3	(3)
Weighted average number of common shares outstanding	basic and diluted	11,121,871	6,995,67	'6

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

# TAXUS CARDIUM PHARMACEUICALS GROUP, INC. AND SUBSIDIAIRES CONSOLIDATED STATEMENTS OF STOCKHOLDERS (DEFICIT)/EQUITY YEARS ENDED DECEMBER 31, 2014 AND 2013

	Common	Stock	Serie Conve Preferre	rtible	Additional Paid-In	Deficit Accumulated During Development	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Capital	Stage	(Deficit)
Balance January 1, 2013	6,460,586	\$ 646		\$	\$ 102,779,469	\$ (96,414,325)	\$ 6,365,790
Issuance of common stock for cash, net of							
issuance costs of \$20,000	17,187	2			65,741		65,743
Stock option compensation					40,750		40,750
Issuance of Series A preferred stock for cash, net of issuance costs of \$45,000			4,012		3,627,101		3,627,101
Issuance of common stock on conversion			1,012		3,027,101		3,027,101
of preferred stock	2,332,851	233	(2,512)		(233)		
Net Loss						(8,914,293)	(8,914,293)
Balance December 31, 2013	8,810,624	881	1,500		106,512,828	(105,328,618)	1,185,091
Issuance of common stock for cash, net of							
issuance costs of \$170,000	3,510,620	351			2,129,573		2,129,924
Stock-based compensation					508,628		508,628
Issuance of common stock on conversion							
of preferred stock	453,800	46	(324)		(46)		
Net Loss						(5,505,536)	(5,505,536)
Balance December 31, 2014	12,775,044	\$ 1,278	1,176	\$	\$ 109,150,983	\$ (110,834,154)	\$ (1,681,893)

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

# $TAXUS\ CARDIUM\ PHARMACEUTICALS\ GROUP, INC.\ AND\ SUBSIDIARIES$

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	De	Years Ended December 31,	
Cook Flour From On anding Anti-ities	2014		2013
Cash Flows From Operating Activities  Not loss applicable to common steelihelders	¢ (5 505 5	26)	\$ (8,914,293)
Net loss applicable to common stockholders  Adjustments to reconcile net loss to net cash used in operating activities:	\$ (5,505,5	30)	\$ (8,914,293)
Depreciation	13,7	on	72,357
Amortization intangibles	15,7	32	123,280
Amortization and write-off technology and licenses			100,807
Write-off of technology licenses			1,097,511
Provision for obsolete inventory	159,8	31	(62,482)
Reserve for product returns	137,0	<i>J</i> 1	(76,000)
Stock based compensation expense	508,6	28	40,750
Impairment loss on investments	1,834,6		10,720
Deferred rent	1,03 1,0	,_	(50,370)
Changes in operating assets and liabilities			(20,270)
Accounts receivable			222,110
Inventories			620,698
Prepaid expenses and other assets	106,2	43	90,130
Deposits	120,0		54,847
Payables advance from officer	161,9		2 1,0 11
Accounts payable	214,0		517,490
Accrued liabilities	(75,7		137,789
Net cash used in operating activities	(2,462,1	80)	(6,025,376)
Cash Flows Used in Investing Activities			
Purchases of property and equipment			(23,053)
Cash Flows From Financing Activities			
Proceeds from officer s loan	526,5	00	
Restricted cash collateral for letter of credit			50,000
Proceeds from sale of preferred and common stock, net of issuance costs of \$170,000	2,129,9	24	3,692,844
Net cash provided by financing activities	2,656,4	24	3,742,844
Net increase (decrease) in cash and cash equivalent	194,2	44	(2,305,585)
Cash and cash equivalents at beginning of year	22,4	89	2,328,074
Cash and cash equivalents at end of year	\$ 216,7	33	\$ 22,489
Supplemental Disclosures of Cash Flow Information:			
Cash paid for interest	\$	0	\$ 1,438
Cash paid for income taxes	\$ 3,2	00	\$ 3,200
See accompanying notes, which are an integral part of these consolidated t	financial statements		

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

45

# TAXUS CARDIUM PHARMACEUTICALS GROUP, INC. AND SUBSIDIAIRES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# Note 1. Organization and Liquidity

# **Organization**

Taxus Cardium Pharmaceuticals Group, Inc. (the Company, or Cardium, ) was incorporated in Delaware in December 2003. The Company is a regenerative medicine biotechnology company 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. The Company has a commercial FDA-cleared wound care product, a late clinical stage cardiovascular gene therapy product candidate and corresponding technology platforms as outlined below. The Company also owns LifeAgain Insurance Solutions, Inc., a medical analytics business and holds an investment interest in Healthy Brands Collective, a health products company.

Based on the Company s business strategy of partnering or otherwise monetizing products and product candidates with third party commercialization partners, two subsidiaries have been formed to coordinate the independent monetization and funding activities of its core products and technologies. The Angionetics Inc. subsidiary will focus on the late-stage clinical development and commercialization of the Company s Gener® angiogenic gene therapy product candidate, and the Activation Therapeutics, Inc. subsidiary will focus on the commercialization of the Excellagen ® FDA-cleared wound care product and the joint clinical development of Excellagen product line extensions as an advanced biologic delivery platform for new and innovative wound healing therapeutics.

During 2013, the Company 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. The Company released the first product aimed at individuals with prostate cancer in 2013. LifeAgain Insurance Solutions, Inc. is operated as a wholly-owned subsidiary of Cardium.

The Company s business is focused on the acquisition and strategic development of product opportunities or businesses having the potential to address significant unmet medical needs, and having definable pathways to commercialization. The Company intends to consider various corporate development transactions designed to place its 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.

The Company has yet to generate positive cash flows from operations, and is essentially dependent on debt and equity funding to finance its operations.

# **Reverse Stock Split**

On July 17, 2013, pursuant to board and stockholder approval, the Company filed a Certificate of Amendment to its Restated Certificate of Incorporation with the State of Delaware to affect a reverse split of the Company s 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.

Table of Contents 67

46

# **Liquidity and Capital Resources**

As of December 31, 2014, the Company had approximately \$217,000 in cash and cash equivalents. The Company s working capital deficit at December 31, 2014 was approximately \$2,008,000. The Company has incurred recurring losses and as of December 31, 2014, the Company has accumulated deficit of approximately \$111 million. During the years ended December 31, 2014 and 2013, the Company has used approximately \$2.5 million and \$6 million in its operating activities.

The Company s primary source of capital resources is from proceeds from sales of its debt and equity securities. During the years ended December 31, 2014 and 2013, the Company raised net proceeds of approximately \$2.1 million and \$3.7 million, respectively from the sale of common stock and preferred stock to be used for general corporate purposes, including, but not limited, research and development activities and for working capital.

The Company anticipates that negative cash flows from operations will continue for the foreseeable future. The Company currently, does not have any unused credit facilities. As long as any shares of the Company s Series A Convertible Preferred Stock are outstanding, the Company has agreed that it 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 .

The Company s principal business objectives are to advance the independent monetization and funding activities of its core products and technologies, with its Angionetics Inc. subsidiary being focused on the Generx <sup>®</sup> angiogenic gene therapy product candidate, and its Activation Therapeutics, Inc. subsidiary being focused on the Excellagen <sup>®</sup> FDA-cleared wound care product and the joint clinical development of Excellagen product line extensions as an advanced biologic delivery platform for new and innovative wound healing therapeutics, and/or to complete alterative corporate transactions. If the Company fails to conclude such transaction in a timely manner or alternatively fails to generate sufficient cash from financing activities, the Company will not generate sufficient cash flows to cover its operating expenses.

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

# Note 2 Summary of Significant Accounting Policies

## **Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC).

# **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.

# Use of Estimates and assumptions and critical accounting estimates and assumptions

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date(s) of the financial statements and the reported amounts of revenues and expenses during the reporting period(s).

Critical accounting estimates are estimates for which (a) the nature of the estimate is material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change and (b) the impact of the estimate on financial condition or operating performance is material. The most significant estimates and assumptions used by the management include obsolescence reserve for inventory, valuation allowance for deferred tax assets, and valuation of equity instruments. These significant accounting estimates or assumptions bear the risk of change due to the fact that there are uncertainties attached to these estimates or assumptions, and certain estimates or assumptions are difficult to measure or value.

Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying

values of assets and liabilities that are not readily apparent from other sources.

Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates.

47

# **Principles of Consolidation**

The consolidated financial statements include the accounts of Taxus Cardium Pharmaceuticals Group, Inc. and its consolidated subsidiaries, Angionetics Inc., Activation Therapeutics, Inc. (formerly 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 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**

The Company considers 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 the Company to significant concentrations of credit risk consist of cash and cash equivalents. At times, the Company s 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, 2014, the Company had no cash and cash equivalent balances in excess of the federally insured limit of \$250,000.

#### Inventories, net

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. The Company recorded a reserve against inventory of approximately \$160,000 for the year ended December 31, 2014 and of approximately (\$62,000) for the year ended December 31, 2013.

# Property and Equipment, net

Property and equipment are stated at cost and include equipment, installation costs and materials less accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets. Estimated useful lives of the assets ranging from 3 to 5 years. 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 the Company acquired for the use of fully developed product formulas that it planned to develop as part of the Company s initiative to create a portfolio of nutraceutical products. The Company planned to market these products to consumers principally through convenience stores, pharmacy chains, and wholesale clubs that the Company gained access to as a result of its 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 the Company believed was approximately equal to the useful lives of the underlying product formulas. The Company 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 (ASC 350). Under ASC 350, intangible assets with definite lives are periodically tested for impairment based on an analysis of undiscounted cash flows (as described below). The Company sold its To Go Brand

Business in 2013 and discontinued operation of its nutraceutical business. Management determined it appropriate to write-off of the unamortized balance of \$1.1 million of the technology licenses associated with that product line at that time.

48

# 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. The Company did not believe there was any impairment of long-lived assets at December 31, 2014. During the year ended December 31, 2013 the Company determined to fully reserve the unamortized balance of \$1.1 million for the Company s technology licenses as described above.

#### Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of its preferred stock. Shares that are subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies 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 typically met when the risk of ownership and title passes to the Company s customers.

# **Research and Development**

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

# **Income Taxes**

The Company applies the elements of ASC 740 10 Income Taxes Overall regarding accounting for uncertainty in income taxes. This clarifies the accounting for uncertainty in income taxes recognized in financial statements and requires the impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. As of December 31, 2014, the Company did not have any unrecognized tax benefits. The Company does not expect that the amount of unrecognized tax benefits will significantly increase or decrease within the next twelve months. The Company s policy is to recognize interest and penalties related to tax matters in the income tax provision in the Consolidated Statements of Operations. There were no interest or penalties for the years ended December 31, 2014 and 2013. Tax years beginning in 2011 are generally subject to examination by taxing authorities, (although net operating losses from all years are subject to examinations and adjustments for at least three years following the year in which the attributes are used.)

Deferred taxes are computed based on the tax liability or benefit in future years of the reversal of temporary differences in the recognition of income or deduction of expenses between financial and tax reporting purposes. The net difference, if any, between the provision for taxes and taxes currently payable is reflected in the balance sheet as deferred taxes. Deferred tax assets and/or liabilities, if any, are classified as current and non-current based on the classification of the related asset or liability for financial reporting purposes, or based on the expected reversal date for deferred taxes that are not related to an asset or liability. Valuation allowances are recorded to reduce deferred tax assets to that amount which is more likely than not to be realized.

#### **Common Stock Purchase Warrants**

The Company accounts 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, the Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies 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**

The Company computes 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, 2014 or 2013 because their effect would be anti-dilutive.

As of December 31, 2014, potentially dilutive securities consist of outstanding stock options and warrants to acquire 2,788,242 shares of our common stock. As of December 31, 2013, potentially dilutive securities consisted of outstanding stock options and warrants to acquire 1,122,830 shares of our common stock.

#### **Fair Value Measurement**

## Valuation Hierarchy

The accounting standard of the FASB for fair value measurements establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company s own assumptions used to measure assets and liabilities at fair value. A financial asset or liability s classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company accounts for investments in other entities under the cost method of accounting when the Company does not hold significant interest in nor has any management control over those entities. Based on the assessment, the Company recorded impairment charges of \$1,834,672 and \$0 during the years ended December 31, 2014 and December 31, 2013, respectively. (See Note 3) Investments are classified within Level 3 of the valuation hierarchy.

The following non recurring fair value measurements were recorded during the years ended December 31, 2014 and 2013:

	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2014				
Investment	\$ 300,000	\$	\$	\$ 300,000
December 31, 2013				
Investment	\$ 1,699,672	\$	\$	\$ 1,699,672
Deposit on investment option	\$ 435,000	\$	\$	\$ 435,000

\$ 2,134,672

\$ 2,134,672

The Company performed a valuation to estimate the fair value of its investment in Cell-nique preferred stock as of December 31, 2014. To determine the value of the equity instrument the Company considered the following three possible valuation methods: (1) the income approach, (2) the market approach and (3) the cost approach to estimate the enterprise value.

The income approach focuses on the income-producing capability of a business by estimating value based on the expectation of future cash flows that a company will generate such as cash earnings, cost savings, tax deductions, and the proceeds from disposition. These cash flows are discounted to the present using a rate of return that incorporates the risk-free rate for the use of funds, the expected rate of inflation, and risks associated with the particular investment. The selected discount rate is generally based on rates of return available from alternative investments of similar type, quality and risk.

The market approach valuation method measures the value of an asset or business through an analysis of recent sales or offerings of comparable investments or assets. When applied to the valuation of equity interests, consideration is given to the financial condition and operating performance of the entity being appraised relative to those of publicly traded entities operating in the same or similar lines of business, potentially subject to corresponding economic, environmental and political factors and considered to be reasonable investment alternatives.

The Company selected the Income Approach to estimate the fair value of the Cell-nique preferred stock as of December 31, 2014, based on the financial information provided to the Company by Cell-nique.

The Company used a discounted cash flow model to determine the fair value of the investment in preferred stock of Cell-nique using a discount rate of 14%.

The Company has also fully impaired its deposit on investment in SourceOne since the Company determined it was probable it would not realize any benefit from its rights.

There were no transfers between level 1, 2 or 3 during the years ended December 31, 2014 and December 31, 2013.

50

Change in Level 3 assets measured at fair value on a non recurring basis for the year ended December 31, 2014:

Balance January 1, 2014	\$ 2,134,672
Impairment of investment	(1,399,672)
Impairment of deposit	(435,000)
Balance December 31, 2014	\$ 300,000

### **Stock-Based Compensation**

The Company recognizes compensation expense for all equity based payments in accordance with ASC 718 Compensation Stock Compensation. Under fair value recognition provisions, the Company recognizes equity based compensation net of an estimated forfeiture rate and recognizes compensation cost only for those shares expected to vest over the requisite service period of the award.

The fair value of an option award is estimated on the date of grant using the Black Scholes option valuation model. The Black Scholes option valuation model requires the development of assumptions that are input into the model. These assumptions are the expected stock volatility, the risk free interest rate, the option s expected life, the dividend yield on the underlying stock and the expected forfeiture rate. Expected volatility is calculated based on the historical volatility of the Company s common stock over the expected option life and other appropriate factors. Risk free interest rates are calculated based on continuously compounded risk free rates for the appropriate term. The dividend yield is assumed to be zero as the Company has never paid or declared any cash dividends on its common stock and does not intend to pay dividends on its common stock in the foreseeable future. The expected forfeiture rate is estimated based on historical experience.

Determining the appropriate fair value model and calculating the fair value of equity based payment awards requires the input of the subjective assumptions described above. The assumptions used in calculating the fair value of equity based payment awards represent management s best estimates, which involve inherent uncertainties and the application of management s judgment. As a result, if factors change and the Company uses different assumptions, equity based compensation could be materially different in the future. In addition, the Company is required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If actual forfeiture rate is materially different from the estimates, the equity based compensation could be significantly different from what the Company has recorded in the current period.

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:

	Decem	December 31,	
	2014	2013	
Research and development	\$ 51,408	\$ 5,997	
General and administrative	457,220	34,753	
Total stock-based compensation	\$ 508,628	\$ 40,750	

## **Recent Accounting Pronouncements**

In April 2014, the U.S. Financial Accounting Standards Board issued Accounting Standards Update 2014 08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*. This new standard (*i*) raises the threshold for disposals to qualify as discontinued operations (*ii*) allows companies to have significant continuing involvement and continuing cash flows with the discontinued operation, and (*iii*) provides for new and additional disclosures of discontinued operations and individually material disposal transactions. The Company anticipates adopting the new standard when it becomes effective in the first quarter of 2016.

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014 09, *Revenue from Contracts with Customers*. Amendments in this Update create Topic 606, *Revenue from Contracts with Customers*, and supersede the revenue recognition requirements in Topic 605, *Revenue Recognition*, including most industry specific revenue recognition guidance throughout the Industry Topics of the Codification. In addition, the amendments supersede the cost guidance in Subtopic 605 35, *Revenue Recognition Construction Type and* 

Production Type Contracts, and create new Subtopic 340 40, Other Assets and Deferred Costs Contracts with Customers. In summary, the core principle of Topic 606 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This Accounting Standards Update is the final version of Proposed Accounting Standards Update 2011 230 Revenue

Recognition (Topic 605) and Proposed Accounting Standards Update 2011 250 Revenue Recognition (Topic 605): Codification Amendments, both of which have been deleted. The amendments in Accounting Standards Update 2014 09 are effective for the Company for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently evaluating the effects of ASU 2014 09 on the consolidated financial statements.

In June 2014, FASB issued Accounting Standards Update 2014 12, Compensation Stock Compensation (Topic 718), which clarifies accounting for share based payments for which the terms of an award provide that a performance target could be achieved after the requisite service period. That is the case when an employee is eligible to retire or otherwise terminate employment before the end of the period in which a performance target could be achieved and still be eligible to vest in the award if and when the performance target is achieved. The updated guidance clarifies that such a term should be treated as a performance condition that affects vesting. As such, the performance target should not be reflected in estimating the grant date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. The guidance will be effective for the annual periods (and interim periods therein) ending after December 15, 2015. Early application is permitted. The Company is currently evaluating the effects of Account Standards Update 2014 12 on the consolidated financial statements.

In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014 15, *Presentation of Financial Statements Going Concern*. The Update provides U.S. GAAP guidance on management s responsibility in evaluating whether there is substantial doubt about a company s ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company s ability to continue as a going concern within one year from the date the financial statements are issued. This Accounting Standards Update is the final version of Proposed Accounting Standards Update 2013 300 *Presentation of Financial Statements* (Topic 205): Disclosure of Uncertainties about an Entity s Going Concern Presumption, which has been deleted. The Company is currently evaluating the effects of Accounting Standards Update 2014 15 on the consolidated financial statements.

In November 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014 16, Derivatives and Hedging. For hybrid financial instruments issued in the form of a share, Topic 815 requires an entity to determine the nature of the host contract by considering all stated and implied substantive terms and features of the hybrid financial instrument, weighing each term and feature on the basis of relevant facts and circumstances. Certain classes of shares include features that entitle the holders to preferences and rights (such as conversion rights, redemption rights, voting powers, and liquidation and dividend payment preferences) over the other stockholders. Shares that include embedded derivative features are referred to as hybrid financial instruments, which must be separated from the host contract and accounted for as a derivative if certain criteria are met under Subtopic 815 10. One criterion requires evaluating whether the nature of the host contract is more akin to debt or to equity and whether the economic characteristics and risks of the embedded derivative feature are clearly and closely related to the host contract. In making that evaluation, an issuer or investor may consider all terms and features in a hybrid financial instrument including the embedded derivative feature that is being evaluated for separate accounting or may consider all terms and features in the hybrid financial instrument except for the embedded derivative feature that is being evaluated for separate accounting. The use of different methods can result in different accounting outcomes for economically similar hybrid financial instruments. Additionally, there is diversity in practice with respect to the consideration of redemption features in relation to other features when determining whether the nature of a host contract is more akin to debt or to equity. The amendments apply to all reporting entities that are issuers of, or investors in, hybrid financial instruments that are issued in the form of a share. This Accounting Standards Update is the final version of Proposed Accounting Standards Update EITF 13G Derivatives and Hedging Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity (Topic 815), which has been deleted. This update is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early application is permitted. The Company is currently evaluating the effects of Accounting Standards Update 2014 16 on the consolidated financial statements.

In November 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014 17 *Business Combinations* (Topic 805): Pushdown Accounting. The amendments in Accounting Standards Update 2014-17 provide an acquired entity with an option to apply pushdown accounting in its separate financial statements upon occurrence of an event in which an acquirer obtains control of the acquired entity. An acquired entity may elect the option to apply pushdown accounting in the reporting period in which the change-in-control event occurs. An acquired entity should determine whether to elect to apply pushdown accounting for each individual change-in-control event in which an acquirer obtains control of the acquired entity. If pushdown accounting is not applied in the reporting period in which the change-in-control event occurs, an acquired entity will have the option to elect to apply pushdown accounting in a subsequent reporting period to the acquired entity s most recent change-in-control event. An election to apply pushdown accounting in a reporting period after the reporting period in which the change-in-control event occurred should be considered a change in accounting principle in accordance with Topic 250, Accounting Changes and Error Corrections. If pushdown accounting is applied to an individual change-in-control event, that election is irrevocable. The amendments in Accounting Standards Update 2014- 17 are effective on November 18, 2014. After the effective date, an acquired entity can make an election to apply the guidance to future change-in-control events or to its most recent change-in-control event. However, if the financial statements for the period in which the most recent change-in-control event occurred already have been issued or made available to be issued, the application of

this guidance would be a change in accounting principle. The Company is currently evaluating the effects of Accounting Standards Update 2014 17 on the consolidated financial statements.

#### Reclassifications

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

### NOTE 3 Disposal of Long-Lived Assets and Investment

On November 15, 2013, the Company sold the business conducted by its To Go Brands, Inc. subsidiary to Healthy Brands Collective in exchange for 33,441 shares of preferred stock of Cell-nique Corporation (Cell-nique) (the parent company of Healthy Brands Collective) and the assumption of certain liabilities. Because Cell-nique was a private company at the time of the sale, the Company recorded the value of the shares of preferred stock in the Company s consolidated balance sheet as an investment in Cell-nique at the net asset value of the assets transferred and liabilities assumed by Cell-nique Corporation. The Company 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 was 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 preferred shares are convertible into Cell-nique Corporation common stock at the option of the Company, and at the time of the sale would represent approximately 4% of the fully-diluted voting interests of Cell-nique Corporation. These preferred 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 Corporation s affairs or upon the occurrence of other deemed liquidation events described in Cell-nique Corporation s articles of incorporation.

On the date of sale, the Company calculated the net assets of To Go Brands, Inc. as follows:

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

For the year ended December 31, 2013, 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 Company s discontinued nutraceutical business are presented as a loss from a discontinued operation in the accompanying consolidated statements of operations:

	_	Year ended December 31,2013	
Revenues			
Product sales	\$	1,728,177	
Cost of goods sold		1,002,064	
Gross profit		726,113	
Operating expenses			
Research and development		128,215	
Selling, general and administrative		1,507,210	

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Total operating expenses	1,635,425
Loss from operation	(909,312)
Interest, net	(667)
Net loss from discontinued operations of To Go Brands, Inc.	(909,979)
Write-off of technology licenses associated with the nutraceutical product lines	(1,097,511)
Net loss from discontinued operations	\$ (2,007,490)

During the year ended December 31, 2014, the Company believed there were certain impairment triggering events and circumstances which warranted an evaluation of its investment in the Cell-nique preferred shares and a non-cash impairment charge of \$1,399,672 was recorded. As of December 31, 2014, the remaining fair value of preferred shares in Cell-nique was \$300,000.

### NOTE 4 Intangible Assets and Strategic Investment

On December 20, 2011, the Company 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 the Company issued 75,000 restricted shares of its common stock valued at \$5.80 per share.

Under the SourceOne agreement, the Company also made an equity investment in the form of unregistered, restricted shares of its common stock to acquire an option to purchase to a 15% ownership interest in SourceOne Global Partners. The option was acquired through the issuance into escrow of 75,000 shares of the Company s common stock which were recorded at a value of \$5.80 per share based on the closing price of the Company s stock on December 19, 2011, and is exercisable for an exercise fee of \$10,000.

54

During the year ended December 31, 2014, the Company believed there were certain impairment triggering events and circumstances that warranted an evaluation of its SourceOne agreement and as a result a non-cash impairment charge of \$435,000 was recorded.

## **Note 5 Inventories**

Inventories consisted of the following:

	De	cember 31, 2014	Dec	cember 31, 2013
Raw materials	\$	183,398	\$	183,398
Finished goods				
		183,398		183,398
Less provision for obsolete inventory		(183,398)		(23,567)
Inventories, net	\$		\$	159,831

### Note 6 Property and Equipment

Property and equipment consisted of the following:

	Decem	December 31,	
	2014	2013	
Computer and telecommunication equipment	\$ 425,331	\$ 425,331	
Machinery and equipment	31,779	31,779	
Office equipment	11,490	11,490	
Instrumentation			
Office furniture and equipment	223,206	223,206	
Leasehold improvements	23,053	23,053	
	714,859	714,859	
Accumulated depreciation and amortization	(698,445)	(684,663)	
Property and equipment, net	\$ 16,414	\$ 30,196	

Depreciation and amortization of property and equipment from continuing operations totaled \$13,782 and \$44,973 (\$27,384 related to discontinued operations) for the years ended December 31, 2014 and 2013, respectively.

### Note 7 Accrued Liabilities

Accrued Liabilities consisted of the following:

	Decem	December 31,	
	2014	2013	
Payroll and benefits	\$ 465,512	\$ 511,098	
Other	69,739	99,909	
Total	\$ 535,251	\$ 611,007	

# Note 8 Commitments and Contingencies

### **Lease Commitments**

On August 15, 2013, the Company entered into a lease for approximately 4,419 square feet of office space in San Diego, California to be used as its 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 monthly base rent, the Company is also required to pay its proportionate share of any building operating expenses in excess of 2014 levels. In connection with entering into the lease, the Company 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:

55

	Facilities
Year Ending December 31,	(Operating Lease)
2015	121,596
2016	82,936
Total	\$ 204,532

Rent expense included in continuing operations was \$149,371, and \$435,573 for the years ended December 31, 2014 and 2013 respectively.

#### License Fees

In October 2005, the Company 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, the Company 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. The Company 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, the Company 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 the Company at any time on 60 days notice, following which the Company would continue to be responsible only for obligations and liabilities accrued before termination. Under the agreement, the Company is obligated to pay (1) an annual royalty fee of 2% based on net sales of products incorporating the technology licensed under the agreement, and (2) a minimum annual royalty fee (which may be offset against the net sales-based royalty fee) \$100,000 for 2010, \$100,000 for 2011, \$150,000 for 2012, \$150,000 for 2013 and \$200,000 for 2014 and thereafter, payable on February 28 of the following year. The Company incurred the minimum license fee in 2013 and 2012. As part of the Schering transaction, the Company acquired rights and corresponding obligations under the New York University March 1997 agreement, as amended. Under the agreement, the Company is obligated to pay (1) an annual royalty fee of 3% 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. As part of the Schering transaction, the Company acquired rights and corresponding obligations under the New York University March 1997 Agreement as amended, under which the Company may be obligated to pay an annual fee of \$50,000 per year through the completion of the first full year of sales licensed technology as well as ongoing patent expenses incurred in connection with the licensed technologies. Should licensed products under the agreement reach the stage of filing of a product license application (PLA) and PLA approval or foreign equivalent thereof, the Company may be obligated to pay up to an aggregate amount of approximately \$1.8 million for each product in milestone payments. In addition, beginning in the year in which the Company completes one full year of sales of licensed products and continuing thereafter until the agreement terminates or expires, the Company may also be obligated to pay annual royalty fees equal to 3% on net sales of products incorporating the licensed technology.

### **Legal Proceedings**

In October 2014, the Company received a complaint filed by Biorasi LLC in Broward County, Florida, seeking payments of approximately \$0.5 million related to its activities in connection with the Company s ASPIRE clinical trial conducted in the Russian Federation. The Company plans to defend the action and is awaiting a ruling on its request to dismiss; the Company has not recorded a liability for this contingency as the Company believes that the probability of an adverse outcome is remote.

As of December 31, 2014, neither Cardium nor its subsidiaries were party to any material pending legal proceeding nor was any of their property the subject of any material pending legal proceeding, except as noted above. In the course of business, however, the Company could become engaged in various intellectual property, product-related, and other matters in connection with the technology the Company develops or licenses and the products the Company develops for commercialization. To the extent the Company is not successful in defending against any adverse claims concerning its technology, business relationships or products, the Company 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 the Company finds commercially reasonable or at all, or to pays other forms of compensation or expenses. In addition, any such proceedings, even if decided in the Company s favor, involve lengthy processes, are subject to appeals, and typically result in substantial costs and diversion of resources.

### Note 9 Income Taxes

The Company files income tax returns in the United States (Federal) and California. The Company is no longer subject to Federal, state and local income tax examinations by tax authorities for years prior to 2011.

The Company had U.S. federal and state net operating loss carryovers of \$104.2 million and \$92.5 million as of December 31, 2014 and 2013, respectively. These net operating losses are subject to Internal Revenue Code Section 382,

56

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 2024 for federal income purposes and in 2015 for state income tax purposes.

The ultimate realization of deferred tax assets depends on the generation of future taxable income during the periods in which those net operating losses are available. The Company considers projected future taxable income and tax planning strategies in making its assessment. At present, the Company does not have a sufficient history of income to conclude that it is more-likely-than-not that it will be able to realize all of its tax benefits in the near future and therefore the Company has 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, 2014 and 2013 the change in the valuation allowance was \$9,072,799 and \$1,530,946, respectively.

Our net deferred tax asset consisted of the following at December 31, 2014 and 2013:

	December 31,		
	2014	2013	
Deferred tax asset:			
Net operating loss carryforwards	\$ 41,512,011	\$ 36,837,171	
Deferred compensation	1,082,211	881,025	
Depreciation and amortization	1,161,055	886,149	
License impairment		437,187	
Research and development credits	3,761,004	194,132	
Accrued expenses	47,356	97,326	
Impairment of investments	730,830		
Other	248,933	137,611	
Total deferred tax assets	48,543,400	39,470,601	
Less: Valuation allowance	(48,543,400)	(39,470,601)	
Net deferred tax asset	\$	\$	

The income tax provision (benefit) from income taxes consists of the following at December 31, 2014 and 2013:

	Years Ended December 31,	
	2014	2013
Federal		
Current	\$	\$
Deferred	(6,333,053)	(1,306,714)
State		
Current		
Deferred	(2,739,746)	(224,232)
Total	(9,072,799)	(1,530,946)
Change in valuation allowance	9,072,799	1,530,946
Income tax provision (benefit)	\$	\$

As a result of the Company s significant operating loss carry forwards and the corresponding valuation allowance, no income tax benefit was recorded at December 31, 2014 or 2013. The provision for income taxes using the statutory federal tax rate as compared to the Company s effective tax rate is summarized as follows:

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	December	December 31,	
	2014	2013	
Expected U.S. federal statutory rate	(34.0)%	(34.0)%	
State income taxes, net of federal benefit	(14.6)%	(5.8)%	
Deferred tax true-up	%	18.7%	
R&D credit	%	(1.4)%	
Other permanent differences	%	0.3%	
	(48.6)%	(22.2)%	
Change in valuation allowance	48.6%	22.2%	
Totals	0%	0%	

Note 10 Stockholders Equity

#### Common Stock

On September 28, 2010, the Company entered into a Sales Agreement (Sales Agreement) with Brinson Patrick Securities Corporation to enable the Company to use Brinson Patrick as a sales manager to sell shares of its common stock from time to time in at-the-market transactions pursuant to the Company s shelf registration statement on a best efforts basis. During the first quarter of 2013, the Company raised net proceeds of \$65,743 through the sale of 17,187 shares of common stock under at-the-market transactions.

On February 28, 2014, the Company entered into a strategic collaboration and funding arrangement with Shanxi Taxus Pharmaceuticals Co., Ltd., which is based in the Peoples Republic of China (PRC) and is affiliated with Shenzhen Forntsea Taxus Industry Capital Management (Shanxi Taxus), to support the worldwide clinical and commercial development of Cardium's advanced regenerative medicine therapeutics products, including the Generx product candidate and Excellagen. In connection with this arrangement, the Company entered into a Stock Purchase Agreement with Shanxi Taxus, pursuant to which, 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. In February 2014, the Company closed the initial tranche of funding by selling 714,286 shares of common stock at \$0.70 per share. On May 12, 2014, Shanxi Taxus acquired a second tranche of \$1.5 million by purchasing 2,330,278 shares of common stock at \$0.6437 per share a mutually agreed upon price. In December 2014, Shanxi Taxus acquired a portion of the third tranche of \$300,000 by purchasing 466,056 shares of common stock at \$0.6437 per share a mutually agreed upon price. Although Shanxi Taxus originally had a right to purchase the third, fourth and fifth tranches of \$1.0 million each, with the third tranche not timely closed for the full amount, it no longer has a contractual right to purchase additional shares pursuant to the terms of the Stock Purchase Agreement.

The common stock purchased by Shanxhi Taxus is unregistered, but in the event that the Company files a registration statement for other shares of common stock, 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 in connection with the transaction.

### **Preferred Stock**

In April 2013, the Company entered into a securities purchase agreement with Sabby Healthcare, one of the Company s institutional investors pursuant to which the Company agreed to sell to the investor an aggregate of 4,012 shares of its 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 initial closing under the securities purchase agreement took place in April 2013, at which the Company 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 on July 18, 2013. At December 31, 2014 the investor had converted 2,836 shares of Series A Convertible Preferred Stock into 2,786,652 shares of common stock. After giving effect to these conversions, 1,176 shares of Series A Convertible Preferred Stock were outstanding at December 31, 2014.

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 the Company's 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 the Company's 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 and is currently \$0.6437 per share; the conversion price is subject to downward adjustment if the Company issue common stock or common stock equivalents at a price less than the then effective conversion price. The Company have the right to force conversion if the volume weighted average price for its 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, the Company has agreed that it 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 the Company is common stock, or enter into any related party transactions.

The Company determined the Series A Convertible Preferred Stock contained a beneficial conversion feature at the date of issuance. This beneficial conversion feature amounted to \$233,011 for the first closing and was recorded as a deemed preferred dividend in April 2013. The beneficial conversion feature on the second closing amounted to \$172,861 and was recorded as a deemed preferred dividend in July 2013.

### Stockholder Rights Plan

On July 10, 2006, the Company s Board of Directors approved the adoption of a Stockholder Rights Plan (Rights Plan). Pursuant to the Rights Plan, the Company 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 the Company s common stock while the Rights Plan remains in place, then, unless the 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, the Company s common stock certificates.

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