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Taxus Cardium Pharmaceuticals Group Inc.
Form 10-K
July 28, 2017

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, 2016

001-33635

(Commission file number)

TAXUS CARDIUM PHARMACEUTICALS GROUP INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

27-0075787
(IRS Employer Identification No.)

11568 Sorrento Valley Rd., Suite 14

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 No

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	(Do not check if a small reporting company) Smaller reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of common equity held by non-affiliates, computed on the basis of the closing sale price for the common stock as reported on the OTC QB on June 30, 2015, was \$3.3 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 July 28, 2017, 14,373,544 shares of the registrant's common stock were outstanding.

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EXPLANATORY NOTE

Unless the context requires otherwise, all references in this report to the “Company,” “Taxus Cardium,” “Cardium,” “we,” “our,” and “us” refer to Taxus Cardium Pharmaceuticals Group Inc. and, as applicable, our consolidated subsidiaries: Angionetics, Inc. (“Angionetics”), Activation Therapeutics, Inc. (“Activation Therapeutics”) and LifeAgain Insurance Solutions, Inc. (“LifeAgain”).

Due to financial hardship, we were unable to secure the necessary accounting review and audit of our financial statements and suspended filing of our regular quarterly and annual reports following our Quarterly Report on Form 10-Q for the period ended June 30, 2015. We have subsequently filed our Quarterly Report on Form 10-Q for the period ended September 30, 2015; our Annual Form 10-K for the year ended December 31, 2015; our Quarterly Report on Form 10-Q for the period ended March 31, 2016; our Quarterly Report on Form 10-Q for the period ended June 30, 2016 and our Quarterly Report on Form 10-Q for the period ended September 30, 2016. It is our intention to become current in our reporting obligations under the Securities Exchange Act of 1934, as amended. In the meantime, we have included disclosure concerning our more recent operations in Note 10—Subsequent Events in the footnotes to the consolidated financial statements and elsewhere in this report.

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,” “predicts,” or “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 beliefs and opinions about the anticipated results of our clinical studies and trials, as well as the safety and efficacy of our products and product candidates;
- our ability to generate revenues, and raise sufficient financing, maintain stock price and valuation, and to regain the listing of our common stock on a national exchange;
- our ability to enter into acceptable relationships with one or more contract manufacturers or other service providers, and the ability of such contract manufacturers or other service providers to manufacture biologics, devices, other key products or components, or to provide other services, of an acceptable quality on a timely and cost-effective basis;
- our ability to enter into acceptable relationships with one or more development or commercialization partners to advance the commercialization of new products and product candidates and the timing of any product launches;
-

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

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

the protection expected from our intellectual property rights and those of others, including actual or potential competitors;

the outcome of litigation matters;

the anticipated activities of our personnel, consultants and collaborators;

expectations concerning our operations outside the United States;

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 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

Taxus Cardium was incorporated in Delaware in December 2003. We are an operating company that manages a medical technologies portfolio of equity-based and potential royalty-driven investments as follows: (1) Angionetics, currently a majority-owned subsidiary focused on the late-stage clinical development and commercialization of Generx™, an angiogenic gene therapy product candidate designed for medical revascularization for the potential treatment of patients with myocardial ischemia and refractory angina due to advanced coronary artery disease; (2) Activation Therapeutics, a wholly owned subsidiary focused on the development and commercialization of the Excellagen® technology platform, an FDA-cleared flowable dermal matrix for advanced wound care that we believe has broad potential applications as a delivery platform for small molecule drugs, proteins and biologics; (3) LifeAgain a wholly-owned subsidiary that has developed an advanced medical data analytics (ADAPT®) technology platform focused on developing new and innovative products for the life insurance and healthcare sectors; and (4) a minority investment in Healthy Brands Collective, a functional food and nutraceutical company which acquired the Company's To Go Brands® business.

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.

Business Strategy

We are currently focused on achieving milestones with the potential to offer significant valuation inflection points of our core biotechnology assets, while evaluating options for sales or other monetization of our non-core investments. The key elements of our business strategy include:

- Continue Angionetics' development and commercialization of Generx™, an angiogenic, gene-based biotherapeutic designed for the treatment patients who have late-stage coronary artery disease and refractory angina and other ischemic heart disorders and medical conditions, including support in the funding and operation of the AFFIRM U.S.-based Phase 3 clinical trial.

• Monetize Activation Therapeutics' FDA-cleared pharmaceutically formulated collagen commercial wound care product Excellagen® through either a sale of Activation Therapeutics or its assets or the establishment of strategic partnership for the sale and distribution of Excellagen in selected U.S.-based vertical market channels.

• Leverage Excellagen's advanced regenerative medicine delivery platform by identifying innovative product extensions for tissue regeneration based on stem cells (including exosomes), biologics, peptides and/or small molecule drugs for future development and commercialization with one or more strategic partners.

• Identify a new insurance partner and seek opportunities for the application LifeAgain's Medical analytics to commercialize "Survivable risk" term life insurance for cancer survivors or others with medical conditions who are currently considered uninsurable based on traditional under writing standards as well as other forms of survivable risk programs.

• With the successful monetization of current business interests, we plan to redeploy capital strategically to acquire and develop new and innovative medicine product candidates and create shareholder value.

We have yet to generate positive cash flows from operations, and are dependent on equity and debt funding to finance our operations. We intend to raise capital to finance the operations of Angionetics through a sale of equity in that entity. Alternatively, we are seeking to raise sufficient capital to finance our operations through the sale of equity or assets in our investments in Activation Therapeutics, LifeAgain and Healthy Brands Collective. If we fail to complete a financing or conclude such a transaction in a timely manner, 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. The consolidated

financial statements contained in this report do not include any adjustments related to the recoverability of assets or classifications of liabilities that might be necessary should we be unable to continue as a going concern.

Angionetics Inc. (Generx™)

Angionetics is a majority-owned subsidiary established to hold our Generx™ angiogenic gene therapy product candidate.

Generx™ has been under clinical development for over a decade, under the continual oversight of our highly experienced management team. Our management and consulting team have been responsible for the development of Generx from the initial scientific discoveries by researchers at the University of California, San Diego, through the first in-man U.S.-based clinical studies and late stage clinical studies, the acquisition of the Generx development program by Schering AG following the successful completion of a five-year strategic partnership, and the re-acquisition of the Generx development program by Taxus Cardium after Schering AG was acquired by Bayer Healthcare. Collectively, Angionetics' small and highly focused management team has over 100 years of experience in the fields of gene therapy, cardiovascular product development and biologics.

On September 9, 2016, the U.S. FDA Center for Biologics Evaluation and Research (CBER) cleared Angionetics' AFFIRM Phase 3 clinical study protocol, thus allowing Angionetics to proceed with late-stage clinical evaluation of Generx™. The AFFIRM study patient population and trial design are based on Ad5FGF-4 responder data from the four prior FDA-cleared clinical studies. The primary efficacy endpoint is improvement in exercise treadmill test (ETT) duration in Generx™-treated patients compared to a placebo control group. Enrolled patients must have refractory angina, documented clinical evidence of myocardial ischemia, clinically significant limitation of physical activity due to angina, and angina-limited ETT duration of 3-7 minutes.

On February 3, 2017, Angionetics received notice that the FDA has granted Fast Track designation for the Phase 3 clinical investigation of Generx [Ad5FGF-4] cardiovascular angiogenic gene therapy as a one-time treatment for improving exercise tolerance in patients who have angina that is refractory to standard medical therapy and not amenable to conventional revascularization procedures (coronary artery bypass surgery and percutaneous coronary intervention and stents). Under the FDA Modernization Act of 1997, designation as a Fast Track product means that FDA will take actions, as appropriate, to expedite the development and review of a biologics license application (BLA) for product approval. The FDA's Fast Track process is designed to facilitate clinical and commercial development and expedite the review of new drugs and biologics that are intended to treat serious conditions that demonstrate the potential to address an unmet medical need.

After over two decades of basic, pre-clinical and clinical research in the field of gene therapy by universities, research institutes, as well as pharmaceutical and biotechnology companies worldwide, Angionetics' Generx represents one of only a few cardiovascular DNA-based therapeutic product candidates to successfully advance into late-stage, U.S. Phase 3 clinical study. Our primary business focus is securing the additional capital that we will need to finance the completion of the AFFIRM study. We estimate that we will need an additional \$25 to \$50 million in additional capital to complete that study. We plan to secure that capital through the sale of additional equity or debt securities in that entity. There are no agreements or arrangement for any additional financing in place at this time.

The Generx™ Product Candidate:

Generx™ is a disease-modifying, precision medicine that is designed to improve cardiac perfusion (blood flow) in patients with chronic myocardial ischemia and refractory angina due to advanced coronary artery disease. In our

clinical studies, enhanced cardiac perfusion is expected to improve exercise capacity, reduce the frequency of angina (chest pain) attacks and correspondingly reduce the need for certain anti-anginal drugs, and improve overall cardiovascular disease status. Generx has been designed to improve perfusion by promoting the formation of functional coronary collateral blood vessels within the heart. This process, termed “medical revascularization,” represents a fundamentally new mechanism of action that involves the stimulation of the formation of new biological structures in the heart, through arteriogenesis (enlargement of existing arterioles) and angiogenesis (formation on new capillary vessels), as opposed to currently available pharmacologic therapies which only address the symptoms of angina.

The Generx product candidate is designed to easily fit within the current practice of medicine, as a ready-to-use, one-time treatment, which is administered by interventional cardiologists using standard cardiac balloon catheters, during an approximately one-hour, out-patient, angiogram-like procedure conducted on a non-acute basis, in a hospital or medical center catheter lab setting. Interim study results demonstrate effectiveness similar to that of bypass surgery or stents, but in a significantly less costly and less invasive procedure.

Addressable Market:

Patients experiencing “refractory angina”--chronic and disabling stable angina despite conventional forms of treatment represent a significant and rapidly growing, “no option” patient population. According to the 2016 American Heart Association report, there are approximately 15.5 million Americans with coronary artery disease, 50% of whom have symptomatic angina pectoris. Many of these patients (1) have coronary artery disease that is not limited or localized to large vessels, (2) continue to experience angina after coronary artery bypass surgery (CABG) or percutaneous coronary interventions (PCI), and/or (3) are not suitable candidates for surgical

interventions. Based on a study from the Cleveland Clinic [Mukherjee et al., Am J Cardiol. 1999; 84:598-600], it is estimated that approximately 12% of patients with angina due to coronary artery disease are considered not suitable for CABG or PCI.

For many patients, there are few treatment options for refractory angina, and currently available alternative therapies do not directly address the reversible, stress-induced perfusion defects responsible for refractory angina. We believe that the Generx angiogenic gene therapy product candidate represents a new and innovative biological tool for the interventional cardiologist and potentially a breakthrough therapy for this very substantial unmet market segment, and for multiple small and orphan medical indications that currently have no specific therapeutic products.

We estimate that there are approximately 1.0 million patients in the U.S. with refractory angina who may benefit from Generx angiogenic gene therapy, and that the potential addressable market is estimated to range from \$3.0 billion in the U.S. and up to \$20.0 billion worldwide.

Generx Clinical Studies and FDA developments:

The Generx FDA regulatory dossier represents one of the most extensive and advanced DNA-based clinical data platforms ever compiled. Generx has been evaluated as a treatment for patients with refractory angina in four prior FDA-cleared, multi-center, randomized and placebo-controlled clinical studies (AGENT 1-4, Phase 1/2 to Phase 2b/3) and one small international study (ASPIRE). The combined AGENT studies have enrolled over 650 patients at over 100 medical centers in the U.S. and Western Europe, and have generated over 2,500 patient years of safety data.

In these multiple prior clinical studies, the Generx product candidate appeared safe and well-tolerated, and has generated preliminary findings of efficacy in men and women, in measures of cardiac perfusion, cardiac performance, and angina status, including: (1) significant improvement in exercise duration by Exercise Treadmill Testing (ETT); (2) significant improvement in cardiac perfusion as assessed by SPECT imaging, with observed improvements comparable in magnitude to those seen with coronary artery bypass surgery (CABG) and angioplasty with the use of stents (PCI); (3) significant and durable improvement in physical exertion capacity, as assessed by functional classification of angina out to 12 months post-treatment; (4) improvement in angina status, as assessed by documented reduction in angina episodes and nitroglycerin usage; and (5) significant reduction in incidence of worsening angina.

Generx Technology Platform:

The Generx™ [Ad5FGF-4] angiogenic gene therapy product candidate requires three key elements: a myocardial delivery vector; a therapeutic transgene; and methods of gene delivery. Generx is biologically engineered using an E1-region deleted, replication deficient adenovirus serotype 5 vector to deliver the 621 base pair gene encoding human fibroblast growth factor-4 (FGF-4) under the control of a modified cytomegalovirus (CMV) promoter. Adenovirus is the most well-characterized and widely used gene therapy vector in human clinical studies, and has cGMP manufacturing and testing standards established by the FDA. The Generx FGF-4 transgene has been engineered to include a signal peptide, which enables effective secretion from cells that express the protein (such as cardiac myocytes). Our preclinical studies have shown that therapeutic efficacy is significantly increased by the presence of such a signal sequence in the growth factor DNA construct. [Gao et al., Hum Gene Ther. 2005; 16:1058-64] The CMV promoter is capable of driving high levels of transgene protein expression in transfected cells for up to 3 weeks. This short-term expression is ideal for tissue regeneration clinical applications requiring generation of new biological structures, including promotion of new vessel growth in the heart.

Identifying the optimal route of administration and delivery parameters for Generx angiogenic gene therapy, such as infusion volume, flow rate, vector concentration and dose, are critical to achieving safe and effective levels of vector uptake and FGF-4 transgene expression. We have developed clinically feasible protocols that fit within current medical practice and that are designed to yield reproducible results and reduce inter-patient variability. Generx is administered by an interventional cardiologist into the coronary arteries under transient ischemic conditions through the use of a standard balloon catheter. Generx is distributed into the microvascular pathways of the heart, and transfects cardiac cells by binding to cell surface coxsackievirus-adenovirus receptors (CAR). CAR receptors are found throughout the heart, and our research indicates that the binding of Generx to CAR receptors is enhanced by the induction of transient ischemia and the use of agents like nitroglycerin to boost cell permeability during administration.

The transfected heart cells then express and release FGF-4 protein, which promotes the growth of new blood vessels and increased blood flow to ischemic heart tissue. Recent Company-sponsored research studies have demonstrated that FGF appears to be a key angiogenic regulatory protein that stimulates the release and action of other angiogenic factors, including vascular endothelial growth factors (VEGF), platelet-derived growth factors (PDGF), and hepatocyte growth factor (HGF), to orchestrate and promote the growth of a functional collateral network in ischemic cardiac tissue. The evidence shows that FGF-4 expressed by Ad5FGF-4 has the capacity to enlarge pre-existing collateral arterioles (arteriogenesis) and to form new capillary vessels (angiogenesis) when driven by cardiac hemodynamic-impairment and ischemic stimuli. These studies have further demonstrated a synergistic interaction between FGF-4 expressed by Ad5FGF-4, and endogenous vascular endothelial growth factor (VEGF) in the promotion of neo-vessel formation, with evidence that FGF controls angiogenesis upstream of VEGF.

Commercialization Developments:

Angionetics has continued to refine and advance Generx clinical and commercial development, summarized as follows:

◆ **New Pre-Clinical Research on Ad5 Receptor.** The Company and its research collaborators at Emory University completed in vivo preclinical studies demonstrating that intracoronary Ad5-based gene delivery under conditions of transient ischemia enhances transgene expression in the heart by over two orders of magnitude (>100 fold), as compared to prior intracoronary delivery methods, likely due to ischemia-driven up regulation of the cardiac Coxsackievirus-Adenovirus Receptor (CAR) and enhanced Ad5-mediated gene transfer.

◆ **New Delivery Techniques & Higher Dose Level.** The completion of further international clinical research confirmed recent innovations covering the use of a balloon catheter and transient ischemia during Generx delivery to improve efficacy responses by leveraging pre-conditioning cardiac physiology and our enhanced understanding of cell surface receptor-mediated uptake. This clinical study also confirmed the safety and efficacy of a new higher single dose level of Ad5FGF-4. Both the new catheter delivery techniques and higher dose level have been integrated into the recently FDA-cleared U.S.-based Phase 3 AFFIRM clinical study protocol.

◆ **New Fundamental Research on FGF Signaling.** Company-sponsored research studies have demonstrated that fibroblast growth factor (FGF) appears to be a key angiogenic regulatory protein that stimulates the release and action of other angiogenic factors, including vascular endothelial growth factors (VEGF), platelet-derived growth factors (PDGF), and hepatocyte growth factor (HGF), to orchestrate and promote the growth of cardiac microvasculature (a functional collateral network) in ischemic cardiac tissue.

◆ **New Clinical Data Analytics to Identify Generx Responders.** Angionetics has completed an advanced analysis of patient data from prior clinical studies to characterize male and female patient responders and those who are expected to have the highest likelihood to benefit from Generx angiogenic gene therapy. Data from a pilot International study which employed the new transient-ischemia Generx delivery protocol, identified statistically significant improvement in myocardial perfusion, as measured using SPECT myocardial perfusion imaging in patients treated with a single dose of Generx compared to control, which was consistent and confirmatory of findings from a prior FDA-cleared Phase 2 study. In addition to myocardial ischemia, likely responders have been characterized as having significant limitation of functional/exercise capacity due to angina.

◆ **New Simplified Handling Process for Generx.** Angionetics has pioneered application of the Becton Dickinson PhaSeal Closed System Transfer Device for DNA-based products to simplify the handling of Generx within the medical center and hospital pharmacy and interventional cardiology catheter labs, and has integrated use of the PhaSeal system into the FDA-cleared Generx AFFIRM Phase 3 clinical study protocol.

Angionetics is committed to applying our first-mover scientific and clinical development leadership position in the field of angiogenic gene therapy for the treatment of patients with a variety of cardiovascular conditions which are related by insufficient cardiac perfusion. The core elements of our long-term strategy for Angionetics include:

◆ **Secure the requisite funding and successfully complete the clinical development and commercialization Generx in the United States as a novel, first-in-class therapy for patients with myocardial ischemia and refractory angina.**

◆ **Initiate additional Phase 2 or Phase 4 (post-marketing) clinical studies to expand the Generx product labeling for use for other medical indications related to cardiac perfusion dysfunction that could include ischemic heart failure, Cardiac Syndrome X, and certain other orphan medical indications such as Prinzmetal's and inversa anginas.**

◆ **Establish a Generx patient registry and conduct additional clinical studies to evaluate the safety and clinical efficacy of repeat dosing of Generx in patients as their coronary artery disease advances causing additional perfusion defects.**

◆ **Initiate additional studies to assess the potential long-term prognostic benefits of patients receiving angiogenic therapy through medical revascularization.**

•

Following U.S. registration, initiate the registration process to market and sell Generx in China with our current strategic partner, and consider registration in other prioritized regional markets.

• Commercialize Generx in the U.S. using an internal, highly-targeted interventional cardiology-focused sales force, or enter into strategic partnerships in the U.S. and internationally.

• Strategically deploy capital to develop our portfolio of Generx product candidates and create shareholder value through the worldwide commercialization of our Generx portfolio and royalty agreements.

On June 6, 2016, Angionetics Inc. announced that an entity affiliated with Huapont Life Sciences had entered into an agreement covering a \$3,000,000 private equity investment, to acquire a 15% preferred stock equity stake in Angionetics. In addition, in connection with this equity investment, the Huapont affiliate entered into an exclusive license agreement to co-develop, market and sell Generx in Mainland China.

Huapont Life Sciences is a China-based company focused on the research and development of new and innovative healthcare products, and the manufacture, marketing and sale of leading pharmaceutical products, active pharmaceutical ingredients (known as

APIs), and a portfolio of safe and effective agricultural herbicides serving the agricultural business throughout the US and South American markets. Huapont Life Science's pharmaceutical business includes dermatology products, cardiovascular products, anti-tuberculosis agents, autoimmune-related products and oncology-related products. Huapont Life Science's API business involves the production and sale of bulk pharmaceutical chemicals, pharmaceutical intermediates and preparations of Western medicines, with current annual revenues of approximately US \$1.1 billion, and approximately 7,100 employees operating throughout Mainland China. Huapont Life Sciences is listed on the Shenzhen Stock Exchange (002004.SZ) and carries a current market capitalization of approximately US \$3.0 billion.

On September 12, 2016, Angionetics announced that the U.S. FDA Center for Biologics Evaluation and Research (CBER) had cleared the Generx® product candidate for Phase 3 clinical study as a new, single dose, treatment for patients with myocardial ischemia and refractory angina due to advanced coronary artery disease (the AFFIRM study). Angionetics plans to apply for FDA Fast Track status for the Generx Phase 3 AFFIRM clinical study. The FDA Fast Track program is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria.

After over two decades of basic, pre-clinical and clinical research in the field of gene therapy by universities, research institutes, as well as pharmaceutical and biotechnology companies worldwide, Angionetics' Generx represents one of only a few cardiovascular DNA-based therapeutic product candidates to successfully advance into late-stage, U.S. Phase 3 clinical study.

Activation Therapeutics Inc. (Excellagen®)

Activation Therapeutics is a wholly-owned subsidiary established to hold and manage our assets related to the Excellagen® product and technology platform.

We are looking to monetize Excellagen through the sale of Activation Therapeutics or the technology. Alternatively, we have sought strategic partners to market and sell Excellagen in the United States and elsewhere through multiple marketing channels. We have been in discussions with parties expressing interest in purchasing the business, however, as of the date of this report, such discussions have not resulted in a completed monetization or strategic partnering transaction. We cannot guarantee that it will accept an offer to purchase the Excellagen business or that any such bona fide offer will be made on acceptable terms and conditions.

Without a strategic partner, we do not plan to build inventory or establish an internal marketing and sales force to directly support the commercialization of Excellagen.

Excellagen® Dermal Wound Matrix:

Excellagen has been engineered to activate and promote wound healing through the growth of granulation tissue. Excellagen is a flowable homogenate of highly purified bovine dermal collagen (Type I) in its native 3-dimensional fibrillar configuration.

Excellagen was cleared by FDA via the 510(k) pathway on October 3, 2011 (K110318) for the treatment of chronic dermal wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grfts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. Excellagen has been classified for reimbursement purposes by the U.S. Centers for Medicare

and Medicaid Services as a unique “skin substitute”-- a designation which is consistent with other forms of skin substitutes including living skin equivalents Dermagraft® and Apligraf® and human dermal and amnion placental tissue-based products including Graftjacket® and EpiFix®.

The Excellagen manufacturing process includes steps by which purified full-length Type I collagen molecules are reassembled into collagen’s native, staggered fibrillar configuration. Scanning electron microscopy has demonstrated Excellagen’s 3-dimensional scaffold structure and histological analysis of Excellagen-treated dermal wounds demonstrates efficient infiltration with fibroblasts, and development of patent blood vessels. Excellagen activates human platelets resulting in release of platelet-derived growth factor (PDGF). Excellagen’s ability to activate platelets is functional/biological evidence of its 3-dimensional fibrillar structure, as it has been demonstrated that this structure (as opposed to monomeric or denatured collagen) is required for effective platelet activation.

Excellagen is a cost-effective, easy to use, professional product that is conveniently packaged in prefilled, syringes with accessory flexible applicator tips. Excellagen is topically applied in a thin layer directly to the entire wound surface, providing a structural scaffold for cellular infiltration and wound granulation. The flowable format allows immediate, intimate contact with the entire wound surface, including highly contoured wounds, and can also be easily applied to areas of undermining or tunneling. The wound is first prepared by performing sharp debridement using standard methods to remove debris and necrotic tissue, and then Excellagen should be applied in the presence of a small influx of blood. Application of Excellagen in the presence of a small influx of blood cells and platelets likely contributes to its support of a favorable wound healing environment by triggering immediate, localized release of PDGF and other platelet-derived growth factors and cytokines, providing wound healing cues to the responsive cells exposed by debridement. After application, the treated wound is overlaid with a non-adherent dressing. The treated wound (including non-adherent dressing) is left undisturbed for one week to allow Excellagen to promote new granulation tissue growth. If the wound is not completely healed, Excellagen may be reapplied weekly.

Excellagen Clinical Studies and FDA approval:

Excellagen was studied in a multi-center, randomized, controlled, double-blinded Phase 2b study in patients with diagnosed diabetes (Type I or II) with non-healing ulcers of the lower extremity (with no bone or tendon exposed) that had failed prior therapy, that were present for at least 6 weeks, and were documented to be non-healing ($\leq 30\%$ decrease in ulcer area) during a 2-week run-in period under standard of care treatment (debridement, daily saline-moistened gauze, and off-loading). The study control included the conventional Standard of Care or “SOC”; daily saline-moistened gauze dressing changes, offloading, and sharp debridement. Excellagen was applied only once (day 1) or twice (day 1 and week 4), with offloading and weekly outer dressing changes.

After the 12 week study period, 45% percent of the patients treated with Excellagen (n=31) achieved complete wound closure. This was a 45% relative improvement over wounds treated with SOC therapy alone (n=16; 31% closure incidence). There was a 68% relative improvement with Excellagen for wounds achieving 90-100% area reduction during the 12-week evaluation period. In other words, 74% of wounds receiving only one or two applications of Excellagen achieved $\geq 90\%$ area reduction compared with only 44% of patients receiving daily SOC. The improvement seen with Excellagen compared to SOC was even more dramatic for larger wounds. For wounds that were larger than three centimeters squared, 33% of wounds treated only once or twice with Excellagen achieved complete wound closure at 12 weeks whereas none of the SOC-treated wounds closed.

In the clinical study, Excellagen was applied to wounds only once or twice (with the second application four weeks after the first). Excellagen’s FDA clearance and the instructions for use suggest weekly application such that the accelerated healing and granulation tissue development observed in the Phase 2b study can be sustained, potentially further enhancing and accelerating the healing response. This schedule of weekly application has been followed in post-marketing use with positive reports of rapid, robust granulation tissue formation in chronic diabetic foot ulcers and pressure ulcers that have failed prior therapies.

Excellazome™ Advanced Wound Care Biologics Research:

We believe that Excellagen also represents a unique platform technology for the delivery of biologics for use in regenerative medicine applications. Prior research by Taxus Cardium and its collaborators has demonstrated biocompatibility and functionality of viral-based gene therapies and stem cell biologics when delivered in Excellagen. In addition to DNA- and stem cell-based biologics, Excellagen provides a potential enabling delivery platform for numerous therapeutic product classes, including small molecule drugs, peptides and anti-microbials.

Activation Therapeutics is developing plans to undertake research and preclinical studies to evaluate the toxicology and mechanism of action with respect to the use of Excellagen as a delivery platform for secreted extracellular vesicles (“Exosomes”), which carry factors that stimulate and augment wound healing. Exosomes are small (30-100 nm diameter), cell-derived, lipid bilayer-encapsulated vesicles that are naturally secreted by most cell types. Exosomes are found in, and can be isolated from, almost all bodily fluids and the media of cultured cells. Exosome contents include lipids, proteins, nucleic acids, and soluble factors. First identified in 1983, only in recent years has the therapeutic potential of exosomes been recognized and investigated. They are now known to play a vital role in intercellular communication by delivering their contents to recipient cells, and triggering biologic responses. In addition, exosomes are key secretory products of mesenchymal stem cells (MSC), and recently published preclinical research studies have demonstrated that MSC-derived exosomes can stimulate proliferation and migration of dermal fibroblasts, enhance angiogenesis, and accelerate wound healing in a diabetic mouse model. We believe that Excellagen could be a valuable delivery platform for exosomes in wound healing applications, by facilitating delivery and potentially augmenting the biological response to exosomes.

Based on this new and exciting field of research, we currently plan to retain the exclusive rights to develop, market and sell an advanced biologic product extension utilizing Excellagen as a delivery platform for exosomes (Excellazome), to stimulate and augment wound healing beyond levels already observed with our Excellagen dermal matrix product. Advancing the Excellazome biologic product concept to clinical and commercial readiness will require additional process engineering by exosome manufacturers to establish reproducible and scalable procedures that generate well-characterized end products that meet current Good Manufacturing Practices (cGMP) quality standards.

LifeAgain Insurance Solutions, Inc.

Our LifeAgain subsidiary has developed an advanced medical data analytics (ADAPT®) technology platform focused on developing new and innovative products for the life insurance and healthcare sectors. Our initial product offering was Blue Metric term life, an insurance program for men with prostate cancer. LifeAgain established a relationship with Symetra Financial Corporation to provide the insurance policies to men in the United States, based on actuarial information developed with our ADAPT technology.

On April 4, 2015, we entered into a license agreement with Shenzhen Qianhi Taxus Industry Capital Management Co., Ltd., a company affiliated with Shanxi Taxus Pharmaceuticals Co. Ltd., for the license of LifeAgain's ADAPT technology to develop and commercialize survivable risk life insurance products in Greater China. No products were commercialized or sold based on that license during the year ended December 31, 2015.

On August 11, 2015, Symetra Financial Corporation announced that it entered into a definitive merger agreement with Sumitomo Life Insurance Company pursuant to which Sumitomo Life will acquire all of the outstanding shares of Symetra. Following the transaction, Symetra advised us that it was discontinuing its partnership with LifeAgain. As a result, we are not currently offering the Blue Metric term life product.

LifeAgain plans to continue to seek opportunities for the application of its ADAPT medical analytics platform to commercialize “survivable risk” term life insurance for cancer survivors or others with medical conditions who are currently considered uninsurable based on traditional underwriting standards as well as other forms of survivable risk programs.

Healthy Brands Collective.

On November 15, 2013, we sold the assets of our To Go Brands subsidiary to Healthy Brands Collective® in exchange for shares of preferred stock representing approximately 4% of Healthy Brand Collective’s fully-diluted common stock. Healthy Brands Collective® is the trading name for Cellnique Corporation, a privately-held company that has acquired a portfolio of eight independent brand product platforms (prior to To Go Brands) including Cell-nique®, Cherrybrook Kitchen®, Yumnuts®, Living Harvest/Tempt®, Bites of Bliss®, High Country Kombucha® drinks and Organics European Gourmet Bakery™ (formerly Dr. Oetker) natural and organic baking mixes.

At the time of the transaction, Healthy Brands Collective had announced plans for an initial public offering. Healthy Brands Collective has not completed any liquidity event. During 2015, we took additional impairment against our investment in Healthy Brands Collective, fully reserving our investment. We are looking for opportunities to monetize our investment in Health Brands Collective, but do not have any arrangements or agreements in place at this time.

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.

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 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.

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. 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 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.

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 stimulate and augment 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, such as stents or by-pass surgery, to address large vessel coronary artery disease.

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 small molecule drugs and biological treatments using forms of genes and stem cells.

Ranexa® (ranolazine; Gilead Sciences, Inc.) is a small molecule drug first approved by the FDA in 2006 for the treatment of chronic angina in patients who have not responded to other anti-anginal drugs (long-acting nitrates, calcium channel blockers and beta blockers). In 2008, the FDA approved Ranexa for first line anti-anginal use. Ranexa is taken twice daily, and FDA approval was based on clinical trial findings that both angina attacks per week and nitroglycerin tablet usage per week were reduced by 33% (from 3 to 2 for both). These studies also report that the response in women only was only about 30% of that seen in men. The mechanism of action of Ranexa's antianginal effects has not been determined. Based on public disclosures by Gilead, annualized sales of Ranexa total \$680 Million.

Juventas Therapeutics is developing a non-viral, plasmid gene therapy product candidate (JVS-100) that expresses stromal cell-derived factor-1 (SDF-1) for advanced ischemic heart failure. SDF-1 has been shown to create a homing signal that recruits the body's own stem cells to the site of injury to induce tissue repair and regeneration. In May 2015, Juventas announced Phase 2 clinical study data showing that chronic heart failure patients receiving a single endomyocardial injection of JVS-100 demonstrated improvements at 12 months after treatment as measured by median change in left ventricle ejection fraction (3.5% over placebo) and left ventricular end-systolic volume (8.5 ml over placebo). In June 2015, Juventas announced that FDA had granted fast track status for JVS-100 and approved a Phase 2b study protocol to evaluate JVS-100 in patients with advanced ischemic heart failure and a prior history of heart attack.

Caladrius Biosciences (formerly NeoStem) is developing a stem cell product candidate comprised of autologous bone marrow derived CD34/CXCR4 cells (CLBS10, formerly NBS10) to treat damaged heart muscle following an acute myocardial infarction. CLBS10 is thought to work by increasing microvascular blood flow in the heart muscle via the development and formation of new blood vessels. In November 2014, NeoStem announced initial positive Phase 2 study data in patients with acute myocardial infarction (AMI) treated with intracoronary administration of NBS10. These 6 month results showed a statistically significant mortality benefit ($p < 0.05$) in patients treated with NBS10 as compared to the placebo group; a statistically significant dose-dependent reduction in SAEs ($p < 0.05$); a dose-dependent numerical decrease in major adverse cardiac events; but no meaningful difference in perfusion, as evidenced by SPECT imaging.

Baxalta is developing a CD34+ autologous bone marrow-derived stem cell product for refractory angina. In 2011, results from a Phase 2 study were published, with findings of significant improvement in angina frequency and exercise tolerance in patients who received intromyocardial injections of the cells. Status of a Phase III study is unknown.

The Neovasc Reducer™ is a stainless steel medical device that is implanted into the coronary sinus using a procedure similar to that used for stent implantation. It is designed to create a focal narrowing in the coronary sinus, resulting in increased back pressure and redistribution of blood into ischemic myocardium. In 2015, results from a Phase 2 study were published, reporting that significantly more patients in the treatment group, as compared to control, had an improvement in CCS class and quality of life at 6 months, but no improvement in exercise time. The Neovasc Reducer is currently available only in the European Union. Additional clinical study is required for U.S. FDA approval.

Based on our extensive pioneering pre-clinical and clinical work in the field of angiogenic gene therapy and medical revascularization, we have a leadership position that offers significant competitive advantages and multiple barriers to entry. Through these efforts, we have established appropriate dose levels, optimized our manufacturing process, enhanced delivery techniques and simplified product administration.

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Global Leader in Angiogenic Gene Therapy. Generx has been under clinical development for over a decade, under the continual management of our highly focused team with expertise in myocardial ischemia and angiogenic gene therapy. Generx represents one of only a few cardiovascular DNA-based therapeutic product candidates to successfully advance into late-stage, U.S. Phase 3 clinical study.

• **Novel Mechanism of Action.** The Generx therapeutic product candidate offers a completely novel biologic mechanism of action referred to as “medical revascularization”, in contrast to the classic “mechanical revascularization” procedures that include CABG and PCI.

• **Late-Stage Clinical Development.** The recently FDA-cleared Phase 3 AFFIRM study is preceded in the U.S. by four completed and one early-discontinued study. On a global basis, over 650 patients have been enrolled in FDA-approved studies, 455 of who received a one-time intracoronary administration of Generx, which has consistently been found to be safe and well-tolerated (based on over 2,500 patient years of safety data).

• **Barriers to Entry.** Our know-how and trade secrets, substantial capital investment and the extensive time that would be required to satisfy FDA regulatory hurdles, establish multiple barriers to entry for clinically and commercially comparable gene-based products. Additional protections are afforded to Generx in the U.S. under the Patent Protection and Affordable Care Act of 2010, which will provide twelve years of market exclusivity in the U.S. from the date the product is registered by the FDA.

• **Cost-Effective Manufacture.** The validated Generx cGMP manufacturing process is not anticipated to require significant additional capital investment or major process modifications for commercial manufacture. Product stability enables manufacture in large, cost-effective batch sizes.

• **Fits within Current Medical Practice.** Generx therapy is designed to easily fit within the current practice of medicine, as a ready-to-use, one-time treatment, administered by interventional cardiologists during an approximately one-hour, out-patient, angiogram-like procedure.

• **Pipeline of Follow-on Medical Indications.** A variety of other cardiovascular conditions, including Cardiac Syndrome X, ischemic heart failure, and Prinzmetal's and inverse forms of angina, involve insufficient cardiac perfusion and represent unmet medical needs. Patients with these conditions may also benefit from Generx angiogenic gene therapy.

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.

In the United States, gene therapy products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or "FD&C Act," and the Public Health Service Act, or "PHS Act," and well as other federal, state, and local statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, and efficacy of biological products. 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.

We will rely on contract manufacturing for the Generx product candidate. Based on the recent FDA clearance of the Generx Phase 3 clinical study protocol, all significant Current Good Manufacturing Practices ("cGMP") manufacturing factors have been resolved in preparation for a commercial launch. The cGMP Generx manufacturing processes have been validated and are scalable. We do not anticipate any significant capital expenditures will be required for Generx commercial manufacture.

We have been actively advancing our Generx product candidate's engineering and process technology in preparation for commercialization. The adenovector Ad5FGF-4 is propagated in suspension cultures of fully characterized HEK 293 cells using serum- free/animal product- free growth medium, and aseptically purified using a combination of chromatography and filtration methods. The final product is vialled at a defined viral particle (vp) concentration, and stored at -70°C. Clinical doses are expressed in total number of viral particles.

Generx's long-term product stability (at the current storage temperature of -70°C) makes it possible to manufacture Generx in large, cost effective batch sizes. Based on the current Generx validated cGMP manufacturing processes, we believe that the manufacture of Generx can be scaled to large batch quantities (up to approximately 2.0 million doses annually) without the need for significant additional capital investment or major process technology engineering. This flexibility will allow the manufacture of Generx at a highly economical direct cost, which could yield gross margins that would be approximately equivalent to a classic small molecule drug model. This would represent a significant commercial advantage in the market, and could be orders of magnitude lower than the expected high cost associated

with the manufacture of complex donor-based autologous cell therapies, that are currently under development by other biotechnology companies for cardiovascular applications.

We have established validated test methods and product specifications to ensure that each batch of Generx meets rigorous quality control standards. These quality control test methods include a cell-based vessel formation bioactivity assay that measures and confirms the pro-angiogenic potency of each newly manufactured batch of Generx.

As a result, important process improvements were achieved enabling much higher manufacturing process yields. Anticipated Generx direct manufacturing costs are expected to be highly favorable, capable of generating gross margins greater than 85%.

Marketing and Sales

Our product candidates, such as Generx must undergo clinical trials before any marketing and sales can begin. If we should obtain marketing approvals, we do not currently have the financial resources and internal capabilities to market and sell Generx. Angionetics may develop a direct and highly-focused internal marketing and sale force for the Generx product candidates, or establish strategic partnerships and alliances with pharmaceutical, biotechnology, medical device and cardiac theranostic companies for the marketing and sale of Generx in the United States. Outside the U.S., we expect to rely on strategic partnerships and distributors for marketing and sales of Generx product candidates. However, our marketing and sales strategies may vary by product, medical indication and the size of the addressable market.

For our Excellagen wound care product, we expect to engage in sales principally through or in collaboration with a sales and distribution partner and/or strategic partners. In the past we have entered into distributions agreements for Excellagen, including sales and distribution agreements to market and sell Excellagen to U.S. government medical providers, including Veterans Administration and military hospitals. We did not have the funds to build inventory, to secure reimbursement from third party payor systems, or to support the advertising campaign to generate demand for Excellagen. As our partners did not generate material sales, those distribution arrangements terminated and were not renewed. We did not generate any sales of Excellagen in 2015 or 2016, and have written-off, all of our inventory. We do not expect to generate meaningful levels of sales for Excellagen until strategic partnerships are established, together with sufficient funding to support a product launch into select vertical markets.

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.

In October 2005, we completed a transaction with Schering AG Group, Germany (now part of Bayer AG) and related licensors, including the University of California and New York University, for the transfer or license of certain assets and technology for potential use in treating ischemic and other cardiovascular conditions. Under the terms of the transaction, we paid Schering a \$4 million fee, and would be required to pay a \$10 million milestone payment upon the first commercial sale of each resulting product. We also may be obligated to pay the following future royalties to Schering: (i) 5% on net sales of an FGF-4 based product such as Generx, or (ii) 4% on net sales of other products developed based on technology transferred to Cardium by Schering.

As part of the Schering transaction, we acquired rights and corresponding obligations under the Regents of the University of California (Regents) September 1995 agreement, as amended. Under the University of California agreement, we are obligated to pay (1) an annual royalty fee of 2% based on net sales of products incorporating the technology licensed under the agreement, and (2) a minimum annual royalty fee (which may be offset against the net sales-based royalty fee) \$100,000 for 2010, \$100,000 for 2011, \$150,000 for 2012, \$150,000 for 2013 and \$200,000 for 2014 and thereafter, payable on February 28 of the following year. We incurred the minimum license fee in 2013 and 2012. We may cancel that agreement at any time with 60 days' notice, following which we would continue to be responsible only for obligations and liabilities accrued before termination.

The primary U.S. patent covering certain methods of gene therapy, covered by this University of California license agreement has expired, and the Company did not dispute the University's decision to terminate this license agreement. As a result of such action, the University of California has asserted certain claims and unpaid expenses relating to this license agreement and asserted that an outstanding balance totaling \$1,006,709. As of December 31, 2016, the Company had an accrued unpaid balance totaling \$782,836. The Company booked an additional \$223,873 to reflect the amount asserted by the University of California. While the Company has fully accounted for such amounts claimed due and payable the Company retains the right to challenge any amounts asserted to be outstanding.

As part of the Schering transaction, we acquired rights and corresponding obligations under the New York University March 1997 Agreement as amended, under which we 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, we 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 we complete one full year of sales of licensed products and continuing thereafter until the agreement terminates or expires, we may also be obligated to pay annual royalty fees equal to 3% on net sales of products incorporating the licensed technology.

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

Employees

As of December 31, 2016, we had six full-time employees. We anticipate relying on an outsource model for most of our significant operations, and do not expect our 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.

Available Information

Our website address is www.taxuscardium.com. We make available, free of charge, through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file or furnish such reports to the SEC. The information on our website is not part of this or any other report we file with, or furnish to, the SEC. For additional financial information, including financial information about our business, please see the consolidated financial statements and accompanying notes to the consolidated financial statements included under Item 8 of this report.

ITEM 1A. RISK FACTORS

You should carefully review and consider the risks described below, as well as the other information in this report and in other reports and documents we file with the SEC when evaluating our business and future prospects. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties, not presently known to us, or that we currently perceive as immaterial or remote, 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

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. The audit opinion accompanying our consolidated financial statements for the year ended December 31, 2016, included under Item 8 of this report, includes an explanatory paragraph indicating substantial doubt about our ability

to continue as a going concern.

We expect capital outlays and operating expenditures for Angionetics to increase over the next several years as it works to advance Generx through late stage clinical trials, secure regulatory approval, begin to commercialization. Angionetics will need to raise additional capital to, among other things:

- Fund the completion of its U.S.-based Phase 3 AFFIRM clinical trial for Generx;
- Fund additional clinical trials and preclinical trials for Generx™ as requested or required by regulatory agencies;
- Fund clinical trials and preclinical trials for Generx™ in new indications;
- Sustain commercialization of Generx™ or any other new product candidate;
 - Develop manufacturing capabilities, if any;
- Increase sales and marketing efforts to drive market adoption and address competitive developments;
- Finance general and administrative expenses;
- Maintain, expand and protect its intellectual property portfolio;
- Add operational, financial and management information systems; and
- Hire additional clinical, quality, scientific, and general and administrative personnel.

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 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 cannot be certain that additional financing will be available on acceptable terms, or at all. 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.

If we raise capital through the sale of equity securities it may result in substantial dilution to our existing stockholders.

To the extent we raise additional capital through the sale of equity securities or we issue securities in connection with another transaction, the ownership position of existing stockholders could be substantially diluted. Anti-dilution adjustments to our securities currently outstanding would cause further dilution. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in our assets.

In order to raise capital to fund the development of our Generx™ product candidate we have sold shares in our Angionetics subsidiary. Our management did this because it believed that it could raise capital at a better valuation, and with less dilution to existing stockholders, than if it were to sell shares of Taxus Cardium. If Angionetics continues to issue additional equity securities to third party investors, as is currently planned, it will dilute the interest of Taxus Cardium, and consequently our stockholders in Angionetics and the Generx™ product candidate.

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 of the significant amounts we expect to spend on development activities and clinical trials for our product candidates. As of December 31, 2016, our accumulated deficit was approximately \$117.5 million, and our cash and cash equivalents were \$930,397. 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.

There is a high rate of failure for drug candidates proceeding through clinical trials.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in clinical trials, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. In the event that Angionetics obtains negative results from the AFFIRM Phase 3 clinical study or receives poor clinical results for other product candidates, or the FDA chooses to block progress of the trials, or does not approve our Biologics License Application for Generx, Angionetics may not be able to generate sufficient revenue or obtain financing to continue operations. In such event, our ability to execute on our current business plan will be materially impaired, our reputation in the industry and in the investment community would likely be significantly damaged, and the price of our stock would likely decrease significantly.

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

Side effects of therapeutic technologies can be serious and life threatening. While we are not presently aware of any side effects from the use of Generx™, possible serious side effects of gene transfer include viral or gene product toxicity resulting in inflammation or other injury to the heart or other parts of the body. The development or worsening of cancer in a patient could potentially be a perceived or actual side effect of gene therapy technologies. 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.

If Generx™ or any of our product candidates are found, prior to or after any approval for commercial sale, to cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- We may voluntarily interrupt, delay or halt clinical trials or regulatory authorities may require that we interrupt, delay interrupt, delay or halt clinical trials;
- Regulatory authorities may deny regulatory approval of our product candidates;
- Regulatory authorities may withdraw their approval of the product or impose restrictions on distribution in the form of a risk evaluation and mitigation strategy, or REMS;
- Regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or limitations on the indications for use;
- We may be required to change the way the product is administered or conduct additional clinical trials;
- We could be sued and held liable for harm caused to patients; or
- Our reputation may suffer.

If we elect or are forced to suspend or terminate any planned clinical trial of Generx™ or any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products.

We rely on third party clinical research organizations to manage our clinical trials. Consequently we have less control over the conduct of 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 rely on third party clinical research organizations to assist us in designing, administering and assessing the results of those trials. 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. Our development costs will increase and our business may be negatively impacted, if we experience delays in testing or approvals or if we need to perform more or larger clinical trials than planned, for reasons such as the following:

- the FDA or other health regulatory authorities, or institutional review boards, do not approve a clinical study protocol or place a clinical study on hold;
- suitable patients do not enroll in a clinical study in sufficient numbers or at the expected rate, or data is adversely affected by trial conduct or patient drop out;
- patients experience serious adverse events, including adverse side effects of our drug candidate or device;
- patients die during a clinical study for a variety of reasons that may or may not be related to our 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; or
- 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.

We rely on collaborations or other arrangements with third parties to sell, market and distribute our products. Under these arrangements third parties would be largely responsible for the timing and extent of sales and marketing efforts, they may not dedicate sufficient resources to our product opportunities, and our ability to cause them to devote additional resources or to otherwise promote sales of our products may be limited. In addition, 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 on a direct basis.

We have entered into agreements with third parties to market our Excellagen® product and to date have not been successful in generating material sales. We have also entered into agreements with third parties 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.

Even if approved for marketing, our product candidates may fail to gain market acceptance.

Our ongoing business and future depends on the success of our technologies and product candidates. Gene-based therapy, like our Generx™ product candidate, 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 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 our contract manufacturers 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 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;
- 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 face intense and increasing competition and must cope with rapid technological change, which may adversely affect our financial condition and/or our ability to successfully commercialize and/or market our products and product candidates.

Our competitors and potential competitors include large pharmaceutical and medical device companies and more established biotechnology companies. These companies have significantly greater financial and other resources and greater expertise than us in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and marketing. This may make it easier for them to respond more quickly than us to new or changing opportunities, technologies or market needs. Our larger competitors may be able to devote greater resources to research and development, marketing, distribution and other activities that could provide them with a competitive advantage. Many of these competitors operate large, well-funded research and development programs and have significant products approved or in development. Small companies may also prove to be significant competitors,

particularly through collaborative arrangements with large pharmaceutical companies or through acquisition or development of intellectual property rights. Our potential competitors also include academic institutions, governmental agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for product and clinical development and marketing.

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

Changes and reforms in the health care system or reimbursement policies may adversely affect the sale of our products and future products or our ability to obtain an adequate level of reimbursement or acceptable prices for our products or future products.

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

There have been and will continue to be efforts by governmental and third-party payers to contain or reduce the costs of health care through various means, including limiting coverage and the level of reimbursement. We expect that there will continue to be a number of legislative proposals to implement government controls and 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. Reinhard's 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 involve the controlled storage, use and disposal of certain hazardous and biological materials and waste products. We and our suppliers and other collaborators are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future

environmental laws and regulations.

To the extent 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 we do not obtain protection for our respective intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing products.

Our success, competitive position and future revenues depends in part on our ability to obtain and maintain patent protection for products, methods, processes and other technologies, to preserve trade secrets, to prevent third parties from infringing on their intellectual proprietary rights and to operate without infringing the proprietary rights of third parties.

The patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include but are not limited to the following:

- Patents may not be granted from patent applications.

- Patents that have issued or will issue may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage.

- Countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

- Competitors, many of which have substantially greater resources than and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate their ability to make, use, and sell our potential products either in the United States or in international markets.

- There may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns.

In addition, the U.S. Patent and Trademark Office and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if our subsidiaries are able to obtain patents, the patents may be substantially narrower than anticipated.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with employees, scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are breached, or that trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, we otherwise lose protection for their trade secrets or proprietary know-how, the value of this information may be greatly reduced.

Intellectual property and trade secrets protection are important to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

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.

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 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 Capital Structure

The conversion of our Series A Convertible Preferred Stock will result in substantial dilution to holders of our common stock.

On April 4, 2013, we agreed to issue 4,012 shares of our newly authorized Series A Convertible Preferred Stock (the "Preferred Stock") to Sabby Healthcare Volatility Master Fund, Ltd. ("Sabby") for \$4.0 million in cash. The Preferred Stock is convertible into shares of our common stock. The Preferred Stock had an initial conversion price of \$0.6437 per share. In addition, the conversion price is subject to downward adjustment if we issue common stock or common stock equivalents at a price less than the then effective conversion price. As long as the Preferred Stock is outstanding, we have also agreed not to incur specified indebtedness without the consent of the holders of the Preferred Stock.

These factors may restrict our ability to raise capital through equity or debt offerings in the future.

On July 22, 2015, we entered into an Exchange and Redemption Agreement with Sabby pursuant to which we agreed to reduce the conversion price on the Preferred Stock to \$0.30 per share. The Exchange and Redemption Agreement granted us a right to redeem any or all of the outstanding Preferred Stock for its Stated Value (approximately \$1,000 per share) at any time during a 120 day period after the date of the agreement, and permanently increased the limitation on indebtedness contained in the Certificate of Designation for the Preferred Stock to allow us to borrow up to \$250,000. As a result of the effective conversion price changing from \$0.64 to \$0.30 per share, the 1,176 shares of Preferred Stock outstanding at July 22, 2015 became convertible into 3,918,667 shares of our common stock, an additional 2,092,350 compared to before the conversion price change.

On September 23, 2016, after the period covered by this report, we entered into a second Exchange and Redemption Agreement with Sabby covering the 1,000 shares of Preferred Stock outstanding at that time. Under the terms of the Exchange and Redemption Agreement, we agreed to reduce the conversion price to \$0.18 per share. The Exchange and Redemption Agreement granted us a right to redeem any or all of the outstanding Preferred Stock for its Stated Value (approximately \$1,000 per share) at any time until November 29, 2016. We entered into the agreement to increase our options for retiring the outstanding Preferred Stock and financing our continued business operations. As a result of the conversion price changing from \$0.30 to \$0.18 per share, the 1,000 shares of Series A Convertible Preferred Stock outstanding became convertible to 5,554,667 shares of our common stock, an additional 2,221,867 compared to before the conversion price change. At December 31, 2016, there were 928 shares of Preferred Stock outstanding. A hypothetical conversion of all of the outstanding Preferred Stock into 5,154,674 shares of common stock would increase the common stock outstanding from 13,723,544 shares as of December 31, 2016, to 18,878,218, an increase of 37.6%.

Our outstanding warrants (stock options and warrants to employees and directors) have anti-dilution protection and, if exercised, will significantly dilute the ownership interest of existing stockholders.

At December 31, 2016, we had an aggregate of 12,116,334 stock options and warrants outstanding at exercise prices ranging from \$0.19 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.

Our outstanding warrants have anti-dilution protection. On September 23, 2016, we entered into a second Exchange and Redemption Agreement with Sabby covering the 1,000 shares of Preferred Stock outstanding at the time. Under the terms of the Exchange and Redemption Agreement, Taxus Cardium agreed to reduce the conversion price at which Sabby can convert shares of Preferred Stock to common shares from \$0.30 to an effective price of \$0.18 per share. As a result of this reduction of the conversion price of the preferred stock, the Company was also required to issue an additional 4,823,736 of warrants, to such warrant holders (current and former employees), in accordance with the original terms of their agreements. Additional sales of Taxus Cardium equity securities or derivative securities will result in additional shares of common stock being issuable under the outstanding warrants.

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 the economic performance and/or market valuations of other biotechnology and medical device companies;
- changes in economic conditions in the United States and worldwide;
- 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 list 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 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;
- regulatory developments in the United States and other countries;
- 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. Price volatility may be increased 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 advance 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.

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. Our outstanding Preferred Stock prohibits us from paying any dividends without the consent of the holders of the preferred stock. 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. At December 31, 2016, we leased the following facility:

Location	Nature of Use	Square Feet	Monthly	Lease
			Base Rent	Expiration
11568 Sorrento Valley Road, Suite 14 San Diego, CA USA	Corporate Headquarters Principal executive office	2,830	\$3,500-\$3,934	10/31/2019

ITEM 3. LEGAL PROCEEDINGS

In the course of our business, we are routinely involved in proceedings such as disputes involving goods or services provided by various third parties, 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 result in costs and diversions of resources to pursue and resolve. In October 2014, we received a complaint filed by BioRASI LLC (“BioRASI”) in Broward County, Florida, seeking payments of approximately \$0.5 million allegedly owed for services that BioRASI provided in connection with the Company’s clinical trial conducted in the Russian Federation. In June of 2015, BioRASI amended the complaint to include as plaintiffs additional parties affiliated with bioRASI including Vendevia Group, LLC, Biosciences Research Ltd., and Progressive Scientific Bioresearch, Ltd. We are defending the action and have filed counterclaims. Although at December 31, 2016, the probable outcome of this matter cannot be determined, we believe that we have supportable defenses and any negative decision, if any, is expected to be insignificant. Accordingly, we have not recorded any provisions related to this matter.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR OUR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock currently trades on the OTC QB market 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 bid prices of our common stock for the time it has traded on the OTC QB and the high and low closing sales prices for the time it traded on the NYSE MKT, for each quarter in the years ended December 31, 2016, 2015 and the two quarters ending June 30, 2017:

	2017		2016		2015	
	High	Low	High	Low	High	Low
First Quarter	\$0.26	\$0.15	\$0.35	\$0.16	\$0.21	\$0.16
Second Quarter	\$0.24	\$0.11	\$0.19	\$0.12	\$0.56	\$0.19
Third Quarter	\$-	\$-	\$0.36	\$0.14	\$0.39	\$0.18
Fourth Quarter	\$-	\$-	\$0.25	\$0.13	\$0.34	\$0.15

Holders

As of July 20, 2017, 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.

Repurchases of Equity Securities

During the year ended December 31, 2016, we did not repurchase any shares of our common stock, nor were any repurchases made on our behalf.

Equity Compensation Plan Information

We have an equity incentive plan that was established in 2005 under which 283,058 shares of our common stock were reserved for issuance to employees, non-employee directors and consultants. The 2005 Equity Incentive Plan was approved by our stockholders. The 2005 Equity Incentive Plan expired on October 20, 2015, ten years after its adoption, and we are no longer able to issue share or awards under that plan. All options or other awards issued under the 2005 Equity Incentive plan prior to its expiration remain outstanding in accordance with their terms.

On March 23, 2015, outside of the 2005 Equity Incentive Plan, we issued 1,125,000 common stock warrants to directors, officers and chief medical advisor. The warrants were approved by our Board of Directors, have a ten year term and an exercise price of \$0.60 per share, which represented a 215% premium to the closing stock price on the date of issuance. The warrants had a fair value of \$0.10 per share and vested immediately.

On March 23, 2015, we issued 10,000 non-qualified stock options to directors. The options were approved by our Board of Directors, have a seven year term and an exercise price of \$0.19 per share, which equaled the closing stock price on the date of issuance. The stock options had a fair value of \$0.14 per share.

On May 1, 2015, outside of the 2005 Equity Incentive Plan, we issued 550,000 common stock warrants to directors and employees. The warrants were approved by our Board of Directors, have a ten year term and an exercise price of \$0.60 per share, which represented a 20% premium to the closing stock price on the date of issuance. The warrants had a fair value of \$0.37 per share. 300,000 vested immediately and 250,000 warrants vested on the one year anniversary of the date of grant.

On May 8, 2015, outside of the 2005 Equity Incentive Plan, we issued 100,000 common stock warrants to a consultant. The warrants were approved by our Board of Directors, have a ten year term and an exercise price of \$0.60 per share, which represented a 33% premium to the closing stock price on the date of issuance. The warrants had a fair value of \$0.41 per share. 40,000 warrants vested immediately, and the remaining 60,000 warrants vested over three quarters. On August 4, 2015, the consulting agreement was terminated and the remaining 60,000 unvested warrants were cancelled per the terms of the consulting agreement and the warrant.

On September 23, 2016, we entered into a second Exchange and Redemption Agreement with Sabby covering the 1,000 shares of Preferred Stock outstanding at the time. Under the terms of the Exchange and Redemption Agreement, Taxus Cardium agreed to reduce the conversion price at which Sabby can convert shares of Preferred Stock to common shares from \$0.30 to an effective price of \$0.18 per share. As a result of this reduction of the conversion price of the preferred stock, the Company was also required to issue an additional 4,823,736 of warrants, to such warrant holders (current and former employees), in accordance with the original terms of their agreements. The fair value of these issuances was recorded as compensation expense.

The following table summarizes equity compensation plans approved by stockholders and equity compensation plans that were not approved by stockholders as of December 31, 2016.

Plan Category	(a)	(b)	(c)
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options (excluding securities reflected in column (a))	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by stockholders	17,000	\$ 15.50	—
Equity compensation plans not approved by stockholders	12,099,334	\$ 0.71	—
Total	12,116,334	\$ 0.73	—

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, 2016. 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 an operating company that manages a medical technologies portfolio of equity-based and potential royalty-driven investments as follows: (1) Angionetics, currently a majority-owned subsidiary focused on the late-stage clinical development and commercialization of Generx™, an angiogenic gene therapy product candidate designed for medical revascularization for the potential treatment of patients with myocardial ischemia and refractory angina due to advanced coronary artery disease; (2) Activation Therapeutics, a wholly owned subsidiary focused on the development and commercialization of the Excellagen® technology platform, an FDA-cleared flowable dermal matrix for advanced wound care that we believe has broad potential applications as a delivery platform for small molecule drugs, proteins and biologics; (3) LifeAgain a wholly-owned subsidiary that has developed an advanced medical data analytics (ADAPT®) technology platform focused on developing new and innovative products for the life insurance and healthcare sectors; and (4) a minority investment in Healthy Brands Collective, a functional food and nutraceutical company which acquired the Company's To Go Brands® business.

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.

2016 Developments

We entered 2016 with limited working capital. Our principal operating targets for 2016 were: (1) continue to advance the commercialization of our products and product candidates, (2) secure additional financing to support our continued operations, and (3) manage our operating expenses. Highlights of our efforts against these targets included the following:

Angionetics Contribution Agreement

On May 4, 2016, Bayer Pharma AG agreed to the transfer of the Technology Transfer Agreement from Taxus Cardium to Angionetics. Accordingly, Angionetics has assumed the obligation for any milestone payment required to be paid to Bayer Pharma AG. Under the terms of the Technology Transfer Agreement, Angionetics also may be obligated to pay the following royalties to Bayer Pharma AG: (i) 5% on net sales following a first commercial sale of an FGF-4 based product in the United States, Europe, or Japan, or (ii) 4% on net sales of other products developed based on technology transferred by Bayer Pharma AG (as successor to Schering AG) following a first commercial sale in the United States, Europe, or Japan, and (iii) a royalty of 2.5% (for FGF-4 based technology) or 2% (for other products) in territories where the product would not infringe the patents licensed by Bayer Pharma AG (as successor to Schering AG). Angionetics will also be obligated to reimburse Bayer Pharma AG for patent expenses, including the expenses of any interference or other proceedings, accrued on or after April 1, 2005 in connection with the transferred technologies. To date there have been no sales or payments under this agreement.

On June 6, 2016, we entered into a Contribution Agreement with our Angionetics subsidiary pursuant to which we assigned to Angionetics certain intellectual property and other assets related to the Generx platform technology in consideration of a \$2.0 million technology transfer fee to be paid by Angionetics to Taxus Cardium upon completion of an equity financing in excess of \$20 million or upon change in control of Angionetics. Assets contributed to Angionetics included the Ad5FGF-4 Master Virus Bank (frozen), HEK 293 Producer Cell Bank (frozen), developmental histories and lineages for Master Virus Bank and Master Cell Bank, the Ad5FGF-4 Genomic Sequence, Ad5FGF-4 batch production records, manufacturing testing protocols and specifications, product release testing reports, and certificates of analysis, and stability. In addition, we assigned the clinical sponsorship of the Generx Ad5FGF-4 investigational new drug application to Angionetics, which was accepted by the FDA.

Huapont Life Sciences Financing Agreement

On June 7, 2016, Taxus Cardium and Angionetics entered into a Share Purchase Agreement with Pineworld Capital Limited an entity affiliated with Huapont Life Sciences Co. Ltd, a China-based pharmaceutical, and active pharmaceutical ingredient company (“Huapont”). Pursuant to the Share Purchase Agreement, Angionetics agreed to sell 600,000 shares of its newly authorized Series A Convertible Preferred Stock (the “Shares”) to the Huapont affiliate in exchange for \$3,000,000 in cash. The Shares represent an initial 15% equity interest in Angionetics, resulting in a post-money valuation of \$20.0 million for Angionetics, subject to certain anti-dilution protection described below. The investment from the Huapont affiliate was made in two tranches. The closing of the initial tranche of 200,000 Shares for \$1,000,000 occurred on July 5, 2016. The closing of the second tranche of 400,000 Shares for \$2,000,000 was conditioned upon Angionetics securing FDA clearance to initiate a new U.S.-based Phase 3 clinical study (the AFFIRM study) to evaluate the safety and definitive efficacy of the Generx® [Ad5FGF-4] product candidate for the treatment of patients with ischemic heart disease and refractory angina. On September 28, 2016, following FDA clearance of the Phase 3 AFFIRM study, Angionetics received \$2,000,000 from the closing of the second tranche.

The Angionetics Shares have the following rights, privileges and preferences:

• **Dividends.** Holders of the Shares are entitled to receive dividends as, when and if declared by the Angionetics board of directors on the Angionetics common stock, on an as-converted basis.

• **Liquidation.** In the event of a liquidation of Angionetics, including a change of control transaction, holders of the Shares are entitled to be paid an amount equal to their investment amount before any payment is made to Taxus Cardium or any other holders of Angionetics common stock.

• **Voting.** The Shares generally vote with the Angionetics common stock as a single class on an as-converted basis. Holders of the Shares also have certain special voting rights as a separate class including (a) the right to appoint a member to the Angionetics board of directors, (b) the right to approve any increase or decrease in the number of authorized shares of the Shares or the common stock, any merger or acquisition involving Angionetics, any liquidation or winding up of Angionetics, any increase in the number of directors and any dividend or distribution, and (c) the right to approve any amendment to the Angionetics certificate of incorporation in a manner that adversely affects the rights of the Shares. The voting rights under (a) and (b) terminate if Huapont does not complete the second closing under the share purchase agreement.

• **Conversion.** The Shares are convertible into shares of Angionetics common stock at any time at the holder's election. The Shares automatically convert into common stock upon the closing of a firm commitment underwritten public offering of Angionetics common stock. The Shares are initially convertible on a one to one basis into Angionetics common stock. The Shares are subject to anti-dilution protection, such that in the event of a firm commitment underwritten public offering or a change in control each Share will be convertible into a pro rata portion of 15% of the outstanding Angionetics common stock at the time of the public offering or change in control.

Generx License Agreement in Mainland China

On June 7, 2016, Angionetics entered into a Distribution and License Agreement with Pineworld Capital Limited, an entity affiliated with Huapont. Under the terms of the agreement, the Huapont affiliate has been granted an exclusive license to clinically develop, manufacture, market and sell the Generx® [Ad5FGF-4] angiogenic gene therapy product candidate in mainland China. Angionetics will be responsible for conducting the planned U.S.-based Phase 3 clinical program. Working in cooperation with researchers at Angionetics, Huapont's affiliated entity has agreed to use commercially reasonable efforts to conduct clinical trials, make regulatory filings and take such other actions as may be necessary to commercialize Generx® in mainland China. Huapont's affiliate will be responsible the costs associated with the commercial development of Generx® in mainland China.

The Distribution and License Agreement provides for the Huapont affiliate to make quarterly royalty payments to Angionetics at a rate of 10% of net sales of Generx® products in mainland China, reducing to a 5% royalty based on the volume of annual sales. The royalty payments commence on the first commercial sale and expire on the earlier of the termination of any patent or regulatory exclusivity in China or fifteen years after the first commercial sale. The term of the agreement continues (unless terminated for breach) until Huapont's affiliate has no remaining payment obligations to Angionetics. Upon expiration (but not an earlier termination) Huapont's affiliate shall have a perpetual, non-exclusive, fully paid-up, and royalty free license to Generx® in mainland China.

Termination of Russian Generx Clinical Development Program

Following the formation and initial capitalization of Angionetics, our management team initiated a comprehensive review of the global Generx regulatory and clinical dossier, and elected to primarily focus on the clinical advancement and registration of Generx in the United States and China, which we believe to be the most dynamic medical markets in the world for new and novel breakthrough products such as the Generx product candidate. As a result of this review, on July 13, 2016 we notified Dr. Reddy's Laboratories (NYSE: RDY) of our plan to discontinue Generx development in the Russian Federation. Consequently, our previously reported commercialization opportunity with Dr. Reddy's Laboratories was not advanced to a definitive agreement.

FDA Approval of U.S. based Phase 3 Clinical Trial (AFFIRM)

On September 9, 2016, Angionetics was granted FDA clearance to proceed with a new U.S.-based Phase 3 clinical trial to evaluate the further safety and definitive efficacy of Generx [Ad5FGF-4] for men and women with advanced ischemic heart disease and refractory angina.

On February 3, 2017, Angionetics received notice that the FDA has granted Fast Track designation for the Phase 3 clinical investigation of Generx [Ad5FGF-4] cardiovascular angiogenic gene therapy as a one-time treatment for improving exercise tolerance in patients who have angina that is refractory to standard medical therapy and not amenable to conventional revascularization procedures (coronary artery bypass surgery and percutaneous coronary intervention and stents). Under the FDA Modernization Act of 1997, designation as a Fast Track product means that FDA will take actions, as appropriate, to expedite the development and review of a biologics license application (BLA) for product approval. The FDA's Fast Track process is designed to facilitate clinical and commercial development and expedite the review of new drugs and biologics that are intended to treat serious conditions that demonstrate the potential to address an unmet medical need.

Exchange and Redemption Agreement

On September 23, 2016, we entered into a second Exchange and Redemption Agreement with Sabby covering the 1,000 shares of Taxus Cardium Preferred Stock outstanding at the time. Under the terms of the Exchange and Redemption Agreement, Taxus Cardium agreed to reduce the conversion price at which Sabby can convert shares of Preferred Stock to shares of common stock to an effective price of \$0.18 per share. The Exchange and Redemption Agreement grants Taxus Cardium a right to redeem any or all of the outstanding Preferred Stock for its Stated Value (approximately \$1,000 per share) at any time after the date of the Agreement until November 29, 2016. We entered into the agreement to increase our options for retiring the outstanding Preferred Stock and financing our continued business operations. As a result of the conversion price changing from \$0.30 to \$0.18 per share, the 1,000 shares of Preferred Stock outstanding became convertible to 5,554,667 shares of common stock, an additional 2,221,867 compared to before the conversion price change. A hypothetical conversion of all of the outstanding Preferred Stock of 928 shares as of December 31, 2016 into 5,154,674 common shares would increase the common stock outstanding from 13,723,544 shares as of December 31, 2016, to 18,878,218, an increase of 38%. The reduction in the conversion price under the Exchange and Redemption Agreement triggered an anti-dilution protection in 7,235,600 previously granted common stock purchase warrants not held by Sabby, resulting in an additional 4,823,733 warrant shares to be granted for a total of 12,059,333 common stock purchase warrant with anti-dilutive provisions outstanding. The exercise price per common share in these warrants remains unchanged as the original common stock purchase warrant, a weighted average price of \$0.71 per share.

As of December 31, 2016, there were 13,723,544 shares of common stock issued and outstanding. There were 928 issued and outstanding shares of Series A Convertible Preferred Stock which are convertible into 5,154,674 shares of common stock. In addition, there were 17,000 shares of common stock issuable upon the exercise of stock options which were awarded under the 2005 Equity Incentive Plan, which have a weighted average exercise price of \$15.50 per share. As of December 31, 2016, there were 12,099,334

shares of common stock issuable upon the exercise of outstanding warrants which have an average exercise price of \$0.71 per share for a total conversion price of \$8,602,597, these warrants may also be redeemed through a cashless exercise whereby the warrant holder surrenders the required number of warrants needed to exercise the remaining warrants.

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 (“U.S. GAAP”). The preparation of our financial statements in accordance with U.S. 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 record 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. We calculate the value of equity compensation expense associated with the issuance of warrants and stock options using Black-Scholes Option Model which approximates a binomial lattice 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 we use different assumptions, equity-based compensation could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and recogniz