

Taxus Cardium Pharmaceuticals Group Inc.
Form 10-Q
March 21, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2016

or

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

Commission file number: 001-33635

TAXUS CARDIUM PHARMACEUTICALS GROUP INC.

(Exact name of registrant as specified in its charter)

Delaware

(State of
incorporation)

11568 Sorrento Valley Rd, Suite #14

San Diego, California 92121

(Address of principal executive offices)

27-0075787

(IRS Employer

Identification No.)

(858) 436-1000

(Registrant's telephone number)

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

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 check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

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

As of March 21, 2017, the registrant had 14,273,544 shares of common stock outstanding.

TABLE OF CONTENTS

	Page
<u>EXPLANATORY NOTE</u>	1
<u>SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS</u>	1
<u>PART 1 FINANCIAL INFORMATION</u>	
Item 1. Financial Statements (Unaudited)	
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
<u>PART II OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	24
Item 1A. <u>Risk Factors</u>	24
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
Item 3. <u>Defaults Upon Senior Securities</u>	33
Item 4. <u>Mine Safety Disclosures</u>	33
Item 5. <u>Other Information</u>	33
Item 6. <u>Exhibits</u>	34
<u>SIGNATURES</u>	35

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 Report on Form 10-K for the year ended December 31, 2015, our Quarterly Report on Form 10-Q for the period ended March 31, 2016 and our Quarterly Report on Form 10-Q for the period ended June 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 7—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;

1

- 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").

TAXUS CARDIUM PHARMACEUTICALS GROUP, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,793,350	\$ 21,547
Prepaid expenses and other assets	—	9,231
Total current assets	1,793,350	30,778
Property and equipment, net	144,455	6,525
Deposits	16,294	—
Total assets	\$ 1,954,099	\$ 37,303
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,520,982	\$ 1,790,648
Accrued liabilities	1,708,385	1,094,852
Advances from officer	1,063,865	946,142
Total current liabilities	4,293,232	3,831,642
Total liabilities	4,293,232	3,831,642
Commitments and contingencies		
Stockholders' deficit:		
Taxus Cardium Pharmaceuticals Group, Inc. Series A Convertible Preferred stock, \$0.0001 par value; 40,000,000 shares authorized; issued and outstanding 964 at September 30, 2016 and 1,041 at December 31, 2015, with liquidation preferences of \$1,000	—	—
Angionetics, Inc, Series A Convertible Preferred stock, \$0.0001 par value; 40,000,000 authorized; issued and outstanding 600,000 at September 30, 2016, with a liquidation preference of \$3,000,000	60	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized; issued and Outstanding 13,523,544 at September 30, 2016 and 13,187,544 at December 31, 2015	1,353	1,319
Common stock issuable	600,000	600,000
Additional paid-in capital	113,654,316	110,136,056
Accumulated deficit	(116,594,862)	(114,531,714)
Total stockholders' deficit	(2,339,133)	(3,794,339)
Total liabilities and stockholders' deficit	\$ 1,954,099	\$ 37,303

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

3

TAXUS CARDIUM PHARMACEUTICALS GROUP INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2016	2015	September 30, 2016	2015
Operating expenses				
Research and development	\$ 128,698	\$ 108,671	\$ 290,895	\$ 486,759
Selling, general and administrative	887,241	1,081,189	1,762,375	2,449,745
Total operating expenses	1,015,939	1,189,860	2,053,270	2,936,504
Loss from operations	(1,015,939)	(1,189,860)	(2,053,270)	(2,936,504)
Interest expense	(7,413)	(2,106)	(9,878)	(4,490)
Impairment loss on investment	—	—	—	(300,000)
Net loss	\$(1,023,352)	\$(1,191,966)	\$(2,063,148)	\$(3,240,994)
Deemed dividend on preferred stock	782,879	627,705	782,879	627,705
Net loss applicable to common stockholders	\$(1,806,231)	\$(1,819,671)	\$(2,846,027)	\$(3,868,699)
Net loss per share – Basic and diluted				
Net loss per share – Basic and diluted	\$(0.14)	\$(0.14)	\$(0.21)	\$(0.30)
Weighted average common shares outstanding	13,312,777	12,902,549	13,232,422	12,818,232

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

TAXUS CARDIUM PHARMACEUTICALS GROUP, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended	
	September 30, 2016	2015
Cash Flows From Operating Activities		
Net loss	\$(2,063,148)	\$(3,240,994)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,525	7,677
Stock-based compensation	518,354	961,218
Impairment loss on investments	—	300,000
Changes in operating assets and liabilities		
Prepaid expenses and other assets	(7,063)	183,129
Other long-term assets	—	9,989
Accounts payable	(269,666)	416,982
Accrued liabilities	613,533	432,665
Net cash used in operating activities	(1,201,465)	(929,334)
Cash Flows From Investing Activities		
Purchase of property and equipment	(144,455)	—
Net cash used in investing activities	(144,455)	—
Cash Flows From Financing Activities		
Cash advance from officer	117,723	130,818
Proceeds from note payable	30,000	—
Payments on note payable	(30,000)	—
Proceeds from subscribed shares issuable – common stock	—	600,000
Proceeds from the sale of preferred stock	3,000,000	—
Net cash provided by financing activities	3,117,723	730,818
Net increase (decrease) in cash	1,771,803	(198,516)
Cash and cash equivalents at beginning of period	21,547	216,733
Cash and cash equivalents at end of period	\$1,793,350	\$18,217
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	\$12,878	\$4,490
Cash paid for taxes	\$8,440	\$—

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

TAXUS CARDIUM PHARMACEUTICALS GROUP, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Organization and Liquidity

Organization

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.

Liquidity and Going Concern

As of September 30, 2016, we had approximately \$1.8 million in cash and cash equivalents. Our working capital deficit at September 30, 2016 was approximately \$2.5 million.

We anticipate that negative cash flows from operations will continue for the foreseeable future. We have yet to generate positive cash flows from operations, and are essentially dependent on equity and debt funding to finance our operations. We currently do not have any unused credit facilities. As long as any shares of our Series A Convertible Preferred Stock are outstanding, we have agreed that we will not, without the consent of the holders of two-thirds of the Series A Convertible Preferred Stock, incur indebtedness other than specified "Permitted Indebtedness", incur any liens other than specified "Permitted Liens".

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

Our principal business objectives are to advance the independent monetization and funding activities of our core products and technologies, with our Angionetics Inc. subsidiary being focused on the Generx™ angiogenic gene therapy product candidate, and our Activation Therapeutics, Inc. subsidiary being focused on the Excellagen® FDA-cleared

wound care product and the joint clinical development of Excellagen product line extensions as an advanced biologic delivery platform for new and innovative wound healing therapeutics, and/or to complete alternative corporate transactions. If we fail to conclude such transaction in a timely manner or alternatively fail to generate sufficient cash from financing activities, we will not generate sufficient cash flows to cover our operating expenses.

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with the accounting principles generally accepted in the United States (“GAAP”), which contemplates continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue operations is dependent on the execution of management’s plans, which include the raising of capital through the debt and/or equity markets, until such time that funds provided by operations are sufficient to fund our working capital requirements. The condensed 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 the Company be unable to continue as a going concern. If we were not to continue as a going concern, we would likely not be able to realize our assets at values comparable to the carrying value or the fair value estimates reflected in the balances set out in the condensed consolidated financial statements.

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.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements contained in this report have been prepared in accordance with GAAP for interim financial statements and with Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not contain all information and footnotes required by GAAP for annual financial statements. In the opinion of our management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments necessary (consisting only of normal recurring accruals) to present the financial position of the Company as of September 30, 2016 and the results of operations and cash flows for the periods presented. The results of operations for the three months ended September 30, 2016 are not necessarily indicative of the operating results for the full fiscal year or any future period.

These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015. Our accounting policies are described in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2015, and updated, as necessary, in this Quarterly Report on Form 10-Q.

Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. The most significant estimates impacting the financial statements contained in this report include reserve for inventory, which is currently reserved at 100%, and valuing options and warrants using option pricing models.

Prior Period Reclassifications

Certain prior period amounts that were combined in the December 31, 2015 consolidated financial statements have been reclassified for comparability with the current presentation. These reclassifications had no effect on previously reported net loss.

Investments

We adjust the carrying amount of our investments for any impairments that might occur due to other-than-temporary impairment ("OTTI") declines. We consider the need for impairment if and when indicators of other than temporary declines in value are present. Management evaluates investments for OTTI declines on at least a quarterly basis, and more frequently when economic or market conditions warrant such an evaluation.

Fair Value of Financial Instruments

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

Principles of Consolidation

The consolidated financial statements include the accounts of Taxus Cardium Pharmaceuticals Group, Inc. and its consolidated subsidiaries, Angionetics Inc., Activation Therapeutics, Inc. and LifeAgain Insurance Solutions, Inc. All significant inter-company transactions and balances have been eliminated in consolidation.

Preferred Stock

We apply the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of our preferred stock. Shares that are subject to mandatory redemption, if any, are classified as liability instruments and are measured at fair value. We classify conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are

either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within our control, as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

Research and Development

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

Income Taxes

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

The portion of the benefit associated with tax positions taken that exceed the amount measured as described above should be reflected as a liability for uncertain tax benefits in the accompanying balance sheet along with any associated interest and penalties that would be payable to the taxing authorities upon examination.

Common Stock Purchase Warrants

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

Earnings (Loss) Per Common Share

We compute earnings (loss) per share, in accordance with ASC Topic 260 "Earnings per Share", which requires dual presentation of basic and diluted earnings per share. Basic earnings (loss) per common share is computed by dividing earnings (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per common share is computed by dividing earnings (loss) by the weighted average number of common shares outstanding, plus the issuance of common shares, if dilutive, that could result from the exercise of outstanding stock options and warrants. As of September 30, 2016 and 2015, potentially dilutive securities consist of preferred stock convertible into 5,354,574 and 3,718,804 shares of common stock, respectively and outstanding stock options and warrants to acquire 12,116,334 and 7,353,848 shares of common stock, respectively.

These potentially dilutive securities were not included in the calculation of loss per common share for the three and nine month periods ended September 30, 2016 or 2015 because their effect would be anti-dilutive.

Stock-Based Compensation

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

8

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

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

	For the Three Months Ended	
	September 30, 2016	2015
	(unaudited)	
Research and development	\$ 18,467	\$ 32,551
General and administrative	465,425	670,833
Total stock-based compensation	\$ 483,892	\$ 703,384

	For the Nine Months Ended	
	September 30, 2016	2015
	(unaudited)	
Research and development	\$ 18,467	\$ 32,551
General and administrative	499,887	928,667
Total stock-based compensation	\$ 518,354	\$ 961,218

Recent Accounting Standards

In March, 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This standard is intended to improve the accounting for employee share-based payments and affects all organizations that issue share-based payment awards to their employees. Several aspects of the accounting for share-based payment award transactions are simplified, including income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2016. Early adoption is permitted. We do not believe the adoption of this standard will have a material effect on our consolidated financial position and results of operations.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). ASU 2016-02 increases the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Certain qualitative and quantitative disclosures are required, as well as a retrospective recognition and measurement of impacted leases. The new ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2018, with early adoption permitted. We are currently evaluating this ASU to determine its impact on our consolidated net income, financial position, cash flows and disclosures.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes. ASU 2015-17 simplifies the presentation of deferred taxes by requiring deferred tax assets and liabilities be classified as noncurrent on the balance sheet. We do not believe the adoption of this standard will have a material effect on our consolidated financial position and results of operations.

In August 2014, the FASB issued Accounting Standards Update ASU 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern . This ASU is intended to provide guidance on the responsibility of reporting entity management. Specifically, this ASU provides guidance to management related to evaluating whether there is substantial doubt about the reporting entity’s ability to continue as a going concern and about related financial statement note disclosures. The FASB issued this guidance to require management evaluation and potential financial statement disclosures. ASU 2014-15 is effective for financial statements with periods ending after December 15, 2016. We are currently evaluating ASU 2014-15 to determine its impact on our financial position, results of operations or cash flows.

Note 3—Accrued Liabilities

Accrued liabilities consisted of the following:

	September 30, 2016	December 31, (unaudited) 2015
Payroll and benefits	\$ 1,086,885	\$ 789,852
Other	621,500	305,000
Total	\$ 1,708,385	\$ 1,094,852

Note 4—Advances From Related Party - Officer

Officers of the Company occasionally incur or advance expenses on behalf of the Company, which are subsequently reimbursed to the officers along with any associated costs. As of September 30, 2016 and December 31, 2015, \$1,063,865 and \$946,142, respectively, in net Company expenses incurred in the ordinary course of business have been paid by or with cash advanced by the Company's Chief Executive Officer. During the three month period ended September 30, 2016, \$6,254 was repaid. During the nine months ended September 30, 2016 \$117,723 in net expenses were paid by or with cash advanced by our Chief Executive Officer.

Note 5—Stockholders' Equity

Common Stock

On April 4, 2015, we entered into a term sheet with Shenzhen Qianhai Taxus Capital Management Co., Ltd. ("Shenzhen Qianhai Taxus"), a company affiliated with Shanxi Taxus Pharmaceuticals Co. Ltd., whereby we proposed to sell Shenzhen Qianhai Taxus 600,000 shares of common stock in our Angionetics subsidiary in exchange for \$3.0 million in cash. The \$3.0 million was to be paid in tranches that were to be completed by May 31, 2015. Shenzhen Qianhai Taxus paid \$600,000 of the financing, which was recorded as common stock issuable. Shenzhen Qianhai Taxus did not complete this transaction. This subscription is committed and not refundable to Shenzhen Qianhai Taxus. Shenzhen Qianhai Taxus is eligible to apply this amount toward the purchase of common stock of the Company or its subsidiaries based on terms and conditions approved by the Company's Board of Directors.

Preferred Stock

Taxus Cardium Series A Convertible Preferred Stock.

On April 4, 2013, we entered into a securities purchase agreement with Sabby Healthcare Volatility Master Fund, Ltd. ("Sabby"), pursuant to which we sold 4,012 shares of our newly authorized Series A Convertible Preferred Stock (the "Preferred Stock") for \$4.0 million. The Preferred Stock was convertible into shares of our common stock at an initial conversion price of \$0.6437 per share. The conversion price is subject to downward adjustment if we issue common stock or common stock equivalents at a price less than the then effective conversion price. Sabby is limited to hold no more than 10% of Taxus Cardium's issued and outstanding common stock at any time. 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 relating to the 1,176 outstanding shares of Preferred Stock that remained outstanding at that time. Under the terms of the Exchange and Redemption Agreement, we agreed to reduce the conversion price of the Preferred Stock to \$0.30 per share from \$0.64 per share in exchange for a limited redemption right (which has now expired) and an increase in the limitation on certain indebtedness.

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 to an effective price of \$0.18 per share. The Exchange and Redemption Agreement granted 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. As a result of the conversion price changing from \$0.30 to \$0.18 per share, the 1,000 shares of Preferred Stock outstanding are convertible to 5,554,667 shares of Taxus Cardium common stock, an additional 2,221,867 compared to before the conversion price change. At September 30, 2016, there were 964 shares of Preferred Stock outstanding. A hypothetical conversion of all of the outstanding Preferred Stock as of September 30, 2016 into 5,354,674 shares of common stock would increase the

common stock outstanding from 13,523,544 shares as of September 30, 2016, to 18,878,218, an increase of 39.6%. As a result of such holder entering into the Agreement, for which the fair value of preferred stock before and after the modification was a substantially different, the modification was accounted for as an extinguishment. Consequently, we recorded a deemed dividend totaling \$782,879 in the statement of operations in arriving at net loss to common shareholders.

Angionetics Series A Convertible Preferred Stock

On June 7, 2016, Taxus Cardium and Angionetics entered into a Share Purchase Agreement with 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 agreement called for the investment from the Huapont affiliate to be made in two tranches—the closing of the initial tranche of 200,000 Shares for \$1,000,000 shortly following the execution of the agreement and 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. The closings took place, and the Shares were issued, on July 5, 2016 and September 28, 2016, respectively.

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.

• **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.

Stock Options and Other Equity Compensation Plans

We have an equity incentive plan that was established in 2005 under which 283,058 shares of the Company's common stock were reserved for issuance to employees, non-employee directors and consultants of the Company. 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.

At September 30, 2016, the following shares were subject to option awards outstanding under the 2005 Equity Incentive Plan:

	Shares	Available
Plan	Shares	for
2005 Equity Incentive Plan	Outstanding	Issuance
	17,000	—

On February 28, 2014, outside of the 2005 Equity Incentive Plan, we issued 1,457,100 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 \$0.80 per share, which represented a 57% premium to the closing stock price on the date of issuance. The warrants had a fair value of \$0.34 per share and vested immediately.

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 216% 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

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

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 is a summary of stock option and warrant activity under the 2005 Equity Incentive Plan as well as the warrants issued outside of the plan to employees and consultants, during the nine months ended September 30, 2016:

	Number of	Weighted	Weighted
	Options or	Average	Remaining
	Warrants	Exercise	Contractual
		Price	Life
			(in years)
Balance outstanding, December 31, 2015	7,337,598	\$ 0.94	8.62
Granted	4,823,736	0.71	—
Cancelled (unvested)	—	—	—
Expired (vested)	(45,000)	32.67	—
Balance outstanding, September 30, 2016	12,116,334	\$ 0.73	7.92
Balance exercisable, September 30, 2016	12,109,330	\$ 0.73	7.92

As of September 30, 2016, the Company had \$892 of unvested stock-based compensation at fair value remaining to be expensed.

As of September 30, 2016, there was no intrinsic value to the outstanding and exercisable options and warrants as their exercise price exceeded the market price of our common stock.

Warrants

In addition to the warrants that we have issued as a form of compensation above, we have issued warrants to investors in connection with certain financing transactions. The following table summarizes outstanding warrants as of September 30, 2016:

Number of	Weighted	Weighted
Warrants	Average	Average
	Exercise	Remaining
	Price	Contractual

			Life
			(in years)
Balance outstanding, December 31, 2015	716,748	\$ 15.98	0.20
Warrants expired	(716,748)	15.98	—
Balance outstanding, September 30, 2016	—	\$ —	—
Warrants exercisable at September 30, 2016	—	\$ —	—

As of September 30, 2016, there were no finance warrants outstanding, each of such warrants having expired in accordance with their terms.

Note 6—Commitments and Contingencies

Office Lease

On June 23, 2016, we entered into a thirty-eight month lease agreement to lease office space commencing on September 30, 2016. The approximate base monthly rent in the first, second and third years is \$3,500, \$3,700, and \$3,800 respectively. The base monthly rent in the final two months of the agreement is \$3,900. The total base rent over the lease term equals \$139,800.

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, BioRASI LLC (“BioRASI”) filed a complaint 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 September 30, 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.

Note 7—Subsequent Events

We have evaluated events that occurred subsequent to September 30, 2016 and through the date the condensed consolidated financial statements were issued.

Retirement of Members of the Board of Directors

In November 2016, Tyler Dylan-Hyde, Ph.D. and Mr. Lon Otremba retired as directors of the Company’s Board of Directors after almost a decade of service.

FDA Approval of Phase 3 Clinical Trial for Generx™

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.

ITEM 2.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 three and nine month period ended September 30, 2016. You should read the following discussion and analysis together with our unaudited condensed consolidated financial statements and the notes to the condensed consolidated financial statements included under Item 1 in this report, as well as the risk factors and other information included in Part II, Item 1A, in our annual report on Form 10-K for our year ended December 31, 2015 (our “2015 Annual Report”), and other reports and documents we file with the United States Securities and Exchange Commission (“SEC”). Our future financial condition and results of operations will vary from our historical financial condition and results of operations described below.

Overview

The following overview does not address all of the matters covered in the other sections of this Item 2 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 2 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.

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.

•Monetize our equity stake in Healthy Brands Collective investment.

•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.

Recent highlights of our operating activities include the following:

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.

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/grrafts, 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 writeoffs 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.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements included under Item 1 in this report have been prepared in accordance with GAAP. The preparation of our financial statements in accordance with GAAP requires that we make estimates and assumptions that affect the amounts reported in our financial statements and their accompanying notes.

We have identified certain policies that we believe are important to the portrayal of our financial condition and results of operations, including obsolescence reserve for inventory, valuation of equity instruments, and impairment of long-lived assets. These significant accounting estimates or assumptions bear the risk of change due to the fact that there are uncertainties attached to these estimates or assumptions, and certain estimates or assumptions are difficult to measure or value. We base our estimates on our historical experience, industry standards, and various other assumptions that we believe are reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions. An adverse effect on our financial condition, changes in financial condition, and results of operations could occur if circumstances change that alter the various assumptions or conditions used in such estimates or assumptions.

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

Our other significant accounting policies are described in the notes to our condensed consolidated financial statements.

Results of Operations

For the Three Months Ended September 30, 2016 compared to the Three Months Ended September 30, 2015

Research and development expenses for the three months ended September 30, 2016 were \$128,698 compared to \$108,671 for the same period in 2015. The increase of \$20,027 was the result of a \$20,487 increase in clinical trial expenses and a \$460 decrease in personnel related costs.

Selling, general and administrative expenses for the three months ended September 30, 2016 were \$887,241 compared to \$1,081,189 for the same period in 2015. The decrease of \$193,948 was the result of a \$205,408 decrease in stock-based compensation offset by a \$43,043 increase in personnel and related costs, an increase of \$27,273 in professional services expense, a \$959 decrease in storage costs, a \$970 reduction in travel related expenses, a \$44,916 reduction in occupancy, office and liability insurance related expenses and a \$12,011 reduction in investor relations expenses and other selling, general and administration related expenses.

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

Interest expense for the three months ended September 30, 2016 was \$7,413 compared to \$2,106 for the same period in 2015. The increase of \$5,307 was the result of interest charges for expenditures made on our credit card in 2016.

Net loss for the three months ended September 30, 2016 was \$1,023,352 (including \$483,892 of stock-based compensation) compared to a net loss of \$1,191,966 (including \$703,384 of stock-based compensation) for the same period of 2015. The decrease of \$168,614 in net loss was primarily a result of the change in operating and interest expenses described above.

For the Nine Months Ended September 30, 2016 compared to the Nine Months Ended September 30, 2015

Research and development expenses for the nine months ended September 30, 2016 were \$290,895 compared to \$486,759 for the same period in 2015. The decrease of \$195,864 was the result of a \$29,978 increase in personnel and related costs, a \$14,084 decrease in stock-based compensation, decreased costs of \$6,958 related to clinical studies, a decrease of \$4,800 in outside consulting fees and a \$200,000 write-off of a prepaid vendor credit during the nine months ended September 30, 2015.

Selling, general and administrative expenses for the nine months ended September 30, 2016 were \$1,762,375 compared to \$2,449,745 for the same period in 2015. The decrease of \$687,370 was the result of a \$428,780 reduction in stock-based compensation, a \$181,112 reduction in professional fees, a \$51,695 reduction in office, occupancy and insurance related costs, a \$36,383 reduction in travel related costs and \$84,958 reduction in public relations costs. Offsetting the reduction in expense was a \$79,603 increase in personnel and related costs and a \$15,953 increase in other selling, general and administrative expenses.

Interest expense for the nine months ended September 30, 2016 was \$9,878 compared to \$4,490 for the same period in 2015. The increase of \$5,388 was the result of interest charges for expenditures made on our credit card in 2016.

Net loss for the nine months ended September 30, 2016 was \$2,063,148 (including \$518,354 of stock-based compensation) compared to a net loss of \$3,240,994 (including \$961,218 of stock-based compensation) for the same period of 2015. The decrease in net loss of \$1,177,846 was primarily a result of the decrease in operating and interest expenses described above and decrease of impairment loss on investment of \$300,000 and a \$200,000 write-off of a prepaid vendor credit during the nine months ended September 30, 2015.

Liquidity and Capital Resources

As of September 30, 2016, we had approximately \$1.8 million in cash and cash equivalents. Our working capital deficit at September 30, 2016 was approximately \$2.5 million.

Net cash used in operating activities was \$1,201,465 for the nine months ended September 30, 2016 compared to \$929,334 for the nine months ended September 30, 2015. The increase of \$272,131 in net cash used in operating activities, despite the lower net loss, was due primarily to changes in operating assets and liabilities and a reduction in non-cash expenses such as impairments and stock-based compensation.

Net cash used in investing activities for the nine months ended September 30, 2016 was \$144,455 compared to no cash used in investing activities for the same period in 2015. The increase of \$144,455 was related to leasehold improvements, property and equipment purchases associated with our move into our new office space. At September 30, 2016, we did not have any significant capital expenditure requirements.

Net cash provided by financing activities was \$3,117,723 for the nine months ended September 30, 2016 compared to \$730,818 for the same period in 2015. For the nine month period ended September 30, 2016 net cash received from financing activities included \$3,000,000 net cash from a Huapont affiliate for the purchase of 600,000 shares of Series A Convertible preferred stock in Angionetics, Inc. and \$117,723 of cash advanced or expenses paid on our behalf by

the Chief Executive Officer to cover ordinary Company expenses. For the nine month period ended September 30, 2015 the \$600,000 net cash received from financing activities were payments from Shenzhen Qianhai Taxus Industry Capital Management Co. for an equity stake in either the Company or Angionetics and \$130,818 net cash advances received from our Chief Executive Officer to cover ordinary Company expenses.

We anticipate that negative cash flows from operations will continue for the foreseeable future. We do not have any unused credit facilities. We intend to secure additional working capital through sales of additional equity and debt securities to finance our operations. As long as any shares of our Preferred Stock are outstanding, we have agreed that we will not, without the consent of the holders of two-thirds of the Series A Convertible Preferred Stock, incur indebtedness other than specified "Permitted Indebtedness", or incur any liens other than specified "Permitted Liens".

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"). Huapont is 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 (including NC16, NC34, NC36, NC125, NC201) serving the agricultural business throughout the U.S.

and South American markets. Huapont's pharmaceutical business includes dermatology products, cardiovascular products, anti-tuberculosis agents, autoimmune-related products and oncology-related products. Huapont'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 \$1.1 billion, and approximately 7,100 employees operating throughout mainland China. Huapont is listed on the Shenzhen Stock Exchange (002004.SZ) and trades at a current market capitalization of approximately \$3.0 billion.

In connection with this agreement, Angionetics sold 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.

The agreement called for the investment from the Huapont affiliate to be made in two tranches—the closing of the initial tranche of 200,000 Shares for \$1,000,000 shortly following the execution of the agreement and 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. The closings took place, and the Shares were issued, on July 5, 2016 and September 28, 2016, respectively.

Angionetics will require substantial additional capital to complete the Phase 3 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.

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.

Off-Balance Sheet Arrangements

As of September 30, 2016, we did not have any significant off-balance sheet debt nor did we have any transactions, arrangements, obligations (including contingent obligations) or other relationships with any unconsolidated entities or other persons that have or are reasonably likely to have a material current or future effect on financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenue or expenses material to investors.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. Based on this evaluation, management concluded that our disclosure controls were not effective for their intended purposes described above as a result of a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis. For the year ended December 31, 2015, we noted the following material weaknesses in the operation of our internal controls as follows:

- We did not maintain a sufficient complement of personnel with the appropriate level of accounting knowledge, experience and training in the application of GAAP commensurate with our financial reporting requirements; and
- We did not maintain a sufficient complement of personnel to permit the segregation of duties among personnel with access to the Company's accounting and information systems and controls.

22

Our management does not believe that the material weakness in internal controls has resulted in any inaccuracy or misstatement in the financial statements included in this report. We plan to remediate these material weaknesses by hiring additional qualified accounting personnel when the Company has the financial resources to support those expenses. However, these material weaknesses continued to exist during the quarterly period ended September 30, 2016.

There were no changes to our internal control over financial reporting during the quarterly period ended September 30, 2016 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. 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, BioRASI LLC (“BioRASI”) filed a complaint 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 September 30, 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 1 A. 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, 2015 included 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 September 30, 2016, our accumulated deficit was approximately \$117 million, and our cash and cash equivalents were approximately \$1.8 million. 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;

25

- 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;

29

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, 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 September 30, 2016, there were 964 shares of Preferred Stock outstanding. A hypothetical conversion of all of the outstanding Preferred Stock as of September 30, 2016 into 5,354,674 shares of common stock would increase the common stock outstanding from 13,523,544 shares as of September 30, 2016, to 18,878,218, an increase of 39.6%.

As a result of such holder entering into the Agreement, for which the fair value of preferred stock before and after the modification was a substantially different, the modification was accounted for as an extinguishment. Consequently, we recorded a deemed dividend totaling \$782,879 in the statement of operations in arriving at net loss to common shareholders.

Our outstanding warrants have anti-dilution protection and, if exercised, will significantly dilute the ownership interest of existing stockholders.

At September 30, 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. The fair value of these issuances was recorded as compensation expense.

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.

32

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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibit index shows those exhibits filed with this report and those incorporated by reference:

EXHIBIT INDEX

Exhibit Number	Description	Incorporated By Reference To
4.1	Form of Warrant Agreement issued to directors and officers in February 2014.	Exhibit 4.1 of our Form 10-Q, filed with the Commission on May 15, 2014.
4.2	Certificate of Designation of Series A Convertible Preferred Stock of Angionetics Inc.	Exhibit 99.1 of our Current Report on Form 8-K filed with the Commission on July 11, 2016.
10.1	Securities Purchase Agreement dated February 21, 2014 between the registrant and Shanxi Taxus Pharmaceuticals Co., Ltd.	Exhibit 10.2 of our Current Report on Form 8-K filed with the Commission on March 4, 2014.
10.2	Exchange Redemption Agreement dated July 22, 2015 between the registrant and Sabby Healthcare Volatility Master Fund, Ltd.	Exhibit 10.1 of our Current Report on Form 8-K filed with the Commission on July 23, 2015.
10.3	Contribution Agreement dated June 6, 2016 between the registrant and Angionetics Inc.	Exhibit 10.2 of our Current Report on Form 8-K filed with the Commission on July 11, 2016.
10.4	Services Agreement dated June 6, 2016 between the registrant and Angionetics Inc.	Exhibit 10.3 of our Current Report on Form 8-K filed with the Commission on July 11, 2016.
10.5	Share Purchase Agreement dated June 7, 2016 among the registrant , Angionetics Inc. and Pineworld Capital Limited	Exhibit 10.1 of our Current Report on Form 8-K filed with the Commission on July 11, 2016.

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

10.6	Distribution and License Agreement dated June 7, 2016 between Angionetics Inc. and Pineworld Capital Limited	Exhibit 10.1 of our Current Report on Form 8-K filed with the Commission on July 11, 2016.
10.7	Exchange Redemption Agreement dated September 23, 2016 between the registrant and Sabby Healthcare Volatility Master Fund, Ltd.	Exhibit 10.1 of our Current Report on Form 8-K filed with the Commission on September 23, 2016.
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer	Filed herewith.
32	Section 1350 Certification	Filed herewith.
101	The following financial statements and footnotes from the Taxus Cardium Pharmaceuticals Group, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Cash Flows; and (iv) the Notes to Condensed Consolidated Financial Statements.	Filed herewith.

SIGNATURES

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

Date: March 21, 2017

TAXUS CARDIUM PHARMACEUTICALS
GROUP, INC.

By: /s/ CHRISTOPHER J. REINHARD
Christopher J. Reinhard,
Chief Executive Officer (Principal Executive
and Accounting Officer)