GENEREX BIOTECHNOLOGY CORP
Form 10-Q
January 18, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended October 31, 2016

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 0-25169

GENEREX BIOTECHNOLOGY CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**98-0178636**

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

4145 NORTH SERVICE ROAD, SUITE 200

BURLINGTON, ONTARIO

CANADA L7L 6A3

(Address of principal executive offices)

(416) 364-2551

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required 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 (§232.405 of this chapter) 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 definitions 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

The number of outstanding shares of the registrant's common stock, par value $.001, was 908,541,475 as of December 29, 2016.

GENEREX BIOTECHNOLOGY CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
UNAUDITED CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS

	October 31, 2016	July 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$6,454	$16,899
Other current assets	11,353	8,077
Total Current Assets	17,807	24,976
Property and Equipment	—	1,298
TOTAL ASSETS	$17,807	$26,274
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities:		
Accounts payable and accrued expenses (Note 4)	$9,154,886	$8,950,870
Loan payable (Note 4)	50,000	50,000
Total Current Liabilities	9,204,886	9,000,870
Derivative Warrant Liability (Note 7 and 8)	1,462,359	2,048,846
Derivative Additional Investment Rights Liability (Note 7 and 8)	—	193,408
Total Liabilities	10,667,245	11,243,124
Commitments and Contingencies (Note 5)		
Stockholders' Deficiency (Note 7):		
Series A 9% Convertible Preferred Stock, $1,000 par value; authorized 5,500 shares, -0- issued shares at October 31, 2016 and July 31, 2016, respectively	—	—
Series B 9% Convertible Preferred Stock, $1,000 par value; authorized 2,000 shares, -0- issued shares at October 31, 2016 and July 31, 2016, respectively	—	—
Series C 9% Convertible Preferred Stock, $1,000 par value; authorized 750 shares, -0- issued shares at October 31, 2016 and July 31, 2016, respectively	—	—
Series D 9% Convertible Preferred Stock, $1,000 par value; authorized 750 shares, -0- issued shares at October 31, 2016 and July 31, 2016, respectively	—	—
Series E 9% Convertible Preferred Stock, $1,000 par value; authorized 2,450 shares, -0- issued shares at October 31, 2016 and July 31, 2016, respectively	—	—
Series F 9% Convertible Preferred Stock, $1,000 par value; authorized 4,150 shares, 120 issued shares at October 31, 2016 and July 31, 2016, respectively	—	—
Series G 9% Convertible Preferred Stock, $1,000 par value; authorized 1,000 shares, Shares, 500 issued shares at October 31, 2016 and July 31, 2016, respectively	—	—

Common stock, $.001 par value; authorized 2,450,000,000 and 2,450,000,000 shares at October 31, 2016 and July 31, 2016, respectively; 908,541,475 and 908,541,475 issued and outstanding at October 31, 2016 and July 31, 2016, respectively	908,542	908,542
Additional paid-in capital	362,780,108	362,780,108
Accumulated deficit	(375,144,134)	(375,704,372)
Accumulated other comprehensive income	806,046	798,872
Total Stockholders' Deficiency	(10,649,438)	(11,216,850)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	$17,807	$26,274

The accompanying notes are an Integral part of the financial statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
UNAUDITED CONDENSED INTERIM CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For Three Months Ended October 31,	
	2016	2015
Operating Expenses:		
Research and development	$—	$177,570
General and administrative	102,818	1,140,009
Total Operating Expenses	102,818	1,317,579
Operating Loss	(102,818)	(1,317,579)
Other Income (Expense):		
Interest expense	(116,839)	(97,723)
Change in fair value of derivative liabilities (Note 8)	779,895	(315,963)
Net Income (Loss) and Net Income (Loss) Available to Common Stockholders	$560,238	$(1,731,265)
Basic and Diluted Net Income (Loss) Per Common Share (Note 6)	$.001	$(.002)
Weighted Average Number of Shares of Common Stock Outstanding - basic and diluted (Note 6)	908,541,475	850,126,309
Other Comprehensive Income:		
Net Income (Loss)	560,238	(1,731,265)
Change in foreign currency translation adjustments	7,174	(2,936)
Comprehensive Income (Loss) and Comprehensive Income (Loss) Available to Common Stockholders	$567,412	$(1,734,201)

The accompanying notes are an Integral part of the financial statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
UNAUDITED CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICI

	Preferred Stock		Common Stock					To
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Sto Def
Balance at July 31, 2015	1,170	$—	825,496,238	$825,496	$362,556,710	$(372,481,263)	$808,737	$(8,2
Issuance of common stock in exchange for services	—		300,000	300	4,200	—	—	4,5
Issuance of common stock upon conversion of preferred stock	(550)		36,666,665	36,667	(36,667)	—	—	—
Issuance of common stock for preferred stock make whole payments			20,139,207	20,139	128,361	—	—	148
Exercise of stock options for cash	—		25,939,365	25,940	(25,940)	—	—	—
Issuance of stock options for compensation liabilities	—		—	—	123,147	—	—	123
Issuance of stock options as compensation	—		—	—	30,297	—	—	30,2
Net loss	—		—	—	—	(3,223,109)	—	(3,2
Currency translation adjustment	—		—	—	—	—	(9,865)	(9,8
Balance at July 31, 2016	620	$—	908,541,475	$908,542	$362,780,108	$(375,704,372)	$798,872	$(11
Net income						560,238		560
Currency translation	—		—	—	—	—	7,174	7,1

adjustment								
Balance at October 31, 2016	620	$—	908,541,475	908,542	362,780,108	(375,144,134)	806,046	(10

The accompanying notes are an Integral part of the financial statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
UNAUDITED CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

	For Three Months Ended October 31,	
	2016	2015
Cash Flows From Operating Activities:		
Net income (loss)	$560,238	$(1,731,265)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	—	52,661
Stock compensation expense	—	27,344
Common stock issued for services rendered	—	4,500
Gain on disposal of property and equipment	1,276	—
Common stock issued for make-whole payments on preferred stock	—	113,400
Change in fair value of derivative liabilities	(779,895)	315,963
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	211,546	522,064
Other current assets	(3,537)	(784)
Net Cash Used in Operating Activities	(10,372)	(696,117)
Cash Flows From Financing Activities:		
Proceeds from exercise of stock options	—	2,952
Net Cash Provided by Financing Activities	—	2,952
Effect of Exchange Rates on Cash	(73)	(4,372)
Net (Decrease) in Cash and Cash Equivalents	(10,445)	(697,537)
Cash and Cash Equivalents, Beginning of Period	16,899	749,965
Cash and Cash Equivalents, End of Period	$6,454	$52,428

The accompanying notes are an Integral part of the financial statements.

Note 1 – Basis of Presentation:

The accompanying unaudited interim consolidated financial statements ("interim statements") have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by generally accepted accounting principles for complete financial statements are not included herein. The interim statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's latest Annual Report on Form 10-K. The results for the three month period ended October 31, 2016 may not be indicative of the results for the entire year.

Interim statements are subject to possible adjustments in connection with the annual audit of the Company's accounts for fiscal year 2017. In the Company's opinion, all adjustments necessary for a fair presentation of these interim statements have been included and are of a normal and recurring nature.

The Company has a limited history of operations and limited revenue to date. Although the Company has had several product candidates that are in various research or early stages of pre-clinical and clinical development, due to its lack of funding the Company has effectively ceased these operations and is now seeking new investment opportunities (see Note 9). There can be no assurance that the Company will be successful in completing these investment opportunities and maintaining its position as a going concern.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has experienced negative cash flows from operations since inception and has an accumulated deficit of approximately $375 million and a working capital deficiency of approximately $9.2 million at October 31,2016. The Company has funded its activities to date almost exclusively from debt and equity financings, as well as the sale of non-essential real estate assets in fiscal 2012 through the first quarter of fiscal 2014.

The Company will continue to require substantial funds to implement its new investment acquisition plans. Management's plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments. Management is also actively pursuing financial and strategic alternatives, including strategic investments and divestitures, industry collaboration activities and strategic partners.

These factors raise substantial doubt regarding the Company's ability to continue as a going concern. There are no assurances that such additional funding will be achieved and that the Company will succeed in its future operations. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's inability to obtain required funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations.

Note 2 – Effects of Recent Accounting Pronouncements:

Recently Issued Accounting Pronouncements

In November 2014, the FASB issued guidance regarding *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity.* The guidance became effective this quarter. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

In August 2014, the FASB issued guidance regarding disclosure of uncertainties about an entity's ability to continue as a going concern. The guidance became effective this quarter. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

Note 3 – Stock-Based Compensation:

As of October 31, 2016, the Company had two stockholder-approved stock incentive plans under which shares and options exercisable for shares of common stock have been or may be granted to employees, directors, consultants and advisors. A total of 12,000,000 shares of common stock are reserved for issuance under the 2001 Stock Option Plan (the 2001 Plan) and 135,000,000 shares of common stock are reserved for issuance under the 2006 Stock Plan as amended (the 2006 Plan). At October 31, 2016, there were 4,138,916 and 64,484,808 shares of common stock reserved for future awards under the 2001 Plan and 2006 Plan, respectively. The Company issues new shares of common stock from the shares reserved under the respective Plans upon conversion or exercise of options and issuance of restricted shares.

The 2001 and 2006 Plans (the Plans) are administered by the Board of Directors (the Board). The Board is authorized to select from among eligible employees, directors, advisors and consultants those individuals to whom options are to be granted and to determine the number of shares to be subject to, and the terms and conditions of the options. The Board is also authorized to prescribe, amend and rescind terms relating to options granted under the Plans. Generally, the interpretation and construction of any provision of the Plans or any options granted hereunder is within the discretion of the Board.

The Plans provide that options may or may not be Incentive Stock Options (ISOs) within the meaning of Section 422 of the Internal Revenue Code. Only employees of the Company are eligible to receive ISOs, while employees and non-employee directors, advisors and consultants are eligible to receive options which are not ISOs, i.e. “Non-Qualified Options.” The options granted by the Board in connection with its adoption of the Plans were Non-Qualified Options. In addition, the 2006 Plan also provides for restricted stock grants.

The fair value of each option granted is estimated on the grant date using the Black-Scholes option pricing model or the value of the services provided, whichever is more readily determinable. The Black-Scholes option pricing model takes into account, as of the grant date, the exercise price and expected life of the option, the current price of the underlying stock and its expected volatility, expected dividends on the stock and the risk-free interest rate for the term of the option. The Black-Scholes option pricing model was not used to estimate the fair value any option grants in the quarter ended October 31, 2016 or in the fiscal year ended July 31, 2016.

The following is a summary of the common stock options granted, forfeited or expired and exercised under the Plans for the three months ended October 31, 2016:

Options

		Weighted Average Exercise Price per Share	Aggregate Intrinsic Value
Outstanding: Aug. 1, 2016 and Oct. 31, 2016	19,639,477	$ 0	$129,647
Exercisable, October 31, 2016	19,639,477	$ 0	$129,647

The 19,639,477 outstanding options at October 31, 2016 had a weighted average remaining contractual term of 2.54 years. Options typically vest over a period of two to four years and have a contractual life of five to ten years.

There were no non-vested common stock options granted, vested or forfeited under the Plan for the three months ended October 31, 2016. There was no unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans at October 31, 2016.

Note 4 – Accounts Payable and Accrued Expenses:

Accounts payable and accrued expenses consist of the following:

	October 31, 2016	July 31, 2016
Accounts Payable and Accruals – General and Administrative	$3,813,412	$3,750,638
Accounts Payable and Accruals – Research and Development	4,505,916	4,395,061
Accounts Payable and Accruals – Selling and Marketing	326,116	326,229
Accrued Make-whole Payments on Convertible Preferred Stock (see Note 7)	167,400	167,400
Executive Compensation and Directors' Fees Payable	342,042	311,542
Total	$9,154,886	$8,950,870

In addition to accounts payable and accrued expenses, the Company has a loan payable in the amount of $50,000. This loan is unsecured, due on demand and bears interest at 9% per annum.

Note 5 – Commitments and Contingencies:

Pending Litigation

In February 2001, a former business associate of the former Vice President of Research and Development ("VP") of the Company and an entity known as Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against the Company and the VP seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between this former associate and the VP that ceased in July 1996. The plaintiffs' statement of claim also seeks to enjoin the use, if any, by the Company of three patents allegedly owned by CTI. The three patents are entitled *Liquid Formulations for Proteinic Pharmaceuticals*, *Vaccine Delivery System for Immunization, Using Biodegradable Polymer Microspheres*, and *Controlled Releases of Drugs or Hormones in Biodegradable Polymer Microspheres*. It is the Company's position that the buccal drug delivery technologies which are the subject matter of the Company's research, development, and commercialization efforts, including Generex Oral-lyn™ and the RapidMist™ Diabetes Management System, do not make use of, are not derivative of, do not infringe upon, and are entirely different from the intellectual property identified in the plaintiffs' statement of claim. On July 20, 2001, the Company filed a preliminary motion to dismiss the action of CTI as a nonexistent entity or, alternatively, to stay such action on the grounds of want of authority of such entity to commence the action. The plaintiffs brought a cross motion to amend the statement of claim to substitute Centrum Biotechnologies, Inc. ("CBI") for CTI. CBI is a corporation of which 50 percent of the shares are owned by the former business associate and the remaining 50 percent are owned by the Company. Consequently, the shareholders of CBI are in a deadlock. The court granted the Company's motion to dismiss the action of CTI and denied the plaintiffs' cross motion without prejudice to the former business associate to seek leave to bring a derivative action in the name of or on behalf of CBI.

The former business associate subsequently filed an application with the Ontario Superior Court of Justice for an order granting him leave to file an action in the name of and on behalf of CBI against the VP and the Company. The Company opposed the application. In September 2003, the Ontario Superior Court of Justice granted the request and issued an order giving the former business associate leave to file an action in the name of and on behalf of CBI against the VP and the Company. A statement of claim was served in July 2004. The Company is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

On May 20, 2011, Ms. Perri filed a statement of claim (subsequently amended) in the Ontario Superior Court of Justice, naming as defendants the Company and certain directors of the Company, Mr. Barratt, Ms. Masterson, Mr. McGee, and Mr. Fletcher. In this action, Ms. Perri has alleged that defendants engaged in discrimination, harassment, bad faith and infliction of mental distress in connection with the termination of her employment with the Company. Ms. Perri is seeking damages in this action in excess of $7,000,000 for, among other things, breach of contract, breach of fiduciary duty, violations of the Ontario Human Rights Code and aggravated and punitive damages. On September 20, 2011, the defendants filed a statement of defense and counterclaim, also naming Time Release Corp., Khazak Group Consulting Corp., and David Khazak, C.A. as defendants by counterclaim, and seeking damages of approximately $2.3 million in funds that the defendants allege Ms. Perri wrongly caused the Company to pay to third parties in varying amounts over several years and an accounting of certain third-party payments, plus interests and costs. The factual basis for the counterclaim involves payments made by the Company to third parties believed to be related to Ms. Perri. The Company intends to defend this action and pursue its counterclaim vigorously and is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

On June 1, 2011, Golden Bull Estates Ltd. filed a claim (subsequently amended) in the Ontario Superior Court of Justice, naming the Company, 1097346 Ontario, Inc. and Generex Pharmaceuticals, Inc. as defendants. The plaintiff, Golden Bull Estates Ltd., is controlled by Ms. Perri. The plaintiff alleges damages in the amount of $550,000 for breach of contract, $50,000 for punitive damages, plus interest and costs. The plaintiff's claims relate to an alleged contract between the plaintiff and the Company for property management services for certain Ontario properties owned by the Company. The Company terminated the plaintiff's property management services in April 2011. Following the close of pleadings, the Company served a motion for summary judgment. The plaintiff responded by amending its statement of claim to include a claim to the Company's interest in certain of its real estate holdings. The plaintiff moved for leave to issue and register a Certificate of Pending Litigation in respect of this real estate. The motion was not successful in respect of any current real estate holdings of the Company. The Company is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

In December 2011, a vendor of the Company commenced an action against the Company and its subsidiary, Generex Pharmaceuticals, Inc., in the Ontario Superior Court of Justice claiming damages for unpaid invoices including interest in the amount of $429,000, in addition to costs and further interest. The Company responded to this statement of claim and also asserted a counterclaim in the proceeding for $200,000 arising from the vendor's breach of contract and detinue, together with interest and costs. On November 16, 2012, the parties agreed to settle this action and the Company has agreed to pay the plaintiff $125,000, following the spinout of its subsidiary Antigen, from the proceeds of any public or private financing related to Antigen subsequent to such spinout. Each party agreed to execute mutual releases to the claim and counterclaim to be held in trust by each party's counsel until payment of the settlement amount. Following payment to the plaintiff, the parties agree that a Consent Dismissal Order without costs will be filed with the court. If the Company fails to make the payment following completion of any post-spinout financing related to Antigen or any other subsidiaries, the Plaintiffs may take out a judgment in the amount of the claim plus interest of 3% per annum and costs fixed at $25,000.

The Company is involved in certain other legal proceedings in addition to those specifically described herein. Subject to the uncertainty inherent in all litigation, the Company does not believe at the present time that the resolution of any of these legal proceedings is likely to have a material adverse effect on the Company's consolidated financial position, operations or cash flows.

With respect to all litigation, as additional information concerning the estimates used by the Company becomes known, the Company reassesses its position both with respect to accrued liabilities and other potential exposures.

Note 6 – Net (Loss) / Income Per Share ("EPS"):

Basic EPS and diluted EPS for the three-month period ended October 31, 2016 have been computed by dividing the net loss available to common stockholders for the period by the weighted average shares outstanding during the period. All outstanding stock options, non-vested restricted stock, warrants and common stock underlying convertible preferred stock, representing 401,373,216 incremental shares at October 31, 2016, have been excluded from the computation of diluted EPS as they are anti-dilutive.

Basic EPS and diluted EPS for the three-month period ended October 31, 2015 have been computed by dividing the net loss available to common stockholders for the period by the weighted average shares outstanding during the period. All outstanding stock options, non-vested restricted stock, warrants and common stock underlying convertible preferred stock, representing 606,644,111 incremental shares at October 31, 2015, have been excluded from the computation of diluted EPS as they are anti-dilutive.

Note 7 – Stockholders' Deficiency:

Common Stock

During the three months ended October 31, 2016, the Company has not issued any shares of common stock.

No options were exercised during the three months ended October 31, 2016.

Warrants

There are 329,332,081 warrants outstanding as of October 31, 2016. There were no warrants issued, or exercised for the three months ended October 31, 2016. 54,545,440 warrants expired during the period. The outstanding warrants at October 31, 2016 have a weighted average exercise price of $0.015 per share and have a weighted average remaining life of 2.1 years.

As of October 31, 2016, the Company has 329,332,081 warrants with a current exercise price of $0.015 which have price protection provisions that allow for the reduction in the current exercise price upon the occurrence of certain events, including the Company's issuance of common stock or securities convertible into or exercisable for common stock, such as options and warrants, at a price per share less than the exercise price then in effect. For instance, if the Company issues shares of its common stock or options exercisable for or securities convertible into common stock at an effective price per share of common stock less than the exercise price then in effect, the exercise price will be reduced to the effective price of the new issuance. Simultaneously with any reduction to the exercise price, the number of shares of common stock that may be purchased upon exercise of each of these warrants shall be increased proportionately, so that after such adjustment the aggregate exercise price payable for the adjusted number of warrants shall be the same as the aggregate exercise price in effect immediately prior to such adjustment. There are a limited number of permitted types of stock and equity instrument issuances for each series of warrants which will not invoke the price protection provisions of these warrants.

The Company accounts for the warrants with price protection provisions in accordance with FASB ASC Topic 815 as described in *Note 8 - Derivative Liabilities* below. As of October 31, 2016, there were a total of 329,332,081 warrants with an estimated fair value of $1,462,359, which are identified on the interim consolidated balance sheets under the caption "Derivative Warrant Liability".

Series A, B, C, D and E 9% Convertible Preferred Stock

All of the Company's Series A, B, C, D and E 9% Convertible Preferred Stocks were converted prior to the beginning of the Company's 2017 fiscal year.

Series F and G 9% Convertible Preferred Stock

The Company has authorized 4,150 shares of Series F 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated March 27, 2014, the Company sold an aggregate of 2,075 shares of Series F convertible preferred stock, as well as accompanying warrants to purchase 69,166,667 shares of common stock. An aggregate of 69,166,667 shares of the Company's common stock were issuable upon conversion of the Series F convertible preferred stock which was issued at the closing on March 27, 2014.

The Company has authorized 1,000 shares of Series G 9% Convertible Preferred Stock with a stated value of one thousand ($1,000) per share. Pursuant to a securities purchase agreement dated June 24, 2015, the Company sold an aggregate of 500 shares of Series G convertible preferred stock, as well as accompanying warrants to purchase 33,333,333 shares of common stock. An aggregate of 33,333,333 shares of the Company's common stock are issuable upon conversion of the Series G convertible preferred stock which was issued at the closing on June 24, 2015.

Subject to certain ownership limitations, the convertible preferred stock is convertible at the option of the holder at any time into shares of the Company's common stock at an effective conversion price of $0.015 per share (Note: The conversion price for the Series F Convertible Preferred Stock was adjusted from $0.03 to $0.015 in conjunction with the Series G Convertible Preferred Stock financing on June 24, 2015), and will accrue a 9% dividend until the third year anniversary of the issuances. On each one-year anniversary thereafter, such dividend rate will increase by an additional 3%. The dividend is payable quarterly on September 30, December 31, March 31 and June 30, beginning on June 30, 2014 and June 30, 2015, respectively, and on each conversion date in cash, or at the Company's option, in shares of common stock. In the event that the Series F and G convertible preferred stock is converted prior to March 27, 2017 and June 24, 2018, respectively, the Company will pay the holder of the converted preferred stock an amount equal to $270 per $1,000 of stated value of the convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. Such "make-whole payment" may be made in cash or, at the Company's option, in shares of its common stock. In addition, beginning on the third anniversary date of the issuances, the Company will pay dividends on shares of preferred stock equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, and if such dividends are paid. The Company will incur a late fee of 18% per annum on unpaid dividends.

The conversion price of the convertible preferred stock is subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The conversion price will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then conversion price, except in the event of certain exempt issuances. In addition, the holders of convertible preferred stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had converted all of their shares of convertible preferred stock. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the holders of convertible preferred stock will be entitled to receive, upon conversion of their shares, any securities or other consideration received by the holders of the Company's common stock pursuant to the fundamental transaction. The conversion price for the Series F Convertible Preferred Stock was adjusted from $0.03 to $0.015 in conjunction with the Series G Convertible Preferred Stock on June 24, 2015 and the number of common shares underlying the 838 Series F Convertible Preferred Stock outstanding at that date increased from 27,941,667 to 55,883,333.

In conjunction with the issuance of the Series F convertible preferred stock in March 2014 and the issuance of the Series G convertible preferred stock in June 2015, the Company also issued 69,166,667 and 33,333,333 warrants, respectively to the investors. Subject to certain ownership limitations, the warrants will be exercisable at any time after their respective dates of issuance and on or before the fifth-year anniversary thereafter at an exercise price of $0.015 per share of common stock (Note: The conversion price for the warrants issued in the Series F Convertible Preferred Stock financing was adjusted from $0.03 to $0.015 in conjunction with the Series G Convertible Preferred Stock financing on June 24, 2015 and the number of warrants increased from 69,166,667 to 138,333,334). The exercise price of the warrants and, in some cases, the number of shares issuable upon exercise, are subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The exercise price and number of shares of common stock issuable upon exercise will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then exercise price, except in the event of certain exempt issuances. In addition, the warrant holders will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had exercised all of their warrants. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the warrant holders will be entitled to receive, upon exercise of their warrants, any securities or other consideration received by the holders of the Company’s common stock pursuant to the fundamental transaction. These warrants have been classified as derivative liabilities and are described further in *Note 8 – Derivative Liabilities***.**

In addition, until the first anniversary date of the March 2014 securities purchase agreement and the first anniversary of the August 19, 2015 shareholder approval of the increase in authorized stock, respectively, each investor may, in its sole determination, elect to purchase, severally and not jointly with the other investors, in one or more purchases, in the ratio of such investor's original subscription amount to the original aggregate subscription amount of all investors, additional units consisting of convertible preferred stock and warrants at a purchase price of $1,000 per unit with an aggregate subscription amount thereof of up to $2,075,000 and $500,000, respectively, which units will have terms identical to the units of convertible preferred stock and warrants issued in connection with the March 2014 and June 2015 closings. These additional investment rights of the investors have been classified as derivative liabilities and are described further in *Note 8 – Derivative Liabilities***.** The March 2014 additional investment rights expired on March 27, 2015 and none had been exercised up to that date. The June 2015 additional investment rights expire on August 19, 2016 and none have been exercised.

As of October 31, 2016, 1,955 of the Series F convertible preferred stock had been converted to common stock. There were 89,108,331 shares of common stock issued upon the conversion of the Series F convertible preferred stock and 36,533,878 shares of common stock issued as “make-whole payments” on such conversions. As of October 31, 2016, none of the Series G convertible preferred stock had been converted to common stock.

Accounting for proceeds from the Series F convertible preferred stock financing

The initial cash proceeds, net of issuance costs of $55,000, from the Series F convertible preferred stock financing in March 2014 were $2,020,000. The proceeds from the financing were allocated first to the warrants that were issued in the financing, second to the additional investment rights associated with the financing and then to the make whole payments and subsequent issuance costs. As the assigned fair values were greater than the net cash proceeds from the transaction, the excess was treated as a “deemed dividend” for accounting purposes and was reported on the Company’s consolidated statement of comprehensive (loss) / income for the fiscal year ended July 31, 2014 under the caption “Preferred Stock Dividend”. The calculation methodologies for the fair values of the derivative warrant liability and the derivative additional investment rights liability are described in *Note 8 – Derivative Liabilities* below. The fair values assigned to each component and the calculation of the amount of the deemed dividend are as follows:

Accounting allocation of initial proceeds	
Net proceeds	$2,020,000
Derivative warrant liability fair value	(2,016,064)
Derivative additional investment rights fair value	(863,735)
Other issuance costs (finders’ fee)	(166,000)
Make whole payments liability	(560,250)
Deemed dividend	$(1,586,050)

The initial “make-whole payments” of $560,250 on the Series F convertible preferred stock were accrued as of the date of the financing and the remaining balance of $32,400 after conversions (July 31, 2016 - $32,400) is included in Accounts Payable and Accrued Expenses (see Note 4) at October 31, 2016.

Accounting for proceeds from the Series G convertible preferred stock financing

The initial cash proceeds, net of issuance costs of $25,000, from the Series G convertible preferred stock financing in June 2015 were $475,000. The proceeds from the financing were allocated first to the warrants that were issued in the financing, second to the additional investment rights associated with the financing and then to the make whole payments and subsequent issuance costs. As the assigned fair values were greater than the net cash proceeds from the transaction, the excess was treated as a "deemed dividend" for accounting purposes and was reported on the Company's consolidated statement of comprehensive (loss) / income for the fiscal year ended July 31, 2015 under the caption "Preferred Stock Dividend". The calculation methodologies for the fair values of the derivative warrant liability and the derivative additional investment rights liability are described in *Note 8 – Derivative Liabilities* below. The fair values assigned to each component and the calculation of the amount of the deemed dividend are as follows:

Accounting allocation of initial proceeds	
Net proceeds	$475,000
Derivative warrant liability fair value	(354,535)
Derivative additional investment rights fair value	(285,048)
Other issuance costs (finders' fee)	(40,000)
Make whole payments liability	(135,000)
Deemed dividend	$(339,583)

The initial "make-whole payments" of $135,000 on the Series G convertible preferred stock were accrued as of the date of the financing and the balance (no conversions have taken place) is included in Accounts Payable and Accrued Expenses (see Note 4) at October 31, 2016 and July 31, 2016.

Note 8 – Derivative Liabilities:

Derivative warrant liability

The Company has warrants outstanding with price protection provisions that allow for the reduction in the exercise price of the warrants in the event the Company subsequently issues stock or securities convertible into stock at a price lower than the exercise price of the warrants. Simultaneously with any reduction to the exercise price, the number of shares of common stock that may be purchased upon exercise of each of these warrants shall be increased or decreased proportionately, so that after such adjustment the aggregate exercise price payable for the adjusted number of warrants shall be the same as the aggregate exercise price in effect immediately prior to such adjustment.

Accounting for Derivative Warrant Liability

The Company's derivative instruments have been measured at fair value at October 31, 2016 and July 31, 2016 using the binomial lattice model. The Company recognizes all of its warrants with price protection in its consolidated balance sheets as a liability. The liability is revalued at each reporting period and changes in fair value are recognized currently in the consolidated statements of comprehensive income. The initial recognition and subsequent changes in fair value of the derivative warrant liability have no effect on the Company's consolidated cash flows.

The derivative warrants outstanding at October 31, 2016 are all currently exercisable with a weighted-average remaining life of 2.1 years.

The revaluation of the warrants at the end of the respective reporting periods resulted in the recognition of a gain of $586,487 within the Company's consolidated statements of operations for the three months ended October 31, 2016 and a loss of $161,900 within the Company's consolidated statements of comprehensive (loss) / income for the three months ended October 31, 2015, which are included in the consolidated statement of comprehensive (loss) / income under the caption "Change in fair value of derivative liabilities". The fair values of the warrants at October 31, 2016 and July 31, 2016 were $1,462,359 and $2,048,846, respectively, which are reported on the consolidated balance sheets under the caption "Derivative Warrant Liability". The following summarizes the changes in the value of the derivative warrant liability from August 1, 2016 until October 31, 2016:

	Value	No. of Warrants
Balance at August 1, 2016 – Derivative warrant liability	$2,048,846	383,877,521
Forfeited or expired	(172,422)	(54,545,440)
Decrease in fair value of derivative warrant liability	(414,065)	n/a
Balance at October 31, 2016 – Derivative warrant liability	$1,462,359	329,332,081

Fair Value Assumptions Used in Accounting for Derivative Warrant Liability

The Company has determined its derivative warrant liability to be a Level 2 fair value measurement and has used the binominal lattice pricing model to calculate the fair value as of October 31, 2016 and July 31, 2015. The binomial lattice model requires six basic data inputs: the exercise or strike price, time to expiration, the risk free interest rate, the current stock price, the estimated volatility of the stock price in the future, and the dividend rate. Because the warrants contain the price protection feature, the probability that the exercise price of the warrants would decrease as the stock price decreased was incorporated into the valuation calculations. The key inputs used in the October 31, 2016 and July 31, 2016 fair value calculations were as follows:

	October 31, 2016	July 31, 2016
Current exercise price	$0.02	$0.02
Time to expiration	2.1 years	2.1 years
Risk-free interest rate	1 %	0.76 %
Estimated volatility	100 %	101 %
Dividend	—	—
Stock price at period end date	$0.01	$0.01

Fair Value Assumptions Used in Accounting for Derivative Additional Investment Rights Liability

The Company has determined the derivative additional investment rights liability to be a Level 2 fair value measurement and has used the binominal lattice pricing model to measure the fair value. The series F additional investment rights expired in March 2015. The series G additional investment rights expired in August 2016. As all additional investment rights have expired, their value at October 31, 2016 is nil (July 31, 2016 - $193,408)

The key inputs used in the fair value calculation at July 31, 2016 were as follows:

	July 31, 2016
Underlying number of units of convertible preferred stock	500
Underlying number of units of warrants	33,333,333
Current exercise price of warrants	$0.015
Current conversion price of preferred stock	$0.015
Time to expiration	0.05 years
Risk-free interest rate	0.38 %
Estimated volatility	13 %

Dividend	-0-
Stock price at period end date	$0.008

The revaluation of the additional investment rights in the three-month period ended October 31, 2016, resulted in the recognition of a gain of $193,408 and in the three-month period ended October 31, 2015, the revaluation resulted in the recognition of a loss of $154,063. The respective loss and gain are recorded within the Company's consolidated statements of comprehensive (loss) / income under the caption "Change in fair value of derivative liabilities".

Note 9 – Subsequent Events:

On August 26, 2016, the Company signed a Letter of Intent to acquire 51% of Hema Diagnostic Systems, LLC ("HDS") for consideration of $250,000 worth of the Company's restricted common stock. The number of stock issued for the transaction will be calculated based on the average over-the-counter closing price of the Company's common stock for the ten trading days immediately preceding the Closing Date. The Company will also issue, in consideration for the purchase, a warrant to acquire 15,000,000 shares of Generex common stock, at a per-share strike price equal to the over-the-counter closing price of the Company's stock on the date that the restricted common stocks were issued. It is the Company's intention to initiate a reverse stock-split following the acquisition of HDS. This acquisition of HDS has not been finalized as at the date of yet, and it is expected to finalize during the fiscal year 2017.

On December 27, 2016, the Company filed a Certificate of Amendment to effect a reverse stock split. Upon approval by the Financial Industry Regulatory Authority ("FINRA"), each 1,000 shares of the Corporation's common stock issued and outstanding at the effective time shall automatically be combined into one issued, fully paid and non-assessable share of common stock. This potential reverse stock-split has not been reflected in the share or per share amounts disclosed in these financial statements.

The Company has evaluated subsequent events occurring after the balance sheet date through the date the consolidated financial statements were issued.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

As used herein, the terms the “Company,” “Generex,” “we,” “us,” or “our” refer to Generex Biotechnology Corporation, a Delaware corporation. The following discussion and analysis by management provides information with respect to our financial condition and results of operations for the three month periods ended October 31, 2016 and 2015. This discussion should be read in conjunction with the information contained in *Part I, Item 1A - Risk Factors* and *Part II, Item 8 - Financial Statements and Supplementary Data* in our Annual Report on Form 10-K for the year ended July 31, 2016, as amended, and the information contained in *Part I, Item 1 - Financial Statements* and *Part II, Item 1A- Risk Factors* in this Quarterly Report on Form 10-Q for the fiscal quarter ended April 30, 2016.

Forward-Looking Statements

We have made statements in this *Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations* and elsewhere in this Quarterly Report on Form 10-Q of Generex Biotechnology Corporation for the fiscal quarter ended October 31, 2016 that may constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Act"). The Act limits our liability in any lawsuit based on forward-looking statements that we have made. All statements, other than statements of historical facts, included in this Quarterly Report that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. These statements can be identified by introductory words such as “may,” "expects," “anticipates,” "plans," "intends," "believes," "will," "estimates" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Our forward-looking statements address, among other things:

- our expectations concerning product candidates for our technologies;
- our expectations concerning existing or potential development and license agreements for third-party collaborations, acquisitions and joint ventures;
- our expectations of when different phases of clinical activity may commence and conclude;
- our expectations of when regulatory submissions may be filed or when regulatory approvals may be received; and
- our expectations of when commercial sales of our products may commence and when actual revenue from the product sales may be received.

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may differ materially from what is expressed or implied in our forward-looking statements. Among the factors that could affect future results are:

- the inherent uncertainties of product development based on our new and as yet not fully proven technologies;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when tested clinically;
- the inherent uncertainties associated with clinical trials of product candidates;
- the inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates;
- the inherent uncertainties associated with commercialization of products that have received regulatory approval;
- the further decline in our stock price;
- our ability to pay dividends on our recently issued preferred stock; and
- our current lack of financing for operations and our ability to obtain the necessary financing to fund our operations and effect our strategic development plan.

Additional factors that could affect future results are set forth in *Part I, Item 1A Risk Factors* of our Annual Report on Form 10-K for the year ended July 31, 2016, as amended, and in *Part II, Item 1A. Risk Factors* of this Quarterly Report on Form 10-Q. We caution investors that the forward-looking statements contained in this Quarterly Report must be interpreted and understood in light of conditions and circumstances that exist as of the date of this Quarterly Report. We expressly disclaim any obligation or undertaking to update or revise forward-looking statements to reflect any changes in management's expectations resulting from future events or changes in the conditions or circumstances upon which such expectations are based.

Executive Summary

Preliminary Note

As of October, 2015, (the first quarter of fiscal 2016), we laid off all of our employees, and ceased compensating our officers, and suspended substantially all of our operations due to lack of funds. The description below related to our historical business. If we do not receive substantial financing, we will need to completely shut down our operations

Overview of Business

We are engaged primarily in the research and development of drug delivery systems and technologies. Our primary focus at the present time is our proprietary technology for the administration of formulations of large molecule drugs to the oral (buccal) cavity using a hand-held aerosol applicator. Through our wholly-owned subsidiary, Antigen Express, Inc. ("Antigen"), we have undertaken work on immunomedicines incorporating proprietary vaccine formulations.

We believe that our buccal delivery technology is a platform technology that has application to many large molecule drugs and provides a convenient, non-invasive, accurate and cost-effective way to administer such drugs. We have identified several large molecule drugs as possible candidates for development, including estrogen, heparin, monoclonal antibodies, human growth hormone and fertility hormones, but to date have focused our development efforts primarily on one pharmaceutical product, Generex Oral-lyn™, an insulin formulation administered as a fine spray into the oral cavity using our proprietary hand-held aerosol spray applicator known as RapidMist™.

Our wholly-owned subsidiary, Antigen, concentrates on developing proprietary vaccine formulations that work by stimulating the immune system to either attack offending agents (i.e., cancer cells, bacteria, and viruses) or to stop attacking benign elements (i.e., self proteins and allergens). Our immunomedicine products are based on two platform technologies and are in the early stages of development. We have undertaken clinical development work in respect of Antigen's synthetic peptide vaccines designed to stimulate a potent and specific immune response against tumors expressing the HER-2/neu oncogene for patients with HER-2/neu positive breast cancer in a Phase II clinical trial and patients with prostate cancer and against avian influenza in two Phase I clinical trials. The synthetic vaccine technology has certain advantages for pandemic or potentially pandemic viruses, such as the H5N1 avian and H1N1 swine flu. In addition to developing vaccines for pandemic influenza viruses, we have undertaken vaccine development efforts for seasonal influenza virus, HIV, HPV, melanoma, ovarian cancer, allergy and Type I diabetes mellitus.

Financial Condition

We are a development stage company and do not expect sufficient revenues to support our operation in the immediately foreseeable future. To date, we have not been profitable and our accumulated net loss available to shareholders was $375,144,134 at October 31, 2016. As of October 31, 2016, our current cash position is not sufficient to meet our working capital needs for the next twelve months. As of that date, we had suspended most of our operations. To re-commence substantial operations, we will require additional funds to support our working capital requirements and any development activities, or will need to suspend operations completely. Management is seeking various alternatives to ensure that we can meet some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. In addition, management is actively seeking strategic alternatives, including strategic investments and divestitures. Management has sold non-essential real estate assets which were classified as Assets Held for Investment to augment its cash position. We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations.

Generex Oral-lyn™

Regulatory Approvals and Clinical Trials

To date, we have received regulatory approval in Ecuador, India (subject to marketing approval of in-country clinical study), Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™. No dossier related activities took place in any other countries during fiscal 2016 or the first quarter of fiscal 2017, nor are any expected during the remainder of fiscal 2017.

In March 2008, we initiated Phase III clinical trials for this product in the U.S. with the first patient screening for such trials at a clinical study site in Texas in April 2008. Approximately 450 patients have been enrolled to date at approximately 70 clinical sites around the world, including sites in the United States, Canada, Bulgaria, Poland, Romania, Russia, Ukraine and Ecuador. The first Oral-lyn™ global Phase III trial initiated in April 2008 had a final patient visit date in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn™ clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite meta-analysis of all safety data. We do not currently plan to expend significant resources on additional clinical trials of Oral-lyn™ until after such time that we secure additional financing.

Marketing

We have entered into licensing and distribution agreements with a number of multinational distributors to assist us with the process of gaining regulatory approval for the registration, marketing, distribution, and sale of Generex Oral-lyn™ in countries throughout the world. Under these licensing and distribution agreements, excluding one with Dong Sung Pharm Co. in South Korea, we may or may not receive an upfront license fee, but the distributor will bear any and all costs associated with the procurement of governmental approvals for the sale of Generex Oral-Lyn™, including any clinical and regulatory costs. We possess the worldwide marketing rights to our oral insulin product.

In India, a marketing plan has been submitted by Shreya Life Sciences Pvt. Ltd., to Generex on the marketing strategy for the distribution of Oral Recosulin™, the trademark under which Shreya will market Generex Oral-lyn™ within India. The marketing plan also includes post-approval marketing studies. Per the requirements of the regulatory approval in India, an in-country clinical study must be completed in India with Oral Recosulin™ before commercial sales can commence. The field portion of the study was completed in the third calendar quarter of 2012. The marketing acceptance dossier has been submitted to the Indian regulatory authority. Generex has provided additional, detailed

scientific data to support the Shreya submission. We have not recognized any revenues from the sale of Generex Oral-lyn™ in India through the first quarter of the 2016 fiscal year.

We do not currently plan to expend significant resources on additional clinical trials or to further the commercialization of Generex Oral-lyn™ until after such time that we secure additional financing.

Cancer and Immunotherapeutic Vaccine Platforms

Our wholly-owned subsidiary Antigen Express is developing proprietary vaccine formulations based upon two platform technologies that were discovered by its founder, the Ii-Key hybrid peptides and Ii-Suppression. These technologies are applicable for either antigen-specific immune stimulation or suppression, depending upon the dosing and formulation of its products. Using active stimulation, we are focusing on major diseases such as breast, prostate and ovarian cancer, melanoma, influenza (including H5N1 avian and H1N1 swine flu) and HIV. Autoimmune diseases such as diabetes and multiple sclerosis are the focus of our antigen-specific immune suppression work.

Antigen’s immunotherapeutic vaccine AE37 is currently in Phase II clinical trials for patients with HER-2/neu positive breast cancer. The trial is being conducted with the United States Military Cancer Institute's (USMCI) Clinical Trials Group and will examine the rate of relapse in patients with node-positive or high-risk node-negative breast cancer after two years. The study is randomized and will compare patients treated with AE37 plus the adjuvant GM-CSF versus GM-CSF alone. The Phase II trial follows a Phase I trial that demonstrated safety, tolerability, and immune stimulation of the AE37 vaccine in breast cancer patients.

Based on positive results in trials of the AE37 vaccine in breast cancer patients, we entered into an agreement in August 2006 with the Euroclinic, a private center in Athens, Greece, to commence clinical trials with the same compound as an immunotherapeutic vaccine for prostate cancer. A Phase I trial involving 29 patients was completed in August 2009, which similarly showed safety, tolerability and induction of a specific immune response. Agreements, as well as a protocol, are in place for initiation of a Phase II clinical trial once additional funding is available.

The same technology used to enhance immunogenicity is being applied in the development of a synthetic peptide vaccine for H5N1 avian influenza and the 2009 H1N1 swine flu. In April 2007, a Phase I clinical trial of Antigen’s proprietary peptides derived from the hemagglutinin protein of the H5N1 avian influenza virus was initiated in healthy volunteers in the Lebanese-Canadian Hospital in Beirut, Lebanon. We have completed the first portion of the Phase I trial. Modified peptide vaccines for avian influenza offer several advantages over traditional egg-based or cell-culture based vaccines. Modified peptide vaccines can be manufactured by an entirely synthetic process which reduces cost and increases both the speed and quantity of vaccine relative to egg- or cell-culture based vaccines. Another advantage is that the peptides are derived from regions of the virus that are similar enough in all H5N1 and H1N1 virus strains such that they would not have to be newly designed for the specific strain to emerge in a pandemic.

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A Physician's Investigational New Drug ("IND") application for the Phase I and Phase II trials in patients with stage II HER-2/neu positive breast cancer has been filed with the FDA. The Phase I trial was completed at the Walter Reed Army Medical Center in Washington, D.C., and the Phase II trial is taking place at 13 sites, including 11 in the U.S., one in Germany and one in Greece. A Physician's Investigational New Drug application for a Phase I trial in patients with breast or ovarian cancer also has been filed with the FDA and this Phase I trial is being conducted in Dallas, Texas at the Mary Crowley Cancer Center. Applications were filed and approvals obtained for a Phase I prostate cancer trial using AE37 in Athens, Greece from the Hellenic Organization of Drugs, and this Phase I trial was completed in August 2009. The Ministry of Health in Lebanon gave approval for Phase I trial of our experimental H5N1 prophylactic vaccine in Beirut, Lebanon following submission of an application. All other immunomedicine products are in the pre-clinical stage of development.

Competition

We face competition from other providers of alternate forms of insulin. Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, have announced that they will discontinue development and/or sale of their inhalable forms of insulin. Generex Oral-lyn™ is not an inhaled insulin; rather, it is a buccally absorbed formulation with no residual pulmonary deposition. We believe that our buccal delivery technology offers several advantages, including the ease of use, portability, avoidance of pulmonary inhalation and safety profile. Furthermore, insulin administered through the Generex Oral-lyn™ RapidMist™ technology is absorbed directly into the blood stream and not only acts rapidly, but returns to baseline quickly, thereby minimizing the chance of developing hypoglycemia.

In May 2009, MannKind Corporation submitted an NDA to the FDA requesting approval to market AFREZZA ® (insulin human [rDNA origin]) Inhalation Powder, for the treatment of adult patients with Type 1 and Type 2 diabetes for the control of hyperglycemia. In January 2011, MannKind announced that it had received a complete response letter from the FDA for AFREZZA ® . In August 2011, MannKind announced that it has confirmed with the FDA the design of the two additional clinical studies which are required for AFREZZA ® .. In August 2013, MannKind announced positive late-stage data on its inhaled insulin AFREZZA® from the two additional Phase III studies on Type 1 and Type 2diabetes and has resubmitted a new drug application to the FDA in October 2013 seeking approval for the marketing of AFREZZA ® .. Mannkind received FDA approval in June 2014 and this product is now commercially available in the United States. In addition to other delivery systems for insulin, there are numerous products, such as sulfonylureas (Amaryl®and Glynase®), biguanides (branded and generic metformin products), thiazolidinediones (Avandia®and Actos®), glucagon-like peptide 1 (Byetta®and Victoza®), and dipeptidyl peptidase IV inhibitors (Januvia® and Onglyza™), which have been approved for use in the treatment of Type 2 diabetics in substitution of, or in addition to, insulin therapy. These products may also be considered competitive with insulin products.

Large pharmaceutical companies, such as Merck & Co., Inc., GlaxoSmithKline PLC, Novartis, Inc., MedImmune Inc. (a subsidiary of Astra-Zeneca, Inc.) and others, also compete against us in the oncology, immunomedicine and vaccine markets. These companies have competing experience and expertise in securing government contracts and grants to support research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, as well as manufacturing and marketing approved products. As such, they are also

considered significant competitors in these fields of pharmaceutical products and therapies. There are also many smaller companies which are pursuing similar technologies in these fields who are considered to be competitors of Generex.

Brief Company Background

We are a development stage company. From inception through the end of the quarter ended October 31, 2016, we have received only limited revenues from operations. We did not have any revenue for the three months ended October 31, 2016 or in the fiscal year ended July 31, 2016

We operate in only one segment: the research and development of drug delivery systems and technologies for metabolic and immunological diseases.

We were incorporated in the State of Delaware in 1997. Our principal executive offices are located at 4145 North Service Road, Suite 200, Burlington, Ontario, Canada, and our telephone number at that address is (416) 364-2551. We maintain an Internet website at *www.generex.com* . We make available free of charge on or through our website our filings with the SEC.

Accounting for Research and Development Projects

Our major research and development projects are the refinement of our platform buccal delivery technology, our buccal insulin project (Generex Oral-lyn™) and Antigen's peptide immunotherapeutic vaccines.

Due to lack of funds, we did not expend any resources on research and development in the first quarter of fiscal 2017. Previously, we expended resources on the clinical testing and results analysis of our buccal insulin product, Generex Oral-lyn™. In July 2007, we received no objection from the FDA to proceed with our long-term multi-center Phase III study protocol for Generex Oral-lyn™. The first Oral-lyn global Phase III trial initiated in April 2008 had a final patient visit date in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite meta-analysis of all safety data. The completion of late-stage trials in Canada and the United States will require significantly greater funds than we currently have on hand. We do not currently plan to expend significant resources on additional clinical trials of Oral-lyn™ until after such time that we secure additional financing.

Previously, ,we expended resources on research and development relating to Antigen's peptide immunotherapeutic vaccines and related technologies. Antigen has one vaccine currently in Phase II clinical trials in the United States involving patients with HER-2/neu positive breast cancer and has completed a Phase I clinical trial for a vaccine for H5N1 avian influenza at the Lebanese-Canadian Hospital in Beirut. Antigen's prostate cancer vaccine based on AE37 has been tested in a completed (August 2009) Phase I clinical trial in Greece.

Because of various uncertainties, we cannot predict the timing of completion and commercialization of our buccal insulin in all jurisdictions or Antigen's peptide immunotherapeutic vaccines or related technologies. These uncertainties include the success of current studies, our ability to obtain the required financing and the time required to obtain regulatory approval even if our research and development efforts are completed and successful, our ability to enter into collaborative marketing and distribution agreements with third-parties, and the success of such marketing and distribution arrangements. For the same reasons, we cannot predict when any products may begin to produce net cash inflows.

Most of our buccal delivery research and development activities to date have involved developing our platform technology for use with insulin. Insubstantial amounts have been expended on projects with other drugs, including morphine and fentanyl, and those projects involved a substantial amount of platform technology development. As a result, we have not made significant distinctions in the accounting for research and development expenses among products, as a significant portion of all research has involved improvements to the platform technology in connection with insulin, which may benefit all of our potential buccal products.

We did not expend any resources on research and development in the first quarter of fiscal 2017. Previously, in accounting for research and development of Antigen's products, because these products are in initial phases of clinical trials or early, pre-clinical stage of development (with the exception of the Phase II clinical trials of Antigen HER-2/neu positive breast cancer vaccine that are underway), all of the expenses were accounted for as basic research

and no distinctions were made as to particular products. Due to the early stage of development, we cannot predict the timing of completion of any products arising from this technology, or when products from this technology might begin producing revenues.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our interim consolidated financial statements which have been prepared in conformity with accounting principles generally accepted in the United States of America for interim financial statements. These principles require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We consider certain accounting policies related to impairment of long-lived assets, intangible assets and accrued liabilities to be critical to our business operations and the understanding of our results of operations:

Going Concern. As shown in the consolidated interim financial statements, we have not been profitable and have reported recurring losses from operations. These factors raise substantial doubt about our ability to continue to operate in the normal course of business. The consolidated interim financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Impairment of Long-Lived Assets. Management reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable under the provisions of accounting for the impairment of long-lived assets. If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Statement of Operations. As of October 31, 2016, there were no indications of any impairments of our long-lived assets.

Intangible Assets . We have intangible assets related to patents. The determination of the related estimated useful lives and whether or not these assets are impaired involves significant judgments. In assessing the recoverability of these intangible assets, we use an estimate of undiscounted operating income and related cash flows over the remaining useful life, market conditions and other factors to determine the recoverability of the asset. If these estimates or their related assumptions change in the future, we may be required to record impairment charges against these assets. All of the Company’s patents had been written down in the fiscal year ended July 31, 2016.

Estimating accrued liabilities, specifically litigation accruals . Management's current estimated range of liabilities related to pending litigation is based on management's best estimate of future costs. While the final resolution of the

litigation could result in amounts different than current accruals, and therefore have an impact on our consolidated financial results in a future reporting period, management believes the ultimate outcome will not have a significant effect on our consolidated results of operations, financial position or cash flows.

Share-based compensation. Management determines value of stock-based compensation to employees in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, Compensation – Stock Compensation. Management determines value of stock-based compensation to non-employees and consultants in accordance with and ASC 505, Equity-Based Payments to Non-Employees.

Derivative liabilities . FASB ASC 815, Derivatives and Hedging, requires all derivatives to be recorded on the balance sheet at fair value for fiscal years beginning after December 15, 2008. As a result, certain derivative warrant liabilities are now separately valued as of August 1, 2009 and accounted for on our balance sheet, with any changes in fair value recorded in earnings. For our balance sheets as of April 30, 2016 and July 31, 2015, we used the binomial lattice model to estimate the fair value of these derivative liabilities. Key assumptions of the binomial lattice option-pricing model include the market price of our stock, the exercise price of the warrants, applicable volatility rates, risk-free interest rates, expected dividends and the instrument's remaining term. These assumptions require significant management judgment. In addition, changes in any of these variables during a period can result in material changes in the fair value (and resultant gains or losses) of this derivative instrument.

Results of Operations

Three months ended October 31, 2016 compared to three months ended October 31, 2015

We had a net income for the quarter ended October 31, 2016 in the amount of $560,238 versus net loss of $1,731,265 in the corresponding quarter of the prior fiscal year. The income in this year's fiscal quarter was attributable to a gain due to the change in fair value of the derivative liabilities of $779,895. In the first quarter of the prior year. We had a loss from the change in fair value of derivative liabilities of $315,963. Our operating loss for the quarter ended October 31, 2016 decreased to $102,818 compared to $1,317,579 in the same fiscal quarter of fiscal 2015. The decrease in operating loss resulted from a decrease in general and administrative expenses (to $102,818 from $1,140,009) and a decrease in research and development expenses (to $0 from $177,570). The decrease in expenses was due to the suspension of most of our operations due to lack of funds. We did not have revenue in either of the quarters ended October 31, 2016 or 2015.

Our interest expense in the first quarter of fiscal 2017 was $116,839 compared to the previous year's fiscal quarter at $97,723.

Financial Condition, Liquidity and Resources

Sources of Liquidity

To date we have financed our development stage activities primarily through private placements of our common stock and securities convertible into our common stock.

As of October 31, 2016, our current cash position is not sufficient to meet our working capital needs for the next twelve months. We have been required to lay-off all of our employees, and our officers ceased receiving compensation as of October, 2015. Therefore, we will require additional funds to support our working capital requirements and any development or other activities

While we have financed our development stage activities to date primarily through private placements of our common stock and securities convertible into our common stock and raised approximately $534,000 million during fiscal 2016 and 2015 (including proceeds from warrant exercises, short term loans and the issuance of preferred stock), our cash balances have been low throughout fiscal 2016 and during the fiscal quarter ended October 31, 2016.

Our stockholders approved a reverse split proposal at our annual general meeting held on August 19, 2015, which approval allows the Board to implement a reverse split in its discretion at any time prior to December 31, 2016 and is not contingent upon listing our common stock on a national stock exchange. However, the terms of the securities purchase agreements that we entered into on January 14, 2014, March 27, 2014 and June 24, 2015 prohibit us from undertaking a reverse or forward stock split or reclassification of our common stock without the consent of the purchasers of the securities, except for a reverse stock split made in conjunction with a listing of the common stock on a national securities exchange.

Management may seek to meet all or some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities.

Upon the filing of our Annual Report on Form 10-K on October 14, 2011, we were no longer eligible to use Form S-3 to register shares sold to investors, as the aggregate market value of our outstanding voting and non-voting common equity held by non-affiliates was less than $75 million. As we are required under the registration rights agreements that we entered into on January 31, 2012, August 8, 2012, December 10, 2012, June 17, 2013, January 14, 2014, March 27, 2014 and June 24, 2015 with certain investors to register shares of our common stock issuable upon conversion or exercise of the securities purchased by the investors, we filed the respective registration statements on Form S-1. We incurred additional legal and accounting fees in connection with the preparation of these Form S-1 registration statements.

In addition, management is actively pursuing financial and strategic alternatives, including strategic investments and divestitures, industry collaboration activities, and potential strategic partners. Management has sold non-essential real estate assets which are classified as Assets Held for Investment to augment the company’s cash position and reduce its long-term debt.

We will continue to require substantial funds to continue research and development, including preclinical studies and clinical trials of our product candidates, further clinical trials for Oral-lyn™ and to commence sales and marketing efforts if the FDA or other regulatory approvals are obtained.We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. We have suspended most of our operations due to lack of capital. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations completely.

Equity Financings

We did not engage in any equity financing during fiscal 2016 or fiscal 2017 to date.

Proceeds from Warrant Exercises

We may receive additional proceeds from the exercise of warrants issued in February 2012, August 2012, December 2012, June 2013, January 2014, March 2014 and June 2015 in connection with the issuance of the Series C 9% Convertible Preferred Stock, Series D 9% Convertible Preferred Stock, Series E 9% Convertible Preferred Stock, Series F 9% Convertible Preferred Stock and Series G 9% Convertible Preferred Stock, although some of the warrants include a cashless exercise feature.

- In connection with the securities purchase agreement dated August 8, 2012, we sold an aggregate of 750 shares of our Series C 9% Convertible Preferred Stock and issued warrants exercisable for up to 9,375,000 shares of our common stock to investors.

- In connection with the securities purchase agreement dated December 10, 2012, we sold an aggregate of 750 shares of our Series D 9% Convertible Preferred Stock and issued warrants exercisable for up to 24,999,999 shares of our common stock to investors.

- In connection with the securities purchase agreement dated June 17, 2013, we sold an aggregate of 1,225 shares of our Series E 9% Convertible Preferred Stock and issued warrants exercisable for up to 40,833,335 shares of our common stock to investors.

- In connection with the securities purchase agreement dated January 14, 2014, we sold an aggregate of 800 shares of our Series E 9% Convertible Preferred Stock and issued warrants exercisable for up to 26,666,668 shares of our common stock to investors.

- In connection with the securities purchase agreement dated March 27, 2014, we sold an aggregate of 2,075 shares of our Series F 9% Convertible Preferred Stock and issued warrants exercisable for up to 69,166,667 shares of our common stock to investors.

- In connection with the securities purchase agreement dated June 24, 2015, we sold an aggregate of 500 shares of our Series G 9% Convertible Preferred Stock and issued warrants exercisable for up to 33,333,333 shares of our common stock to investors.

As of April 30, 2016, all of the warrants issued in the aforementioned registered direct offerings were exercisable. At April 30, 2016, outstanding warrants issued in connection with the February 2012, August 2012, December 2012, June 2013, January 2014, March 2014 and June 2015 private placements were as follows (after adjustment for anti-dilution provisions and subsequent exercises):

Date Issued	*Aggregate No. of Shares Unexercised*	*Exercise Price*	*Expiration Date*
February 1, 2012*	11,350,454	$ 0.015	February 1, 2017
August 10, 2012*	9,999,998	0.015	August 10, 2017
December 10, 2012*	16,648,288	0.015	December 12, 2017
June 17, 2013*	68,333,338	0.015	June 17, 2018
January 15, 2014*	51,333,336	0.015	January 15, 2019
March 27, 2014*	138,333,334	0.015	March 27, 2019
June 25, 2015*	33,333,333	0.015	June 25, 2020

**Upon issuance of securities at a price per share of common stock less than the then applicable exercise price, the warrants are subject to anti-dilution adjustment of the exercise price and to the number of shares of common stock that may be purchased upon exercise of each warrant such that the aggregate exercise price payable upon exercise of the warrant will be the same as the aggregate exercise price in effect immediately prior to such adjustment. Due to the anti-dilution adjustment provision of these warrants, they have been reclassified on Generex's balance sheet as a liability under the caption "Derivative Warrant Liability" with any changes in fair value at each reporting period recorded in earnings in accordance with ASC 815.*

Cash Flows for the Three months ended October 31, 2016

For the three months ended October 31, 2016, we used $10,372 in cash to fund our operating activities. The use for operating activities included a net loss of $560,238, changes to working capital including an increase of $211,546 related to accounts payable and accrued expenses, offset by a increase related to other current assets of $3,537.

We had no cash provided by financing activities in the three months ended October 31, 2016.

Our net working capital deficiency at April 30, 2016 increased to $9,187.079 from $8,975,894 at July 31, 2016.

Conversion of Outstanding Series A, Series B, Series C, Series D, Series E and Series F 9% Convertible Preferred Stock

As of October 31, 2016, all of the 2,575 shares of our Series A 9% Convertible Preferred Stock had been converted into shares of our common stock. A total of 17,166,666 shares of common stock have been issued upon the conversion of 2,575 shares of Series A convertible preferred stock. Upon conversion, we paid the holders of the Series A convertible preferred stock a “make whole” payment equal to $270 per $1,000 of stated value of the Series A convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. We issued 6,129,666 additional shares of common stock on such conversions of the Series A convertible preferred stock as “make-whole payments”.

As of October 31, 2016, all of the 2,000 shares of our Series B 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 38,520,832 shares of common stock upon the conversion of the Series B convertible preferred stock and an additional 14,819,679 shares of common stock were issued as “make-whole payments” on such conversions.

As of October 31, 2016, all of the 750 shares of our Series C 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 22,916,665 shares of common stock upon the conversion of the Series C convertible preferred stock and an additional 6,664,863 shares of common stock were issued as “make-whole payments” on such conversions.

As of October 31, 2016, all of the 750 shares of our Series D 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 24,999,999 shares of common stock upon the conversion of the Series D convertible preferred stock and an additional 7,825,191 shares of common stock were issued as “make-whole payments” on such conversions.

As of October 31, 2016, all of the 2,025 shares of our Series E 9% Convertible Preferred Stock had been converted into shares of our common stock. We issued 68,333,333 shares of common stock upon the conversion of the Series E convertible preferred stock and an additional 19,035,193 shares of common stock were issued as “make-whole payments” on such conversions.

As of October 31, 2016, 1,905 shares of the Series F convertible preferred stock had been converted to common stock. There were 85,774,998 shares of common stock issued upon the conversion of the Series F convertible preferred stock and 34,658,878 shares of common stock issued as “make-whole payments” on such conversions.

As of April 30, 2016, no shares of our Series G 9% Convertible Preferred Stock had been converted into shares of our common stock.

Funding Requirements and Commitments

If we obtain necessary financing, we expect to devote substantial resources to obtaining regulatory approval of Generex Oral-lyn™ in the U.S., Canada and Europe and to commercializing Generex Oral-lyn™. We may also devote resources to obtaining approval for the importation, marketing and commercialization of Generex Oral-lyn™ in other countries where we have licensed distributors.

In addition to the resources that we will dedicate to regulatory approval and commercialization of Generex Oral-lyn™, we will expend resources on further clinical development of our immunotherapeutic vaccines.

Our future funding requirements and commitments and our ability to raise additional capital will depend on factors that include:

- the timing and amount of expense incurred to complete our clinical trials;
- the costs and timing of the regulatory process as we seek approval of our products in development;
- the advancement of our products in development;
-

our ability to generate new relationships with industry partners throughout the world that will provide us with regulatory assistance and long-term commercialization opportunities;

- the timing, receipt and amount of sales, if any, from Generex Oral-lyn™ in India, Lebanon, Algeria and Ecuador;
- the cost of manufacturing (paid to third parties) of our licensed products, and the cost of marketing and sales activities of those products;
- the costs of prosecuting, maintaining, and enforcing patent claims, if any claims are made;
- our ability to maintain existing collaborative relationships and establish new relationships as we advance our products in development;
- our ability to obtain the necessary financing to fund our operations and effect our strategic development plan; and
- the receptivity of the financial market to biopharmaceutical companies.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors, and we do not have any non-consolidated special purpose entities.

Certain Related Party Transactions

See *Part III, Item 13 – Certain Relationships and Related Transactions, and Directors Independence* in our Annual Report on Form 10-K for the year ended July 31, 2016, for further descriptions of our transactions with related parties during the last fiscal year.

Recently Adopted Accounting Pronouncements

None

Recently Issued Accounting Pronouncements

In November 2014, the FASB issued guidance regarding *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity.* The guidance became effective this quarter. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

In August 2014, the FASB issued guidance regarding disclosure of uncertainties about an entity's ability to continue as a going concern. The guidance became effective this quarter. The Company has determined that this accounting standard has no impact on its consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Generex is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management did not evaluate of the effectiveness of Generex's disclosure controls and procedure prior to the filing of this Quarterly Report.

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended October 31, 2016, there were no changes in Generex's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, Generex's internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

See *Note 5 – Commitments and Contingencies (Pending Litigation)* of the Notes to the Consolidated Financial Statements set forth under Item 1 of Part I of this Quarterly Report for a description of legal proceedings in which we are currently involved.

We are involved in certain other legal proceedings in addition to those specifically described in this Quarterly Report. Subject to the uncertainty inherent in all litigation, we do not believe at the present time that the resolution of any of these legal proceedings is likely to have a material adverse effect on our financial position, operations or cash flows.

With respect to all litigation matters, as additional information concerning the estimates used by us becomes known, we reassess each matter's position both with respect to accrued liabilities and other potential exposures.

Item 1A. Risk Factors.

In addition to the other information included in this Quarterly Report on Form 10-Q, you should carefully review and consider the factors discussed in *Part I, Item 1A - Risk Factors* of our Annual Report on Form 10-K for the year ended July 31, 2016, as amended, certain of which have been updated below. These factors materially affect our business, financial condition or future results of operations. The risks, uncertainties and other factors described in our Annual Report on Form 10-K and below are not the only ones facing our company. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations, financial condition or operating results. Any of the risks, uncertainties and other factors could cause the trading price of our common stock to decline substantially.

Risks Related to Our Financial Condition

We will require additional financing to continue our operations.

As of October 31, 2016, our current cash position is not sufficient to meet our working capital needs for the next twelve months and we have substantially suspended operations. To re-commence operations, we will require additional funds to support our working capital requirements and any expansion or other activities, or will need to cease operations completely. Management is seeking various alternatives to ensure that we can meet some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. In addition, management is actively seeking strategic alternatives, including strategic investments and divestitures. Management has sold non-essential real estate assets which were classified as Assets Held for Investment to augment its cash position.

We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations completely.

We have a history of losses and will incur additional losses.

We are a development stage company with a limited history of operations, and do not expect sufficient revenues to support our operation in the immediately foreseeable future. We do not expect to receive significant revenues in Ecuador, Algeria and Lebanon where we have been approved for commercial sale in the next twelve months. While we have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor, we do not anticipate recognizing significant revenue from sales of Generex Oral-lyn™ in India in the next twelve months, as our Indian partner has to receive marketing approval of a completed in-country clinical study before the product can be offered for commercial sale in India.

To date, we have not been profitable and our accumulated net loss available to shareholders was $375,144,134 at October 31, 2016. Our losses have resulted principally from costs incurred in research and development, including clinical trials, and from general and administrative costs associated with our operations. While we seek to attain profitability, we cannot be sure that we will ever achieve product and other revenue sufficient for us to attain this

objective.

With the exception of Generex Oral-lyn™, which has received regulatory approval in Ecuador, India (subject to marketing approval of an in-country clinical study), Lebanon and Algeria, our product candidates are in research or early stages of pre-clinical and clinical development. We will need to conduct substantial additional research, development and clinical trials. We will also need to receive necessary regulatory clearances both in the United States and foreign countries and obtain meaningful patent protection for and establish freedom to commercialize each of our product candidates. We must also complete further clinical trials and seek regulatory approvals for Generex Oral-lyn™ in countries outside of Ecuador, India, Lebanon and Algeria. We cannot be sure that we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future.

Our independent auditors have expressed substantial doubt about our ability to continue as a going concern as of July 31, 2016.

To date, we have not been profitable and our accumulated net loss available to shareholders was $375,144,134 at April October 31, 2016, and our consolidated balance sheet reflected a stockholders' deficiency of 10,649,438 at that date. We received a report from our independent auditors for the year ended July 31, 2015 that included an explanatory paragraph describing an uncertainty as to Generex's ability to continue as a going concern. We must secure financing to continue our operations.

Due to material weaknesses in our internal controls over financial reporting, our internal controls were determined not to be effective for the prior fiscal year ended July 31, 2012. Our disclosure controls and procedures and internal controls over financial reporting may not be effective in future periods as a result of existing or newly identified material weaknesses in internal controls.

Effective internal controls are necessary for us to provide reasonable assurance with respect to our financial reports and to effectively prevent fraud. If we cannot provide reasonable assurance with respect to our financial reports and effectively prevent fraud, our reputation and operating results could be harmed. Pursuant to the Sarbanes-Oxley Act of 2002, we are required to furnish a report by management on internal control over financial reporting, including management's assessment of the effectiveness of such control. Internal control over financial reporting may not prevent or detect misstatements because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud. Therefore, even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. If we fail to maintain the adequacy of our internal controls, including any failure to implement required new or improved controls, or if we experience difficulties in their implementation, our business and operating results could be adversely impacted, we could fail to meet our reporting obligations, and our business and stock price could be adversely affected.

At July 31, 2012, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) and concluded that, subject to the inherent limitations identified in Item 9A of Part II of the Form 10-K filed on October 15, 2012, our disclosure controls and procedures were not effective due to the existence of material weaknesses in our internal control over financial reporting because of inadequate segregation of duties over authorization, review and recording of transactions, as well as the financial reporting of such transactions. Our independent auditors issued an adverse attestation report regarding the effectiveness of the Company's internal control over financial reporting at July 31, 2012.

We believe we have taken appropriate and reasonable steps to make the necessary improvements to remediate these deficiencies, however we cannot be certain that our remediation efforts will ensure that our management designs, implements and maintains adequate controls over our financial processes and reporting in the future or that the changes made will be sufficient to address and eliminate the material weaknesses previously identified. Our inability to remedy any additional deficiencies or material weaknesses that may be identified in the future could, among other things, have a material adverse effect on our business, results of operations and financial condition, as well as impair our ability to meet our quarterly, annual and other reporting requirements under the Securities Exchange Act of 1934 in a timely manner, and require us to incur additional costs or to divert management resources.

Risks Related to the Market for Our Common Stock

Our stock price is below $5.00 per share and is treated as a "penny stock", which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as "penny stock" under the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act, and the rules promulgated thereunder. The SEC has adopted regulations that define "penny stock" to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements:

- broker-dealers must deliver, prior to the transaction a disclosure schedule prepared by the SEC relating to the penny stock market;
- broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative;
- broker-dealers must disclose current quotations for the securities;
- if a broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealers presumed control over the market; and
- a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares.

Because we were delinquent in our SEC filings, we have been removed from the OTCQB.

We did not timely file this Quaretrly Report or our Annual Report for the year ended July 31, 2016, and therefore our common stock is no longer quoted on the OTCQB. Since being removed from the OTCQB, quotes for our common stock have only appeared on the OTCPINK, with a notation that we have not provided current information. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares, and the liquidity of the market for our shares may be greatly reduced.

The price of our common stock may be affected by a limited trading volume, may fluctuate significantly and may not reflect the actual value of our business.

There may be a limited public market for our common stock on the over the counter bulletin board market, and there can be no assurance that an active trading market will continue. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock in short time periods, or at all. Our common stock has experienced, and is likely to experience in the future, significant price and volume fluctuations that could adversely affect the market price of our common stock without regard to our operating performance. In addition, we believe that factors, such as our sale of securities in connection with capital raising activities, changes in the overall economy and the volatility of the financial markets, could cause the price of our common stock to fluctuate substantially. Thus, the price at which shares of our common stock may trade from time to time may not reflect the actual value of our business or the actual value of our common stock.

Our recent equity financing will dilute current stockholders and could prevent the acquisition or sale of our business.

The equity financing transactions into which we have recently entered have and will dilute current stockholders. At October 31, 2016, there were _299,332,081shares of common stock issuable upon exercise of the warrants that we issued the registered direct offerings in February 2012, August 2012, December 2012, June 2013, January 2014, March 2014 and June 2015. In addition, in connection with the private placements that closed on June 17, 2013, March 27, 2014 and June 24, 2015, an additional 65,000,000 shares of common stock are issuable upon conversion of the remaining Series F and G 9% Convertible Preferred Stock at April 30, 2016. Together the shares of common stock issuable upon exercise or conversion of the above-mentioned warrants and preferred stock represent approximately 66% of the shares of common stock outstanding at October 31, 2016. Assuming the holders of the warrants convert and exercise all of the warrants into shares of common stock, the number of shares of issued and outstanding common stock will increase significantly, and current stockholders will own a smaller percentage of the outstanding common stock of Generex. The issuance of shares of common stock pursuant to the warrants will also have a dilutive effect on earnings per share and may adversely affect the market price of the common stock.

In addition, the issuance of shares of common stock upon exercise of the warrants issued in the March 2008 private placement and the private placements in February 2012, August 2012, December 2012, June 2013, January 2014, March 2014 and June 2015, could have an anti-takeover effect because such issuance will make it more difficult for, or discourage an attempt by, a party to obtain control of Generex by tender offer or other means. The issuance of common stock upon the exercise of the warrants or conversion of convertible preferred stock will increase the number of shares entitled to vote, increase the number of votes required to approve a change of control of the company, and dilute the interest of a party attempting to obtain control of the company.

If we raise funds through one or more additional equity financings in the future, it will have a further dilutive effect on existing holders of our shares by reducing their percentage ownership. The shares may be sold at a time when the market price is low because we are in need of the funds. This will dilute existing holders more than if our stock price was higher. In addition, equity financings normally involve shares sold at a discount to the current market price. Most of our outstanding warrants have price protection provisions, which decrease the exercise price of the warrant and increase the number of shares which may be purchased upon exercise of the warrants, if we sell additional equity at an effective price per common share less than the current exercise price of the warrant. Therefore, equity financings at a low price per share will result in even more dilution to existing shareholders.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

In the fiscal quarter ended October 31, 2016, we did not sell, or enter into commitments to issue, common stock and other securities in transactions in reliance upon exemptions from the registration requirements of the Securities Act **.**

Issuer Purchases of Equity Securities

Neither Generex nor any affiliated purchaser (as defined in Section 240.10 b-18(a)(3) of the Exchange Act) purchased any of its equity securities during the fiscal quarter ended April 30, 2016.

Item 3. Defaults Upon Senior Securities.

None.

Item 5. Other Information.

Reference is made to the disclosure set forth under *Part II, Item 2 - Unregistered Sales of Equity Securities and Use of Proceeds* under the caption *Unregistered Sales of Equity Securities* in this Quarterly Report on Form 10-Q, which is incorporated by reference herein.

Item 6. Exhibits.

Exhibits are incorporated herein by reference or are filed with this quarterly report as set forth in the Exhibit Index beginning on page 33 hereof.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GENEREX BIOTECHNOLOGY CORPORATION
(Registrant)

Date: January 17, 2017 By: /s/ Mark A. Fletcher
Mark A. Fletcher
President and Chief Executive Officer and Principal Financial Officer

Date: January 17, 2017 By: /s/ David Brusegard
David Brusegard
Chief Operating Officer

EXHIBIT INDEX

Exhibit Number	Description of Exhibit [1]
1	Amendment dated as of April 7, 2010 to Placement Agent Agreement Placement Agency Agreement, dated June 8, 2009, by and between Generex Biotechnology Corporation and Midtown Partners & Co., LLC and amendments dated August 5, August 18, and September 11, 2009 (incorporated by reference to Exhibit 1.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on April 8, 2010)
2	Agreement and Plan of Merger among Generex Biotechnology Corporation, Antigen Express, Inc. and AGEXP Acquisition Inc. (incorporated by reference to Exhibit 2.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 15, 2003)
3(i)(a)	Restated Certificate of Incorporation of Generex Biotechnology Corporation (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Post-Effective Amendment No. 1 to the Registration Statement on Form S-8 filed on October 26, 2009)
3(i)(b)	Certificate of Designation of Preferences, Rights and Limitations of Series A 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
3(i)(c)	Certificate of Designation of Preferences, Rights and Limitations of Series B 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on February 1, 2012)
3(i)(d)	Certificate of Designation of Preferences, Rights and Limitations of Series C 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 8, 2012).
3(i)(e)	Certificate of Designation of Preferences, Rights and Limitations of Series D 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on December 11, 2012)

3(i)(f)	Certificate of Amendment to Restated Certificate of Incorporation of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3(i)(f) to Generex Biotechnology Corporation's Current Report on Registration Statement on Form S-1 (File No. 333-187656) filed on April 1, 2013)
3(i)(g)	Certificate of Designation of Preferences, Rights and Limitations of Series E 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on June 17, 2013)
3(i)(h)	Certificate of Designation of Preferences, Rights and Limitations of Series F 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on March 28, 2014)
3(i)(i)	Certificate of Designation of Preferences, Rights and Limitations of Series G 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on June 25, 2015)
3(ii)	Amended and Restated By-Laws of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3.2(ii) to Generex Biotechnology Corporation's Report on Form 8-K filed December 5, 2007)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Registration Statement on Form S-1 (File No. 333-82667) filed on July 12, 1999)
4.2.1	Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.2	Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.3	Form of Warrant granted to Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.3	

	Form of replacement Warrant issued to warrant holders exercising at reduced exercise price in May and June 2003 (incorporated by reference to Exhibit 4.13.7 to Generex Biotechnology Corporation's Report on Form 10-K for the period ended July 31, 2003 filed on October 29, 2003)
4.4.1	Securities Purchase Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.2	Registration Rights Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.3	Form of Warrant issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.4	Form of Additional Investment Right issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.5.1	Securities Purchase Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.2	Registration Rights Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.3	Warrant issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.4	Additional Investment Right issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.1	Securities Purchase Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.2	Registration Rights Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.3	Warrant issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.4	Additional Investment Right issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.1	Securities Purchase Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.2	

	Registration Rights Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.10 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.3	Warrant issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.11 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.4	Additional Investment Right issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.12 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.5	Escrow Agreement, dated February 26, 2004, by and among Generex Biotechnology Corporation, Eckert Seamans Cherin & Mellott, LLC and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.13 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.1	Securities Purchase Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.14 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.2	Registration Rights Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.15 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.3	Additional Investment Right issued in connection with Exhibit 4.8.1 (incorporated by reference to Exhibit 4.17 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.1	Securities Purchase Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.18 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.2	Registration Rights Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.19 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.3	Warrant issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.4	Additional Investment Right issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.21 Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.10.1	Securities Purchase Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.2	Registration Rights Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.3	Form of Warrant issued in connection with Exhibit 4.10.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.4	

	Form of Additional Investment Right issued in connection Exhibit 4.10.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.11.1	Securities Purchase Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.2	Form of 6% Secured Convertible Debenture issued in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.3	Registration Rights Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.4	Form of Voting Agreement entered into in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.12	Warrant issued to The Aethena Group, LLC on April 28, 2005 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)
4.13.1	Amendment No. 4 to Securities Purchase Agreement and Registration Rights Agreement entered into by and between Generex Biotechnology Corporation and the Purchasers listed on the signature pages thereto on January 19, 2006 (incorporated by reference herein to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
4.13.2	Form of Additional AIRs issued in connection with Exhibit 4.13.1 (incorporated by reference herein to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
4.14	Form of Warrant issued by Generex Biotechnology Corporation on January 23, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 24, 2006)
4.15.1	Agreement to Amend Warrants between Generex Biotechnology Corporation and Cranshire Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.2	Agreement to Amend Warrants between Generex Biotechnology Corporation and Omicron Master Trust dated February 27, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.3	Agreement to Amend Warrants between Generex Biotechnology Corporation and Iroquois Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.4	Agreement to Amend Warrants between Generex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 27, 2006 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.5	Form of Warrant issued by Generex Biotechnology Corporation on February 27, 2006 (incorporated by reference to Exhibit 4.26 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16,

2006)

4.16.1	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Cranshire Capital, L.P. dated February 28, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.2	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Omicron Master Trust dated February 28, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.3	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Iroquois Capital LP dated February 28, 2006 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.4	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 28, 2006 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.5	Form of Additional AIR Debenture issued by Generex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.31 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
4.16.6	Form of Additional AIR Warrant issued by Generex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.32 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
4.17.1	Form of Agreement to Amend Warrants between Generex Biotechnology Corporation and the Investors dated March 6, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006).
4.17.2	Form of Warrant issued by Generex Biotechnology Corporation on March 6, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006)
4.18	Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.33 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006)
4.19	Form of Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to certain employees (incorporated by reference to Exhibit 4.34 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006).
4.20.1	Securities Purchase Agreement entered into by and between Generex Biotechnology Corporation and four Investors on June 1, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)
4.20.2	Form of Warrant issued by Generex Biotechnology Corporation on June 1, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)
4.21.1	Form of Amendment to Outstanding Warrants (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)

4.21.2	Form of Warrant issued by Generex Biotechnology Corporation on June 1, 2006 in connection with Exhibit 4.39 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)
4.22.1	Securities Purchase Agreement, dated as of March 31, 2008 among the Registrant and each of the purchasers named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.2	Form of 8% Secured Convertible Note, as amended (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Registration Statement (333-150562) on Form S-3 filed on October 31, 2008)
4.22.3	Form of Series A Warrant, as amended (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)
4.22.4	Form of Series A-1 Warrant, as amended (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)
4.22.5	Form of Series B Warrant, as amended (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)
4.22.6	Form of Series C Warrant, as amended (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)
4.22.7	Registration Rights Agreement, dated March 31, 2008, among Registrant and each of the purchasers under Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.8	Security Agreement (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.9	Form of Guaranty (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.23.1	Form of Securities Purchase Agreement, dated May 15, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 1.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on May 18, 2009)
4.24.1	Form of Securities Purchase Agreement, dated June 15, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.24.2	Form of Warrant issued in connection with Exhibit 4.24.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.24.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.24.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.25.1	

	Form of Securities Purchase Agreement, dated August 6, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.25.2	Form of Warrant issued in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.25.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.28 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.26.1	Form of Securities Purchase Agreement, dated September 11, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.2	Form of Warrant issued in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.27.1	Common Stock Purchase Agreement dated April 7, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
4.27.2	First Amendment to Common Stock Purchase Agreement dated April 28, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 29, 2010)
4.27.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with the Placement Agency Agreement and in connection with Exhibit 4.27.1 hereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
4.28.1	Form of Securities Purchase Agreement, dated January 24, 2011, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 25, 2011)
4.28.2	Form of Warrant issued in connection with Exhibit 4.28.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 25, 2011)
4.28.3	Amendment to Purchase Agreement dated March 25, 2011 (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on March 30, 2011).
4.28.4	Second Amendment to Purchase Agreement dated April 13, 2011 (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on April 14, 2011).

4.29.1	Form of Securities Purchase Agreement, dated July 8, 2011, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
4.29.2	Form of Common Stock Warrant issued in connection with Exhibit 4.29.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
4.30.1	Form of Securities Purchase Agreement, dated January 31, 2012, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on February 1, 2012).
4.30.2	Form of Common Stock Warrant issued in connection with Exhibit 4.30.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 1, 2012).
4.30.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 1, 2012)
4.31.1	Form of Securities Purchase Agreement, dated August 8, 2012, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 8, 2012).
4.31.2	Form of Common Stock Warrant issued in connection with Exhibit 4.30.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 8, 2012).
4.31.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 8, 2012)
4.32.1	Form of Securities Purchase Agreement, dated December 10, 2012, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on December 11, 2012).

4.32.2	Form of Common Stock Warrant issued in connection with Exhibit 4.30.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on December 11, 2012).
4.32.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on December 10, 2012)
4.33.1	Form of Securities Purchase Agreement, dated June 17, 2013, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on June 17, 2013).
4.33.2	Form of Common Stock Warrant issued in connection with Exhibit 4.33.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 17, 2013).
4.33.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 17, 2013)
4.34.1	Form of Securities Purchase Agreement, dated January 14, 2014, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on January 14, 2014).
4.34.2	Form of Common Stock Warrant issued in connection with Exhibit 4.34.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 14, 2014).
4.35.1	Form of Securities Purchase Agreement, dated March 27, 2014, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on March 28, 2014).
4.35.2	Form of Common Stock Warrant issued in connection with Exhibit 4.35.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 28, 2014).

4.35.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 28, 2014)
4.36.1	Form of Securities Purchase Agreement, dated June 24, 2015, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on June 25, 2015).
4.36.2	Form of Common Stock Warrant issued in connection with Exhibit 4.36.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 25, 2015).
4.36.3	Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 25, 2015)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Operating Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of Chief Executive Officer and Chief Operating Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) In the case of incorporation by reference to documents filed by the Registrant under the Exchange Act, the Registrant's file number under the Exchange Act is 000-25169.