GENEREX BIOTECHNOLOGY CORP
Form 10-Q
March 16, 2018

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 January 31, 2018

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.)**

10102 USA TODAY WAY

MIRAMAR, FL 33025

(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 1,065,093 as of March 16, 2018.

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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

	January 31, 2018	July 31, 2017
ASSETS		
Current Assets		
Cash and cash equivalents	$2,048,066	$2,879,165
Accounts receivable, net	175	—
Inventory, net	12,046	10,035
Other current assets	226,988	21,891
Total current assets	2,287,275	2,911,091
Property and equipment (Note 9)	48,857	573
Call option (Note 8)	3,257,655	4,237,829
Intangible asset (Note 8 and 9)	3,187,757	2,911,377
Patents, net	24,551	25,851
Other assets, net	7,824	7,824
TOTAL ASSETS	$8,813,919	$10,094,545
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities		
Accounts payable and accrued expenses	$10,384,280	$10,172,610
Notes Payable (Note 9)	320,000	—
Loans from related parties (Note 3)	13,864,241	13,738,140
Total Current Liabilities	24,568,522	23,910,750
Warrants to be issued (Note 8)	46,303,223	66,060,026
Total Liabilities	70,871,744	89,970,776
Stockholders' Deficiency (Note 6)		
Series F 9% Convertible Preferred Stock, $1,000 par value; authorized 4,150 shares, -0- and -0- issued shares at January 31, 2018 and July 31, 2017, respectively	—	—
Series G 9% Convertible Preferred Stock, $1,000 par value; authorized 1,000 shares, -0- and -0- issued shares at January 31, 2018 and July 31, 2017, respectively	—	—
Series H Convertible Preferred Stock, $.001 par value; authorized 109,000 shares, 3,000 and 3,000 issued shares at January 31, 2018 and July 31, 2017, respectively	3	3
Series I Convertible Preferred Stock, $.001 par value; authorized 6,000 shares, 790 and 790 issued shares at January 31, 2018 and July 31, 2017, respectively	1	1

Common stock, $.001 par value; authorized 750,000,000 and 2,450,000 shares at January 31, 2018 and July 31, 2017, respectively; 1,068,101 and 1,068,101 issued and outstanding at January 31, 2018 and July 31, 2017, respectively	1,068	1,068
Common stock payable	2,168,951	2,168,951
Additional paid-in capital	368,409,627	368,409,627
Accumulated deficit	(427,814,171)	(445,720,566)
Accumulated other comprehensive income	779,252	783,150
Non-controlling interest	(5,602,556)	(5,518,465)
Total Stockholders' Deficiency	(62,057,825)	(79,876,231)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	$8,813,919	$10,094,545

Going Concern (Note 1)
Commitments & Contingencies (Note 4)

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements

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

	Three Months Ended		Six Months Ended	
	January 31, 2018	2017	January 31, 2018	2017
Revenue				
Sales	$—	$—	$2,218	$—
Licensing income (Note 1)	700,000	—	700,000	—
Total Revenue	700,000	—	702,218	—
Operating expenses				
Research and development	150,897	75,640	388,679	75,640
General and administrative	714,689	140,087	1,116,050	242,905
Total operating expenses	865,586	215,727	1,504,729	318,545
Operating Loss	(165,586)	(215,727)	(802,511)	(318,545)
Other Income (Expense):				
Interest expense	(142,245)	(126,669)	(277,190)	(243,508)
Changes in fair value of contingent purchase consideration (Note 8)	(9,521,747)	—	18,776,629	—
Impairment of goodwill (Note 8)	—	(14,335,822)	—	(14,335,822)
Change in fair value of derivative liabilities	—	(1,104,969)	—	(325,074)
Net Income (loss)	(9,829,578)	(15,783,187)	17,696,928	(15,222,949)
Net (loss) attributable to noncontrolling interests	(92,934)	(27,283)	(209,467)	(27,283)
Net Income (loss) Available to Common Stockholders	$(9,736,644)	$(15,755,904)	$17,906,395	$(15,195,666)
Net Income (loss) per Common Share (Note 5)				
Basic	$(9.12)	$(17.16)	$16.76	$(16.63)
Diluted	$(9.12)	$(17.16)	$6.90	$(16.63)
Shares Used to Compute Income (loss) per Share (Note 5)				
Basic	1,068,101	918,416	1,068,101	913,479
Diluted	1,068,101	918,416	2,595,974	913,479
Comprehensive Income (Loss):				
Net Income (Loss)	$(9,736,644)	$(15,755,904)	$17,906,395	$(15,195,666)
Change in foreign currency translation adjustments	(15,730)	1,339	(3,898)	8,513
Comprehensive Income (Loss) Available to Common Stockholders	$(9,752,374)	$(15,754,565)	$17,902,497	$(15,187,153)

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements

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

	Preferred Stock		Common Stock							
	Shares	Amount	Shares	Amount	Common Stock Payable	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Sub Total	Nonco Intere
Balance at July 31, 2016	620	—	908,541	909	—	363,687,741	(375,704,372)	798,872	(11,216,850)	—
Issuance of common stock upon conversion of preferred stock	(620)	—	41,333	41	—	(41)	—	—	—	—
Issuance of common stock for preferred stock make whole payments	—	—	19,529	20	—	167,380	—	—	167,400	—
Exercise of warrants for cash	—	—	3,333	3	—	49,997	—	—	50,000	—
Cashless exercise of warrants	—	—	31,195	31	1,071,851	460,455	—	—	1,532,337	—
Issuance of common stock for acquisition	—	—	53,211	53	1,097,100	253,763	—	—	1,350,916	—
Issuance of series H preferred stock for cash	3,000	3	—	—	—	2,999,997	—	—	3,000,000	—
Issuance of series I preferred stock for conversion of debt	790	1	—	—	—	790,346	—	—	790,347	—
True-up rounding shares for reverse stock split	—	—	10,958	11	—	(11)	—	—	—	—
	—	—	—	—	—	—	—	—	—	1,297

Noncontrolling interest										
Net loss	—	—	—	—	—	—	(70,016,194)	—	(70,016,194)	(6,81
Currency translation adjustment	—	—	—	—	—	—	—	(15,722)	(15,722)	—
Balance at July 31, 2017	3,790	4	1,068,100	1,068	2,168,951	368,409,627	(445,720,566)	783,150	(74,357,766)	(5,51
Net Income (loss)	—	—	—	—	—	—	17,906,395	—	17,906,395	(209,
Investment in subsidiary by noncontrolling interest	—	—	—	—	—	—	—	—	—	125,3
Currency translation adjustment	—	—	—	—	—	—	—	(3,898)	(3,898)	—
Balance at January 31, 2018	3,790	4	1,068,100	1,068	2,168,951	368,409,627	(427,814,171)	779,252	(56,455,269)	(5,60

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements

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

	Six Months Ended January 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income (Loss)	$17,696,928	$(15,222,949)
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	2,022	—
Loss on goodwill impairment	—	14,335,822
Changes in fair value of contingent purchase consideration	(18,776,629)	—
Gain on disposal of property and equipment	—	1,276
Common stock issued for make-whole payments on preferred stock	—	72,900
Change in fair value of derivative liabilities	—	325,074
Changes in operating assets and liabilities:		
Accounts receivable	(175)	—
Inventory	(2,011)	—
Accounts payable and accrued expenses	211,670	256,046
Other current assets	(205,097)	(24,535)
Net cash (used) in operating activities	(1,073,292)	(256,366)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Deposit on investment	—	(500,000)
Purchase of fixed assets	(5,385)	—
Investment in non-controlling interest	—	99,593
Net cash used by investing activities	(5,385)	(400,407)
CASH FLOWS FROM FINANCING ACTIVITIES		
Loan proceeds from related party	126,101	656,153
Investment in subsidiary by noncontrolling interest	125,376	—
Proceeds from exercise of warrants	—	50,000
Net cash provided by financing activities	251,477	706,153
Net increase (decrease) in Cash and Cash Equivalents	(827,201)	49,380
Effects of currency translation on cash and cash equivalents	(3,898)	8,760
Cash and Cash Equivalents, Beginning of Period	2,879,165	16,899
Cash and Cash Equivalents, End of Period	$2,048,066	$75,039
Supplemental Disclosure of Cash Flow Information		
Note payable issued for acquisition of a business	$320,000	$—

The accompanying notes are an integral part of these unaudited condensed interim consolidated financial statements

Generex Biotechnology Corporation and Subsidiaries

Notes to the Unaudited Condensed Interim Consolidated Financial Statements

Note 1 – Organization of Business and Going Concern:

Generex Biotechnology Corporation ("Generex" or the "Company"), was formed in the State of Delaware on September 4, 1997 and its year-end is July 31. It is engaged primarily in the research and development of drug delivery systems and the use of the Company's proprietary technology for the administration of formulations of large molecule drugs to the oral (buccal) cavity using a hand-held aerosol applicator; and through the Company's wholly-owned subsidiary, Antigen Express, Inc. ("Antigen"), has undertaken work on immunomedicines incorporating proprietary vaccine formulations.

On January 18, 2017, the Company closed an Acquisition Agreement pursuant to which the Company acquired a 51% interest in Hema Diagnostic Systems, LLC ("HDS"), a Florida limited liability company established in December 2000 to market and distribute rapid test devices including infectious diseases. Since 2002, HDS has been developing an expanding line of rapid diagnostic tests (RDTs) including such diseases as Human Immunodeficiency Virus (HIV) – 1/2, tuberculosis, malaria, hepatitis, syphilis, typhoid and dengue as well as other infectious diseases.

On December 28, 2017, the Company completed the acquisition of the assets and 100% of the membership interests of two pre-operational pharmacies, Empire State Pharmacy Holdings, LLC and Grainland Pharmacy Holdings, LLC.

The accompanying unaudited condensed 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 consolidated 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 Company's accounting policies did not include Revenue Recognition in the latest Annual Report on Form 10-K.

On November 29, 2017, the Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen"), entered into a License and Research Agreement (the "License Agreement") with Shenzhen BioScien Pharmaceuticals Co., Ltd., ("Shenzhen"). Under the License Agreement, Antigen granted Shenzhen an exclusive license (the "License") to use

Antigen's patents, know-how, data and other intellectual property relating to Antigen's AE37 peptide to develop and sell products for the prevention and treatment of prostate cancer in China (including Taiwan, Hong Kong and Macau).

In exchange for the License, Shenzhen has agreed, *inter alia*, to the following financial consideration:

- a $700,000 non-refundable initial payment;
- milestone payments of $1,000,000 each upon completion of Phase II and Phase III studies;
- a milestone payment of $2,000,000 upon regulatory approval of a product covered by the License; and
- a 10% royalty on net sales, provided the patents are in force and there are no approved generic equivalents.

Shenzhen, generally, will be responsible for conducting clinical trials, securing Chinese regulatory approvals, and marketing in China for all products developed under the Agreement.

In the three and six-month period ended January 31, 2018 the Company recognized revenue for an amount equal to $700,000 representing the non-refundable initial payment, in accordance with FASB ASC 605, Revenue Recognition. ASC 605 requires that four basic criteria are met (1) persuasive evidence of an arrangement exists, (2) delivery of products and services has occurred, (3) the fee is fixed or determinable and (4) collectability is reasonably assured.

The results for the three and six-month period ended January 31, 2018 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 2018. 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.

On March 14, 2017, the Company effected a one-for-one thousand (1:1,000) reverse stock split whereby the Company (i) decreased the number of authorized shares of Common Stock by a ratio equal to one-for-one thousand (1:1,000) (the "Reverse Split Ratio"), and (ii) correspondingly and proportionately decreased, by a ratio equal to the Reverse Split Ratio, the number of issued and outstanding shares of Common Stock (the "Reverse Stock Split"). Proportional adjustments for the reverse stock split were made to the Company's outstanding stock options, warrants and equity incentive plans for all periods presented.

On August 24, 2017, the Company and Core Tech Solutions, Inc. ("Core Tech") entered into a letter of intent ("LOI") contemplating Company's acquisition of a controlling interest of the outstanding capital stock of Core Tech. This LOI was terminated on December 18, 2017.

Certain prior period amounts have been reclassified in the Consolidated Cash Flow Statement for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations.

Going Concern

The accompanying unaudited condensed interim consolidated financial statements have been prepared in conformity with US GAAP, which contemplate continuation of the Company as a going concern. The Company has experienced negative cash flows from operations since inception and has an accumulated deficit of approximately $428 million and a working capital deficiency of approximately $22 million at January 31, 2018. The Company has funded its activities to date almost exclusively from debt and equity financings.

The Company will continue to require substantial funds to pursue its extant business initiatives and 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, and 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.

It is management's opinion that these conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of twelve months from the balance sheet date. There are no assurances that such additional funding will be achieved and that the Company will succeed in its future operations. The unaudited condensed interim consolidated 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:

We have reviewed the FASB issued Accounting Standards Update ("ASU") accounting pronouncements and interpretations thereof that have effective dates during the periods reported and in future periods. The Company has carefully considered the new pronouncements that alter previous generally accepted accounting principles and does not believe that any new or modified principles will have a material impact on the Company's reported financial position or operations in the near term. The applicability of any standard is subject to the formal review of our financial management and certain standards are under consideration.

The FASB issued several updates on Topic 606 "Revenue from Contracts with Customers", including:

- ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)"
- ASU 2016-08 "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)."
- ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing."
- ASU 2016-11, "Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF (Emerging Issue Task Force) Meeting."
- ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients."
- ASU 2016-20, "Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers."
- ASU 2017-13, "Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840) and Leases (Topic 842). Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments."

The standards provide companies with a single model for use in accounting for revenue arising from contracts with customers that supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted, to be effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. The Company plans to adopt this guidance effective August 1, 2018, as required. The Company does not expect this guidance to have a significant impact on how it recognizes revenue and related expenses. The Company is evaluating the impact of this update on its consolidated financial statement disclosures. The Company expects to complete its assessments prior to adoption of the guidance.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities* (“ASU 2016-01”). This standard affects the accounting for equity instruments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. In February 2018, the FASB issued ASU 2018-03, “Technical Corrections and Improvements to Financial Instruments (Subtopic 825-10) – Recognition and Measurement of Financial Assets and Financial Liabilities”. This update was issued to clarify certain narrow aspects of guidance concerning the recognition of financial assets and liabilities established in ASU No. 2016-01, “Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities”. This includes an amendment to clarify that an entity measuring an equity security using the measurement alternative may change its measurement approach to a fair valuation method in accordance with Topic 820, Fair Value Measurement, through an irrevocable election that would apply to that security and all identical or similar investments of the same issued. The update is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years beginning after June 15, 2018. The Company is evaluating the impact of the adoption of ASU 2016-01 on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (“ASU 2016-02”). In January 2018, the FASB issued ASU 2018-01, which provides additional implementation guidance on the previously issued ASU 2016-02. Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The Company does not plan to elect early adoption for this pronouncement.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing diversity in practice regarding how certain cash receipts and cash payments are presented in the statement of cash flows. The standard provides guidance on the classification of the following items: (1) debt prepayment or debt extinguishment costs, (2) settlement of zero-coupon debt instruments, (3) contingent consideration payments made after a business combination, (4) proceeds from the settlement of insurance claims, (5) proceeds from the settlement of corporate-owned life insurance policies, (6) distributions received from equity method investments, (7) beneficial interests in securitization transactions, and (8) separately identifiable cash flows. The Company is required to adopt ASU 2016-15 for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017 on a retrospective basis. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact of adoption of ASU 2016-15 and does not expect any material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash,* which requires that a statement of cash flows should include the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. The Company is evaluating the effect that ASU 2016-18 will have on its consolidated financial statements and is considering early adoption of the standard. The update is effective for fiscal years beginning after December 15, 2017. The adoption is not expected to have a material impact on the consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment* (Topic 350), which eliminates Step 2 from the goodwill impairment test. Instead, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business." These amendments clarify the definition of a business. The amendments affect all companies and other reporting organizations that must determine whether they have acquired or sold a business. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The amendments are intended to help companies and other organizations evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This update is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted under certain circumstances. The amendments should be applied prospectively as of the beginning of the period of adoption. The Company is currently considering early adoption and assessing the impact that this standard will have on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “Compensation-Stock Compensation” (Topic 718): Scope of Modification Accounting. The amendments provide guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718 Compensation-Stock Compensation. An entity should account for the effects of a modification unless all the following are met: 1. The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification. 2. The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified. 3. The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The ASU is effective for all entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The Company is currently assessing the impact that this standard will have on its condensed consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception.* Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating *Topic 480, Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable non-controlling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. The Company is evaluating the effect that ASU 2017-11 will have on its consolidated financial statements and is considering early adoption of the standard.

In February 2018, the FASB issued ASU 2018-02, *Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which was issued to address the income tax accounting treatment of the stranded tax effects within other comprehensive income due to the prohibition of backward tracing due to an income tax rate change that was initially recorded in other comprehensive income. This issue came about from the enactment of the TCJA on December 22, 2017 that changed the Company's federal income tax rate from 35% to 21%. The ASU changed current accounting whereby an entity may elect to reclassify the stranded tax effect from accumulated other comprehensive income to retained earnings. The amendments in this ASU are effective for interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. Adoption of this ASU is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the tax laws or rates were recognized. The Company is currently evaluating the impact, if any, ASU 2018-02 will have on its financial position, results of operations, and its consolidated financial statement disclosures. The Company's evaluation process includes, but is not limited to, identifying transactions and accounts within the scope of the guidance, reviewing its accounting and disclosures for these transactions and accounts, and identifying and implementing any necessary changes to its accounting and disclosures as a result of the guidance. The Company is evaluating the effect that ASU 2018-02 will have on its consolidated financial statements and is considering early adoption of the standard.

Note 3 - Loans from Related Parties

On January 16, 2017, Joseph Moscato, Chief Executive Officer and director ("Moscato"), and Lawrence Salvo, then Senior Vice President and director ("Salvo"), each made unsecured $250,000, non-interest bearing, advances to the Company, $500,000 in the aggregate, which the Company paid to Emmaus Life Sciences, Inc. pursuant to the Emmaus Letter of Intent ("Emmaus LOI"). Both Moscato and Salvo made other advances ($75,820 and $82,803,

respectively) to permit the Company to pay certain third-party expenses in connection with the implementation of the Company's repurposed business plan, including legal, accounting, transfer agent, Edgarization, and press release fees. On April 27, 2017, the Company converted 100% of such advances, $658,622 in the aggregate (the "Moscato – Salvo Advances") into 790 shares of Series I preferred stock (see Note 6).

HDS received substantially all of its funding from a shareholder, who owned 98.9% of HDS prior to the acquisition of HDS by the Company. The loan is unsecured, matures on December 31, 2019 and accrued interest at 0.75% per annum through January 19, 2017, and bearing no interest thereafter. Upon acquisition of HDS by the Company (see Note 8), the outstanding principal balance was $13,239,837 and total accrued interest of $191,869. This loan is subject to a call option (Note 8) which, if exercised, the principal and accrued interest through January 18, 2017 would be eliminated. From January 19, 2017 through January 31, 2018, the loan principal increased by $624,404. As of January 31, 2018, the outstanding principal balance was $13,864,241.

Note 4 - Commitments and Contingencies:

Pending Litigation

The Company is a defendant in one legal proceeding relating to alleged breach of contract and claims against certain of the Company's original buccal delivery patents. The Company is also a defendant in two legal proceedings brought by a former executive officer and her affiliate. These legal proceedings have been reported in the Company's prior periodic reports. No activity has occurred in these cases in several years, and the Company now considers them immaterial.

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.

On August 22, 2017, Generex received a letter from counsel for Three Brothers Trading LLC, d/b/a Alternative Execution Group ("AEXG"), claiming breach of a Memorandum of Understanding ("MOU") between Generex and AEXG. The MOU related to AEXG referring potential financing candidate to Generex. The letter from AEXG counsel claimed that Generex's acceptance of $3,000,000 in financing from Pharma Trials, LLC, in March 2017, violated the provisions of the MOU prohibiting Generex from seeking other financing, with certain exceptions, for a period of 60 days after execution of the MOU. AEXG has demanded at least $210,000 in cash and 84,000 warrants for Generex stock convertible at $2.50 per share, for attorney's fees and costs. On November 27, 2017, AEXG filed a demand for arbitration with the American Arbitration Association's International Centre for Dispute Resolution. The Company has filed a response. As of March 7, 2018, an arbitrator has been chosen, but no hearings have yet been scheduled. Generex management believes the Pharma Trials, LLC Financing was not subject to the prohibitions because the representative of Pharma Trials, LLC was a director of Generex, and for other reasons. No provisions have been made for these claims.

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 5 - Net Income / Income Per Share ("EPS"):

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Basic income per share is calculated by dividing income available to common shareholders by the weighted average number of shares of common stock outstanding during the period. Diluted income per share is calculated by dividing income available to common shareholders by the weighted average number of common shares outstanding for the period and, when dilutive, potential shares from stock options and warrants to purchase common stock, using the treasury stock method. Common stock equivalents are included in the diluted income per share calculation only when option exercise prices are lower than the average market price of the common shares for the period presented.

The weighted average number of common stock equivalents not included in diluted income per share, because the effects are anti-dilutive, was 850 for the six months ended January 31, 2018.

The weighted average number of common stock equivalents not included in diluted loss per share, because the effects are anti-dilutive, was 1,534,095 for the three months ended January 31, 2018.

For the three and six-month periods ended January 31, 2017 all outstanding stock options, non-vested restricted stock, warrants and common stock underlying convertible preferred stock, representing 375,972 incremental shares at January 31, 2017, have been excluded from the computation of diluted EPS as they are anti-dilutive.

Note 6 - Stockholders' Deficiency:

Common Stock

On January 18, 2017, the Company issued 53,211 shares of common stock for the acquisition of 51% of HDS and is obligated to issue 230,000 shares of common stock upon the conclusion of the Company's reverse stock split. As of January 31, 2018, the shares have yet to be issued.

During January 2017, the Company issued 8,000 shares of common stock for the conversion of 120 shares of Series F convertible preferred stock, plus 4,235 shares for the related make-whole payments issued to convert the accumulated dividend payable.

During January 2017, the Company issued 10,000 shares of common stock for the conversion of 150 shares of Series G convertible preferred stock, plus 4,688 shares for the related make-whole payments issued to convert the accumulated dividend payable.

During February 2017, the Company issued 23,333 shares of common stock for the conversion of 350 shares of Series G convertible preferred stock, plus 10,606 shares for the related make-whole payments issued to convert the accumulated dividend payable.

On February 9, 2017, the Company offered all current warrant holders an option to exercise immediately all outstanding common stock purchase warrants on a cashless basis at a reduced exercise price of $7.40 per share from $15.00 per share. The Company agreed to issue a total of 103,809 shares of common stock in connection with the exercise of 314,649 warrants in connection with the following outstanding warrants:

	Warrants Exercised	Shares Agreed to be Issued
Series C 9% Convertible Preferred Stock	10,000	3,299
Series D 9% Convertible Preferred Stock	16,649	5,492
Series E 9% Convertible Preferred Stock	119,667	39,481
Series F 9% Convertible Preferred Stock	138,333	45,639
Series G 9% Convertible Preferred Stock	30,000	9,898
	314,649	103,809

As of the date of this filing, 31,195 shares have been issued and 72,614 shares remain to be issued resulting in additional common stock payable $1,071,851 as of January 31, 2018.

Warrants

As of January 31, 2018 and July 31, 2017, there are no warrants issued or outstanding.

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Series A, B, C, D, E, F, and G 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.

All of the Company's Series F and G 9% Convertible Preferred Stocks were converted prior to the beginning of the Company's 2018 fiscal year.

Series H and Series I Convertible Preferred Stock

The Company has authorized 109,000 shares of designated non-voting Series H Convertible Preferred Stock with a stated value of $1,000 per share and authorized 6,000 shares of designated non-voting Series I Convertible Preferred Stock with a stated value of $1,000 per share pursuant to the Purchase Agreement dated March 27, 2017. The Series H Preferred Stock was scheduled to be sold in four tranches to the Purchaser. Under the Securities Purchase Agreement, in the event the Purchaser failed to purchase 100% of the shares of Preferred Stock at any given Closing, the Company can decline to sell any further securities to the Purchaser (the "Purchase Agreement").

The Series H and Series I Convertible Preferred Stock are convertible at the option of the holder at any time into shares of the Company's common stock at an effective conversion price of $2.50 per share. An aggregate of 46,000,000 shares of the Company's common stock would be issuable upon conversion of both the Series H and Series I Preferred Stock if all shares of such preferred stock contemplated by the securities purchase agreement are issued.

Neither Series H nor Series I Convertible Preferred Stock have special dividend rights. If the Company pays dividends on its common stock, the holders of the preferred stock will receive dividends in the amount they would have received had they converted the preferred stock to common stock.

At closing of the first tranche on March 28, 2017, the Company issued 3,000 shares of Series H Preferred Stock for a purchase price of $3,000,000. The proceeds of this sale were paid directly on the Company's behalf to Emmaus as an additional deposit under the Company's Emmaus LOI. The full amount of such proceeds were repaid to the Company in July 2017 upon termination of the Emmaus LOI. As of January 31, 2018, an aggregate of 1,200,000 shares of the Company's common stock are issuable upon conversion of the Series H Preferred Stock sold.

On April 17, 2017, the Purchaser failed to close the sale of Series I Preferred Stock despite the Company being ready, willing and able to proceed and the Company terminated the Purchaser's rights on April 23, 2017. Under the Securities Purchase Agreement, in the event the Purchaser fails to purchase 100% of the shares of Preferred Stock, the Company can decline to sell any further securities to the Purchaser. On April 23, 2017, the Company notified the Purchaser in writing that its rights to purchase additional shares were forfeit.

Conversion of Debt to Officers into Series I Preferred Stock

On April 27, 2017, the Company converted the "Moscato – Salvo Advances" (Note 3) after applying a 20% original issue discount, the same as the original issue discount negotiated at arm's length with Alpha on March 6, 2017. Moscato converted $390,984 (including $65,164 original issue discount) into 391 shares of Series I Convertible Preferred Stock. Salvo converted $399,363 (including $66,560 original issue discount) into 399 shares of Series I Convertible Preferred Stock.

Noncontrolling Interest

During the six months ended in January 31, 2018, there was a net loss attributable to the non-controlling interest (49%) in Hema Diagnostic Systems, LLC of $209,467 and contributions made of $125,376. The net change in the non-controlling interest as of January 31, 2018 was $84,091. For the periods ending January 31, 2018 and July 31, 2017, the non-controlling interest in Hema Diagnostic Systems, LLC was $5,602,556 and $5,518,465, respectively

Note 7 - Stock-Based Compensation:

Stock Option Plans

As of January 31, 2018, 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 shares of common stock are reserved for issuance under the 2001 Stock Option Plan (the 2001 Plan) and 135,000 shares of common stock are reserved for issuance under the 2006 Stock Plan as amended (the 2006 Plan). At January 31, 2018, there were 4,139 and 64,485 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 of any option grants in the six months ended January 31, 2018 and 2017.

The following is a summary of the common stock options granted, forfeited or expired and exercised under the Plan:

	Options	Weighted Average Exercise Price per Share
Outstanding - July 31, 2017	18,095	$ 31.02
Granted	—	—
Forfeited or expired	—	—
Exercised	—	—
Outstanding - January 31, 2018	18,095	$ 31.02

The 18,095 outstanding options at January 31, 2018 had a weighted average remaining contractual term of 0.6 years.

There were no non-vested common stock options granted, vested or forfeited under the Plan for the period ended January 31, 2018. As of January 31, 2018, the Company did not have any unrecognized compensation cost related to

non-vested share-based compensation arrangements granted under the Plan.

The Company did not grant any options during the six months ended January 31, 2018.

The following table summarizes information on stock options outstanding at January 31, 2018:

Range of Exercise Price	Options Outstanding and Options Exercisable Number Outstanding at January 31, 2018	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$1.00	17,245	$1.00	0.53	47,424
$640.00	850	$640.00	2.10	—
	18,095	$31.02	0.61	$47,424

Note 8 - Acquisition of Hema Diagnostics Systems, LLC

On January 18, 2017, the Company acquired a 51% interest in Hema Diagnostic Systems, LLC ("HDS"), pursuant to the Acquisition Agreement. At closing, the Company acquired 4,950 of HDS's 10,000 previously outstanding limited liability company units in exchange for 53,191 shares of Generex common stock valued at $253,721, plus 20 shares of Generex common stock issued to HDS in exchange for 300 new limited liability company units. The Acquisition Agreement also provides the Company with a call option to acquire the remaining 49% of HDS and a retirement of HDS shareholder loans in the amount of $13,431,706 (including interest) (the "Call Option") for the aggregate purchase price of $1.

Following the closing and the completion of Company's reverse stock split, the Company is required to issue a further 230,000 shares of common stock and issue a warrant to a former shareholder of HDS to acquire 15,000,000 additional shares of Generex common stock for $2.50 per share. The issue of this warrant is contingent upon the Company obtaining approval from its shareholders for an increase in its authorized share capital. The total consideration was valued at $1,350,916 on the date of the acquisition.

Fair Value of the HDS Assets

The intangibles assets acquired include In–Process Research & Development ("IPR&D"). The Fair Value of the IPR&D intangible asset using an Asset Cost Accumulation methodology as of January 18, 2017 (the "Valuation Date") was determined to be $2,911,377.

The net purchase price of HDS was determined to be as follows:

Shares **Fair**

	Stock Price at Closing		**Value**
Purchase price:			
Common Stock at closing	$ 4.77	53,191	$253,721
Common Stock after closing	$ 4.77	20	95
Common Stock post reverse stock split	$ 4.77	230,000	1,097,100
Total purchase price			$1,350,916

As of January 18, 2017, the issue of the warrant to acquire 15,000,000 additional common shares of Generex was contingent upon shareholder approval of an increase in the Company's authorized capital stock. No warrant has been issued by the Company until such time that an increase in authorized capital has been approved. At the time of closing, Management determined that is was remote that the warrant would be issued and the Call Option would be exercised, accordingly no values have been attributed to the warrant and Call Option at closing. During the fiscal year 2017, after the issuance of Series I Preferred Stock, management made a redetermination and concluded that it was probable that the shareholder approval to increase authorized share capital would be obtained and the Call Option will be exercised. Accordingly, management recorded the fair value of the warrant of $66,060,026 as a liability and the Call Option of $4,237,829 as an asset as of July 31, 2017. During the fiscal year 2018, there was an increase in authorized shares, but the warrants still have not been issued.

As of January 31, 2018, the fair value of the warrant and Call Option was $46,303,223 and $3,257,655, respectively. For the six months ended January 31, 2018, the change in the fair value of the contingent purchase consideration of $18,776,629 was recorded as a gain in the condensed interim consolidated statements of operations and comprehensive income (loss). For the three months ended January 31, 2018, the change in the fair value of the contingent purchase consideration of $9,521,747 was recorded as a loss in the condensed interim consolidated statements of operations and comprehensive income (loss).

Fair Value Assumptions Used in Accounting for Warrants

The Company used the Black-Scholes option-pricing model to calculate the fair value of the warrants as of January 31, 2018. The Black-Scholes option-pricing 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. The key inputs used in the fair value calculations were as follows:

	January 31, 2018	July 31, 2017
Exercise price	2.50	2.50
Time to expiration	3.96 years	4.47 years
Risk-free interest rate	2.29 %	1.84 %
Estimated volatility	120.67 %	122.7 %
Dividend	—	—
Stock price at valuation date	$3.75	5.05

Fair Value Assumptions Used in Accounting for Call Option

The Company used the Monte Carlo model to calculate the fair value of the call option as of January 31, 2018. The valuations are based on assumptions as of the valuation date with regard to the value of the asset acquired net of impairment, the risk-free interest rate, the estimated volatility of the stock price in the future, the time to expiration and the stock price at the date of valuation.

The following assumptions were used in estimating the value of the Call Option:

	January 31, 2018	July 31, 2017
Risk-free interest rate	2.14 %	1.34 %
Estimated volatility	154.5%	143.9%
Remaining Term	1.96	2.47
Stock price at valuation date	$3.75	5.05

Goodwill and Intangible Assets

The change in the carrying amount of goodwill and other intangible assets for the period ended January 31, 2018, is as follows:

	Other Intangibles, net	Goodwill	Total
Balance as of July 31, 2017	$2,911,377	$ —	$2,911,377
Current period amortization	—	—	—
Additions from pharmacy acquisition	276,380		276,380
Balance as of January 31, 2018	$3,187,757	$ —	$3,187,757

Intangible assets are generally amortized on a straight-line basis over the useful lives of the assets. The Company is currently not amortizing the in-process research and development until it becomes commercially viable and placed in service. At the time when the intangible assets are placed in service the Company will determine a useful life.

Goodwill for HDS was valued at $14.3 million as of the date of acquisition. It was later determined that the value of goodwill was $13.4 million due to the change in estimates of in-process research and development.

Goodwill represents the excess of the purchase price over the fair market value of net assets acquired. Goodwill for HDS was $14.3 million as of the date of the acquisition. When the acquisition transaction closed in January 2017, HDS was a development-stage entity and its liabilities exceeded the aggregate value of its assets. Utilizing discounted cash flow (DCF) valuation methodology, Generex determined that HDS has forecasted losses throughout the reasonably foreseeable future with a nominal terminal value. In addition, there was a high degree of uncertainty as to the future cash flows of HDS. Therefore, the Company concluded that the implied goodwill arising out of the acquisition was zero and should be properly characterized as fully impaired as of July 31, 2017.

Note 9 - Acquisition of Pharmacies

On December 28, 2017, the Company completed the acquisition of the assets and 100% of the membership interests of two pre-operational pharmacies, Empire State Pharmacy Holdings, LLC and Grainland Pharmacy Holdings, LLC, pursuant to the bills of sale for a consideration of $320,000 Promissory Note due and payable in full on June 28, 2018 bearing an annual interest rate of 3%.

The purchase price has been allocated as of the acquisition date based on management's preliminary estimates as follows:

Intangible assets	$276,380
Property and Equipment	19,879
Leasehold Improvements	17,761
Computer Software	5,980
Total Assets Acquired	$320,000

The intangible assets represent the licenses obtained to operate a pharmacy in the respective state of each of the acquired pharmacies. Intangible assets are generally amortized on a straight-line basis over the useful lives of the assets. The Company is currently not amortizing the pharmacy license until the pharmacies becomes commercially viable and operations begin in the acquired pharmacies. At the time, when the intangible assets are placed in service, the Company will determine a useful life.

The Company has determined that the acquisition of the two pharmacies was a non-material business combination. As such, pro forma disclosures are not required and are not presented within this filing.

Note 10 - Subsequent Events:

The Company has evaluated subsequent events occurring after the balance sheet date through the date the unaudited condensed interim 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 six month periods ended January 31, 2018 and 2016. Effective January 18, 2017, we acquired a 51% interest in Hema Diagnostic Systems, LLC, a Florida limited liability company (referred to as “HDS”). Our balance sheet at January 31, 2018 includes our interest in HDS and our interest in the results of operations of HDS for the period January 18, 2017 through January 31, 2018 is included in our Consolidated Statement of Operations and Comprehensive Loss for the quarter ended January 31, 2018. 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 January 31, 2018.

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 January 31, 2018 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 are based on currently available operating, financial and competitive information. 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 funding of obligations related to potential acquisitions and generally completing acquisitions;
- our expectations concerning existing or potential development and license agreements for third-party collaborations, acquisitions and joint ventures;
- our expectations concerning product candidates for our technologies;
- our expectations regarding the cost of raw materials and labor, consumer preferences, the effect of government regulations on the Company’s business, the Company’s ability to compete in its industry, as well as future economic and other conditions both generally and in the Company’s specific geographic markets.
- our expectations concerning product candidates for our technologies;

- 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 in development 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 decline in our stock price; 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 of our historical business 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. Additional factors that could affect future results of HDS are set forth under *Risk Factors* in *Item 2.01. Completion of Acquisition or Disposition of Assets*," in our Current Report on Form 8-K January 17, 2017. 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, ceased compensating our officers, and suspended substantially all of our operations due to lack of funds. On January 17, 2017, we entered into an Acquisition Agreement (the "Acquisition Agreement") with the equity owners of Hema Diagnostic Systems, LLC ("HDS") pursuant to which we acquired a majority of the equity interests in HDS in exchange for shares of our common stock and our obligation to issue common stock purchase warrants (the "Acquisition"). The Acquisition closed on January 18, 2017. We have the right to acquire the remainder of the HDS equity interests for nominal consideration provided that the stock and warrants have a specified value and we have registered for resale the Company's shares issued to the HDS equity owners. We intend to focus resources on HDS' business as well as other potential acquisition candidates going forward, but do not intend to discontinue our pre-Acquisition activities.

References to HDS include its two wholly owned subsidiaries, Rapid Medical Diagnostics Corp. and Hema Diagnostic Systems Panama, S.A. Rapid Medical Diagnostics Corp. was established to develop products and hold patents used by Hema Diagnostic Systems, LLC. Hema Diagnostic Systems Panama, S.A. was established to distribute Hema Diagnostic Systems, LLC's products in Central and South America. Prior to the Acquisition, equity interest in Hema Diagnostic Systems Panama, S.A. and Rapid Diagnostic Systems were separately held by the equity owners of HDS, and financial statements of the three companies were prepared on a combined basis, as they were under common control and management. Immediately prior to closing of the Acquisition, the equity owners contributed to HDS the equity of the other two companies, making them wholly owned subsidiaries of HDS.

The description below of our results of operations relates primarily to our historical business. We will not pursue our historical business if we do not receive substantial financing for that purpose.

Overview of Business

Generex's Historical Business

We have been engaged primarily in the research and development of drug delivery systems and technologies. Our primary focus was 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.

Hema Diagnostic Systems

Hema Diagnostic Systems LLC (which we refer to as "HDS") was established in December 2000 to market and distribute rapid test devices for infectious diseases. Since 2002, we have been developing an expanding line of rapid diagnostic tests (RDTs) for such diseases as Human Immunodeficiency Virus (HIV) – 1/2, tuberculosis, malaria, hepatitis, syphilis, typhoid and dengue as well as other infectious diseases. We distribute our own products and manufacture our devices in-house as well as through contract manufacturers. Some sub-components, made to our specifications, are produced in China, India and Germany. Our products are rapid immunochromatographic medical diagnostics that are administered at the point of care (POC) level and which can produce results as in as little as 10-15 minutes.

Due to the potential infectious character of the whole blood test sample, our Express series of RDTs are designed to perform and deliver test results while within the sealed Express housing, carefully controlling the potentially infectious test sample. This design helps to increase our ability to control the possibility of cross-contamination. Most of our competitors' products, while inexpensive, are not as user-friendly, require substantially more training and have greater risk of cross- contamination.

Our products are subject to extensive regulatory oversight by government and other organizations and rely on international regulatory approvals for sale into markets outside of the USA. Domestically, our devices would require U.S. Food and Drug Administration ("FDA") approval and in some cases, international sales require World Health Organization ("WHO") approval.

We maintain a FDA registered facility in Miramar, Florida and are certified under both ISO9001 and ISO13485 for the "Design, Development, Production and Distribution" of the in-vitro devices. Approval of our HIV rapid test has been issued by the United States Agency for International Development ("USAID"). USAID approval allows us to offer our product to those countries where USAID provides such funding. Some of our products have qualified for and use the European Union issued "CE" Mark, which allows us to enter into CE Member countries subject to individual country documentation and approval. Currently, two malaria rapid tests are approved under World Health Organization ("WHO") guideline, and we anticipate approval of a third by the end of calendar 2017. WHO approval is necessary for those countries which rely upon the expertise of the WHO, as well as for non-governmental organization ("NGO") funding. HDS products have also received registrations and approvals issued by other foreign governments. HDS is currently in the planning phase for entering into the newly announced, WHO "Pre-Qualified Approval" process for other HDS tests. This process allows expedited approval of rapid tests, reducing the current 24-30 month process time down to approximately 6-9 months. HDS products are also listed and offered internationally through the UNICEF and UNDP. On February 2016, we entered into a Long Term Agreement with the WHO for the approved rapid tests. While receiving small orders resulting from this Agreement, we anticipate larger orders from the WHO as our relationship expands.

We maintain current U.S. Certificates of Exportability that are issued by two FDA divisions-CBER and CDRH. CBER (Center for Biologicals Evaluation and Research) is the FDA regulatory division that oversees biological devices and which include our HIV, Hepatitis B and Hepatitis C. The other division, Center for Devices and Radiological Health ("CDRH"), is responsible for the oversight of other HDS devices which include Tuberculosis, Syphilis, and the remaining product line. Certificates of Exportability are issued to Hema Diagnostic Systems. Our HDS facility maintains FDA Establishment Registration status and is in accord with GMP (Good Manufacturing Practice) as confirmed by the FDA.

We do not currently have FDA approval to sell any of our products in the United States. We anticipate submitting our devices to the FDA under a Pre-Market Approval Application (PMA) or through the 510K process. The 510K would require the appropriate regulatory administrative submissions as well as a limited scientific review by the FDA to determine completeness (acceptance and filing reviews); in-depth scientific, regulatory, and Quality System review by appropriate FDA personnel (substantive review); review and recommendation by the appropriate advisory committee (panel review); and final deliberations, documentation, and notification of the FDA decision. The PMA process is more extensive, requiring clinical trials to support the application. We expect to apply to FDA for approval of our first RDT to be submitted to the FDA for 510K approval within the next few months. We anticipate the FDA process will be completed within 9 months after submission. During this timeline we will be preparing documentation for additional rapid tests to undergo either the FDA PMA or 510k process.

Financial Condition

Generex's historical business was in the development stage and we do not expect sufficient revenues to support our operation in the immediately foreseeable future. To date, neither Generex nor HDS has been profitable. HDS' owner's deficit was $13,622,289 at December 31, 2016. Generex's consolidated net income available to shareholders was $17,906,397 for the six months ended January 31, 2018. As of January 31, 2018, our current cash position is not sufficient to meet our working capital needs for the next twelve months. In addition, we do not have sufficient funds to carry out our strategic development plans. During fiscal 2016, we were required to lay-off all of our employees, our officers ceased receiving compensation. Certain officers began receiving compensation in June 2017. We will require additional funds to support our working capital requirements and any development or other activities. HDS' past activities have been primarily financed by loans and capital contributions from its former primary owner. That source of funds will no longer be available. HDS entered into the Acquisition with the expectation that the existence of a public market for Generex's stock would enable it to access financing from various sources. We cannot provide any assurance that we will obtain the required funding. 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. 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 are underway in other countries at this juncture.

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.

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.

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.

In-Vitro Medical Diagnostic Devices Administered At The Point Of Care Level

HDS develops, manufactures, and distributes in-vitro medical diagnostics for infectious diseases administered at the point of care level with results as soon as 10-15 minutes. We manufacture and sell rapid diagnostic devices based upon its own proprietary EXPRESS technology as well as cassette devices based on customary designs used generally in the industry. Since its founding, Hema has been developing and continues to develop an expanding line of Rapid Diagnostic Tests (RDTs) including those for the following infectious diseases such as Human Immunodeficiency Virus (HIV) – ½ w/p24Ab, tuberculosis-XT, malaria, hepatitis, syphilis, typhoid, dengue and other infectious diseases. Recent advances in device platform technology can be directly applied to individual test strip which is disease specific line. These technologies further increase the performance capabilities of each test and its' ability to detect diseases in an efficient and cost-effective manner.

HDS is also in the process of developing the platform for the qualitative testing for other infectious diseases including Typhoid, Chikungunya, Zika and other diseases. A new HDS housing, designated as the Rapid 1-2-3 Hema Express III Sepsis, is currently in the design evaluation process phase.

Due to the potential infectious character of the whole blood test sample, HDS' Express series of RDTs are designed to perform and deliver test results while within the sealed Express housing. This increases the ability to control the possibility of cross-contamination.

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 over inhalation, 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.

The following descriptions of our competitors for buccal insulin products and immunomedicine technology were obtained from their filings with the Securities and Exchange Commission, information available on their web sites and industry research reports.

- MannKind Corporation’s product candidates include AFREZZA®, a mealtime insulin therapy being studied for use in adult patients with type 1 and type 2 diabetes. MannKind received FDA approval in June 2014 and the product is now commercially available in the United States.
- Amylin Pharmaceuticals, Inc. received FDA approval in January 2012 for Bydureon, an extended-release injectable formulation, which is the first once-a-week therapy for the treatment of type 2 diabetes.
- There are several companies that are working on developing products which involve the oral delivery of analogs of insulin. Oramed Pharmaceuticals is developing an orally ingestible insulin capsule which is currently in Phase II clinical trials. Biocon Limited has developed IN-105, a tablet for the oral delivery of insulin, which is currently in phase II trials. Diabetology has developed Capsulin IR, an insulin capsule which is currently in Phase II clinical trials. Access Pharmaceuticals has developed Cobalamin, an oral insulin which is currently in pre-clinical trials. Dance Pharmaceuticals is developing an inhaled insulin product based on Aerogen’s proprietary OnQ Aerosol Generator technology.
- There are also a number of companies developing alternative means of delivering insulin in the form of oral pills, transdermal patches, and intranasal methods, which are at early stages of development. 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 to compete with insulin products.

- Bavarian Nordic, Inc. employs a DNA vector-based technology platform to design and develop immunotherapeutic vaccines for different cancers. Their most advanced compound, PROSTVAC, is in a pivotal Phase III trial in patients with prostate cancer. Additionally, they have a HER2 vaccine in a Phase I/II trial in patients with breast cancer. They have recently presented data on studies combining their MVA-BN-HER2 cancer vaccine with different immune checkpoint inhibitors.
- Advaxis, Inc. uses a proprietary technique to bioengineer Listeria bacteria to create a specific antigen that can stimulate an immune response after recognition by the recipient's immune system. Advaxis' most advanced product candidate is ADXS-HPV, which is in Phase II trials for HPV-associated CIN (cervical intraepithelial neoplasia) and recurrent cervical cancer. The company has recently partnered with MedImmune to initiate combination studies utilizing their most advanced ADXS-HPV with MedImmune's anti-PD-L1 immune checkpoint inhibitor in patients with advanced, recurrent or refractory human papillomavirus (HPV)-associated cervical or head and neck cancer.
- Amgen Inc.'s BiTE® technology uses the body's cell destroying T cells to attack tumor cells. Amgen's lead product candidate blinatumomab (MT103) has completed a Phase II clinical trial in patients with minimal residual disease positive acute lymphoblastic leukemia.
- Sanofi Pasteur Inc., the vaccine division of sanofi-aventis and one of the largest vaccines companies in the world, has product candidates including inoculations against 20 varieties of infectious diseases. It received FDA approval for an H5N1 avian influenza vaccine in April 2007 and for an H1N1 vaccine in September 2009.
- Galena Biopharma's (formerly Rxi Pharmaceuticals Corporation) NeuVax™, is currently in Phase III clinical trials to evaluate NeuVax™ for the treatment of early stage, HER2-positive breast cancer. Clinical trials are currently underway to test NeuVax™ as a treatment for prostate cancer, and to use NeuVax™ in combination with Herceptin® to target breast cancer.
- In May 2010, BioSante Pharmaceuticals, Inc. announced that it was restarting development of the GVAX™ vaccine for the treatment of prostate cancer (originally developed by Cell Genesys, Inc.) and is in Phase II human clinical trials. In addition to GVAX prostate product, BioSante has several other cancer vaccines which are in Phase II clinical development including vaccines for leukemia, breast cancer and pancreatic cancer and has vaccines in Phase I clinical development including vaccines for colorectal cancer and melanoma.

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.

The medical diagnostics industry is a multi-billion dollar international industry and is intensely competitive. Many of our competitors in this industry are substantially larger and have greater financial, research, manufacturing and marketing resources. We believe our scientific and technological capabilities as well as our proprietary technology and know-how relating to our rapid tests, particularly for the development and manufacture of tests for the detection of antibodies to infectious diseases, are very strong.

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Alere, Inmc. is our main competitor and one of the major player in RTDs for infectious diseases. Alere markets the Alere HIV Combo Ag/Ab test, which uses the lateral flow technology patent. Alere acquired the patent from Abbott over a decade ago. Alere subsequently acquired Standard Diagnostics of Korea and Accon of China.

Standard Diagnostics was a state-funded entity in South Korea established to build and expand into the international markets under its own brand until it was acquired by Inverness, the predecessor to Alere, in 2006.

With funding from Inverness for regulatory registrations and a previously established cassette product line, Standard was able to capture a strong market share of purchased for use in Africa with funding from WHO and the Global Fund. Currently, Standard is the strongest competitor on an international basis, incorporating a cassette design into each of their products.

Chembio Diagnostic Systems, Inc. is a publicly-traded diagnostic company that develops, manufactures and commercializes diagnostic solutions. Chembio uses its patented Next Generation DPP (Dual Path Platform) technology that makes claims of significant advantages over the Alere's lateral-flow technology.

It has continued building its product line and entered into US FDA approval for a rapid HIV test approved for professional use only in the United States.

As infectious diseases are epidemic and in the minds of the public, there will be more competitors coming into the market place. However, we believe competition will be based upon the implementation of a cassette or a "dipstick" format.

Brief Company Background

Prior to our acquisition of a controlling interest in HDS, we were a development stage company. From inception through the end of the quarter ended January 31, 2018, we have received only limited revenues from operations, except for licensing income of $700,000 from our agreement with Shenzhen Pharmaceuticals in the second quarter of 2018. Our non-HDS business did not have any revenue for the six months ended January 31, 2018 or in the fiscal year ended July 31, 2017

We operate in two segments. Our historical business operates in the research and development of drug delivery systems and technologies for metabolic and immunological diseases. HDS operates in the development, manufacture and distribution of in-vitro medical diagnostic devices (RDTs) administered at the point of care level.

We were incorporated in the State of Delaware in 1997. Our principal executive offices are located at 10102 USA Today Way Miramar, Florida 33025. Our telephone number 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 second quarter of fiscal 2018. 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 second quarter of fiscal 2018. 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.

Inventory. HDS' inventory is stated at the lower of cost or net realizable value. Cost is determined using the Weighted Average method. We periodically evaluate our inventory for any obsolete or slow moving items based on production lots and advances in production design or technology. Any inventory determined to be obsolete or slow moving is removed from inventory and disposed or a provision is made to reduce slow moving inventory to its net realizable value. At December 31, 2016, HDS recorded a reserve for obsolescence of zero.

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. Pursuant to the acquisition of HDS at the time of closing on January 18, 2017, the Company recorded $13,380,377 of goodwill, and as of January 31, 2018, the Company fully impaired the goodwill.

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. Prior to the acquisition of HDS, all of the Company's patents had been written down in the fiscal year ended July 31, 2016. Pursuant to the acquisition of HDS, the Company recorded a stepped-up basis in In-Process Research and Development of HDS in the amount of $1,955,932 to be amortized over ten (10) years. Our intangible assets consist of patent patented technology and trademarks. In addition, from the pharmacy acquisition in December 2018 the Company recognized $287,380 of intangible asset relating to pharmacy licenses.

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 July 31, 2017 and January 31, 2018, 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 January 31, 2018 compared to three months ended January 31, 2017

We had a net loss for the three months ended January 31, 2018 of $9,736,644 versus a net loss of $15,755,904 in the corresponding three months of the prior fiscal year. The income in this year’s fiscal three months was caused primarily by a loss in the changes in fair value of contingent purchase consideration of $9,521,747, offset by our operating income of $700,000 from the license and research agreement between Antigen Express, Inc. and Shenzhen Bioscience Pharmaceuticals Co. The operating loss in the corresponding three months of the prior year was due to a loss on impairment of goodwill of $14,355,822, a loss in the change in fair value of derivative liabilities of $1,104,969, our operating expenses of $215,727 and interest expense of $126,669.

Our operating loss for the three months ended January 31, 2018 decreased to $165,586 compared to $215,727 in the same fiscal period of 2017. The decrease in operating loss resulted primarily from the $700,000 licensing revenue offset by the resumption of our operations late in the second quarter of fiscal 2017, from an increase in research and development expenses (to $150,897 from $75,640) and an increase in general and administrative expenses (to $714,685 from $140,087).

The increase in research and development expenses in the three months ended January 31, 2018 versus the comparative three months in the previous fiscal year is primarily due to our clinical trials of Antigen's AE37 cancer vaccine in patients with triple negative breast cancer in collaboration with Merck and research and development costs attributed to the acquisition of HDS.

Our interest expense in the three months ended January 31, 2018 was $142,245 compared to the previous year's fiscal three months of $126,669. Change in fair value of derivative liabilities was $-0- in the three months ended January 31, 2018 compared to a loss of $1,104,969 corresponding three months of the prior fiscal year.

The net operating losses attributed to HDS in three-month periods ended January 31, 2018 amount to $92,934, compared to the previous year's fiscal three months of $27,283.

Six months ended January 31, 2018 compared to six months ended January 31, 2017

We had a net income for the six months ended January 31, 2018 of $17,906,935 versus a net loss of $15,195,666 in the corresponding six months of the prior fiscal year. The income in this year's fiscal six months was caused primarily by a gain in the changes in fair value of contingent purchase consideration of $18,776,629 and our operating income of $700,000 from the license and research agreement between Antigen Express, Inc. and Shenzhen Bioscience Pharmaceuticals Co. The operating loss in the corresponding six months of the prior year was due to a loss on impairment of goodwill of $14,355,822, a loss in the change in fair value of derivative liabilities of $325,074, our operating expenses of $318,545 and interest expense of $243,508.

Our operating loss for the six months ended January 31, 2018 increased to $1,504,724 compared to $318,545 in the same fiscal period of 2017. The increase in operating loss resulted primarily from the resumption of our operations late in the second quarter of fiscal 2017, from an increase in research and development expenses (to $388,679 from $75,640) and an increase in general and administrative expenses (to $1,116,050 from $242,905), offset by the $700,000 licensing revenue.

The increase in research and development expenses in the six months ended January 31, 2018 versus the comparative three months in the previous fiscal year is primarily due to our clinical trials of Antigen's AE37 cancer vaccine in patients with triple negative breast cancer in collaboration with Merck and research and development costs attributed to the acquisition of HDS.

Our interest expense in the six months ended January 31, 2018 was $277,190 compared to the previous year's fiscal six months of $243,508. Change in fair value of derivative liabilities was $-0- in the six months ended January 31, 2018 compared to a loss of $325,074 corresponding six months of the prior fiscal year.

The net operating losses attributed to HDS in six-month period ended January 31, 2018 amount to $209,467, compared to the previous year's fiscal six months of $27,283.

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. HDS financed its development stage activities primarily from capital contributions and loans from its previous primary owner.

As of January 31, 2018, our current cash position is not sufficient to meet our working capital needs for the next twelve months. We will require additional funds to support our working capital requirements and any development or other activities. HDS will require additional funds to support its working capital requirements and any development or other activities, or will need to curtail its research and development and other planned activities or suspend operations. HDS will no longer be able to rely on its former primary owner for necessary financing. Going forward, HDS will rely on Generex financing activities to fund HDS operations, development and 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 we did not receive any funds from these activities. Prior to January 31, 2018, we eliminated through amendment, exercise and conversion of all of our outstanding common stock purchase warrants (other than the Berkman warrant) and the outstanding shares of our Series G 9% Convertible Preferred Stock. All of the warrants were exercised on a “cashless” basis. This will result in the elimination of a significant derivative liability on our balance sheet for periods after February 9, 2017. Because the warrants were issued on a cashless basis, however, we received no funds from the exercise of the warrants.

Management will seek to meet all or some of our operating cash flow requirements through financing activities, such as private placements 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 may pursue 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

On March 6, 2017 we received $500,000 in net proceeds from the sale of our Convertible Note Due March 6, 2018 ("Note") in the principal amount of $674,855**.** The purchase price of the Note was $562,379 comprised of $500,000 in cash, the cancellation of a $50,000 demand Note the Company had issued to the investor in May 2016, $3,879 in accrued interest on the prior note and $8,500 in legal fees for the investor's counsel, which the Company was obligated to pay pursuant to the Securities Purchase Agreement. The remaining $112,476 of principal amount represents original issue discount. The entire net proceeds of this Note were used to pay a $500,000 deposit to Emmaus Life Sciences, Inc. ("Emmaus") pursuant to our Letter of Intent with Emmaus, as amended. On May 30, 2017, the Company received notice from the investor's counsel declaring the Note due and payable due to the termination of the Letter of Intent. In July 2017, the principal balance of the Convertible Note was fully repaid. In addition, the Company agreed to pay a late fee of $75,000 to Alpha.

On February 9, 2017, Generex entered into a Right to Shares Agreement with the holder of the Preferred Shares pursuant to which that holder agreed convert 100% of those preferred shares into an aggregate of 33,939 shares of Generex common stock based on the February 6, 2017 VWAP. The Company initially will deliver 1,000 shares pursuant to The Right to Shares Agreement. Those remaining 32,939 shares of the Company's common stock, together with the Warrant shares issuable to that holder, will be delivered to that holder from time to time based on draw down notices submitted to the Company by that holder. Under the Right to Shares Agreement, the holder may not request issuance of shares, to the extent that after giving effect to such issuance after exercise, the holder (together with the holder's Affiliates, and any other Persons acting as a group together with the holder or any of the holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation. The Beneficial Ownership Limitation is initially 4.99%. From and after sixty-one (61) days after the date of the Right to Shares Agreement, the Beneficial Ownership Limitation shall be increased from 4.99% to 9.99%.

On March 28, 2017, the Company entered into a securities purchase agreement with an investor ("Purchaser") pursuant to which the Company agreed to sell an aggregate of 109,000 shares of its newly designated non-voting Series H Convertible Preferred Stock ("Series H Preferred Stock") and 6,000 shares of its newly designated Series I Convertible Preferred Stock ("Series I Preferred Stock").

The Series H Preferred Stock was scheduled to be sold in four tranches to the Purchaser. At closing of the first tranche, the Company issued 3,000 shares of Series H Preferred Stock for a purchase price of $3,000,000. The proceeds of this sale were paid directly on the Company's behalf to Emmaus an additional deposit under the Company's letter of intent with Emmaus.

On April 17, 2017, the Purchaser failed to close the sale of Series I Preferred Stock despite the Company being ready, willing and able to proceed. Under the Securities Purchase Agreement, in the event the Purchaser fails to purchase 100% of the shares of Preferred Stock, the Company can decline to sell any further securities to the Purchaser. On April 23, 2017 the Company notified the Purchaser in writing that its rights to purchase additional shares were forfeit.

On April 27, 2017, the Company retired $658,622 of advances made by Joseph Moscato (President & CEO) and Lawrence Salvo (Senior Vice President) ($325,820 and $332,803, respectfully) The Company applied the 20% original issue discount, the same as original issue discount negotiated at arm's length with Alpha Capital Anstalt ("Alpha") in respect of the promissory note issued by the Company to Alpha on March 6, 2017. The 20% original issue discount Moscato and Salvo were 80% of the debt recognized and converted into Series I Preferred Stock providing 391 shares of Series I Convertible Preferred Stock to Moscato to retire indebtedness of $390,984; and 399 shares of Series I Convertible Preferred Stock to Salvo to retire indebtedness of $399,363.

Cash Flows for the six months ended January 31, 2018

For the six months ended January 31, 2018, we used $1,073,292 in cash to fund our operating activities. The use for operating activities included a net income of $17,696,928, changes to working capital including a change in fair value of contingent purchase consideration of $18,776,629, an increase of $211,670 related to accounts payable and accrued expenses, offset by an increase related to other current assets of $205,097.

The former majority shareholder of HDS has made contributions of $125,376 and advances to HDS of $126,101 for the six months ended January 31, 2018. Otherwise, we had no cash provided by financing activities in the six months ended January 31, 2018.

Our net working capital deficiency at January 31, 2018 increased to $22.3 million from $21 million at July 31, 2017.

As of January 31, 2018, 150 shares of the Series G 9% Convertible Preferred Stock had been converted to common stock. On February 9, 2017, we entered into a Right to Shares Agreement with the holder of our Series G Convertible Preferred Stock pursuant to which that holder agreed convert 100% of those preferred shares into an aggregate of 33,939 shares of Generex common stock. The conversion was at effective price of $10.31 per share. The Company initially delivered 1,000 shares (on a post reverse split basis) pursuant to The Right to Shares Agreement. At the same time, the holder exercised Warrants through cashless exercise for an aggregate of 103,809 shares of Generex common stock. Pursuant to a Right to Shares Agreement, the remaining 33,939 shares of the Company's common stock issued upon conversion of the preferred stock, together with the 103,809 Warrant shares issuable to that holder, will be delivered to that holder from time to time based on draw down notices submitted to the Company by that holder.

Funding Requirements and Commitments

If we obtain necessary financing, we expect to expend resources towards regulatory approval and commercialization of Generex Oral-lyn™ and 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.

On March 6, 2017 we received $500,000 in net proceeds from the sale of our Convertible Note Due March 6, 2018 (“Note”) in the principal amount of $674,855**.** The purchase price of the Note was $562,379 comprised of $500,000 in cash, the cancellation of a $50,000 demand Note the Company had issued to the investor in May, 2016, $3,879.13 in accrued interest on the prior note and $8,500 in legal fees for the investor’s counsel, which the Company was obligated to pay pursuant to the Securities Purchase Agreement with the investor. The remaining $112,476 of principal amount represents original issue discount. The entire net proceeds of this Note were used to pay the initial deposit to Emmaus pursuant to our Letter of Intent, as described below. On May 30, 2017, the Company received notice from the investor’s counsel declaring the Note due and payable due to the termination of the Letter of Intent. In July 2017, the principal balance of the Convertible Note was fully repaid. In addition, the Company agreed to pay a late fee of $75,000 to Alpha.

Stephen Berkman (“Berkman”), who holds a 49% ownership interest in HDS, has continued to provide additional advances and unsecured loans to HDS, and we expect that Berkman will do so until such time that the Company completes additional financing. As of January 31, 2018, Berkman held $13,864,241 in unsecured loans against HDS. The loan matures on December 31, 2019 and accrued interest for the 2016 calendar year at 0.75% per annum, which was increased from 0.21% for the 2015 calendar year.

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

On January 16, 2017, Joseph Moscato, the Company's Chief Executive Officer and director, and Lawrence Salvo, then Company's Senior Vice President and director, advanced the Company $500,000, which the Company paid to Emmaus Life Sciences, Inc. pursuant to our Letter of Intent with Emmaus. In addition to the Emmaus payment, during the nine-month period ended April 30, 2017, Mr. Moscato and Mr. Salvo advanced to Generex an aggregate of $131,725 for legal and accounting and other expenses incurred in the acquisition of HDS, preparing and filing SEC reports, paying our transfer agent and other expenses. On April 27, 2017, the Company retired these in exchange for Series I Convertible Preferred Stock after applying a 20% original issue discount, the same as original issue discount negotiated at arm's length with Alpha on March 6, 2017. The 20% original issue discount provided Moscato and Salvo of ($65,164 and $66,56, respectfully) was 80% of the debt recognized and converted into Series I Preferred Stock providing 391 shares of Series I Convertible Preferred Stock to Moscato to retire indebtedness of $390,984; and 399 shares of Series I Convertible Preferred Stock to Salvo to retire indebtedness of $399,363.

Stephen Berkman ("Berkman"), who holds a 49% ownership interest in HDS, has continued to provide additional advances and unsecured loans to HDS, and we expect that Berkman will do so until such time that the Company completes additional financing. As of January 31, 2018, Berkman held $13,864,241 in unsecured loans against HDS. The loan matures on December 31, 2019 and accrued interest for the 2016 calendar year at 0.75% per annum, which was increased from 0.21% for the 2015 calendar 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.

In February 2015, the FASB issued ASU 2015-02, Consolidation (Topic 810)—Amendments to the Consolidation Analysis ("ASU 2015-02"), which provides guidance on evaluating whether a reporting entity should consolidate certain legal entities. Specifically, the amendments modify the evaluation of whether limited partnerships and similar legal entities are variable interest entities ("VIEs") or voting interest entities. Further, the amendments eliminate the presumption that a general partner should consolidate a limited partnership, as well as affect the consolidation analysis of reporting entities that are involved with VIEs, particularly those that have fee arrangements and related party relationships. ASU 2015-02 is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. A reporting entity may apply the amendments using a modified retrospective approach or a full retrospective application. We are currently evaluating the impact, if any, that adopting ASU 2015-02 will have on HDS' financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*, which will amend current lease accounting to require lessees to recognize (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. ASU 2016-02 does not significantly change lease accounting requirements applicable to lessors; however, certain changes were made to align, where necessary, lessor accounting with the lessee accounting model. This standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are currently reviewing the provisions of this ASU to determine if there will be any impact on our results of operations, cash flows or financial condition.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting*, which relates to the accounting for employee share-based payments. This standard addresses several aspects of the accounting for share-based payment award transactions, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. This standard will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We are currently reviewing the provisions of this ASU to determine if there will be any impact on our results of operations, cash flows or financial condition.

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

Prior to the filing of this Quarterly Report on Form 10-Q, an evaluation was performed under the supervision of and with the participation of Generex's management, including the President and Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of the Company's disclosure controls and procedures. Based on the evaluation, the CEO and CFO have concluded that, as of January 31, 2018, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to the Company's management, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended January 31, 2018, 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 6 – 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.

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 January 31, 2018, 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 any 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 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 $427,814,171 at January 31, 2018. 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, 2017.

To date, we have not been profitable and our accumulated net loss available to shareholders was $427,814,171 at January 31, 2018, and our consolidated balance sheet reflected a stockholders' deficiency of $62,057,825 at that date. We received a report from our independent auditors for the year ended July 31, 2017 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 fiscal year ended July 31, 2012. Our disclosure controls and procedures and internal controls over financial reporting may not be effective in periods thereafter 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.

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 Exchange Act in a timely manner, and require us to incur additional costs or to divert management resources.

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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 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 were removed from the OTCQBÔ Venture Market.

We did not timely file Quarterly Reports or our Annual Report for the year ended July 31, 2016, and therefore our common stock was no longer quoted on the OTCQBÔ Venture Market. After being removed from the OTCQBÔ Venture Market, quotes for our common stock only appeared on the OTC Pink Market. On November 30, 2017, the Company's common stock resumed quotation on the OTCQBÔ Venture Market.

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 financing may dilute current stockholders.

In the past we have raised significant funds from the issuance of convertible preferred stock and common stock purchase warrants. These securities had conversion and exercise had price protection provisions, which decreased the exercise price of the warrant and conversion price of the preferred stock, and increased the number of shares which would be issued upon exercise of the warrants or conversion of the preferred stock. This feature diluted the prior holders of common stock. All of the convertible preferred stock and warrants outstanding as of October 31, 2016 were exercised or converted in February 2017, and therefore all dilution attributable to these securities has occurred.

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, and may have price protection features.

RISK FACTORS RELATING TO HDS' BUSINESS

Risks related to our industry, business and strategy

Because we may not be able to obtain or maintain the necessary regulatory approvals for some of our products, we may not generate revenues in the amounts we expect, or in the amounts necessary to continue our business. Our existing products, as well as our manufacturing facility must meet quality standards and are subject to inspection by a number of domestic regulatory and other governmental and non-governmental agencies.

All of HDS' proposed and existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Agriculture ("USDA") and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacturing, labeling, distribution and marketing of our products. The process of obtaining required approvals or clearances varies according to the nature of, and uses for, a specific product. These processes can involve lengthy and detailed laboratory testing, human or animal clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for that product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may determine to devote our resources to different products.

Changes in government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

We can manufacture and sell our products only if we comply with regulations and quality standards established by government agencies such as the FDA and the USDA as well as by non-governmental organizations such as the International Organization for Standardization ("ISO") and WHO. We have implemented a quality control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with FDA quality system regulation and that also require meeting certain documentary requirements regarding the approval of the product in export markets. Although we believe that we meet the regulatory standards required for the export of our products, these regulations could change in a manner that could adversely impact our ability to export our products.

Our products may not be able to compete with new diagnostic products or existing products developed by well-established competitors, which would negatively affect our business.

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Some of our principal competitors may have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to, Chembio Diagnostics and Abbot Laboratories. Furthermore, these and/or other companies have or may have products incorporating molecular and/or other advanced technologies that over time could directly compete with our testing product line. As new products incorporating new technologies enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold.

There are competing products that could significantly reduce our U.S. sales of rapid HIV tests.

In 2006 Alere, Inc. acquired a division from Abbott Diagnostic located in Japan that manufactured and marketed a rapid HIV test product line called Determine®. The Determine® format was developed for the developing world and remote settings and, central to the needs of that market. The format is essentially a test strip that is integrated into a thin foil wrapper. When opened, the underside of the wrapper serves as the test surface for applying the blood sample and performing the test. This design reduces costs and shipping weights and volumes and provides an advantage for the developing world markets it serves. Some of the disadvantages of the platform are the amount of blood sample that is needed (50 microliters versus 2.5, 5 and 10 for our lateral flow barrel, lateral flow cassette, and DPP® products respectively), the open nature of the test surface, and the absence of a true control that differentiates biological from other kinds of samples.

The so-called "3rd generation" version of this product has been marketed for many years and is the leading rapid HIV test that is used in a large majority of the national algorithms of countries funded by PEPFAR and the Global Fund, as well as many other countries in the world. That product is not FDA-approved though it is CE marked. The newest Determine® HIV version, which was developed and manufactured by Alere's subsidiary in Israel, Orgenics, is the so-called "4th Generation" version Determine® test. According to its claims, this product detects HIV antibodies and P24 HIV antigens. Because the P24 antigen is known to occur in HIV-positive individuals' blood samples before antibodies do, the 4th generation Determine® test is designed to detect HIV infection earlier than tests that solely rely on antibody detection. HDS’ tests, as well as all of the other currently FDA-approved rapid HIV tests, only detect antibodies.

The initial "4th generation" Alere Determine® rapid test product that was also CE marked and that Alere launched internationally some years ago, has not been successfully commercialized to the best of our knowledge and at least certain published studies were not favorable for this product. However, the 4th generation product that is now

FDA-approved was apparently modified as compared to the initial international version, and it may perform better. Alere received FDA approval of this modified product in August 2013 and a waiver under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) for it in December 2014. Alere is also aggressively pursuing development of the market for this product. Moreover, there is support by a number of key opinion leaders for the public health value of such 4th generation tests, and this product represents a significant competitive threat to Chembio as well as to each of the other rapid HIV test manufacturers (OraSure and Trinity primarily).

During 2011, Biolytical, Inc. of Vancouver, Canada received FDA approval and in 2012 received CLIA waiver of a flow-through rapid HIV test called "INSTI". The flow-through technology used in the INSTI test is older than lateral flow, and requires handling of multiple components (3 vials of solution) to perform the test in multiple steps. However, these steps can be accomplished in less than ten minutes, and the actual test results occur in only one minute after those steps are completed. Therefore sample-to-result time is shorter than any of the competitive products. The product also has good performance claims. There are settings where that reduced total test time, despite the multiple steps required, may be a distinct advantage, and we believe Biolytical has made some progress in penetrating certain public health markets.

Therefore, even though our lateral flow products currently enjoy a substantial market share in the U.S. rapid HIV test market, and we have an additional rapid HIV test, the DPP® HIV 1/2 Assay, there a number of risks and uncertainties concerning current and anticipated developments in this market. Although we have no specific knowledge of any other new product that is a significant competitive threat to our products, or that will render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use products developed by our competitors, which could result in a loss of revenues and cash flow.

More generally, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services. As new technologies are introduced into the point-of-care diagnostic testing market, we may be required to commit considerable additional efforts, time and resources to enhance our current product portfolio or develop new products. We may not have the available time and resources to accomplish this, and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, which would materially harm our operating results.

Our use of third-party suppliers, some of which may constitute our sole supply source, for certain important product components presents a risk that could have negative consequences for other business.

A number of the components and critical raw materials used in the manufacture of our products are provided by third-party suppliers, some of which may be sole-source suppliers, which impacts our ability to manufacture or sell product if our suppliers cannot or will not deliver those materials in a timely fashion, or at all, due to an interruption in their supply, quality or technical issues, or any other reason. If this occurs, we could expend substantial expense and time in re-establishing relationships with third-party suppliers that meet the appropriate quality, cost and regulatory requirements needed for commercially viable manufacture of our products or in re-designing our products to incorporate different components and raw materials that are available from third-party suppliers. Thus, the loss of any one or more of our current third-party suppliers could prevent us from commercial production of our products, and there is no guarantee that we would be able to establish relationships with new third-party suppliers of the same or different components and raw materials in the future.

New developments in health treatments or new non-diagnostic products may reduce or eliminate the demand for our products.

The development and commercialization of products outside of the diagnostics industry could adversely affect sales of our products. For example, the development of a safe and effective vaccine to HIV or treatments for other diseases or conditions that our products are designed to detect, could reduce or eventually eliminate the demand for our HIV or

other diagnostic products and result in a loss of revenues.

We may not have sufficient resources to effectively introduce and market our products, which could materially harm our operating results.

Introducing and achieving market acceptance for our products will require substantial marketing efforts and will require us and/or our contract partners, sales agents, and/or distributors to make significant expenditures of time and money. In some instances, we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, sales agents, and/or distributors. If they do not have or commit the expertise and resources to effectively market the products that we manufacture, our operating results will be materially harmed.

The success of our business depends on, in addition to the market success of our products, our ability to raise additional capital through the sale of debt or equity or through borrowing, and we may not be able to raise capital or borrow funds on attractive terms and/or in amounts necessary to continue our business, or at all.

Our liquidity and cash requirements will depend on several factors. These factors include, among others, (1) the level of revenues; (2) the extent to which, if any, that revenue level improves operating cash flows; (3) our investments in research and development, facilities, marketing, regulatory approvals, and other investments we may determine to make; and (4) our investment in capital equipment and the extent to which it improves cash flow through operating efficiencies. We do not expect to generate positive cash flow in next twelve months, and we cannot be sure that we will be successful in raising sufficient capital to fund our needs. If we are not able to raise additional capital from another source, we will be required to substantially reduce our operating costs, including the possibilities of suspending our unfunded research and development activities, and quickly curtailing any cash flow negative product initiatives.

Our near term sales are difficult to predict in the uncertain status of pending orders and certain regulatory approvals, and the uncertain time until we have approval to sell in the US. We believe that underlying demand for HIV rapid testing in the U.S. remains strong; however, with the current uncertainty in the U.S. health insurance market and the possible repeal of the Affordable Care Act, we cannot be certain that we would receive adequate reimbursement, or any at all, for our products from insurance payers (public or private) in the U.S. Furthermore, developing new customers in the U.S. market for this product is likely to be costly and time-consuming.

Currently, we are dependent on international markets for sales of our products, subjecting us to increased volatility in sales, additional regulatory and/or donor-funded mandates, and potential risks of anti-corruption violations by our employees, agents and distributors.

At the present time, we are dependent on international sales of our products, since we have no products approved by the FDA for US sales.

A number of factors can slow or prevent international sales increases or cause sales decreases, or substantially increase the cost of achieving sales assuming they are achieved. These factors include:

- economic conditions and the absence of or reduction in available funding sources;
- regulatory requirements and customs regulations;
- cultural and political differences;
- foreign exchange rates, currency fluctuations and tariffs;
- dependence on and difficulties in managing international distributors or representatives;
- the creditworthiness of foreign entities;
- difficulties in foreign accounts receivable collection;
- competition;
- pricing; and
- any inability we may have in maintaining or increasing revenues.

These factors are exacerbated by our dependence on sales to international donor-funded programs and/or government agencies, where we experience volatility in demand from period to period, depending on ordering patterns of such programs or agencies. Furthermore, in the donor-funded markets in Africa where we sell our products, there is significant oversight from PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols.

In addition, although we have no knowledge of any practices by our employees, agents or distributors that could be construed as in violation of such policies, our business includes sales of products to countries where there is or may be

widespread corruption. We have a policy in place prohibiting our employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the U.S. Foreign Corrupt Practices Act. Nevertheless, because we work through independent sales agents and distributors in a number of the countries that historically have experienced systemic corruption and do not have control over the day-to-day activities of such independent agents and distributors, we face a greater risk under applicable anti-corruption laws and regulations.

Although we have an ethics and anti-corruption policy in place, and have no knowledge or reason to know of any practices by our employees, agents or distributors that could be construed as in violation of such policies, our business includes sales of products to countries where there is or may be widespread corruption.

HDS has a policy in place prohibiting its employees, distributors and agents from engaging in corrupt business practices, including activities prohibited by the United States Foreign Corrupt Practices Act (the "FCPA"). Nevertheless, because we work through independent sales agents and distributors outside the United States, we do not have control over the day-to-day activities of such independent agents and distributors. In addition, in the donor-funded markets in Africa where we sell our products, there is significant oversight from PEPFAR, the Global Fund, and advisory committees comprised of technical experts concerning the development and establishment of national testing protocols. This is a process that includes an overall assessment of a product which includes extensive product performance evaluations including five active collaborations and manufacturer's quality systems, as well as price and delivery. In Brazil, where we have had a total of six product collaborations with FIOCRUZ, the programs through which our products may be deployed are all funded by the Brazilian Ministry of Health. Although FIOCRUZ is affiliated with the Brazilian Ministry of Health, and is its sole customer. We have no knowledge or reason to know of any activities by our employees, distributors or sales agents of any actions which could be in violation of the FCPA, although there can be no assurance of this.

To the extent that we are unable to collect our outstanding accounts receivable, our operating results could be materially harmed.

There may be circumstances and timing that require us to accept payment terms, including delayed payment terms, from distributors or customers, which, if not satisfied, could cause financial losses. We generally accept payment terms which require us to ship product before the contract price has been paid fully, and there also are circumstances pursuant to which we may accept further delayed payment terms pursuant to which we may continue to deliver product. To the extent that these circumstances result in significant accounts receivables and those accounts receivables are not paid on a timely basis, or are not paid at all, especially if concentrated in one or two customers, we could suffer financial losses.

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

No reportable transactions occurred in the fiscal quarter ended January 31, 2018.

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 January 31, 2018.

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Item 3. Defaults Upon Senior Securities.

None in the fiscal quarter ended January 31, 2018.

Item 5. Other Information.

As reported in our Current Report on Form 8-K dated November 21, 2017, at our Annual meeting of Stockholders, the stockholders approved an amendment to the Company's Restated Certificate of Incorporation to increase the authorized number of shares of common stock from 2,450,000 shares to 750,000,000 shares. A Certificate of Amendment effecting the increase was filed with the Delaware Secretary of State on November 27, 2017. In addition, the stockholders approved our 2017 Equity Incentive Plan which authorizes the issuance of stock and option grants for up to 240,000,000 shares of common stock. No grants have been made under the 2017 Equity Plan as of the date this Quarterly report was filed.

On December 28, 2017, the Company, through a new wholly-owned subsidiary NuGenerex Distribution Solutions, LLC, acquired two pre-operational pharmacies, Empire State Pharmacy LLC in New York State and Grainland Pharmacy LLC in the State of Kansas. It is expected that both locations will be fully operational in 2018 The Company issued a non-recourse promissory note, payable with 5% interest on July 28, 2018. The only remedy of seller for the Company's failure to pay is the reacquisition of the pharmacy assets by the seller.

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 43 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: March 16, 2018 By: */s/ Joseph Moscato*

Joseph Moscato
President and Chief Executive Officer

Date: March 16, 2018 By: */s/ Mark Corrao*

Mark Corrao
Chief Financial 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)
10.37.1	Form of Acquisition Agreement by and among Generex Biotechnology Corporation and Hema Diagnostic Systems, LLC and other parties listed on the signature pages thereto (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2017)
10.38.1	Form of Letter of Intent Acquisition Agreement by and among Generex Biotechnology Corporation and Emmaus Life Sciences, Inc., the acquire thereto (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2017.
31.1	Certification of President and Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of President and Chief Executive Officer and Chief Financial 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.