

GENEREX BIOTECHNOLOGY CORP
Form 10-Q
March 25, 2019

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, 2019

**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

(State or other jurisdiction of incorporation or organization)

98-0178636

(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 60,362,143 as of March 25, 2019.

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, 2019	July 31, 2018
ASSETS		
Current Assets		
Cash and cash equivalents	\$2,186,377	\$1,046,365
Accounts receivable, net	2,466,138	33,555
Inventory, net	1,099,508	12,075
Other current assets	280,271	96,251
Total current assets	6,032,294	1,188,246
Property and equipment	645,607	31,536
Notes receivable - noncurrent (Note 11)	1,406,051	—
Call option (Note 8)	—	2,168,211
Goodwill and intangible asset (Note 9,10 and 11)	64,939,874	3,187,757
Patents, net	21,987	23,280
Other assets, net	18,821	7,824
TOTAL ASSETS	\$73,064,634	\$6,606,854
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities		
Accounts payable and accrued expenses	\$16,917,095	\$11,044,774
Notes payable, current (Note 9, 11, and 12)	40,919,835	320,000
Loans from related parties (Note 3)	13,200	13,864,241
Deferred tax liability	1,930,495	—
Total Current Liabilities	59,780,625	25,229,015
Notes payable - noncurrent	149,637	—
Derivative liability (Note 11 and 12)	2,545,810	—
Warrants to be issued (Note 8)	—	24,962,507
Total Liabilities	62,476,072	50,191,522
Commitments and Contingencies (Note 4)		
Stockholders' Deficiency (Note 6)		
Series H Convertible Preferred Stock, \$.001 par value; authorized 109,000 shares, 0 and 63,000 issued shares at January 31, 2019 and July 31, 2018, respectively	—	3
	—	1

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Series I Convertible Preferred Stock, \$.001 par value; authorized 6,000 shares, 0 and 16,590 issued shares at January 31, 2019 and July 31, 2018, respectively		
Regentys Series A Redeemable Convertible Preferred Stock, \$0.0001 par value; authorized 2,793,192 shares, issued shares at January 31, 2019 and July 31, 2018, respectively.	1,815,575	—
Olaregen Series A Preferred Stock, \$0.001 par value; authorized 592,683 and 0 shares at January 31, 2019 and July 31, 2018, respectively; 592,683 and 0 issued shares at January 31, 2019 and July 31, 2018, respectively	1,000,000	—
Common stock, \$.001 par value; authorized 750,000,000 and 750,000,000 shares at January 31, 2019 and July 31, 2018, respectively; 60,362,164 and 22,430,121 issued and outstanding at January 31, 2019 and July 31, 2018, respectively	60,362	22,430
Common stock payable	201,294	2,168,951
Additional paid-in capital	384,414,252	368,388,265
Treasury stock	—	
Accumulated deficit	(403,460,965)	(409,386,468)
Accumulated other comprehensive income	800,446	798,422
Non-controlling interest (Note 8)	25,757,598	(5,576,272)
Total Stockholders' Deficiency	10,588,562	(43,584,668)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY	\$73,064,634	\$6,606,854
Going Concern (Note 1)		
Commitments & Contingencies (Note 4)		
Subsequent Events (Note 13)		

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 INCOME

	Three Months Ended January 31,		Six Months Ended January 31,	
	2019	2018	2019	2018
Revenue				
Revenue, net	\$4,848,794	\$—	\$6,567,942	\$2,218
Licensing income	—	700,000	—	700,000
Total Revenue	4,848,794	700,000	6,567,942	702,218
Cost of Goods Sold	2,011,679	—	2,882,300	—
Gross Profit	2,837,115	700,000	3,685,642	702,218
Operating expenses				
Research and development	810,938	150,897	991,005	388,679
General and administrative	7,595,469	714,689	9,868,110	1,116,050
Total operating expenses	8,406,407	865,586	10,859,115	1,504,729
Operating Loss	(3,557,613)	(165,586)	(7,173,473)	(802,511)
Other Income (Expense):				
Interest expense	(2,097,220)	(142,245)	(2,262,936)	(277,190)
Interest income			768	—
Changes in fair value of contingent purchase consideration (Note 8)	(4,397,507)	(9,521,747)	15,147,591	18,776,629
Change in fair value of derivative liability			142,725	
Other income, net	(51,322)	—	(47,436)	—
Net Income	(10,345,801)	(9,829,578)	5,565,100	17,696,928
Net loss attributable to noncontrolling interests (Note 8)	(272,147)	(92,934)	(360,403)	(209,467)
Net Income Available to Common Stockholders	\$(10,073,654)	\$(9,736,644)	\$5,925,503	\$17,906,395
Net Income per Common Share				
Basic	\$(0.28)	\$(9.12)	\$0.16	\$16.76
Diluted	\$(0.28)	\$(9.12)	\$0.16	\$6.90
Shares Used to Compute Income per Share (Note 5)				
Basic	36,387,206	1,068,101	36,387,206	1,068,101
Diluted	36,387,206	1,068,101	36,387,206	2,595,974
Comprehensive Income:				
Net Income	\$(10,073,654)	\$(9,736,644)	\$5,925,503	\$17,906,395
Change in foreign currency translation adjustments	—	(15,730)	2,024	(3,898)
	\$(10,073,654)	\$(9,752,374)	\$5,927,527	\$17,902,497

Comprehensive Income Available to Common
Stockholders

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 CHANGES IN STOCKHOLDERS' DEFICIT

	Preferred Stock		Common Stock		Common Stock Payable	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income
	Shares	Amount	Shares	Amount				
Balance at July 31, 2017	79,590	\$4	22,430,121	\$22,430	\$2,168,951	\$368,388,265	\$(445,720,566)	\$783,150
Net Income (Loss)	—	—	—	—	—	—	36,334,098	—
Investment in subsidiary by noncontrolling interest	—	—	—	—	—	—	—	—
Currency translation adjustment	—	—	—	—	—	—	—	15,272
Balance at July 31, 2018	79,590	\$4	22,430,121	\$22,430	\$2,168,951	\$368,388,265	\$(409,386,468)	\$798,422
Net Income (Loss)	—	—	—	—	—	—	5,925,503	—
Investment in subsidiary by noncontrolling interest	—	—	—	—	—	—	—	—
Issuance of common stock	—	—	—	—	—	—	—	—
Conversion of preferred series H	(63,000)	(3)	6,630,624	6,631	—	(6,631)	—	—
Conversion of preferred series I	(16,590)	(1)	25,200,000	25,200	—	(25,200)	—	—
Additional Paid In Capital on Acquisition of Regentys	—	—	—	—	—	(2,215,575)	—	—
Additional Paid In Capital on Acquisition of Olagaren	—	—	—	—	—	(750,541)	—	—
Elimination of non-controlling interest	—	—	—	—	—	(6,951,015)	—	—

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Issuance of common stock payable	—	—	6,068,517	6,068	(1,967,657)	1,961,589	—	—
Issuance of stock options	—	—	—	—	—	924,845	—	—
Extinguishment of debt	—	—	32,881	33	—	14,056,079	—	—
Preferred shares series A acquired in acquisition of Regentys	2,793,192	1,815,575	—	—	—	—	—	—
Preferred shares series A acquired in acquisition of Olaregen	592,683	1,000,000	—	—	—	—	—	—
Issuance of warrants	—	—	—	—	—	9,032,435	—	—
Acquisition of NCI of Veneto	—	—	—	—	—	—	—	—
Acquisition of NCI of Regentys	—	—	—	—	—	—	—	—
Acquisition of NCI of Olaregen	—	—	—	—	—	—	—	—
Acquisition of NCI of HDS	—	—	—	—	—	—	—	—
Currency translation adjustment	—	—	—	—	—	—	—	2,024
Balance at January 31, 2019	3,385,875	\$2,815,575	60,362,143	\$60,362	\$201,294	\$384,414,252	\$(403,460,965)	\$800,446

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

	January 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income	\$5,565,100	\$17,696,928
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	73,034	2,022
Issuance of stock options as compensation	924,845	—
Changes in fair value of contingent purchase consideration	(15,147,591)	(18,776,629)
Change in fair value of derivative liabilities	202,500	—
Changes in operating assets and liabilities:		
Accounts receivable	516,822	(175)
Inventory	389,924	(2,011)
Accounts payable and accrued expenses	3,285,386	211,670
Accrued interest on notes receivable	(18,288)	—
Other current assets	9,094	(205,097)
Other assets	(10,997)	
Net used in operating activities	(4,210,171)	(1,073,292)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(10,070)	(5,385)
Disposal of property and equipment	(5,393)	
Issuance of note payable	13,986	—
Cash received in acquisition of a business	1,722,814	—
Net cash used in investing activities	1,721,337	(5,385)
CASH FLOWS FROM FINANCING ACTIVITIES		
Loan proceeds from related party	(3,305)	126,101
Payment of notes payable	(28,011)	—
Proceeds from note payable	3,524,460	—
Investment in subsidiary by noncontrolling interest	133,679	125,376
Net cash provided by financing activities	3,626,823	251,477
Effects of currency translation on cash and cash equivalents	2,024	(3,898)
Net increase (decrease) in Cash and Cash Equivalents	1,140,012	(831,098)
Cash and Cash Equivalents, Beginning of Period	1,046,365	2,879,165
Cash and Cash Equivalents, End of Period	\$2,186,377	\$2,048,067

Supplemental Disclosure of Cash Flow Information

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. Subsequently, on December 1, 2018, the Company exercised its call option and closed the acquisition of remaining 49% interest in HDS to become a wholly owned subsidiary of the Company.

On October 3, 2018, the Company entered into an Asset Purchase Agreement with Veneto Holdings, L.L.C. (“Veneto”) to purchase certain assets of Veneto and its subsidiaries. The Agreement bifurcated the closing. On October 3, 2018 (the “First Closing”), the Company purchased substantially all the operating assets of Veneto including (a) system of dispensing pharmacies, (b) one central adjudicating pharmacy, (c) a wholesale pharmaceutical purchasing company, and (d) an in-network laboratory in exchange for a secured promissory note in the principal amount of \$15,000,000. On November 1, 2018 the Company consummated the acquisition of the Second Closing Assets, consisting primarily of Veneto’s management services organization business and two additional ancillary services. The aggregate price for the First Closing Assets and the Second Closing Assets was \$30,000,000. The Company issued a promissory note in the principal amount of \$35,000,000 (the “New Note”) consisting of the \$30,000,000 purchase price and a \$5,000,000 original issue discount, as the sole consideration payable on the Second Closing Date. On January 15, 2019, the Company entered into an Amendment Agreement (the “Amendment”) with Veneto and the equity owners of Veneto entered into restructuring payment of the Note. At the time of filing the Amendment is still negotiating terms and as such, has not been finalized.

On January 7, 2019, the Company closed two separate Acquisition Agreements pursuant to which the Company acquired a 51% interest in both Regentys Corporation (“Regentys”) and Olaregen Therapeutix Inc. (“Olaegen”). Regentys is a regenerative medicine company focused on developing novel treatments for patients with gastrointestinal (GI) disorders. Olaegen is a New York based regenerative medicine company that is preparing to launch its proprietary, patented, wound conforming gel matrix, Excellagen, an FDA 510K Cleared wound healing product. The terms of the Regentys acquisition included an upfront payment of \$400,000, plus \$14,600,000 to be paid according to a milestone-based schedule. The terms of the Olaegen acquisition included an upfront payment of \$400,000, plus \$11,600,000 to be paid according to a milestone-based schedule.

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 \$403 million and a working capital deficiency of approximately \$54 million at January 31, 2019. The Company has funded its activities to date almost exclusively from debt and equity financings.

The Company will continue to require substantial funds to implement its new investment acquisition plans. Management’s plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings, 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 – Summary of Significant Accounting Policies:

Revenue Recognition—Revenue is recognized when: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

Revenue from the provision of pharmacy services is recognized when the prescription is dispensed (picked up by the patient or shipped to the patient using common carrier or delivered by the pharmacies own personnel). At the time of dispensing each pharmacy has a contract with the insurance payor (item (i)); the insurance payor has accepted the claim for reimbursement from the pharmacy and informed the pharmacy how much will be paid for the prescription (item (iii)); the insurance payor is now legally obligated to make payment on the accepted claim within a given period proscribed by statute (item (iv)); and, the prescription has been taken from the pharmacy inventory, placed into an individually labeled container specific to the patient, and the patient is able to take possession of the prescription (item (ii)). Shipment to or pick up by the patient is the first time that all criteria for revenue recognition have been met.

Revenue from the provision of laboratory services is recognized upon the completion of accessions (the requested laboratory test has been performed and the report has been issued to the requesting physician). After the test has been performed and reported, the insurance company and/or patient has an obligation to pay for medically necessary laboratory tests (items (i) and (ii)). Unlike the pharmacy services model, laboratory services are provided prior to insurance company approval; as a result, the seller's price to buyer is not known until payment is provided (items (iii) and (iv)). Based on historical collections, the Company estimates the expected revenues associated with similar tests and recognizes the revenue when testing results have been provided.

Provisions for estimated sales returns and uncollectible accounts are recorded in the period in which the related sales are recognized based on historical and anticipated rates.

The Company determines whether it is the principal or agent for its retail pharmacy contract services on a contract by contract basis. In the majority of its contracts, the Company has determined it is the principal due to it: (i) being the primary obligor in the arrangement, (ii) having latitude in changing the product or performing part of the service, (iii) having discretion in supplier selection, (iv) having involvement in the determination of product or service specifications, and (v) having credit risk. The Company's obligations under its client contracts for which revenues are reported using the gross method are separate and distinct from its obligations to the third-party pharmacies included in its retail pharmacy network contracts. Pursuant to these contracts, the Company is contractually required to pay the third-party pharmacies in its retail pharmacy network for products sold, regardless of whether the Company is paid by

its clients. The Company's responsibilities under its client contracts typically include validating eligibility and coverage levels, communicating the prescription price and the co-payments due to the third-party retail pharmacy, identifying possible adverse drug interactions for the pharmacist to address with the prescriber prior to dispensing, suggesting generic alternatives where clinically appropriate, and approving the prescription for dispensing. Although the Company does not have credit risk with respect to Retail Co-Payments or inventory risk related to retail network claims, management believes that all of the other applicable indicators of gross revenue reporting are present. For contracts under which the Company acts as an agent, revenue is recognized using the net method.

Cost of Goods Sold—Costs and directly related expenses to sell the Company’s products and services are recorded as cost of goods sold when the related revenue is recognized. The Company records shipping and handling costs related to delivery of products to customers within cost of goods sold.

Inventories—Inventories, which consist of finished goods, are stated at the lower of cost, determined principally under the first-in, first-out method, or net realizable value. Inventories include the cost of pharmaceuticals, reagents, and consumables. Obsolete or excess inventories are reflected at their estimated realizable values. Net realizable value is the estimated sales revenue for a normal period of activity less expected selling costs. Allowances for excess and obsolete inventory are recognized for excess amounts, obsolescence and declines in net realizable value below cost. Estimation and judgment are required in determining the value of the allowance for excess and obsolete inventory at each statement of financial position date. Management specifically analyzes estimates of future demand for products when determining allowances for excess and obsolete inventory. Changes in these estimates could result in revisions to the valuation of inventory in future periods.

Property and Equipment—Property, equipment and improvements to leased premises are depreciated using the straight-line method over the estimated useful lives of the assets, or when applicable, the term of the lease, whichever is shorter. Major renewals or replacements that substantially extend the useful life of an asset are capitalized and depreciated. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which are generally as follows:

Leasehold improvements	The shorter of the expected useful life of the improvement or the lease term
Computers and technological assets	3-5 years
Machinery and equipment	5 years
Furniture and fixtures	7 years

Assets acquired through finance lease arrangements or long-term rental arrangements that transfer substantially all the risks and rewards associated with ownership of the asset to the Company (as lessee) are capitalized.

Reclassifications to Prior Period Financial Statements and Adjustments

Certain reclassifications have been made in the Company’s financial statements of the prior year to conform to the current year presentation. These reclassifications have no impact on previously reported net income.

Adoption of New Accounting Standards

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.

- 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. The guidance was adopted as of August 1, 2018. The Company performed a cumulative adjustment and found that the adoption did not have a material effect on the Company’s consolidated financial statements and related disclosures.

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 guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

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. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

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 update is effective for fiscal years beginning after December 15, 2017. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company's consolidated financial statements and related disclosures.

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. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company's consolidated financial statements and related disclosures.

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. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Standards

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 is required to adopt ASU 2016-02 for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018. The Company does not plan to elect early adoption for this pronouncement.

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 Company will adopt the standard effective October 1, 2020. The Company is evaluating the effect that ASU 2017-04 will have on its 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.

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.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement", which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. The Company is evaluating the effect that ASU 2018-13 will have on its consolidated financial statements.

Note 3 - Loans from Related Parties

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 bears 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.

Pursuant to the January 18, 2017 Acquisition, Mr. Berkman agreed, under certain conditions to transfer the remaining 49% of the HDS equity to the Company for a consideration of \$1.00. On December 1, 2018, the Company and Mr. Berkman entered into an Agreement, Assignment and Release, pursuant to which Mr. Berkman transferred the remaining HDS equity interests to the Company, waiving and releasing any conditions to such transfer. HDS is now a wholly owned subsidiary of the Company. In addition to the assignment of the HDS interests, Mr. Berkman released these loans in exchange for shares of the Company's common stock valued at the aggregate of such amount using the

closing price for the common stock on November 30, 2018. The closing price was \$18.99, resulting in 32,881 shares issuable to Mr. Berkman. This transaction resulted in \$624,404 plus the remaining 49% of the Company's shares of the HDS debt being removed from Company debt and added to the Company's stockholders' equity.

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 dormant.

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. This has been accrued in the unaudited condensed interim consolidated financial statements.

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 December 2, 2018, an arbitrator awarded Three Brothers Trading LLC, d/b/a Alternative Execution Group ("AEXG") an aggregate of \$315,695 in damages, costs and fees as well as warrants exercisable for 84,000 shares of Generex Common Stock at an exercise price of \$2.50 per share. The awards were made pursuant to claims under a Memorandum of Understanding ("MOU") between Generex and AEXG related to AEXG referring potential financing candidate to Generex. AEXG filed a petition to confirm the arbitrator's award in the United States District Court for the Southern District of New York. The petition includes a demand of \$3,300,360 as the value of the Warrants. The arbitrator did not award the specific amount of \$3.3 million, but only liquidated damages in the amount of \$220,000 and the value of 84,000 warrants "as of today" (the date of the award) plus attorney's fees, certain costs, prejudgment and post-judgment interest (which

continues to run on a daily basis) and arbitration fees. Generex has responded that the value of the warrants on the date of the award is \$0 or some figure far less than the value calculated by AEXG. The petition to confirm the arbitrator's award and Generex's opposition are pending before the Court for a decision.

On June 28, 2018, the Company was named in respect of a claim by Burrard Pharmaceutical Enterprises Ltd. and Moa'yeri Kayhan for unspecified damages and other remedies issued by the Supreme Court of British Columbia. The claim is made in connection with one advanced against Burrard and Kayhan by Middle East Pharmaceutical Factory L.L.C., a foreign corporation, for fraudulent or negligent misrepresentation. Middle East alleges that it was misled by Burrard and Kayhan into believing that Burrard had rights to distribute Generex product in the Middle East. Burrard and Kayhan allege that they did have rights in that regard, which the Company denies. The matter remains at the pleadings stage and the Company is investigating the facts.

On October 26, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note Due October 26, 2019 ("Note") in the principal amount of \$682,000. On January 25, 2018, Generex received a letter from the purchaser's counsel stating that the Note was in default because Generex's common stock was not listed on NASDAQ within 90 days after the issuance of the Note. The letter demanded repayment in full. On February 12, 2019, the Purchaser filed a Motion for Summary Judgment in lieu of complaint in the Supreme Court of New York, demanding the aggregate principal amount, default interest and costs. Counsel for Generex and Alpha have engaged in settlement discussions which are likely to result in an agreement by Generex to pay an amount more than the existing note payable balance of \$600,000 but less than the full amount demanded over a period of four months.

In connection with the second closing of the acquisition of certain operating assets of Veneto Holdings, L.L.C. and its affiliates, Generex's wholly owned subsidiary agreed to assume outstanding debt of Veneto subsidiaries to Compass Bank, including obligations under a term loan and a revolving line of credit. Claiming three separate types of default, Compass Bank has demanded payment in full of amounts due under the term loan and revolving line of credit, in an aggregate amount of approximately \$3,413,000. Generex believes it has defenses to such demand, including that the bank was not an intended beneficiary of the subsidiary's agreement to assume the debt.

There are rental agreements in effect at Hema Diagnostics Systems, Grainland Pharmacy Inc. and Empire State Pharmacy Inc. and paid out in the following periods: \$45,271 in fiscal year 2019, \$82,469 in fiscal year 2020 and \$9,306 in fiscal year 2021.

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 Per Share ("EPS"):

Basic net income or loss per share is calculated using the weighted average number of common shares outstanding during the period. Diluted net 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 17,850 for the three and six months ended January 31, 2019.

	Three Months Ended	Three Months Ended
	January 31, 2019	January 31, 2018
Weighted average number of common shares outstanding - Basic	49,967,615	22,430,121
Potentially dilutive common stock equivalents	5,127,472	32,085,329
Weighted average number of common and equivalent shares outstanding-Diluted	55,095,087	54,515,450

	Six Months Ended	Six Months Ended
	January 31, 2019	January 31, 2018
Weighted average number of common shares outstanding - Basic	36,387,185	22,430,121
Potentially dilutive common stock equivalents	5,127,472	32,085,329
Weighted average number of common and equivalent shares outstanding-Diluted	41,514,657	54,515,450

Note 6 - Stockholders' Deficiency:

Common Stock

On October 3, 2018, the Company declared a stock dividend on our outstanding Common Stock for stockholders of record date to be determined (the "Record Date"). As a result, all stockholders on the Record Date received twenty new shares of Common Stock for each share of Common Stock owned by them as of that date. Proportional adjustments for the reverse stock split were made to the Company's outstanding stock options, and warrants including all share and per-share data, for all amounts and periods presented in the consolidated financial statements.

On January 18, 2017, the Company issued 1,117,431 shares of common stock for the acquisition of 51% of HDS and is obligated to issue 4,830,000 shares of common stock upon the conclusion of the Company's reverse stock split. On October 26, 2018, 4,830,000 shares were issued.

During January 2017, the Company issued 168,000 shares of common stock for the conversion of 120 shares of Series F convertible preferred stock, plus 88,935 shares for the related make-whole payments issued to convert the accumulated dividend payable.

During January 2017, the Company issued 210,000 shares of common stock for the conversion of 150 shares of Series G convertible preferred stock, plus 98,448 shares for the related make-whole payments issued to convert the accumulated dividend payable.

During February 2017, the Company issued 489,993 shares of common stock for the conversion of 350 shares of Series G convertible preferred stock, plus 222,726 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 \$0.35 per share from \$0.71 per share. The Company agreed to issue a total of 2,179,989 shares of common stock in connection with the exercise of 6,607,629 warrants in connection with the following outstanding warrants:

Warrants	Shares
Exercised	Agreed to

		be Issued
Series C 9% Convertible Preferred Stock	210,000	69,279
Series D 9% Convertible Preferred Stock	349,629	115,332
Series E 9% Convertible Preferred Stock	2,513,007	829,101
Series F 9% Convertible Preferred Stock	2,904,993	958,419
Series G 9% Convertible Preferred Stock	630,000	207,858
	6,607,629	2,179,989

During the six months ended January 31, 2019, 1,238,517 common stock payable was issued. As at January 31, 2019, 349,545 shares remain to be issued resulting in common stock payable \$201,294.

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 \$1000 per share and authorized 6,000 shares of designated non-voting Series I Convertible Preferred Stock with a stated value of \$47.61 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 \$.12 per share. An aggregate of 966,000,000 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 63,000 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 was repaid to the Company in July 2017 upon termination of the Emmaus LOI. On December 1, 2018, after payment of the dividend, B-H Sanford, LLC, converted all shares of its holding of the Company's Series H Convertible Preferred Stock owned by it into 25,200,000 shares of common stock.

Prior to payment of Generex's 20 for 1 common stock dividend, on November 30, 2018, Joseph Moscato, the Company's President and Chief Executive Officer, and Lawrence Salvo, a member of the Company's Board of Directors, converted all shares of the Company's Series I Convertible Preferred Stock owned by them. Mr. Moscato received 3,276,000 shares of the Company's Common Stock upon conversion. Mr. Salvo received 3,354,645 shares of the Company's Common Stock upon conversion.

Noncontrolling Interest

Mr. Berkman agreed, under certain conditions to transfer the remaining 49% of the HDS equity to the Company for a consideration of \$1.00. On December 1, 2018, the Company and Mr. Berkman entered into an Agreement, Assignment and Release, pursuant to which Mr. Berkman transferred the remaining HDS equity interests to the Company, waiving and releasing any conditions to such transfer. As of December 1, 2018, HDS is a wholly owned subsidiary of the Company. During the six months ended in January 31, 2019, there was a net loss attributable to the non-controlling interest (49%) in HDS of \$122,692 and contributions made of \$174,371. As of January 31, 2019, and July 31, 2018, the non-controlling interest in HDS was \$0 and \$5,576,272, respectively.

On November 28, 2018, the Company and Regentys closed on an agreement to acquire 51% of the outstanding capital stock of Regentys for a total consideration of fifteen million dollars (\$15,000,000). In connection with the acquisition, the Company was issued 12,048,161 shares of Regentys common stock. As of January 31, 2019, Regentys had authorized a total of 18,623,278 shares of common stock and 2,793,192 Series A voting preferred stock for a total of 21,416,470 total voting shares outstanding. As such, the Company has 9,368,309 of non-controlling shares for a 43.74% non-controlling interest in Regentys.

On November 27, 2018, the Company and Olaregen closed on an agreement to acquire 51% of the outstanding capital stock of Olaregen for a total consideration of twelve million dollars (\$12,000,000). In connection with the acquisition, the Company was issued 3,282,632 shares of common stock. As of January 31, 2019, Olaregen had authorized a total of 5,648,819 shares of common stock and 592,683 Series A voting preferred stock for a total of 6,241,502 total voting shares outstanding. As such, the Company has 2,958,870 of non-controlling shares for a 47.41% non-controlling interest in Olaregen.

On November 1, 2018, the Company completed its second closing of Veneto Holdings, L.L.C. (“Veneto”) which granted the Company with a 99% non-controlling interest in Rapport Services, LLC (“Rapport”).

Note 7- Stock-Based Compensation:**Stock Option Plans**

As of January 31, 2019, 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 2,835,000 shares of common stock are reserved for issuance under the 2006 Stock Plan as amended (the 2006 Plan) and 5,040,000,000 shares of common stock reserved for issuance under the 2017 Stock Option Plan (the 2017 Plan). At January 31, 2019, there were 2,817,150 and 5,033,799,375 shares of common stock reserved for future awards under the 2006 Plan and 2017 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 2006 and 2017 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 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, 2018	232,218	\$ 1.46
Granted	6,220,625	0.47
Forfeited or expired	(214,371)	(0.05)
Exercised	—	—
Outstanding - January 31, 2019	6,238,472	\$ 0.56

The 6,221,475 outstanding options at January 31, 2019 had a weighted average remaining contractual term of 9.68 years.

There were 942,695 vested common stock options under the Plan for the period ended January 31, 2019. As of January 31, 2019, the Company had \$212,121 of unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan.

The Company granted 6,220,625 options during the six months ended January 31, 2019 and none during the year ended July 31, 2018.

The Company estimated the fair value of each stock option on the grant date using a Black-Scholes option-pricing model. Black-Scholes option-pricing models requires the Company to make predictive assumptions regarding future stock price volatility, recipient exercise behavior, and dividend yield. The Company estimated the future stock price volatility using the historical volatility over the expected term of the option. The following assumptions were used in the Black-Scholes option-pricing model:

	January 31, 2019
Exercise price	\$0.64 - 1.08
Time to expiration	10 years
Risk-free interest rate	2.56% - 3.14%
Estimated volatility	135.2% - 143.1%
Dividend	—
Stock price at valuation date	\$0.64 - 1.08

The following table summarizes information on stock options outstanding at January 31, 2019:

Range of Exercise Price	Options Outstanding and Options Exercisable		Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
	Number Outstanding at January 31, 2019	Weighted Average Exercise Price		
\$0.11	2,730,000	\$0.11	9.93	\$5,525,000
0.64	1,328,125	0.64	9.68	1,978,906
0.78	1,712,500	0.78	9.87	2,311,875
0.92	200,000	0.92	9.92	242,000
1.08	250,000	1.08	9.93	262,500
\$30.48	17,850	\$30.48	1.10	—
	6,238,475	5.95	9.74	\$10,320,281

The intrinsic value is calculated as the difference between the market value and the exercise price of the shares on January 31, 2019. The market values as of January 31, 2019 was \$2.13 based on the closing bid price for January 31, 2019

Note 8 – Acquisitions:

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 1,117,011 shares of Generex common stock valued at \$253,721, plus 420 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 was required to issue a further 4,830,000 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. As of January 31, 2019, all warrants relating to this acquisition have been issued. On November 30, 2018, the call option was exercised, and the Company acquired the remaining 49% of HDS.

On December 1, 2018, the Company issued to Stephen L. Berkman a Warrant exercisable for 15,000,000 shares of common stock. The Warrant is exercisable until December 1, 2019 at an exercise price of \$2.50 per share. The Warrant contains a provision prohibiting the exercise of the Warrant to the extent that, after exercise, Mr. Berkman would own more than 9.99% of the Company's common stock. The Warrant was issued pursuant to the January 18, 2017 Acquisition Agreement among the Company, Hema Diagnostic Systems, LLC ("HDS"), Stephen L. Berkman and the other equity owners of HDS. Despite the warrants being issued after the effective date of the 20 for 1 stock dividend, per an agreement with warrant holder, such warrants were not subject to the stock dividend and no adjustment was made to the exercise price.

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:

	Stock Price at Closing	Shares	Fair Value
Purchase price:			
Common Stock at closing	\$.23	1,117,011	\$253,721
Common Stock after closing	\$.23	420	95
Common Stock post reverse stock split	\$.23	4,830,000	1,097,100
Total purchase price		5,947,431	\$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 was not of the opinion that it is more likely than not that the warrant will be issued and the Call Option will be exercised, accordingly no values have been attributed to the warrant and Call Option at closing. During 2017, management made a redetermination and estimated that it was more likely than not that the shareholder approval to increase authorized share capital would be obtained and the Call Option will be exercised.

On November 30, 2018, the warrant was issued by the Company and the Company exercised the Call Option and acquired the remaining 49% non-controlling interest in HDS. Accordingly, the fair values of the warrants and call

option was updated through the issuance and exercise date and the change in the change in the fair value of the contingent purchase consideration of \$(4,397,507) and \$15,147,591 was recorded and included in the in the consolidated statements of operations and comprehensive income for the three- and six-months ending January 31, 2019. Due to the issuance of the warrants and exercise of the call option, the Company will no longer report a value for the call option and due to the Company's sequencing policy further described below, the Company determine there are sufficient authorized shares related the possible exercise of these warrants and no further warrant liability or derivative liability is required.

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, 2019. 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,		July 31,	
	2019		2018	
Exercise price	2.50		2.50	
Time to expiration	3.18 years		3.47 years	
Risk-free interest rate	3.01	%	2.77	%
Estimated volatility	138.61	%	143.97	%
Dividend	—		—	
Stock price at valuation date	\$0.9		\$0.1	

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 six months ended January 31, 2019 and year ended July 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:

	December 1,		July 31,	
	2019		2018	
Risk-free interest rate	2.52	%	2.44	%
Estimated volatility	164.43	%	129.95	%
Remaining Term	1.13 years		1.47 years	
Stock price at valuation date	\$0.9043		\$0.0976	

Grainland and Empire Pharmacies:

On December 28, 2017, the Company through its wholly owned subsidiary NuGenerex, 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 note was extended by six months and set to mature with the same terms on December 28, 2018.

We finalized our allocation of the purchase price as of January 31, 2019. The final allocation of the purchase price as of January 31, 2019, is as follows:

	Preliminary Allocation as of December 28, 2017	Allocation Adjustments	Final Allocation
Intangible assets	\$ 276,380	\$ (88,311)	\$ 188,069
Property and equipment	19,879	(7,652)	12,226

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Leasehold Improvements	5,981	(2,872)	3,109
Computer software acquired	17,761	(1,165)	16,596
Total assets acquired	320,000	(100,000)	220,000
Consideration:			
Note Payable	320,000		320,000
Goodwill	\$—		\$ 100,000

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.

Since acquisition, the Grainland Pharmacy Holdings, LLC recently ceased to operate and the value of its assets and associated goodwill of \$100,000 will be fully impaired.

Goodwill and Intangible Assets

The change in the carrying amount of goodwill and other intangible assets for the year ended July 31, 2018 and six-month period ended January 31, 2019, is as follows:

	Total	Goodwill	Other Intangibles, net
Balance as of July 31, 2018	\$3,187,757	\$—	\$3,187,757
	8,946,073	8,883,982	62,091
Balance as of January 31, 2019	\$12,133,830	\$8,883,982	\$3,249,848

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 January 31, 2019.

Veneto:

On October 3, 2018, we entered into an Asset Purchase Agreement (the “Agreement”) with Veneto Holdings, L.L.C. (“Veneto”) to purchase certain assets of Veneto.

Effective as at October 3, 2018, NuGenerex Distribution Solutions, LLC assigned the Veneto Asset Purchase Agreement to NuGenerex Distribution Solutions 2, LLC. The sole member of that LLC is NuGenerex Management Services, Inc., a wholly-owned subsidiary of Generex Biotechnology Corporation.

The aggregate purchase price for the Assets, is \$35,000,000 including the Promissory Note. At the Second Closing, the Company will pay the principal of the Promissory Note plus interest to Veneto, (i) \$9,000,000 will be paid by the Company into a trust or other fiduciary account acceptable to Veneto to be used exclusively for satisfaction of certain contingent liabilities of Veneto and subsidiaries of Veneto not being acquired by the Company, (ii) \$3,000,000 will be paid by the Company into an escrow account to secure potential obligations of Veneto in respect of the Second Closing date working capital and under the indemnification provisions of the Agreement and (iii) the balance will be payable directly to Veneto in cash.

The Company has also entered into a temporary fee-for-service arrangement with Veneto and one of its subsidiaries for Veneto to provide management, personnel, operational, administrative and other services with respect to the First Closing Assets pending the Second Closing. At the Second Closing, all of Veneto personnel providing these services are expected to become employees or consultants of the Company, and Veneto will no longer provide the services.

As the First Closing, the Promissory Note issued to Veneto in the original principal amount of \$15,000,000 with interest at an annual rate of 5.0% and guaranteed by Generex and Joseph Moscato, and secured by a first priority security interest in the Company's assets other than the First Closing Assets was subsequently cancelled upon the issuance of the a new promissory note on the Second Closing in the principal amount of \$35,000,000 with an annual of 12.0% and guaranteed by Generex and Joseph Moscato. There was \$62,500 of accrued interest on the \$15,000,000 note and an additional \$1,050,000 of accrued interest on the new \$35,000,000 promissory note for a total of \$1,112,500 of accrued interest for the six months ended January 31, 2019.

On November 1, 2018 we consummated the acquisition of the Second Closing Assets, consisting primarily of Veneto's management services organization business and two additional ancillary services. The aggregate price for the First Closing Assets and the Second Closing Assets was \$30,000,000. The Company issued a promissory note in the principal amount of \$35,000,000 (the "New Note") consisting of the \$30,000,000 purchase price and a \$5,000,000 original issue discount, as the sole consideration payable on the Second Closing Date. In addition, we agreed to assume approximately \$3.8 million in outstanding institutional debt of Veneto subsidiaries, but will have use of Veneto cash which would otherwise have been applied to paying down the debt.

On January 15, 2019, the Company entered into an Amendment Agreement (the "Amendment") with Veneto and the equity owners of Veneto entered into restructuring payment of the Note which was not yet closed as of January 31, 2019. The Company and the owners of Veneto are in further negotiations that is anticipated to result in a further amendment that may reduce the purchase price and payment terms.

The terms of the Amendment were as follows:

Payment of \$15,750,000 by delivery of Generex common stock, initially valued at \$2.50 per share.

If, on the first to occur of (i) the ninetieth (90th) day after closing under the Amendment and (ii) the effective date of a registration statement filed with the SEC including the Generex shares pursuant to the Amendment, the average volume weighted average price ("VWAP") of Generex common stock for the preceding five (5) trading days is less than \$2.50 share, Generex will deliver additional Generex Shares such that the aggregate number of shares delivered under this Agreement equals $\$15,750,000 \div$ such average VWAP.

The remainder of the principal and interest under the Note shall be payable on April 15, 2019; provided that on that maturity date, Veneto shall have the option of (i) payment of principal and interest in cash and (ii) payment of principal and interest by Generex's delivery of Generex Shares valued at \$2.50 per share.

All Generex shares issued pursuant to the Amendment will be delivered pro rata to the six equity owners of Veneto as distributions from Veneto.

Fair Value of the Veneto Acquisition

"First Closing" completed on	"Second Closing"	Total
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		completed on	
	October 3, 2018	November 1, 2018	
Cash and cash equivalents	\$2,410,150	\$—	\$2,410,150
Accounts receivable, net	1,935,078	—	1,935,078
Inventory, net	1,068,856	—	1,068,856
Prepaid expenses	95,803	—	95,803
Property and equipment, net	652,590	—	652,590
Other receivables	1,014,316	—	1,014,316
Notes receivable - LT	1,387,763	—	1,387,763
Other assets, net	61,348	—	61,348
Intangible assets, net	—	7,110,000	7,110,000
Total assets acquired	8,625,905	7,110,000	15,735,905
Total current liabilities	2,509,887	—	2,509,887
Notes payable	—	3,403,948	3,403,948
Total liabilities assumed	2,509,887	3,403,948	5,913,835
Net identifiable assets acquired	6,116,018	3,706,052	9,822,070
Goodwill	8,883,982	16,293,948	25,177,930
Total consideration transferred	\$15,000,000	\$20,000,000	\$35,000,000

The following table summarizes the allocation of the preliminary purchase price as of the Veneto acquisition as of the First Closing and the Second Closing:

The significant intangible assets identified in the purchase price allocation discussed above include developed software and technology, referral base (recurring revenue from the MSO investments and their use of Company owned pharmacies) and non-compete agreements with continued employment of key employees. Tradenames and trademarks were not valued as tradenames and trademarks will not be maintained going forward. To value the developed software and technology, the Company utilized the relief from royalty method, a form of the income approach to value the developed software and technology which assumes a limited technology life and market share adjusted by assumed obsolescence with a terminal value. The referral base was valued using a multi-period excess earnings method, a form of the income approach. The Company utilized the with and without method, a form of the income approach to value non-compete agreements with Generex.

The preliminary amounts assigned to the identifiable intangible assets, the estimated useful lives, and the estimated amortization expense related to these identifiable intangible assets are as follows:

	Preliminary Fair Value	Average Estimated Life	Amortization for Year Ended July 31, 2018
Developed Software/Technology	\$780,000	5	\$156,000
Referral Base	3,920,000	15	261,333
Non-compete agreements	2,410,000	3	803,333
	\$7,110,000		\$1,220,667

Intangible assets are generally amortized on a straight-line basis over the useful lives of the assets.

Goodwill represents the excess of the purchase price over the fair market value of net assets acquired. Goodwill for Veneto Acquisition was \$8.9 million as of the date of the First Closing and \$16.3 million as of the date of the Second Closing.

Regentys:

On November 28, 2018, Generex Biotechnology Corporation (the “Company”) and Regentys Corporation. (“Regentys”) closed the acquisition of 51% of the outstanding capital stock of Regentys for a total consideration of fifteen million dollars (\$15,000,000). On January 7, 2019 the Company completed a definitive Stock Purchase Agreement and related documents effecting the transactions contemplated by the LOI.

Consideration for Proposed Acquisition

Pursuant to a Stock Purchase Agreement between the Company and Regentys (the “Purchase Agreement”) the Company purchased 12,048,161 newly issued shares of the Regentys common stock representing 51% percent of the issued and outstanding capital stock of Regentys (“Regentys Shares”).

In addition to \$400,000 paid to Regentys upon signing of the LOI, the purchase price for the Regentys Shares will consist of the following cash payments, with the proceeds intended to be used for specific purposes, as noted:

- \$3,450,000 to initiate pre-clinical activities on or before January 15, 2018.
- \$2,000,000 to initiate patient recruitment activities on or before May 1, 2019.
- \$3,000,000 to initiate a first-in-human pilot study on or before September 1, 2019.
- \$5,000,000 to initiate a human pivotal study on or before February 1, 2020.
- \$1,150,000 to submit a 510(k) de novo submission to the FDA on or about February 1, 2021.

The Company issued its Promissory Note in the amount of \$14,600,000 (the “Note”) representing its obligation to pay the above amounts. The Note is secured by a pledge of the Regentys pursuant to a Pledge and Security Agreement. In the event that Generex does not make any of the first three payments listed above, at Regentys’ option either:

• Generex will forfeit all of the Regentys shares issued with no refund of amounts paid; or
• Generex will issue shares of its common stock to Regentys equivalent to 110% of the value of the missing payment, which shares will be registered for resale.

In the event Generex does not make either or both of the fourth and fifth payments, its share ownership of Regentys will be proportionately reduced.

On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the first tranche of Guaranteed Payments amounting to \$2,800,000 on or before April 1, 2019.

The Company accounted for the Acquisition of Regentys as a business combination using the purchase method of accounting as prescribed in Accounting Standards Codification 805, Business Combinations (“ASC 805”) and ASC 820 – Fair Value Measurements and Disclosures (“ASC 820”). In accordance with ASC 805 and ASC 820, we used our best estimates and assumptions to accurately assign fair value to the tangible assets acquired, identifiable intangible assets and liabilities assumed as of the acquisition dates. Goodwill as of the acquisition date is measured as the excess of purchase consideration over the fair value of tangible and identifiable intangible assets acquired and liabilities assumed.

The fair values assigned to Regentys’ tangible and identifiable intangible assets acquired, and liabilities assumed are based on management’s estimates and assumptions. The estimated fair values of these assets acquired, and liabilities assumed are considered preliminary and are based on the information that was available as of the date of the acquisition. The preliminary estimated fair values of assets acquired, and liabilities assumed, and identifiable intangible assets may be subject to change as additional information is received. Thus, the provisional measurements of fair value are subject to change. We expect to finalize the valuation as soon as practicable, but not later than one year from the closing date.

Olaregen:

On November 27, 2018, Generex Biotechnology Corporation (the “Company”) and Olaregen Therapeutix Inc. (“Olaregen”) entered into a binding letter of intent (“LOI”) contemplating the Company’s acquisition of 51% of the outstanding capital stock of Olaregen for a total consideration of twelve million dollars (\$12,000,000). As of January 7, 2019, the Company completed a definitive Stock Purchase Agreement (“Purchase Agreement”) and related documents effecting the transactions contemplated by the LOI.

Consideration for Proposed Acquisition

The Company will purchase 3,282,632 newly issued shares of the Olaregen common stock representing 51% percent of the issued and outstanding capital stock of Olaregen (“Olaregen Shares”).

In addition to \$400,000 paid to Olaregen upon signing of the LOI, the purchase price for the Olaregen Shares will consist of the following cash payments:

- \$800,000 on or before January 15, 2019.
- \$800,000 on or before January 31, 2019.
- \$3,000,000 on or before February 28, 2019.
- \$1,000,000. On or before May 31, 2019.
- \$6,000,000.00 on or before September 30, 2019.

Generex issued its Promissory Note in the amount of \$11,600,000 (the “Note”) representing its obligation to pay the above amounts. The Note is secured by a pledge of the Olaregen Shares pursuant to a Pledge and Security Agreement. In the event that Generex fails to pay the installment due on September 30, 2019, Generex will forfeit the shares allocated to that installment (1,600,000 Olaregen Shares) and Olaregen will be entitled to “claw back” fifty percent (50%) of any and all shares paid for by the prior payments.

On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the first tranche of Guaranteed Payments amounting to \$2,800,000 on or before April 1, 2019.

In the event Generex does not make any other payments, its share ownership of Olaregen will be proportionately reduced.

Generex has a limited anti-dilution right under the Purchase Agreement, to ensure that Generex will retain 51% ownership in Olaregen for a period of time.

The Company accounted for the Acquisition of Regentys as a business combination using the purchase method of accounting as prescribed in Accounting Standards Codification 805, Business Combinations (“ASC 805”) and ASC 820 – Fair Value Measurements and Disclosures (“ASC 820”). In accordance with ASC 805 and ASC 820, we used our best estimates and assumptions to accurately assign fair value to the tangible assets acquired, identifiable intangible assets and liabilities assumed as of the acquisition dates. Goodwill as of the acquisition date is measured as the excess of purchase consideration over the fair value of tangible and identifiable intangible assets acquired and liabilities assumed.

The fair values assigned to Regentys’ tangible and identifiable intangible assets acquired, and liabilities assumed are based on management’s estimates and assumptions. The estimated fair values of these assets acquired, and liabilities assumed are considered preliminary and are based on the information that was available as of the date of the acquisition. The preliminary estimated fair values of assets acquired, and liabilities assumed, and identifiable intangible assets may be subject to change as additional information is received. Thus, the provisional measurements of fair value are subject to change. We expect to finalize the valuation as soon as practicable, but not later than one year from the closing date.

Unaudited Supplemental Pro Forma Data

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Unaudited pro forma results of operations for the six months ended January 31, 2018 and 2017 as though the Company acquired HDS, Veneto, Olaregen, Grainland, Empire and Regentys (the “Acquired Companies”) on the first day of each fiscal year are set forth below.

	Six months Ended	
	January 31, 2019	
	2018	2017
Revenues	\$5,839,903	\$19,407,319
Cost of revenues	2,810,874	7,622,676
Gross profit	3,029,029	11,784,643
Operating expenses	6,406,594	13,592,954
Operating loss	(3,377,565)	(1,808,311)
Other income (expense)	(202,760)	(123,688)
Net loss	\$(3,580,325)	(1,931,999)
Comprehensive net loss	\$(3,580,325)	\$(1,931,999)

Note 9– Notes Payable

On October 26, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note Due October 26, 2019 (“Note”) in the principal amount of \$682,000. The purchase price of the Note was \$550,000 from which Generex was required to pay the \$15,000 fee of the investor’s counsel. The remaining \$122,000 of principal amount represents original issue discount. The Note does not bear any stated interest in addition to the original issue discount. The effective interest is 27.5%.

On November 25, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note Due November 26, 2019 (“Note”) in the principal amount of \$1,060,000. The purchase price of the Note was \$1,000,000. The remaining \$60,000 of principal amount represents original issue discount. The Note does not bear any stated interest in addition to the original issue discount.

On January 24, 2019, Generex entered into Securities Purchase Agreements with 3 investors pursuant to which the Company agreed to sell and sold convertible notes bearing interest at 10% per annum (the “Notes”) in the aggregate principal amount of \$2,110,000. The purchase price of the Notes was \$2,010,000 and the remaining \$100,000 of principal amount represents original issue discount. Pursuant to the Securities Purchase Agreements, the Generex also sold warrants to the Investors to purchase up to an aggregate 120,570 shares of common stock.

Subject to certain ownership limitations, the Notes will be convertible at the option of the holder at any time into shares of the Company’s common stock at an effective conversion price determined as follows: the lesser of

- A price determined as of the date of closing; and
- 70% of the lowest volume weighted average trading price of the common stock on the ten days prior to conversion.

On November 27, 2018, Generex and Olaregen Therapeutix Inc. (“Olaegen”) entered into a binding letter of intent (“LOI”) contemplating the Company’s acquisition of 51% of the outstanding capital stock of Olaegen for a total consideration of twelve million dollars (\$12,000,000) in accordance with the terms and conditions of the LOI. As of January 7, 2019, the Company completed a definitive Stock Purchase Agreement and related documents effecting the transactions contemplated by the LOI. After paying \$400,000 at signing, Generex issued a promissory note as it relates to the acquisition. The note is due in multiple installments with the final payment due September 30, 2019.

On November 28, 2018, Generex Biotechnology Corporation (the “Company”) and Regentys Corporation. (“Regentys”) entered into a binding letter of intent (“LOI”) contemplating the Company’s acquisition of 51% of the outstanding capital

stock of Regentys for a total consideration of fifteen million dollars (\$15,000,000) in accordance with the terms and conditions of the LOI (the "Proposed Acquisition").

On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the second payment and the third payment of Guaranteed Payments amounting to \$600,000 on or before April 1, 2019.

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.

Generex Biotechnology Corporation (“Generex”) will issue to holders of Generex common stock a dividend of shares of its wholly owned subsidiary Antigen Express, Inc., d/b/a NuGenerex Immuno-Oncology. Generex shareholders will receive a dividend of one share of Antigen Express, Inc. for every four shares of Generex common stock. The Record Date for the dividend was January 30, 2019, the Payment Date is February 25, 2019.

On February 8, 2019, Generex Biotechnology Corporation (the “Company”) closed under a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold a convertible note bearing interest at 10% per annum (the “Note”) in the principal amount of \$750,000. The purchase price of the Note was \$712,500 and the remaining \$37,500 of principal amount represents original issue discount. Pursuant to the Securities Purchase Agreements, the Company also sold to the Investor warrants to purchase up to an aggregate 45,000 shares of common stock.

On February 15, 2019, Generex Biotechnology Corporation (the “Company”) entered into, and on February 22, 2019, Generex closed under a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold a convertible note bearing interest at 10% per annum (the “Note”) in the principal amount of \$750,000. The purchase price of the Note was \$712,500 and the remaining \$37,500 of principal amount represents original issue discount. Pursuant to the Securities Purchase Agreements, the Company also sold to the Investor warrants to purchase up to an aggregate 57,143 shares of common stock.

On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the second payment and the third payment of Guaranteed Payments amounting to \$600,000 on or before April 1, 2019.

On March 14, 2019, the Company and Regentys amended the Stock Purchase Agreement and Promissory Note to extend the due date of the remaining balance of the first tranche of Guaranteed Payments amounting to \$2,800,000 on or before April 1, 2019.

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, 2019 and 2018. We engaged in certain acquisition transactions during the six months ended January 31, 2019, with effectives as follows:

Effective October 3, 2018, we purchased certain assets of Veneto Holdings, L.L.C. (“Veneto”), and its subsidiaries (the “First Closing Assets”). We acquired additional assets of Veneto effective November 1, 2018 (the “Second Closing Assets” and together with the First Closing Assets, the “Acquired Veneto Assets.”). Our balance sheet at January 31, 2019 includes our interest in the Acquired Veneto Assets, the obligations issued in connection with the purchase of the Acquired Veneto Assets. Our interest in the results of operations of the First Closing Assets since October 3, 2018 and the Second Closing Assets since November 1, 2018 is included in our Consolidated Statement of Operations and Comprehensive Loss for the quarter ended January 31, 2019.

Effective January 7, 2019, we purchased a majority interest in the capital stock of Regentys Corporation. (“Regentys”). Our balance sheet at January 31, 2019 includes our interest in Regentys and our interest in the results of operations of Regentys for the period January 7, 2019 through January 31, 2017 is included in our Consolidated Statement of Operations and Comprehensive Loss for the quarter ended January 31, 2019.

Effective January 7, 2019, we purchased a majority interest in the capital stock of Olaregen Therapeutix Inc. (“Olaegen”). Our balance sheet at January 31, 2019 includes our interest in Olaregen and our interest in the results of operations of Olaregen for the period January 7, 2019 through January 31, 2017 is included in our Consolidated Statement of Operations and Comprehensive Loss for the quarter ended January 31, 2019.

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, 2018, 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, 2019.

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, 2019 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 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, 2018, as amended, and in *Part II, Item 1A. Risk Factors* of this Quarterly Report on Form 10-Q. We caution investors that the forward-looking statements contained in this Quarterly Report must be interpreted and understood in light of conditions and circumstances that exist as of the date of this Quarterly Report. We expressly disclaim any obligation or undertaking to update or revise forward-looking statements to reflect any changes in management's expectations resulting from future events or changes in the conditions or circumstances upon which such expectations are based

Executive Summary

Preliminary Note

On January 17, 2017, we acquired a 51% interest in Hema Diagnostic Systems, LLC (“HDS”). On December 2, 2018, we acquired the remaining equity of HDS, and HDS became a wholly owned subsidiary. 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.

On October 3, 2018, we acquired the First Closing Assets from Veneto, primarily consisting of the operating assets of (a) system dispensing pharmacies, (b) a central adjudicating pharmacy, (c) a wholesale pharmaceutical purchasing company, and (d) an in-network laboratory.

On November 1, 2018 we consummated the acquisition of the Second Closing Assets, consisting primarily of Veneto's management services organization business and two additional ancillary services. The aggregate price for the First Closing Assets and the Second Closing Assets was \$30,000,000. We issued a promissory note in the principal amount of \$35,000,000 (the "New Note") consisting of the \$30,000,000 purchase price and a \$5,000,000 original issue discount, as the sole consideration payable on the Second Closing Date. In addition, we agreed to assume approximately \$3.8 million in outstanding institutional debt of Veneto subsidiaries, but will have use of Veneto cash which would otherwise have been applied to paying down the debt.

On January 15, 2019, we entered into an Amendment Agreement (the “Amendment”) with Veneto and the equity owners of Veneto entered into restructuring payment of the Note as follows:

Payment of \$15,750,000 by delivery of Generex common stock, initially valued at \$2.50 per share.

If, on the first to occur of (i) the ninetieth (90th) day after closing under the Amendment and (ii) the effective date of a registration statement filed with the SEC including the Generex shares pursuant to the Amendment, the average volume weighted average price (“VWAP”) of Generex common stock for the preceding five (5) trading days is less than \$2.50 share, Generex will deliver additional Generex Shares such that the aggregate number of shares delivered under this Agreement equals $\$15,750,000 \div$ such average VWAP.

The remainder of the principal and interest under the Note shall be payable on April 15, 2019; provided that on that maturity date, Veneto shall have the option of (i) payment of principal and interest in cash and (ii) payment of principal and interest by Generex’s delivery of Generex Shares valued at \$2.50 per share.

All Generex shares issued pursuant to the Amendment will be delivered pro rata to the six equity owners of Veneto as distributions from Veneto

As of the date of filing this quarterly report, we had not yet delivered the shares of Generex Common Stock to the Veneto equity owners.

On January 7, 2019, we acquired a majority interest in Regentys Corporation for an aggregate of \$15,000,000. \$400,000 was paid in cash and the remainder was paid by the issuance of a promissory note. An aggregate of \$650,000 has been paid in addition the \$400,000 initial payment. Regentys is developing a non-surgical treatment for inflammatory bowel diseases such as ulcerative colitis and Crohn’s disease.

On January 7, 2019, we acquired a majority interest in Olaregen Therapeutix Inc. (“Olaregen”) for an aggregate of \$12,000,000. \$400,000 was paid in cash and the remainder was paid by the issuance of a promissory note. An aggregate of \$1,000,000 has been paid in addition the \$400,000 initial payment. Olaregen is launching an FDA-510(k) cleared wound care product.

We intend to focus resources on HDS’ business, and on the businesses of Regentys, Olaragen and the MSAO business acquired from Veneto, as well as additional acquisition targets, but do not intend to discontinue our historical activities. However, we will not pursue our historical business if we do not receive substantial financing for that purpose. Olaregen is launching an FDA 5 a wound healing product.

Overview of Business

HDS Diagnostic Products.

Our majority owned subsidiary, Hema Diagnostic Systems, is in the business of developing, manufacturing, and distributing of 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 our own proprietary EXPRESS platforms as well as cassette devices based on customary designs used generally in the industry.

Since its founding, HDS 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) – 1/2 w/p24Ab, tuberculosis-XT, malaria, hepatitis, syphilis, typhoid, dengue and other infectious diseases.

Today, we have developed a substantial line of RDT's known as ready to "go-to-market."

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 sealed within the 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 allowing for increased user-error and requires substantially more training and have greater risk of cross-contamination.

We have been designing and engineering delivery systems that incorporate advanced technologies of rapid test strips for use in our Express series of devices and which yield a rapid response for point-of-care patient testing and treatment.

Each RDT incorporates an accurate test strip that has been striped with specific antigens or antibodies combined in a proprietary cocktail and then incorporated into an easy-to-use and user-friendly delivery system. The HDS delivery systems include our standard “cassette” design, our patented “Express” housing device as well as our new “Express II”.

Each system delivers its own advantages which enhance the use, application and performance of each diagnostic. This ease of use in the Express delivery systems ensure that our RDTs perform efficiently and effectively providing the most accurate and repeatable test results available while, at the same time, minimizing the transference of a potentially infected blood sample.

The Company maintains a Federal Drug Administration (FDA) registered facility in Miramar, Florida and is 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). Additionally, some of our products qualified for and carry the European Union “CE” Mark, which allow us to enter into CE Member countries subject to individual country requirements. Currently, we have two malaria rapid tests approved under World Health Organization (WHO) guidelines. We anticipate that a third malaria test will be approved by the end of 2016. Our 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 down to approximately 6-9 months. WHO approval is necessary for our products to be used in those countries which rely upon the expertise of the WHO, as well as for NGO funding for the purchase of diagnostic products.

Pharmacy and MSO Business

On October 3, 2018, we acquired from Veneto the operating assets of system dispensing pharmacies, (b) a central adjudicating pharmacy, (c) a wholesale pharmaceutical purchasing company, and (d) an in-network laboratory.

On November 1, 2018, we acquired Veneto’s management services organization (MSO) business and two additional ancillary services.

Regentys Business

Regentys is a development stage, regenerative medicine company focused on developing treatments for patients with gastrointestinal (GI) disorders. Their first product, ExtraCellular Matrix Hydrogel (ECMH), is a first-in-class,

non-pharmacologic, non-surgical treatment option for patients suffering from Ulcerative Colitis.

Olaregen Business.

Olaregen's primary product, Excellagen, is an FDA-510(k) cleared aseptically-manufactured, syringe-based, ready to use 3-dimensional wound conforming matrix that supports a favorable wound healing environment. Excellagen is indicated for the management of wounds including; partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/graft, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds.

Generex Historical Business

We have historically engaged primarily in the research and development of drug delivery systems and technologies. Our primary focus at the present time is our proprietary technology for the administration of formulations of large molecule drugs to the oral (buccal) cavity using a hand-held aerosol applicator. Through our wholly-owned subsidiary, Antigen, we have expanded our focus to include immunomedicines incorporating proprietary vaccine formulations. On January 18, 2017, we acquired a majority of the equity interests in Hema Diagnostic Systems, LLC ("Hema" or "HDS"). We have the right to acquire the remainder of the HDS equity interests for nominal consideration provided that the Generex stock and warrants issued to the HDS equity owners in connection with the initial acquisition have a specified value and we have registered for resale the Company's shares issued to the HDS equity owners. is in the business of developing, manufacturing, and distributing of in-vitro medical diagnostics for infectious diseases administered at the point of care level with results as soon as 10-15 minutes. HDS manufactures and sells rapid diagnostic devices based upon our own proprietary EXPRESS technology as well as cassette devices based on customary designs used generally in the industry. We intend to focus on HDS's business and in identifying other areas for expansion, but do not intend to discontinue our pre-Acquisition activities.

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 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. Prior to exhausting our funds, we continued clinical development 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. We also initiated an additional Phase I clinical trial in patients with either breast or ovarian cancer. The synthetic vaccine technology has certain advantages for pandemic or potentially pandemic viruses, such as the H5N1 avian and H1N1 swine flu. We have established collaborations with clinical investigators at academic centers to advance these technologies.

To date, we have received regulatory approval in Ecuador, India (subject to regulatory approval of a 2012 in-country study), Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™. We have previously submitted regulatory dossiers for Generex Oral-lyn™ in a number of other countries, including Bangladesh, Kenya, Jordan and Armenia. While we believe these countries will ultimately approve our product for commercial sale, we do not anticipate recognizing revenues in any of these jurisdictions in the next twelve months. No dossier related activities or product shipments have taken place during fiscal 2017 or 2018, nor are any expected to these countries during the remainder of calendar year 2018 or in calendar year 2019.

In March 2008, we initiated Phase III clinical trials for Generex Oral-lyn™ 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 were enrolled at approximately 70 clinical sites around the world, including sites in the United States, Canada, Bulgaria, Poland, Romania, Russia, Ukraine and Ecuador. The final subjects completed the trial 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 metanalysis 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 sufficient additional financing. However, we have initiated a project with the University Health Network of the University of Toronto, and the University of Guelph, Ontario to enhance the formulation of Generex Oral-lyn™ in order to reduce the number of puffs required for prandial use.

In November 2008 we, together with our marketing partner Shreya Life Sciences Pvt. Ltd., officially launched Generex Oral-lyn™ in India under marketing name of Oral Recosulin™. Each package of Oral Recosulin™ contains two canisters of our product along with one actuator. The product received regulatory price approval in India in January 2009. 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. Shreya has advised Generex that the dossier was submitted in December of 2012 to the Drugs Controller General (India) (DCGI), Central Drugs Standard Control Organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India. Generex has provided additional, detailed scientific data to support the Shreya submission. We have not recognized any revenues from the sale of Generex Oral-lyn™ in India through fiscal year ended July 31, 2018.

In December 2008, we, together with our marketing partner Benta S.A., received an approval to market Generex Oral-lyn™ in Lebanon. The official product launch in Lebanon took place in May 2009. In May 2009, the Algerian health authorities granted us permission to import and sell Generex Oral-lyn™ for the treatment of diabetes in Algeria. The official product launch in Algeria took place in October 2009. To date, we have not recognized any revenue from the sales of Generex Oral-lyn™ in Algeria and very minimal revenues in Lebanon. We do not anticipate any revenues to be recognized from these jurisdictions in the next twelve months.

We face competition from other providers of alternate forms of insulin. Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, have discontinued development and/or sale of their inhalable forms of insulin. MannKind introduced a new pulmonary insulin which was approved by the FDA in 2014, and MannKind subsequently partnered with sanofi-aventis for a period of time to market the product under the tradename of Afrezza.

Generex Oral-lyn™ is not an inhaled insulin; rather, it is a buccally absorbed formulation with no pulmonary deposition. We believe that our buccal delivery technology offers several advantages, including the ease of use, portability, avoidance of pulmonary inhalation and safety profile. Furthermore, insulin administered through the Generex Oral-lyn™ RapidMist™ technology is absorbed directly into the blood stream and not only acts rapidly, but returns to baseline quickly, thereby minimizing the chance of developing hypoglycemia.

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.

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. To date, we have not been profitable, and our accumulated deficit was \$510,837,583 at January 31, 2019. As of January 31, 2019, we believe our current cash position is not sufficient to meet our working capital needs for the next twelve months and we may not have sufficient reserves for contingencies. We do not, however, expect to generate significant cash flow from operations during that period and therefore expect to require additional funds after the end of the fiscal year ending July 31, 2019. In addition, we do not have sufficient funds to satisfy the obligations to pay deferred purchase price for the Veneto assets or pursuant to binding letters of intent we signed in November 2018. In addition, we do not have funds to carry out our strategic development plans. Management is seeking various alternatives to ensure that we can meet our operating cash flow requirements and strategic development plans, 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 have sold non-essential real estate assets which were classified as Assets Held for Investment to augment our 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.

We operate in three 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. Our subsidiary, NuGenerex Distribution Solutions 2, LLC, which acquired the Veneto assets, operates in pharmaceutical services.

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.

We did not extend any material resources on our buccal insulin (Generex Oral-lyn™) or other oral delivery products in the fiscal quarters ended January 31, 2019 and 2018 due to lack of funds. The completion of further late-stage trials in Canada and the United States may require significantly greater funds than we currently have on hand.

During the six months ended January 31, 2019 and 2018, we did not expend any resources on research and development relating to Antigen's peptide immunotherapeutic vaccines and related technologies due to our lack of cash. One Antigen vaccine is currently in Phase II clinical trials in the United States involving patients with HER-2/neu positive breast cancer, and we have completed a Phase I clinical trial for an Antigen vaccine for H5N1 avian influenza which was conducted 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.

During the six months January 31, 2019 and 2018, HDS expended \$303,205 and \$190,089 on research and development relating to its rapid diagnostic tests. HDS expects to expend resources on its rapid diagnostic test during the remainder fiscal year ending July 31, 2019.

Because of various uncertainties, we cannot predict the timing of completion and commercialization of our buccal insulin or Antigen's peptide immunotherapeutic vaccines or related technologies. These uncertainties include the success of current stud net operating losses attributed to HDS ies, 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.

Critical Accounting Policies

There are no material changes from the critical accounting policies set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Form 10-K for the year ended July 31, 2018 filed with the SEC on October 26, 2018, except as follows:

We have adopted a sequencing policy whereby, in the event that reclassification of contracts from equity to assets or liabilities is necessary pursuant to ASC 815 due to our inability to demonstrate we have sufficient authorized shares, shares will be allocated on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest grants receiving the first allocation of authorized but unissued shares, and all future instruments being classified as a derivative liability, with the exception of instruments related to share-based compensation issued to employees or directors.

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements which have been prepared in conformity with accounting principles generally accepted in the United States of America. It requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date 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 accompanying consolidated 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 accompanying consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Impairment of Long-Lived Assets. Management reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable under the provisions of accounting for the impairment of long-lived assets. If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Consolidated Statement of Operations.

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

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 January 31, 2019, there was no reserve for obsolescence.

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 warrant liability. FASB ASC 815, Derivatives and Hedging, requires all derivatives to be recorded on the consolidated balance sheet at fair value for fiscal years beginning after December 15, 2008. As a result, certain derivative warrant liabilities (namely those with a price protection feature) 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. On our consolidated balance sheets as of January 31, 2019 and July 31, 2018, we used the binomial lattice model to estimate the fair value of these warrants. 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.

As reported above, the Company has a sequencing policy regarding share settlement wherein instruments with the earliest issuance date would be settled first. The sequencing policy also considers contingently issuable additional shares, such as those issuable upon a stock split, to have an issuance date to coincide with the event giving rise to the additional shares.

On January 24, 2019, the company entered into a note payable with an unrelated party at a percentage discount (variable) exercise price which causes the number to be converted into a number of common shares that “approach infinity”, as the underlying stock price could approach zero. Accordingly, all convertible instruments issued after January 24, 2019 are considered derivatives according to the Company’s sequencing policy.

Results of Operations

Three months ended January 31, 2019 compared to three months ended January 31, 2018

We had a net income for the three months ended January 31, 2019 of \$17,785,747 and \$27,526,507 in the corresponding three months of the prior fiscal year. The income in both periods was caused primarily by the change in fair value of contingent purchase consideration.

The 630,871 increase in research and development expenses in the quarter ended January 31, 2019 versus the comparative previous fiscal quarter is primarily due Antigen’s increase of expenses.

Our interest expense in the three months ended January 31, 2019 was \$2,097,220 compared to the previous year's fiscal three months of \$142,245 which is due to the increase of debt in the current period.

The net operating losses attributed to HDS in six-month periods ended January 31, 2019 amount to \$384,357, compared to the previous year's fiscal six months of \$427,483. The net operating losses attributed to HDS for the three months ended January 31, 2019 arise primarily from general and administrative expenses of \$81,152 and research, development costs of \$303,205.

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, securities convertible into our common stock, and investor loans. 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

Our January 31, 2019 cash position was not sufficient for 12 months of operations. Anticipated revenues associated with the Veneto acquisition are expected to dramatically alter the cash flow landscape.

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, as well as investor notes, and raised approximately \$4,000,000 during fiscal 2017 (including proceeds from warrant exercises, short term loans and the issuance of preferred stock), our cash balances have been low throughout fiscal 2018. We did not raise any cash from the sale of our securities in fiscal 2018.

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

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

We will continue to require substantial funds to continue research and development, including preclinical studies and clinical trials of our product candidates, further clinical trials for Oral-lyn™ and to commence sales and marketing efforts if the FDA or other regulatory approvals are obtained.

Financings

Following is a summary of the financing activities that we have completed since the end of fiscal 2018.

Financing – October 2018

Investor Note Secured by CEO's Stock

On October 26, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note Due October 26, 2019 ("Note") in the principal amount of \$682,000. The purchase price of the Note was \$550,000 from which Generex was required to pay the \$15,000 fee of the investor's counsel. The remaining \$122,000 of principal amount represents original issue discount. The Note does not bear any stated interest in addition to the original issue discount.

Joseph Moscato, the Company's President & Chief Executive Officer, has guaranteed the Company's obligations under the Note. In addition, Mr. Moscato has pledged as collateral for the guaranty 156,400 shares of the Company's common stock.

The Note provided it would become due and payable prior to maturity if the Company's common stock is not listed for trading on a NASDAQ market on or before ninety (90) days after the date of the Note. The listing has not occurred. In January 2019, the Note holder repayment on this basis and in March, 2019, filed suit to recover the principal amount of the Note plus interest. The Company's response to the lawsuit is due shortly after the filing of this Quarterly Report. At the time of filing, the Company was engaged in settlement discussions with the Note holder.

Financing – November 2018

Investor Note Secured by CEO's Stock

On November 25, 2018, Generex entered into a Securities Purchase Agreement with an investor pursuant to which the Company agreed to sell and sold its Note Due November 26, 2019 ("Note") in the principal amount of \$1,060,000. The purchase price of the Note was \$1,000,000. The remaining \$60,000 of principal amount represents original issue discount. The Note does not bear any stated interest in addition to the original issue discount.

Joseph Moscato, the Company's President & Chief Executive Officer, has guaranteed the Company's obligations under the Note. In addition, Mr. Moscato has pledged as collateral for the guaranty 400,000 shares of the Company's post-stock dividend Common Stock owned by him. At the option of either the investor or Mr. Moscato, all or any party of the loan can be paid with shares of the pledged stock valued at \$2.50 per share, without default.

The Company will become obligated to repay the Note prior to maturity upon the occurrence of certain other triggering events, including, breach of the covenants under the Note or Securities Purchase Agreement, breach of certain other contractual obligations, and the occurrence of a change in control of the Company.

If any of these events occur, or if the Company does not pay the principal amount when due, interest will accrue at the rate of 24% per annum on outstanding balance under the Note until paid in full. Late fees will apply on all amounts not paid within five trading days of the payment date.

January-February 2019 Convertible Note Transactions

Between January 24, 2019 and February 15, 2019, the Company issues convertible notes bearing interest at 10% per annum (the “Notes”) in the aggregate principal amount of \$3,610,000. The purchase price of the Notes was \$3,435,000 and the remaining \$175,000 of principal amount represents original issue discount. Pursuant to the Securities Purchase Agreements, the Company also sold to the Investors warrants to purchase up to an aggregate 222,713 shares of common stock.

Subject to certain ownership limitations, the Notes will be convertible at the option of the holder at any time into shares of the Company’s common stock at an effective conversion price determined as follows: the lesser of

- A price determined as of the date of closing; and
- 70% of the lowest volume weighted average trading price of the common stock on the ten days prior to conversion.

Cash Flows for the Six Months ended January 31, 2019

For the fiscal quarter ended January 31, 2019, we used \$4.2 million in cash to fund our operating activities. The use for operating activities included a net income of \$5.8 million and was offset by changes in fair value of contingent purchase consideration of \$15.1M. Changes to working capital including an increase of \$3.3 million related to accounts payable and accrued expenses.

The use of cash was offset by non-cash expenses of \$73,000 related to depreciation and amortization, \$15.1 related to the change in fair value of contingent purchase consideration.

In the three months ended January 31, 2019, we had net cash provided by investing activities of \$ primarily relating to cash received in the acquisition of Veneto.

We had cash provided by financing activities in the fiscal year ended July 31, 2018 of \$625,967, which pertained to proceeds from an investor of \$534,940 and investment in subsidiary by noncontrolling interest \$91,027, primarily consisting of contributions and loan proceeds from Stephen L. Berkman, to HDS.

Our net working capital January 31, 2019 declined to negative \$ from negative \$ at January 31, 2018, which was attributed primarily to an increase in accounts payable and accrued expenses and a decrease in cash.

Funding Requirements and Commitments

In addition to our commitments under the financings described above, we have the following obligations:

Veneto Acquisition Related Debt

On November 1, 2018, in connection with the completion of the acquisition of the pharmacy, management service organization and other assets of Veneto, the Company's subsidiary, NuGenerex Distribution Solutions 2, LLC ("NuGenerex"), issued Veneto a promissory note in the principal amount of \$35,000,000. The note calls for payment in full on or before January 15, 2019 with interest at an annual rate of 12% on the \$30,000,000 portion of the New Note representing the purchase price of the Assets. The note is guaranteed by Generex and Joseph Moscato and secured by a first priority security interest in all of Generex's assets. Mr. Moscato's guaranty is limited to the principal amount of \$15,000,000.

On January 15, 2019, the We entered into an Amendment Agreement (the "Amendment") with Veneto and the equity owners of Veneto entered into restructuring payment of the Note as follows:

Payment of \$15,750,000 by delivery of Generex common stock, initially valued at \$2.50 per share.

If, on the first to occur of (i) the ninetieth (90th) day after closing under the Amendment and (ii) the effective date of a registration statement filed with the SEC including the Generex shares pursuant to the Amendment, the average volume weighted average price ("VWAP") of Generex common stock for the preceding five (5) trading days is less than

\$2.50 share, Generex will deliver additional Generex Shares such that the aggregate number of shares delivered under this Agreement equals $\$15,750,000 \div$ such average VWAP.

The remainder of the principal and interest under the Note shall be payable on April 15, 2019; provided that on that maturity date, Veneto shall have the option of (i) payment of principal and interest in cash and (ii) payment of principal and interest by Generex's delivery of Generex Shares valued at \$2.50 per share.

All Generex shares issued pursuant to the Amendment will be delivered pro rata to the six equity owners of Veneto as distributions from Veneto.

As of the date of filing this quarterly report, we had not yet delivered the shares of Generex Common Stock to the Veneto equity owners and the Amendment Agreement has not closed and subject to change.

In addition, pursuant to the Amendment, NuGenerex agreed to assume approximately \$3.8 million in outstanding institutional debt of Veneto subsidiaries.

Olaregan and Regentys Acquisitions

Olaregen

As of January 7, 2019, the Company completed a definitive Stock Purchase Agreement and related documents relating to the Company's purchase of 3,282,632 newly issued shares of the Olaregen common stock representing 51% percent of the issued and outstanding capital stock of Olaregen for an aggregate \$12,000,000.

In addition to \$400,000 paid to Olaregen upon signing of the LOI, the purchase price for the Olaregen Shares will consists of the following cash payments:

\$800,000 on or before January 15, 2019. The Company has paid this installment.

- \$800,000 on or before January 31, 2019. As of the date this Quarterly Report was filed, the Company has paid \$200,000 of this installment.

- \$3,000,000 on or before February 28, 2019. As of the date this Quarterly Report was filed, the Company has not paid of this installment.

- \$1,000,000. On or before May 31, 2019.

- \$6,000,000.00 on or before September 30, 2019.

Generex issued its Promissory Note in the amount of \$11,600,000 (the "Note") representing its obligation to pay the above amounts. The Note is secured by a pledge of the Olaregen Shares pursuant to a Pledge and Security Agreement.

Regentys

On January 7, 2019 the Company completed a definitive Stock Purchase Agreement and related documents relating to the Company's purchase of 12,048,161 newly issued shares of the Regentys common stock representing 51% percent of the issued and outstanding capital stock of Regentys ("Regentys Shares").

In addition to \$400,000 paid to Regentys upon signing of the LOI, the purchase price for the Regentys Shares consist of the following cash payments, with the proceeds intended to be used for specific purposes, as noted:

\$3,450,000 to initiate pre-clinical activities on or before January 15, 2018. As of the date this Quarterly Report was filed, the Company has paid \$650,000 of this installment.

\$2,000,000 to initiate patient recruitment activities on or before May 1, 2019.

\$3,000,000 to initiate a first-in-human pilot study on or before September 1, 2019.

\$5,000,000 to initiate a human pivotal study on or before February 1, 2020.

\$1,150,000 to submit a 510(k) de novo submission to the FDA on or about February 1, 2021.

The Company issued its Promissory Note in the amount of \$14,600,000 (the "Note") representing its obligation to pay the above amounts. The Note is secured by a pledge of the Regentys pursuant to a Pledge and Security Agreement.

If we obtain necessary financing, we expect to expend resources towards additional acquisitions and regulatory approval and commercialization of Generex Oral-lyn™ and further clinical development of our immunotherapeutic vaccines.

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

- the timing and amount of expense incurred to complete our clinical trials;
- the costs and timing of the regulatory process as we seek approval of our products in development;
- the advancement of our products in development;
- our ability to generate new relationships with industry partners throughout the world that will provide us with regulatory assistance and long-term commercialization opportunities;
- the timing, receipt and amount of sales, if any, from Generex Oral-lyn™ in India, Lebanon, Algeria and Ecuador;

the cost of manufacturing (paid to third parties) of our licensed products, and the cost of marketing and sales activities of those products;

the costs of prosecuting, maintaining, and enforcing patent claims, if any claims are made;

our ability to maintain existing collaborative relationships and establish new relationships as we advance our products in development;

our ability to obtain the necessary financing to fund our operations and effect our strategic development plan; and

the receptivity of the financial market to biopharmaceutical companies.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our 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.

Tabular Disclosure of Contractual Obligations

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.

Recently Issued Accounting Pronouncements

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.”

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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. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

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 guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

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 guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

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 guidance was adopted as of August 1, 2018 and did not have a material effect on the Company’s consolidated financial statements and related disclosures.

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. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company's consolidated financial statements and related disclosures.

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. The guidance was adopted as of August 1, 2018 and did not have a material effect on the Company's consolidated financial statements and related disclosures.

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 October 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 October 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.

On December 2, 2018, an arbitrator awarded Three Brothers Trading LLC, d/b/a Alternative Execution Group (“AEXG”) an aggregate of \$315,695 in damages, costs and fees as well as warrants exercisable for 84,000 shares of Generex Common Stock at an exercise price of \$2.50 per share. The awards were made pursuant to claims under a Memorandum of Understanding (“MOU”) between Generex and AEXG related to AEXG referring potential financing candidate to Generex. AEXG filed a petition to confirm the arbitrator’s award in the United States District Court for the Southern District of New York. The petition includes a demand of \$3,300,360 as the value of the Warrants. The arbitrator did not award the specific amount of \$3.5 million, but only liquidated damages in the amount of \$220,000 and the value of 84,000 warrants “as of today” (the date of the award) plus attorney’s fees, certain costs, prejudgment and post-judgment interest (which continues to run on a daily basis) and arbitration fees. Generex has responded that the value of the warrants on the date of the award is \$0 or some figure far less than the value calculated by AEXG. The petition to confirm the arbitrator’s award and Generex’s opposition are pending before the Court for a decision.

On October 26, 2018, Generex entered into a Securities Purchase Agreement with Alpha Capital Anstalt pursuant to which the Company agreed to sell and sold its Note Due October 26, 2019 (“Note”) in the principal amount of \$682,000. The purchase price of the Note was \$550,000. The remaining \$122,000 of principal amount represents original issue discount. On January 25, 2018, Generex received a letter from Alpha’s counsel stating that the Note was in default because Generex’s common stock was not listed on NASDAQ within 90 days after the issuance of the Note. The letter demanded repayment in full. On February 12, 2019, the Purchaser filed a Motion for Summary Judgment in lieu of complaint in the Supreme Court of New York, demanding the aggregate principal amount, default interest and costs. Counsel for Generex and Alpha have engaged in settlement discussions.

In connection with the second closing of the acquisition of certain operating assets of Veneto Holdings, L.L.C. and its affiliates, Generex's wholly owned subsidiary agreed to assume outstanding debt of Veneto subsidiaries to Compass Bank, including obligations under a term loan and a revolving line of credit. Claiming three separate types of default, Compass Bank has demanded payment in full of amounts due under the term loan and revolving line of credit, in an aggregate amount of approximately \$3,413,000. Generex believes it has defenses to such demand, including that the bank was not an intended beneficiary of the subsidiary's agreement to assume the debt.

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, 2018, 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, 2019, 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 been profitable and our accumulated gain available to shareholders was \$6.2 million at January 31, 2019. 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 our partially-owned subsidiary's Excellagen, which has FDA-510(k) clearance, and 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, 2018.

To date, we have not been profitable and our accumulated net gain available to shareholders was \$6.2 million at January 31, 2019, and our consolidated balance sheet reflected a stockholders' surplus of \$10.8 million at that date. We received a report from our independent auditors for the year ended July 31, 2018 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.

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.

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.

We have raised significant funds from the issuance of convertible notes and common stock purchase warrants. These securities have conversion price provisions which make the notes convertible at a discount to the market price of our common stock and may in other ways decrease the conversion price of the notes and increase the number of shares which would be issued upon conversion of the notes. This feature will dilute the other holders of common stock.

RISK FACTORS RELATING TO OUR MSO and PHARMACEUTICAL DISTRIBUTION BUSINESSES

Regulatory Actions may Affect our Ability to Operate.

Our MSO and pharmaceutical distribution businesses operate in fields that are very highly regulated by the both the federal government and state pharmacy licensing agencies. Adverse decisions by the DEA or state pharmacy regulators could materially and adversely affect our ability to maintain and grow our distributions busines. The Management Service Organizations (MSO) we manage are primarily owned by physicians and serve pharmacy and other healthcare organizations. We believe that our MSO business is structured to comply with laws and regulations governing economic relationships between physicians and other health care providers, such as fraud and abuse laws. If regulators or courts determine our activities did not comply, we may be required to restructure our business in a manner that would reduce or eliminate its profitability.

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, 2019.

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, 2019.

Item 3. Defaults Upon Senior Securities.

Reference is made to Item 1 - Legal Proceedings, above for a description of claims relating to the Note held by Alpha capital Anstalt.

Item 5. Other Information.

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 52 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 25, 2019 By: */s/ Joseph Moscato*
Joseph Moscato
President and Chief Executive Officer

Date: March 25, 2019 By: */s/ Mark Corrao*
Mark Corrao
Chief Financial Officer

EXHIBIT INDEX**Exhibit****Description of Exhibit ⁽¹⁾****Number**

- 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)

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- 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 to 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 with 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)

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- 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)

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- 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)

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- 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

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- 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.

