GENEREX BIOTECHNOLOGY CORP
Form 10-Q
December 11, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended October 31, 2009

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 0-25169

GENEREX BIOTECHNOLOGY CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	98-0178636
(State of other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

33 HARBOUR SQUARE, SUITE 202
TORONTO, ONTARIO
CANADA M5J 2G2
(Address of principal executive offices)

416/364-2551
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year if changed since last report)

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. x 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 x

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

The number of outstanding shares of the registrant's common stock, par value $.001, was 248,522,740 as of December 10, 2009.

GENEREX BIOTECHNOLOGY CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED BALANCE SHEETS

	October 31, 2009 (Unaudited)	July 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,262,140	$ 14,197,048
Accounts receivable	76,367	57,792
Inventory (see Note 5)	1,424,782	1,271,456
Other current assets	1,015,191	766,741
Total Current Assets	28,778,480	16,293,037
Property and Equipment, Net	1,439,598	1,444,770
Assets Held for Investment, Net	3,470,728	3,373,564
Patents, Net	3,646,160	3,702,386
TOTAL ASSETS	$ 37,334,966	$ 24,813,757
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses (see Note 6)	$ 7,609,207	$ 7,486,155
Deferred revenue and rebate liability	108,197	140,883
Current maturities of long-term debt	1,247,772	1,060,788
Current maturities of obligations under capital lease	37,365	43,836
Total Current Liabilities	9,002,541	8,731,662
Obligations Under Capital Lease, Net	--	3,932
Long-Term Debt, Net	1,681,576	1,854,421
Total Liabilities	10,684,117	10,590,015
Commitments and Contingencies		
Stockholders' Equity (see Note 10):		
Special Voting Rights Preferred Stock, $.001 par value; authorized		
1,000 shares at October 31, 2009 and July 31, 2009; -0- shares		
issued and outstanding at October 31, 2009 and July 31, 2009	--	--
Common stock, $.001 par value; authorized 500,000,000 shares at October 31,		

2009 and July 31, 2009; 248,145,032 and 212,628,818 shares issued and		
outstanding at October 31, 2009 and July 31, 2009, respectively	248,144	212,628
Additional paid-in capital	327,892,433	307,401,016
Deficit accumulated during the development stage	(302,180,146)	(294,041,489)
Accumulated other comprehensive income	690,418	651,587
Total Stockholders' Equity	26,650,849	14,223,742
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 37,334,966	$ 24,813,757

The Notes to Consolidated Financial Statements are an integral part of these statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Three Months Ended October 31, 2009 (Unaudited)	2008 (Unaudited)	Cumulative From November 2, 1995 (Date of Inception) to October 31, 2009 (Unaudited)
Revenues, net	$ 97,542	$ 538,346	$ 3,715,436
Cost of Goods Sold	79,237	22,192	720,618
Gross profit	18,305	516,154	2,994,818
Operating Expenses:			
Research and development	3,075,769	4,355,689	106,452,944
Research and development - related party	—	—	220,218
Selling and marketing	1,298,704	837,198	5,731,202
General and administrative	3,825,265	2,847,913	120,626,083
General and administrative - related party	—	—	314,328
Total Operating Expenses	8,199,738	8,040,800	233,344,775
Operating Loss	(8,181,433)	(7,524,646)	(230,349,957)
Other Income (Expense):			
Miscellaneous income (expense)	500	5	196,761
Income from rental operations, net	84,593	88,380	1,656,601
Interest income	10,085	168,465	7,756,959
Interest expense	(52,401)	(4,429,388)	(68,049,569)
Loss on extinguishment of debt	—	—	(14,134,068)
Net Loss Before Undernoted	(8,138,656)	(11,697,184)	(302,923,273)
Minority Interest Share of Loss	—	—	3,038,185
Net Loss	(8,138,656)	(11,697,184)	(299,885,088)
Preferred Stock Dividend	—	—	2,295,057
Net Loss Available to Common Stockholders	$ (8,138,656)	$ (11,697,184)	$ (302,180,145)
Basic and Diluted Net Loss Per Common Share (see Note 8)	$ (.03)	$ (.10)	
Weighted Average Number of Shares of Common Stock Outstanding	233,991,319	118,109,023	

The Notes to Consolidated Financial Statements are an integral part of these statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Three Months Ended October 31,		Cumulative From November 2, 1995 (Date of Inception) to October 31,
	2009 (Unaudited)	2008 (Unaudited)	2009 (Unaudited)
Cash Flows From Operating Activities:			
Net loss	$ (8,138,656)	$ (11,697,184)	$ (299,885,088)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	199,702	216,172	7,972,373
Minority interest share of loss	—	—	(3,038,185)
Reduction of notes receivable - common stock in exchange for services rendered	—	—	423,882
Write-off of uncollectible notes receivable - common stock	—	—	391,103
Write-off of deferred offering costs	—	—	3,406,196
Write-off of abandoned patents	—	—	913,196
Loss on disposal of property and equipment	—	—	911
Loss on extinguishment of debt	—	—	14,134,069
Common stock issued as employee compensation	28,986	55,136	3,708,379
Issuance of options and option modifications as employee compensation	879,000	9,680	985,996
Common stock issued for services rendered	639,224	46,649	10,701,853
Amortization of prepaid services in conjunction with common stock issuance	—	—	138,375
Non-cash compensation expense	—	—	45,390
Stock options and warrants issued for services rendered	5,653	—	7,371,376
Issuance of warrants as additional exercise right inducement	—	—	21,437,909
Preferred stock issued for services rendered	—	—	100
Treasury stock redeemed for non-performance of services	—	—	(138,000)
Amortization of deferred debt issuance costs and loan origination fees	—	153,791	2,405,629
Amortization of discount on convertible debentures	—	4,009,835	38,345,592
Common stock issued as interest payment on convertible debentures	—	252,083	757,514
Interest on short-term advance	—	—	22,190
Founders' shares transferred for services rendered	—	—	353,506
Fees in connection with refinancing of debt	—	—	113,274
Warrant repricing costs	—	—	3,198,604
Changes in operating assets and liabilities (excluding the effects of acquisition):			
Accounts receivable	(26,542)	(30,674)	(99,777)
Miscellaneous receivables	—	—	43,812
Inventory	(145,862)	(60,179)	(1,461,712)
Other current assets	(238,187)	(40,087)	(692,700)

Accounts payable and accrued expenses	1,168,647	(574,680)	13,721,787
Deferred revenue	(33,702)	37,018	105,135
Other, net	—	—	110,317
Net Cash Used in Operating Activities	(5,661,737)	(7,622,440)	(174,506,994)
Cash Flows From Investing Activities:			
Purchase of property and equipment	(132,646)	(1,385)	(4,727,578)
Costs incurred for patents	(42,237)	(30,537)	(2,244,747)
Change in restricted cash	—	—	45,872
Proceeds from maturity of short term investments	—	2,214	195,242,918
Purchases of short-term investments	—	—	(195,242,918)
Cash received in conjunction with merger	—	—	82,232
Advances to Antigen Express, Inc.	—	—	(32,000)
Increase in officers' loans receivable	—	—	(1,126,157)
Change in deposits	—	(608,279)	(652,071)
Change in notes receivable - common stock	—	—	(91,103)
Change in due from related parties	—	—	(2,222,390)
Other, net	—	—	89,683
Net Cash Used in Investing Activities	(174,883)	(637,987)	(10,878,259)

The Notes to Consolidated Financial Statements are an integral part of these statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Three Months Ended October 31,		Cumulative From November 2, 1995 (Date of Inception) to October 31,
	2009	2008	2009
Cash Flows From Financing Activities:			
Proceeds from short-term advance	—	—	325,179
Repayment of short-term advance	—	—	(347,369)
Proceeds from issuance of long-term debt	—	—	2,005,609
Repayment of long-term debt	(23,492)	(21,567)	(2,048,018)
Repayment of obligations under capital lease	(10,403)	(3,024)	(45,637)
Change in due to related parties	—	—	154,541
Proceeds from exercise of warrants	1,517,940	—	45,642,159
Proceeds from exercise of stock options	—	56,000	5,001,916
Proceeds from minority interest investment	—	—	3,038,185
Proceeds from issuance of preferred stock	—	—	12,015,000
Redemption of SVR preferred stock	—	—	(100)
Proceeds from issuance of convertible debentures, net	—	—	40,704,930
Payment of costs associated with convertible debentures	—	—	(722,750)
Repayments of convertible debentures	—	(376,667)	(5,142,424)
Purchase of treasury stock	—	—	(483,869)
Proceeds from issuance of common stock, net	16,400,671	—	112,137,624
Purchase and retirement of common stock	—	—	(497,522)
Net Cash Provided by Financing Activities	17,884,716	(345,258)	211,737,454
Effect of Exchange Rates on Cash	16,996	(14,970)	(90,061)
Net Increase (Decrease) in Cash and Cash Equivalents	12,065,092	(8,620,655)	26,262,140
Cash and Cash Equivalents, Beginning of Period	14,197,048	17,237,510	—
Cash and Cash Equivalents, End of Period	$ 26,262,140	$ 8,616,855	$ 26,262,140
Supplemental Disclosure of Cash Flow Information:			
Cash paid during the period for:			
Interest	$ 52,401	$ 618,099	
Income taxes	$ —	$ —	
Disclosure of non-cash investing and financing activities:			
Issuance of common stock as satisfaction of accounts payable and accrued expenses	$ 1,055,459	$ —	
Par value of common stock issued in conjunction with cashless exercise of warrants	$ 4,466	$ —	
	$ —	$ 3,753,334	

Issuance of common stock as repayment of convertible debentures and advance payments			
Issuance of common stock as convertible debentures advance payments	$	—$	759,450
Purchase of property and equipment through the issuance of obligations under capital lease	$	—$	83,002

The Notes to Consolidated Financial Statements are an integral part of these statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Basis of Presentation

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

Interim statements are subject to possible adjustments in connection with the annual audit of the Company's accounts for the fiscal year 2010. In the Company's opinion, all adjustments necessary for a fair presentation of these interim statements have been included and are of a normal and recurring nature.

The Company is a development stage company, which has a limited history of operations and limited revenue to date. The Company currently is recognizing revenue from the sale of three of its four commercially available products. Additionally, the Company has several product candidates that are in various research or early stages of pre-clinical and clinical development. There can be no assurance that the Company will be successful in obtaining regulatory clearance for the sale of existing or any future products or that any of the Company's products will be commercially viable.

Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has experienced negative cash flows from operations since inception and had an accumulated deficit at October 31, 2009 of approximately $302 million. The Company has funded its activities to date almost exclusively from debt and equity financings.

The Company will continue to require substantial funds to continue research and development, including preclinical studies and clinical trials of its product candidates, and to support sales and marketing efforts, if the FDA or other regulatory approvals are obtained. 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 issuance of debt and convertible debt instruments. Management is also actively pursuing industry collaboration activities including product licensing and specific project financing.

While the Company believes that it will be successful in obtaining the necessary financing to fund its operations, meet revenue projections and manage costs, there are no assurances that such additional funding will be achieved and that it will succeed in its future operations. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should the Company be unable to continue in existence.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

2. Effects of Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements
In November 2007, the FASB issued guidance related to accounting for collaborative arrangements. This guidance defines a collaborative arrangement as a contractual arrangement in which the parties are (i) active participants to the arrangement; and (ii) exposed to significant risks and rewards that depend upon the commercial success of the endeavor. It also addresses the appropriate statement of operations presentation for activities and payments between the participants in a collaborative arrangement as well as for costs incurred and revenue generated from transactions with third parties. This guidance is effective for the Company's fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

In December 2007, the FASB issued an amendment to an existing accounting standard which provides guidance related to business combinations. The amendment retains the fundamental requirements that the acquisition method of accounting be used for all business combinations and for an acquirer to be identified for each business combination. This amendment also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree; b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This amendment applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. This guidance is effective for the Company's fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

In December 2007, the FASB issued guidance related to non-controlling interests in consolidated financial statements. This guidance amends previously issued guidance to establish accounting and reporting standards for the non-controlling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. This guidance is effective for the Company's fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

In April 2008, the FASB issued guidance related to determining the useful life of intangible assets. This guidance amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The objective of the guidance is to improve the consistency between the useful life of a recognized intangible asset and the period of expected cash flows used to measure the fair value of the asset. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

In May 2008, the FASB issued guidance related to accounting for convertible debt instruments that may be settled in cash upon conversion (including partial cash settlements). This guidance requires a portion of this type of convertible debt to be recorded as equity and to record interest expense on the debt portion at a rate that would have been charged on nonconvertible debt with the same terms. The adoption of this guidance did not have a significant impact on the

Company’s consolidated financial statements.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

In June 2008, the FASB issued guidance related to determining whether instruments granted in share-based payment transactions are participating securities. Securities participating in dividends with common stock according to a formula are participating securities. This guidance determined that unvested shares of restricted stock and stock units with nonforfeitable rights to dividends are participating securities. Participating securities require the "two-class" method to be used to calculate basic earnings per share. This method lowers basic earnings per common share. This guidance is effective for the Company's fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

In June 2008, the FASB reached a consensus regarding the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which is the first part of the scope exception related to accounting for derivative instruments and hedging activities. This guidance is effective for the Company's fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

In June 2009, the FASB issued guidance which stipulates the FASB Accounting Standards Codification is the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. This guidance is effective for the Company's fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements
In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605)—Multiple Deliverable Revenue Arrangements ("ASU 2009-13"). ASU 2009-13 eliminates the residual method of allocation and requires the relative selling price method when allocating deliverables of a multiple-deliverable revenue arrangement. The determination of the selling price for each deliverable requires the use of a hierarchy designed to maximize the use of available objective evidence including, vendor specific objective evidence, third party evidence of selling price, or estimated selling price. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, and must be adopted in the same period using the same transition method. If adoption is elected in a period other than the beginning of a fiscal year, the amendments in these standards must be applied retrospectively to the beginning of the fiscal year. Full retrospective application of these amendments to prior fiscal years is optional. Early adoption of these standards may be elected. We are currently evaluating the impact of these new accounting standards on our consolidated financial statements.

3. Stock-Based Compensation

As of October 31, 2009, the Company had three 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 2,000,000 shares of common stock are reserved for issuance under the 2000 Stock Option Plan (the 2000 Plan), a total of 12,000,000 shares of common stock are reserved for issuance under the 2001 Stock Option Plan (the 2001 Plan) and 30,000,000 shares of common stock are reserved for issuance under the 2006 Stock Plan (the 2006 Plan). Restricted shares can only be issued under the 2006 Plan. At October 31, 2009, there were 2,000,000, 8,547,628 and 19,831,340 shares of common stock reserved for future awards under the 2000 Plan, 2001 Plan and 2006 Plan, respectively.

The 2000, 2001 and 2006 Plans (the Plans) are administered by the Board of Directors (the Board). The Board is authorized to select from among eligible employees, directors, advisors and consultants those individuals to whom

options are to be granted and to determine the number of shares to be subject to, and the terms and conditions of the options. The Board is also authorized to prescribe, amend and rescind terms relating to options granted under the Plans. Generally, the interpretation and construction of any provision of the Plans or any options granted hereunder is within the discretion of the Board.

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

The fair value of each option granted is estimated on the grant date using the Black-Scholes option pricing model which 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.

In the case of restricted stock grants under the 2006 Plan, fair market value of the shares is the market price.

The following is a summary of the common stock options granted, forfeited or expired and exercised under the Plan for the three months ended October 31, 2009:

	Options	Weighted Average Exercise Price Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, August 1, 2009	5,067,138	$ 0.44		
Granted	855,000	$ 0.64		
Forfeited or expired	(270,000)	$ 0.92		
Exercised	—	—		
Outstanding, October 31, 2009	5,652,138	$ 0.44	4.91	$ 1,196,754
Exercisable, October 31, 2009	4,753,388			$ 1,196,754
Grant Date Fair Value of Options Granted				$ 0.46
Grant Date Fair Value of Options Forfeited or Expired				$ 0.70
Total Intrinsic Value of Options Exercised				n/a

The following is a summary of the non-vested common stock options granted, vested and forfeited under the Plan:

	Options	Weighted Average Grant Date Fair Value
Outstanding, August 1, 2009	43,750	$ 0.59
Granted	855,000	$ 0.46
Vested	—	n/a
Forfeited	—	n/a
Outstanding, October 31, 2009	898,750	$ 0.47

As of October 31, 2009, the Company had $395,176 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 2.35 years.

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GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

During the three months ended October 31, 2009, the Company modified the terms of 4,535,638 outstanding options which resulted in a charge to operations in the amount of $875,773. The fair value of modification cost is estimated as the difference of options' fair value before and after modification date. The estimates employ Black-Scholes option pricing model, which takes into account the exercise price ($0.001 – $0.94), expected life of the option (5 years), the current price of the underlying stock ($0.59) and its expected volatility (109.05%), expected dividends on the stock($0) and the risk-free interest rate for the term of the option (0.11%).

In August 2007, the Company issued 550,000 shares of common stock under the 2006 Plan in the form of restricted stock awards to officers. The fair value of these shares was based on the quoted market price of the Company's common stock on the dates of the issuance is $830,500. These shares were issued as an incentive to retain key employees and officers. A portion of these shares vested immediately while the remaining portion will vest over two years from the date of the grant. The following table summarizes the Company's non-vested restricted stock activity for the nine months ended October 31, 2009:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested stock, August 1, 2009	14,844	$ 1.51
Granted	—	n/a
Vested	(14,844)	1.51
Forfeited	—	n/a
Non-vested stock, October 31, 2009	—	n/a

4. Comprehensive Income/(Loss)

Comprehensive loss, which includes net loss and the change in the foreign currency translation account, for the three months ended October 31, 2009 and 2008 was $8,099,825 and $12,063,798, respectively.

5. Inventory

A summary of inventory at October 31 and July 31, 2009 is as follows:

	October 31, 2009	July 31, 2009
Raw materials	$ 756,745	$ 728,919
Finished goods	668,037	542,537
Total	$ 1,424,782	$ 1,271,456

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	October 31, 2009	July 31, 2009

Accounts Payable	$	3,263,478	$	2,983,037
Research and Development		1,838,239		1,629,293
Executive Compensation		2,507,490		2,873,825
Total	$	7,609,207	$	7,486,155

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

7. Pending Litigation

In February 2001, a former business associate of the former Vice President of Research and Development ("VP") of the Company and an entity known as Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against the Company and the VP seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between this former associate and the VP that ceased in July 1996. The plaintiffs' statement of claim also seeks to enjoin the use, if any, by the Company of three patents allegedly owned by CTI. The three patents are entitled Liquid Formulations for Proteinic Pharmaceuticals, Vaccine Delivery System for Immunization, Using Biodegradable Polymer Microspheres, and Controlled Releases of Drugs or Hormones in Biodegradable Polymer Microspheres. It is the Company's position that the buccal drug delivery technologies which are the subject matter of the Company's research, development, and commercialization efforts, including Generex Oral-lyn™ and the RapidMist™ Diabetes Management System, do not make use of, are not derivative of, do not infringe upon, and are entirely different from the intellectual property identified in the plaintiffs' statement of claim. On July 20, 2001, the Company filed a preliminary motion to dismiss the action of CTI as a nonexistent entity or, alternatively, to stay such action on the grounds of want of authority of such entity to commence the action. The plaintiffs brought a cross motion to amend the statement of claim to substitute Centrum Biotechnologies, Inc. ("CBI") for CTI. CBI is a corporation of which 50 percent of the shares are owned by the former business associate and the remaining 50 percent are owned by the Company. Consequently, the shareholders of CBI are in a deadlock. The court granted the Company's motion to dismiss the action of CTI and denied the plaintiffs' cross motion without prejudice to the former business associate to seek leave to bring a derivative action in the name of or on behalf of CBI. The former business associate subsequently filed an application with the Ontario Superior Court of Justice for an order granting him leave to file an action in the name of and on behalf of CBI against the VP and the Company. The Company opposed the application. In September 2003, the Ontario Superior Court of Justice granted the request and issued an order giving the former business associate leave to file an action in the name of and on behalf of CBI against the VP and the Company. A statement of claim was served in July 2004. The Company is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

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

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

8. Net Loss Per Share

Basic earnings per shares (EPS) and Diluted EPS for the three months ended October 31, 2009 and 2008 have been computed by dividing the net loss available to common stockholders for each respective period by the weighted average shares outstanding during that period. All outstanding options, warrants, non-vested restricted stock and shares to be issued upon conversion of the outstanding convertible debentures, representing approximately 49,049,654 and 76,837,722 incremental shares, have been excluded from the October 31, 2009 and 2008 computations of Diluted EPS as they are anti-dilutive, due to the losses generated during the respective periods.

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GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

9. Stockholders' Equity

During the three months ended October 31, 2009, the Company issued 23,870,513 shares of common stock and 9,595,622 warrants to acquire the shares of common stock at exercise prices of $0.79 to $1.00 pursuant to private placements, in exchange for net cash proceeds after expenses of $16,400,671. The shares were priced at $0.66 to $0.80 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the three months ended October 31, 2009, the Company issued 957,835 shares of common stock to various consultants for services rendered in the amount of $639,224. The shares were valued at $0.53 to $0.76 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the three months ended October 31, 2009, the Company issued 1,582,640 shares of common stock to various vendors as satisfaction of accounts payable and accrued expenses in the amount of $1,055,459. The shares were valued at $0.55 to $0.77 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the three months ended October 31, 2009, the Company issued 39,174 shares of common stock valued at $25,250 as employee compensation. The shares were valued at $0.60 to $0.73 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the three months ended October 31, 2009, the Company granted 855,000 options to employees as compensation. The total fair value of the options amounted to $393,300. These options vest over a period of 4 years resulting in a charge to operations in the amount of $5,653 in the current quarter. The fair value of each option granted was estimated on the grant date using the Black-Scholes option pricing model, taking into account the grant date exercise price and current price of the underlying stock of $0.64, an expected life of the option of 3.75 years, an expected volatility of 108.9%, expected dividends on the stock of $0 and the risk-free interest rate for the term of the option of 0.12%.

During the three months ended October 31, 2009, the Company modified the terms of 4,535,638 outstanding options resulting in a charge to operations in the amount of $875,773.

During the three months ended October 31, 2009, the Company issued 4,466,239 shares of common stock in conjunction with a cashless exercise of 7,576,565 warrants.

During the three months ended October 31, 2009, the Company received aggregate cash proceeds of $1,517,940 from exercises of warrants. The Company issued 4,599,817 shares of common stock as a result of these exercises.

During the three months ended October 31, 2009, the Company recorded a charge to operations in the amount of $6,963 as amortization of stock-based compensation.

The following is a summary of the warrants issued, forfeited or expired and exercised for the three months ended October 31, 2009:

	Warrants
Outstanding, August 1, 2009	46,478,276

Issued	9,595,622
Forfeited or expired	(500,000)
Exercised	(12,176,382)
Outstanding, October 31, 2009	43,397,516

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
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(UNAUDITED)

The outstanding warrants at October 31, 2009 have a weighted average exercise price of $0.57 per share.

The stockholders' equity transactions as described above are summarized below:

	Common Stock		Additional Paid-In	Total Stockholders'
	Shares	Amount	Capital	Equity
Issuance of common stock in private placement	23,870,513	$ 23,871	$ 16,376,802	$ 16,400,673
Issuance of common stock for services	957,835	$ 958	$ 638,266	$ 639,224
Issuance of common stock as employee compensation	39,174	39	25,211	25,250
Stock-based executive compensation	—	—	6,963	6,963
Warrants exercised for cash	4,599,817	4,600	1,513,340	1,517,940
Issuance of common stock as satisfaction of accounts payable and accrued expenses	1,582,640	1,583	1,053,877	1,055,459
Issuance of common stock in conjunction with cashless exercise of warrants	4,466,239	4,466	(4,466)	—
Grant of stock options as employee compensation	—	—	5,653	5,653
Option re-pricing costs	—	—	875,773	875,773
Total	35,516,218	$ 35,517	$ 20,491,419	$ 20,526,935

10. Subsequent Events

On December 7, 2009, the Company entered into a long-term agreement with Sanofi-Aventis Deutschland GmbH ("sanofi-aventis"). Under this agreement, sanofi-aventis will manufacture and supply recombinant human insulin to the Company in the territories specified in the agreement. Through this agreement, the Company will procure recombinant human insulin crystals for use in the production of Generex Oral-lyn™. The terms of the supply agreement require the Company to make certain minimum purchases of insulin from sanofi-aventis through the period ended December 31, 2011. sanofi-aventis will be the Company's exclusive supplier in certain countries and a non-exclusive supplier in other countries. sanofi-aventis may delete any territory from the agreement in which Generex Oral-lyn™ has not been approved for commercial sale by December 31, 2011. The prices under the supply agreement are subject to adjustment beginning after December 31, 2012.

On December 9, 2009, the Company entered into an agreement with a consultant for financial services which extends until May 31, 2010. In accordance with the agreement, the Company issued a common stock purchase warrant for an aggregate 2,000,000 shares of common stock. One half of the warrants (1,000,000) are immediately exercisable and the Company recorded a charge of approximately $510,000 at the time of issuance. The second half (remaining 1,000,000) will be exercisable only upon the attainment of certain milestones.

The Company has evaluated subsequent events occurring after the balance sheet through the date of December 11, 2009, which is the date the consolidated financial statements were issued.

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

As used herein, the terms the “Company,” “Generex,” “we,” “us,” or “our” refer to Generex Biotechnology Corporation, a Delaware corporation. The following discussion and analysis by management provides information with respect to our financial condition and results of operations for the three- and nine-month periods ended October 31, 2009 and 2008. 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, 2009 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 October 31, 2009.

Forward-Looking Statements

We have made statements in this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Quarterly Report on Form 10-Q of Generex Biotechnology Corporation for the fiscal quarter ended October 31, 2009 that may constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Act"). The Act limits our liability in any lawsuit based on forward-looking statements that we have made. All statements, other than statements of historical facts, included in this Quarterly Report that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. These statements can be identified by introductory words such as "expects," “anticipates,” "plans," "intends," "believes," "will," "estimates," "projects" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Our forward-looking statements address, among other things:

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

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

- the inherent uncertainties of product development based on our new and as yet not fully proven technologies;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when

tested clinically;

- the inherent uncertainties associated with clinical trials of product candidates;
- the inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates;

- the inherent uncertainties associated with commercialization of products that have received regulatory approval;

- the volatility of, and recent decline in, our stock price and the impact on our ability to pay installments due on our outstanding senior secured notes in stock rather than cash; and

- our ability to obtain the necessary financing to fund our operations.

Additional factors that could affect future results are set forth in Part I, Item 1A Risk Factors of our Annual Report on Form 10-K for the year ended July 31, 2009 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.

Compliance with Smaller Reporting Company Disclosure Requirements

Generex has determined that it qualifies as a “smaller reporting company” as defined in Rule 12-b2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and that it will take advantage of the Securities and Exchange Commission’s recently adopted rules permitting a smaller reporting company to comply with scaled disclosure requirements for smaller reporting companies on an item-by-item basis. The Company has elected to comply with the scaled disclosure requirements for smaller reporting companies with respect to Part I, Item 3 – Quantitative and Qualitative Disclosures About Market Risk, which is not applicable to smaller reporting companies.

Executive Summary

Overview of Business

We are engaged primarily in the research, development and commercialization 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.

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 hormone, 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™.

Generex Oral-lyn™

Regulatory Approvals and Clinical Trials

To date, we have received regulatory approval in Ecuador, India, Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™.

In March 2008, we initiated Phase III clinical trials for this product in the U.S. with the first patient screening for such trials at a clinical study site in Texas. The patient screening at other participating clinical sites in the U.S. and Canada is ongoing. Currently over 350 patients have been enrolled in 70 clinical sites around the world, including sites in the United States, Canada, Bulgaria, Poland, Romania, Russia and Ukraine.

In November 2008, we submitted our product dossier to the Ministry of Health in Damascus, Syria through Generex MENA, our branch office in Dubai. The dossier includes Generex Oral-lyn™. We also submitted a file to register our proprietary over-the-counter products, including Glucose RapidSpray™, 7-Day Diet Aid Spray™ (marketed as Crave-Nx™ in the United States and Canada) and BaBOOM!™ Energy Spray. The Syrian Ministry of Health will review the dossier and inform us of any additional requests for information that it may have. There have been no immediate queries, and we anticipate registration in early 2010.

In December 2008, we submitted Generex Oral-lyn™ dossier to the Ministry of Health in Iraq (North) through Generex MENA, our branch office in Dubai and expect to receive an approval to market the product early in 2010.

Special Access Programs

In October 2009, we received approval from the U.S. Food and Drug Administration (the "FDA") to charge to recover costs for the treatment use of Generex Oral-lyn™ in patients with Type 1 or Type 2 diabetes mellitus in the FDA's Treatment Investigational New Drug program that provides for early access to investigational treatments for life-threatening or otherwise serious conditions.

We received a Special Access Program (SAP) authorization from Health Canada for a patient-specific, physician-supervised treatment of Type-1 diabetes with Generex Oral-lyn™ in April 2008. SAP provides access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are not available or unsuitable. We received a similar authorization from health authorities in Netherlands in September 2008. We will continue to expand our SAP participation in additional countries around the world.

Marketing

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. Product has been available for sale in India since January 2009, and an estimated 50 dialectologists are currently prescribing Oral Recosulin there.

In December 2008, we, together with our marketing partner Benta SA., received an approval to market Generex Oral-lyn™ in Lebanon. Benta is currently working on reimbursement policy for Generex Oral-lyn™. 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. We expect commercial launch of the product by the end of calendar year 2009. Through the efforts of our business development team, in association with our Generex MENA office, we have entered into a marketing sub-distribution relationship with Algerian company Continental Pharm Laboratoire. The official product launch in Algeria took place in October 2009.

Over-The-Counter Glucose Product Line

Using our buccal delivery technology, we also have launched a line of over-the-counter glucose and energy sprays , including Glucose RapidSpray™, Crave-NX™ 7-day Diet Aid Spray, and BaBOOM!™ Energy Spray. We believe these products will complement Generex Oral-lyn™ and may provide us with an additional revenue stream prior to the commercialization of Generex Oral-lyn™ in other major jurisdictions. In fiscal 2009, we received modest revenues from sales of our commercially available products, our confectionary, Glucose RapidSpray™, a flavored glucose "energy" spray supplemented with vitamins, BaBOOM!™ Energy Spray, and a fat-free glucose spray to aid in dieting, Crave-NX™. All

three products are available in retail stores and independent pharmacies in the United States and Canada. In addition, the products are being distributed in the Middle East through our Generex MENA office in Dubai. We expect other distribution territories for these products to include South Africa, India, South America and other jurisdictions worldwide. We are currently pursuing European registrations for these products.

Other Product Candidates

In October 2008, we announced the enrollment of subjects in our bioequivalence clinical trial of MetControl™, our proprietary Metformin medicinal chewing gum product. The protocol for the study is an open-label, two-treatment, two-period, randomized, crossover study comparing MetControl™ and immediate release Metformin™ tablets in healthy volunteers. The study results, that we received and analyzed in December 2008 demonstrated bioequivalence and will allow us to proceed with additional research and development initiatives and consider regulatory agency registration applications. We are compiling the data from this study and expect to file with the regulatory agency in early 2010.

Our subsidiary, Antigen Express, concentrates on developing proprietary vaccine formulations that work by stimulating the immune system to either attack offending agents (i.e., cancer cells, bacteria, and viruses) or to stop attacking benign elements (i.e., self proteins and allergens). Our immunomedicine products are based on two platform technologies and are in the early stages of development. We continue 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 trials. An additional Phase I trial has been initiated recently in patients with either breast or ovarian cancer. The synthetic vaccine technology has particularly advantages for pandemic or potentially pandemic viruses, such as the H5N1 avian and H1N1 swine flu. In addition to pandemic influenza viruses, development efforts also are underway for seasonal influenza virus, HIV, HPV, melanoma, ovarian cancer, allergy and Type I diabetes mellitus. We have established collaborations with clinical investigators at academic centers to advance these technologies.

Competition

We face competition from other providers of alternate forms of insulin. Some of our most significant competitors, Pfizer, Eli Lilly, and Novo Nordisk, have announced that they will discontinue development and/or sale of their inhalable forms of insulin. Generex Oral-lyn™ is not an inhaled insulin; rather, it is a buccally absorbed formulation with no residual pulmonary deposition. We believe that our buccal delivery technology offers several advantages over inhaled insulin, including the avoidance of pulmonary inhalation, which requires frequent physician monitoring, ease of use and portability.

Brief Company Background

We are a development stage company. From inception through the end of the fiscal quarter ended October 31, 2009, we have received only limited revenues from operations. In the fiscal years ended July 31, 2009 and 2008, we received approximately $1,118,509 and $124,891 in revenue. The revenue in fiscal 2009 included $550,000 relating to an upfront license fee for the signing of a license and distribution agreement for Generex Oral-lyn™, while the remainder of the revenue in both fiscal periods pertained to the sale of our confectionary products. These numbers do not reflect deferred sales to customers during the respective periods with the right of return.

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

We were incorporated in the State of Delaware in 1997. Our principal executive offices are located at 33 Harbour Square, Suite 202, Toronto, Canada, and our telephone number at that address is (416) 364-2551. We maintain an Internet website at www.generex.com. We make available free of charge on or through our website our filings with the SEC.

Accounting for Research and Development Projects

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

During the last fiscal quarter, we expended resources on the clinical testing and commercialization, of our buccal insulin product, Generex Oral-lyn™. In July 2007, we received no objection from the FDA to proceed with our long-term multi-center Phase III study protocol for Generex Oral-lyn™. Late-stage trials involve testing our product with a large number of patients over a significant period of time. The completion of late-stage trials in Canada and eventually the United States may require significantly greater funds than we currently have on hand.

Generex Oral-lyn™ was approved for commercial sale by drug regulatory authorities in Ecuador in May 2005. PharmaBrand handled the commercial launch of Generex Oral-lyn™ in Ecuador in June 2006. While we anticipate generating revenue from sales of Generex Oral-lyn™ in Ecuador, we do not expect that such revenues will be sufficient to sustain our research and development and regulatory activities.

Generex Oral-lyn™ was approved for importation and commercial sale in India in November 2007. We have entered into a licensing and distribution agreement with Shreya Life Sciences Pvt. Ltd. and since January 2009 Generex Oral-lyn™ is available in India under marketing name of Oral Recosulin.

Generex Oral-lyn™ was approved for importation and commercial sale in Lebanon in December 2008. We have entered into a subdistribution agreement with Benta SA. and officially launched the product in May 2009.

Generex Oral-lyn™ was approved for importation and commercial sale in Algeria in May 2009. We have entered into a subdistribution agreement with Continental Pharm Laboratoire and officially launched the product in October 2009.

We have not yet recognized any revenue from the sale of our oral insulin product in any of the four countries where it is currently approved for commercial sale.

Although we initiated regulatory approval process for our morphine and fentanyl buccal products, we did not expend resources to further this product during our last fiscal year.

During the last fiscal quarter, we expended resources on research and development relating to Antigen's peptide immunotherapeutic vaccines and related technologies. One Antigen vaccine is currently in Phase II clinical trials in the United States involving patients with HER-2/neu positive breast cancer, and an Antigen vaccine for H5N1 avian influenza is in Phase I clinical trials conducted at the Lebanese-Canadian Hospital in Beirut. Antigen's prostate cancer vaccine based on AE37 is currently in Phase I clinical trials in Greece. Preliminary pre-clinical work has commenced with respect to the experimental vaccine for patients with acute myeloid leukemia at Beijing Daopei Hospital in China.

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

Most of our buccal delivery research and development activities to date have involved developing our platform technology for use with insulin. Insubstantial amounts have been expended on projects with other drugs, including morphine and fentanyl, and those projects involved a substantial amount of platform technology development. As a result, we have not made significant distinctions in the accounting for research and development expenses among products, as a significant portion of all research has involved improvements to the platform technology in connection with insulin, which may benefit all of our potential buccal products. During the three months ended October 31, 2009, approximately 85% of our $3,075,769 in research expenses was attributable to insulin and platform technology development, and we did not have any research expenses related to morphine, fentanyl or other buccal projects. During the three months ended October 31, 2008, approximately 88% of our $4,355,689 in research expenses was attributable to insulin and platform technology development, and we did not have any research expenses related to morphine, fentanyl or other buccal projects.

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Approximately 15%, or $446,346, of our research and development expenses for the three months ended October 31, 2009 was related to Antigen's immunomedicine products compared to approximately 12%, or $510,660, of our research and development expenses for the three months ended October 31, 2008. Because these products are in initial phases of clinical trials or early, pre-clinical stage of development (with the exception of the Phase II clinical trials of Antigen HER-2/neu positive breast cancer vaccine that are underway), all of the expenses were accounted for as basic research and no distinctions were made as to particular products. Due to the early stage of development, we cannot predict the timing of completion of any products arising from this technology, or when products from this technology might begin producing revenues.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our 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 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 financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Revenue Recognition. Net sales of Glucose RapidSpray™, BaBOOM!™ Energy Spray and GlucoBreak™ are generally recognized in the period in which the products are delivered. Delivery of the products generally completes the criteria for revenue recognition for the Company. In the event where the customers have the right of return, sales are deferred until the right of return lapses or the product is resold.

Inventory. Inventories are stated at the lower of cost or market with cost determined using the first-in first-out method. Management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time to sell such inventory, inventories shelf life and current market conditions when determining whether the lower cost or market is used. As appropriate, a provision is recorded to reduce inventories to their net realizable value. Inventory also includes the cost of products sold to the customers with the rights of return.

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 Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Statement of Operations.

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.

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 in accordance with Statement of Financial Accounting Standards No. 123(R) “Share-Based Payment” which revises SFAS No. 123 “Accounting for Stock-Based Compensation” for stock and options grants to employees. We also follow the guidance of Emerging Issues Task Force 96-18 “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services” for equity instruments issued to consultants.

Results of Operations
Three Months Ended October 31, 2009 Compared to Three Months Ended October 31, 2008

Our net loss for the quarter ended October 31, 2009 was $8,138,656 versus $11,697,184 in the corresponding quarter of the prior fiscal year. The decrease in net loss in this fiscal quarter versus the corresponding quarter of the prior fiscal year is primarily due to the prior year’s quarter interest expense of $4,429,388, which consisted mainly of non-cash interest charges recorded in connection with our secured convertible debentures. Interest expense for the current year quarter was $52,401. The decrease in net loss was partially offset by the increase in our general and administrative expenses and selling and marketing expenses and the decrease in research and development expenses. Our operating loss for the quarter ended October 31, 2009 increased to $8,181,433 compared to $7,524,646 in the first fiscal quarter of 2008. The increase in operating loss resulted from an increase in general and administrative expenses (to $3,825,265 from $2,847,913) and an increase in selling expense (to $1,298,704 from $837,198), offset by a decrease in research and development expenses (to $3,075,769 from $4,355,689). Our revenues in the first quarter ended October 31, 2009 decreased to $97,542 from $538,346 for the quarter ended October 31, 2008 reflecting only the sales of our over-the-counter products in the current fiscal year quarter, while the comparative prior year quarter included an upfront, non-refundable $500,000 license fee related to our Oral-lyn™ product.

The decrease in research and development expenses in the last fiscal quarter versus the comparative quarter in the previous fiscal year, is primarily due to timing differences related to the clinical costs associated with the global Phase III clinical trials of our oral insulin product and platform technology, as well as the timing of earlier stage (pre-clinical, Phase I and Phase II) clinical trials related to the Antigen immunotherapy products versus the previous fiscal year’s quarter. The increase in general and administrative expenses is primarily related to the non-cash, one time stock option modification charge of $875,773 in the quarter ended October 31, 2009. The increase in selling expenses for the quarter ended October 31, 2009 versus the prior year comparative quarter is associated with increased advertising and promotion of our over-the-counter products, as well as the costs associated with our MENA sales office in Dubai.

Our interest expense in the first quarter of fiscal 2009 decreased to $52,401, compared to interest expense of $4,429,388 in the first quarter of fiscal 2008, due to interest expense and costs of the repriced warrant recognized on the secured convertible notes issued in March 2008 in connection with a private placement recognized in the prior year quarter, but not in the current year. Our interest income decreased to $10,085 in the first quarter of fiscal 2009, compared to $168,465 in the same quarter for the last year, primarily due to lower market interest rates and lower average cash balances. We received a slightly lower income from rental operations (net of expense) of $84,593 in the first quarter of fiscal 2009 compared to $88,380 in the same quarter for the last year.

Financial Condition, Liquidity and Resources

Sources of Liquidity

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

As of October 31, 2009, we believed that our anticipated cash position was sufficient to meet our working capital needs for the next twelve months based on the pace of our planned activities. Beyond that, we anticipate that we will require additional funds to support our working capital requirements or for other purposes.

While we have generally been able to raise equity capital as required, our cash balances were very low during portions of fiscal 2009, although we successfully raised over $31 million (net of issuance costs and expenses) during the period from May 2009 to September 2009. Unforeseen problems with our clinical program, manufacturing and commercialization plans in Ecuador and India or further negative developments in general economic conditions could interfere with our ability to raise additional equity capital as needed, or materially adversely affect the terms upon which such capital is available. Our inability to obtain required funding will have a material adverse effect on one or more of our research or development programs and curtail some of our commercialization efforts.

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, at-market stock issuance programs, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. We have filed a shelf registration statement with the Securities and Exchange Commission ("SEC") to register an indeterminate number of shares of common stock and preferred stock and an indeterminate number of warrants and units, the aggregate initial offering price of which is not to exceed $150,000,000.

We conducted offerings in August and September of 2009, pursuant to this registration statement as described below and raised an aggregate of $16.4 million in net proceeds. On October 14, 2009, we entered into an At Market Issuance Sales Agreement with Wm Smith& Co. under which we may sell an aggregate of $20,000,000 in gross proceeds of our common stock from time to time through Wm Smith, as the agent for the offer and sale of the common stock; however, we determined in late October 2009, that in light of general market conditions, we would not exercise our right to issue and sell shares of our common stock under the At Market Issuance Sales Agreement until further notice.

Management is actively pursuing industry collaboration activities, including product licensing and specific project financing. To secure a reliable long-term insulin supply for our future commercial needs, we entered into a long-term agreement with Sanofi-Aventis Deutschland GmbH ("sanofi-aventis"), on December 7, 2009. Under this agreement, sanofi-aventis will manufacture and supply recombinant human insulin to us in the territories specified in the agreement. Through this agreement, we will procure recombinant human insulin crystals for use in the production of Generex Oral-lyn™. The terms of the supply agreement require us to make certain minimum purchases of insulin from sanofi-aventis through the period ended December 31, 2011. sanofi-aventis will be our exclusive supplier in certain countries and a non-exclusive supplier some other countries. sanofi-aventis may delete any territory from the agreement in which Generex Oral-lyn™ has not been approved for commercial sale by December 31, 2011. The prices under the supply agreement are subject to adjustment beginning after December 31, 2012.

We believe that the commencement of Phase III clinical trial trials for Oral-lyn™ in the United States and Canada represents a significant milestone event. We also anticipate that the commercial launch of Oral-lyn™ in India, Lebanon and Algeria, may provide us with revenue in 2010. We believe that the successful commercial launch of Oral-lyn™ in India and other countries where we have approval would enhance our ability to access additional sources of funding. We will continue to require substantial funds to continue research and development, including preclinical studies and clinical trials of our product candidates, and to commence sales and marketing efforts if the FDA or other regulatory approvals are obtained.

Financing – August 2009

On August 6, 2009, we and certain investors entered into a securities purchase agreement pursuant to which we sold an aggregate of 8,558,013 shares of our common stock and warrants exercisable for up to 2,995,305 shares of our common stock to the investors. The purchase price of each unit (comprised of one share and one warrant to purchase thirty-five percent (35%) of one share of common stock) was $0.6602, and the exercise price per share of the warrants is $0.79. The warrants are exercisable for a period of 5 years beginning 183 days after the closing date. The net proceeds to us from the registered direct public offering, after deducting placement agent fees and our offering expenses, were approximately $5,200,000.

The shares and the warrants were issued pursuant to a prospectus supplement filed with the Securities and Exchange Commission on August 6, 2009, in connection with a takedown from our shelf registration statement on Form S-3 (File No. 333-139637), as amended, which became effective on February 23, 2007 (the "Shelf Registration Statement").

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Midtown Partners & Co., LLC ("Midtown") acted as our exclusive placement agent pursuant to the Placement Agency Agreement that we entered into with Midtown on June 8, 2009. Pursuant to the Placement Agency Agreement, we paid Midtown a cash fee in the aggregate amount of $213,000. This fee represents 4% of the gross purchase price paid for the shares and warrants at the closing by certain specified investors and 2% of the gross purchase price paid for the shares and warrants at the closing by the other investors. In addition, we issued Midtown, or its permitted assigns, a five-year warrant to purchase up to 577,666 shares of our common stock representing 5% of the sum of the number of shares of common stock issued at the closing, and (ii) the number of shares of common stock issuable upon exercise of all warrants issued at the closing. The shares underlying Midtown's warrant will be issued pursuant to the prospectus supplement. The warrant provides for cashless exercise in the event there is no registration statement covering the underlying warrant shares. The exercise price per share is $0.79. We also reimbursed the placement agent for certain fees and legal expenses reasonably incurred in connection with this offering.

Financing – September 2009

On September 14, 2009, we and certain investors entered into a securities purchase agreement pursuant to which we sold an aggregate of 15,312,500 shares of our common stock and warrants exercisable for up to 5,053,125 shares of our common stock to the investors. The purchase price of each unit (comprised of one share and one warrant to purchase thirty-three percent (33%) of one share of common stock) was $0.80, and the exercise price per share of the warrants is $1.00. The warrants are exercisable for a period of 5 years beginning 183 days after the closing date. The net proceeds to us from the registered direct public offering, after deducting placement agent fees and our offering expenses, were approximately $11,660,000.

The shares and the warrants were issued pursuant to a prospectus supplement filed with the Securities and Exchange Commission on September 14, 2009, in connection with a takedown from the Shelf Registration Statement.

Pursuant to an amendment to the Placement Agency Agreement entered into with Midtown on June 8, 2009 and a Placement Agency Agreement entered in to with Maxim Group LLC ("Maxim") on September 11, 2009, we paid each of Midtown and Maxim cash fees in the aggregate amount of $245,000. This fee represented 4% of the gross purchase price paid for the shares and warrants at the closing by certain specified investors brought to the investment by each respective placement agent and 2% of the gross purchase price paid for the shares and warrants at the closing by the other investors. In addition, we issued to each of Midtown and Maxim, or their permitted assigns, a five-year warrant to purchase up to 254,571 shares of common stock of the company representing (A) 2.5% of the sum of (i) the number of shares issued at the closing to investors introduced to the transaction by Midtown or Maxim, as the case may be, and (ii) the number of shares issuable upon exercise of all warrants issued at the closing to investors introduced to the transaction by Midtown or Maxim, as the case may be, and (B) 1.25% of the sum of (i) the number of shares issued at the closing to investors which were not introduced to the transaction by a registered broker-dealer, and (ii) the number of shares issuable upon exercise of all warrants issued at the closing to investors which were not introduced to the transaction by a registered broker-dealer. The shares underlying Midtown and Maxim's warrant were issued pursuant to the prospectus supplement. The warrants provide for cashless exercise in the event there is no registration statement covering the underlying warrant shares. The exercise price per share is $1.00. We also reimbursed the placement agents for certain fees and legal expenses reasonably incurred in connection with this offering.

Proceeds from Warrant Exercises

We may receive additional proceeds from the exercise of warrants issued in the private placements conducted in June, August and September 2009, although some of the warrants include a cashless exercise feature. In the June 2009 private placement, we sold an aggregate of 17,200,000 shares of our common stock and warrants exercisable for up to 8,600,000 shares of our common stock to investors and issued Midtown, our exclusive placement agent for the

transaction, a five-year warrant to purchase up to 244,926 shares of our common stock . As of March 16, 2010, all of the warrants issued in the June, August and September 2009 private placements will be exercisable. At December 10, 2009, outstanding warrants issued in connection with the June, August and September 2009 private placements were as follows:

Date Issued	Aggregate No. of Shares Unexercised	Exercise Price*	Expiration Date
June 15, 2009	8,844,926	0.76	December 15, 2014
August 6, 2009	3,572,971	0.79	February 4, 2015
September 14, 2009	6,022,651	1.00	March 15, 2015

In addition, we may receive additional proceeds from the exercise of warrants issued in connection with the securities purchase agreement and related documents that we entered into on March 31, 2008 with existing institutional investors relating to a private placement of 8% secured convertible notes (the "Notes") and warrants (the "Series Warrants") for aggregate gross proceeds to us of $20,650,000. As of June 1, 2009, the outstanding principal balance and accrued interest on the Notes were satisfied in full.

The Series Warrants issued in connection with the March 2008 securities purchase agreement included:

(i) Series A and A-1 Warrants, which are exercisable for a period of 7 years into an aggregate of 75% of the number of shares of our common stock initially issuable upon conversion of the Notes, with the Series A Warrants being exercisable into 5,257,729 shares immediately upon issuance and the Series A-1 warrants being exercisable into 7,541,857 shares as of October 1, 2008;

(ii) Series B Warrants, which became exercisable on October 1, 2008 into 100% of the shares of our common stock initially issuable upon conversion of the Notes (initially 17,066,166 shares) and remain exercisable for a period of 18 months after the registration statement covering the shares of common stock issuable upon conversion or exercise of the Notes and Warrants was declared effective by the SEC; and

(iii) Series C Warrants, which are exercisable for a period of 7 years as of October 1, 2008, but only to the extent that the Series B Warrant are exercised and only in the same percentage that the Series B Warrants are exercised, up to a maximum percentage of 75% of the number of shares of our common stock initially issuable upon conversion of the Notes (initially a maximum of 12,799,580 shares).

The initial exercise price of each Series Warrant was $1.21. The exercise price of the Series Warrants was subsequently reduced initially to $0.50 and then to $0.33 as a result of an anti-dilution provision triggered by the May 2009 private placement. The Series Warrants include a cashless exercise feature. At October 31, 2009, outstanding Series Warrants were as follows:

Date Issued	Aggregate No. of Shares Unexercised	Exercise Price*	Expiration Date
March 31, 2008	1,768,231	$ 0.33	January 29, 2010
March 31, 2008	14,330,603	$ 0.33	March 31, 2016
March 31, 2008	7,690,902	$ 0.33	September 30, 2016

*Subject to anti-dilution adjustments upon issuance of securities at a price per share of common stock less than the then applicable exercise price or the market price of our common stock at that time, whichever is lower.

At Market Issuance Agreement

On October 14, 2009, we entered into an At Market Issuance Sales Agreement (the "Agreement"), with Wm Smith & Co. ("Wm Smith"), under which we may sell an aggregate of $20,000,000 in gross proceeds of our common stock from time to time through Wm Smith, as the agent for the offer and sale of the common stock. Wm Smith may sell the common stock by any method permitted by law, including sales deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on NASDAQ Capital Market, on any other existing trading market for the common stock or to or through a market maker. Wm Smith may also sell the common stock in privately negotiated transactions, subject to Generex's prior approval. We will pay Wm Smith a commission not to exceed 3% of the gross proceeds of the sales price of all common stock sold through it as sales agent under the agreement.

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The sales agreement will terminate on the earliest of (1) the sale of all of the common stock subject to the agreement, or (2) termination of the agreement by Generex or Wm Smith. Wm Smith may terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change that, in Wm Smith's reasonable judgment, may impair its ability to sell the common stock, Generex's failure to satisfy any condition under of the agreement or a suspension or limitation of trading of our common stock on NASDAQ. We may terminate the sales agreement at any time upon 10 days prior notice, and Wm Smith may terminate the Agreement at any time upon 10 days prior notice.

We announced on October 29, 2009, that, in light of general market conditions, we will not exercise our right to issue and sell shares of our common stock under the sales agreement until further notice.

Cash Flows for the Three Months Ended October 31, 2009

For the three months ended October 31, 2009, we used $5,661,737 in cash to fund our operating activities. The use for operating activities included a net loss of $8,138,656, a net increase in accounts receivable of $26,542, an increase of $145,682 in inventory, an increase of $238,187 in other current assets and a decrease in deferred revenue of $33,702, offset by an increase of $1,168,647 in accounts payable and accrued expenses.

The use of cash was offset by non-cash increases of approximately $199,702 related to depreciation and amortization, $907,986 in stock-based compensation to employees and $644,877 in stock-based compensation issued in exchange for services rendered by consultants.

We had net cash outflows from investing activities of $174,883 in the three months ended October 31, 2009, representing payments for property and equipment of $132,646 and costs incurred for patents of $42,237.

We had net cash flows provided by financing activities of $17,884,716 in the three months ended October 31, 2009. We received $16,400,671 from issuances of common stock in our August and September registered direct offerings. We received $1,517,940 in cash proceeds from exercises of warrants. We made payments related to our capital leases in the amount of $10,403 and long-term debt in the amount of $23,492.

Our net working capital at October 31, 2009 increased to $19,775,939 from $7,561,375 at July 31, 2009, which was attributed largely to the net proceeds raised from the issuance of common stock and exercises of warrants, offset by our net loss for the first quarter of fiscal 2010.

Funding Requirements

We expect to devote substantial resources to obtaining regulatory approval of Generex Oral-lyn™ in the U.S., Canada and Europe and to commercializing Generex Oral-lyn™ in India, Lebanon, Ecuador and Algeria. We also will devote resources to obtaining approval for the importation, marketing and commercialization of Generex Oral-lyn™ in other countries where we have licensed distributors. In addition, we will expend resources on further clinical development of our immunotherapeutic vaccines. Our future funding requirements 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 timing, receipt and amount of sales, if any, from our over-the-counter products;
- 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; and
- the receptivity of the financial market to biopharmaceutical companies.

Off-Balance Sheet Arrangements

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

Certain Related Party Transactions

We utilize a management company to manage all of our real properties. The property management company is owned by Ms. Perri, Ms. Gluskin and the estate of Mark Perri, our former Chairman of the Board. In the three month period ended October 31, 2009 and the fiscal year ended July 31, 2009, we paid the management company approximately $13,375 and $47,981, respectively, in management fees. We believe that the amounts paid to the management company approximate the rates that would be charged by a non-affiliated property management company.

Consulting Fees. Peter Amanatides, a former director, is the Senior Vice-President and Chief Operating Officer of PharmaLogika, Inc., a private consulting firm in the pharmaceuticals regulatory field. At October 31, 2009, we accrued a balance of $50,000 in fees to PharmaLogika. We do not expect to pay any further fees to PharmaLogika going forward. Mr. Amanatides is neither a director nor a shareholder of PharmaLogika.

Private Placement of Notes and Warrants. One of the institutional investors in the March 2008 private placement of the Notes and Series Warrants was Cranshire Capital, L.P. Cranshire purchased Notes in the aggregate principal amount of $5,000,000 and received Series A Warrants initially exercisable for 1,273,058 shares of common stock, Series A-1 Warrants initially exercisable for 1,826,115 shares, Series B Warrants initially exercisable for 4,132,231 and Series C Warrants initially exercisable for 3,099,173. On February 11, 2009, Cranshire jointly filed an amendment to Schedule 13G with Downsview Capital, Inc. and Mitchell P. Kopin reporting beneficial ownership of more 9.99% of our outstanding shares of common stock. The beneficial ownership of Cranshire as of May 29, 2009 was 5.6% based on the number of shares of common stock outstanding as of that date.

See Part III, Item 13 – Certain Relationships and Related Transactions, and Directors Independence in our Annual Report on Form 10-K for the year ended July 31, 2009 for further descriptions of our transactions with related parties during 2009.

New Accounting Pronouncements

In November 2007, the FASB issued guidance related to accounting for collaborative arrangements. This guidance defines a collaborative arrangement as a contractual arrangement in which the parties are (i) active participants to the

arrangement; and (ii) exposed to significant risks and rewards that depend upon the commercial success of the endeavor. It also addresses the appropriate statement of operations presentation for activities and payments between the participants in a collaborative arrangement as well as for costs incurred and revenue generated from transactions with third parties. This guidance is effective for our fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In December 2007, the FASB issued an amendment to an existing accounting standard which provides guidance related to business combinations. The amendment retains the fundamental requirements that the acquisition method of accounting be used for all business combinations and for an acquirer to be identified for each business combination. This amendment also establishes principles and requirements for how the acquirer: a) recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree; b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase and c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This amendment applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. This guidance is effective for our fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In December 2007, the FASB issued guidance related to non-controlling interests in consolidated financial statements. This guidance amends previously issued guidance to establish accounting and reporting standards for the non-controlling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. This guidance is effective for our fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In April 2008, the FASB issued guidance related to determining the useful life of intangible assets. This guidance amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The objective of the guidance is to improve the consistency between the useful life of a recognized intangible asset and the period of expected cash flows used to measure the fair value of the asset. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In May 2008, the FASB issued guidance related to accounting for convertible debt instruments that may be settled in cash upon conversion (including partial cash settlements)." This guidance requires a portion of this type of convertible debt to be recorded as equity and to record interest expense on the debt portion at a rate that would have been charged on nonconvertible debt with the same terms. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In June 2008, the FASB issued guidance related to determining whether instruments granted in share-based payment transactions are participating securities. Securities participating in dividends with common stock according to a formula are participating securities. This guidance determined that unvested shares of restricted stock and stock units with nonforfeitable rights to dividends are participating securities. Participating securities require the "two-class" method to be used to calculate basic earnings per share. This method lowers basic earnings per common share. This guidance is effective for our fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In June 2008, the FASB reached a consensus regarding the determination of whether an instrument (or an embedded feature) is indexed to an entity's own stock, which is the first part of the scope exception related to accounting for derivative instruments and hedging activities. This guidance is effective for our fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In June 2009, the FASB issued guidance which stipulates the FASB Accounting Standards Codification is the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities.
This guidance is effective for our fiscal year beginning August 1, 2009. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

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In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605)—Multiple Deliverable Revenue Arrangements ("ASU 2009-13"). ASU 2009-13 eliminates the residual method of allocation and requires the relative selling price method when allocating deliverables of a multiple-deliverable revenue arrangement. The determination of the selling price for each deliverable requires the use of a hierarchy designed to maximize the use of available objective evidence including, vendor specific objective evidence, third party evidence of selling price, or estimated selling price. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, and must be adopted in the same period using the same transition method. If adoption is elected in a period other than the beginning of a fiscal year, the amendments in these standards must be applied retrospectively to the beginning of the fiscal year. Full retrospective application of these amendments to prior fiscal years is optional. Early adoption of these standards may be elected. We are currently evaluating the impact of these new accounting standards on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we have elected scaled disclosure reporting obligations and therefore is not required to provide the information in this Item 3.

Item 4T. 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 Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of Generex's disclosure controls and procedures. Based on the evaluation, the CEO and CFO have concluded that, as of October 31, 2009, Generex's disclosure controls and procedures are effective to ensure that information required to be disclosed by Generex 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 Generex'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, 2009, 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.

None.

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, 2009, 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 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. In the three months ended October 31, 2009, we received revenues of $97,542 from sales of our over-the-counter confectionary products. In the fiscal year ended July 31, 2009, we received modest revenues of approximately $618,509 from sales of these products. We did not recognize any revenue from the sale of our oral insulin product in Ecuador or India in fiscal 2009, although we did recognize $500,000 in licensing fee revenue relating to the signing of a licensing and distribution agreement for the sale of Generex Oral-lyn™ in Korea. We do not expect to receive any revenues in Ecuador until we enter into a definitive manufacturing and distribution agreement with our business partner there. While we have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor, we do not anticipate significant revenue from the initial commercial launch of Generex Oral-lyn™ in India sometime this fiscal year. We also have entered in subdistribution agreements in Lebanon and Algeria but do not expect any signification revenue from the launch of the product in those countries in calendar year 2009.

To date, we have not been profitable and our accumulated net loss available to shareholders was $302,180,145 at October 31, 2009. Our losses have resulted principally from costs incurred in research and development, including clinical trials, and from general and administrative costs associated with our operations. While we seek to attain profitability, we cannot be sure that we will ever achieve product and other revenue sufficient for us to attain this objective.

With the exception of Generex Oral-lyn™ which is currently available for sale in Ecuador and has been approved for sale in India, Lebanon and Algeria and our over-the-counter glucose and energy spray products, Glucose RapidSpray™, BaBOOM!™ Energy Spray and Crave-Nx™, 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.

Risks Related to the Market for Our Common Stock

Our common stock could be delisted from The NASDAQ Capital Market.

On July 23, 2008, we received notice from The NASDAQ Stock Market that we were not compliance with Marketplace Rule 4310(c)(4) (now known as Listing Rule 5550(a)(2)), which requires us to have a minimum bid price per share of at least $1.00 for thirty (30) consecutive business days. In accordance with this Rule, we had 180 calendar days, or until January 20, 2009, subject to extension, to regain compliance with this Rule.

Our initial compliance period of 180 calendar days ending on January 20, 2009 was subsequently extended until November 9, 2009 due to NASDAQ’s temporary suspension of the minimum bid price requirement from October 16, 2008 until August 3, 2009.

On November 9, 2009, we received a letter from NASDAQ indicating that we had not regained compliance with the $1.00 minimum bid price required for continued listing under Listing Rule 5550(a)(2) within the grace period previously allowed by NASDAQ following the initial notice of noncompliance on July 23, 2008.

Pursuant to Listing Rule 5810(c)(3)(A), NASDAQ has given us an additional 180 calendar day compliance period because we met all other initial inclusion criteria (other than the minimum bid price requirement) as of January 6, 2009. Therefore, we have 180 calendar days, or until May 5, 2010, to regain compliance with the rule. To regain compliance with the minimum bid price requirement, the closing bid price of our common stock must close at $1.00 per share or more for a minimum of ten consecutive business days.

If, by May 5, 2010, we do not regain compliance with Listing Rule 5550(a)(2), we will receive written notification that our stock will be delisted. At that time, we may appeal the delisting determination to a NASDAQ Hearings Panel. An appeal to the Hearings Panel would stay the delisting. . If we are not successful in such an appeal, our stock would be delisted from the NASDAQ Capital Market and likely trade on NASDAQ's over-the-counter bulletin board, assuming we meet the requisite criteria.

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

The equity financing transactions into which we have recently entered have and will dilute current stockholders. Currently approximately 42,680,284 shares of common stock are issuable upon exercise of the warrants that we issued on March 31, 2008, May 15, 2009, June 15, 2009, August 6, 2009 and September 14, 2009 (without regard to additional shares which may become issuable due to anti-dilution adjustments or in connection with payments of interest), which represents approximately 17% of the shares of common stock currently outstanding. Assuming the holders of the warrants convert and exercise all of the warrants into shares of common stock, the number of shares of issued and outstanding common stock will increase significantly, and current stockholders will own a smaller percentage of the outstanding common stock of Generex. The issuance of shares of common stock pursuant to the warrants will also have a dilutive effect on earnings per share and may adversely affect the market price of the common stock.

In addition, the issuance of shares of common stock upon exercise of the warrants sold in the offerings that closed on June 15, 2009, August 6, 2009 and September 14, 2009 and sold in our March 31, 2008 private placement could have an anti-takeover effect because such issuance will make it more difficult for, or discourage an attempt by, a party to obtain control of Generex by tender offer or other means. The issuance of common stock upon the exercise of the warrants will increase the number of shares entitled to vote, increase the number of votes required to approve a change of control of the company, and dilute the interest of a party attempting to obtain control of the company.

If we raise funds through one or more additional equity financings in the future, including if we exercise our right to issue and sell shares under the sales agreement with Wm Smith, it will have a further dilutive effect on existing holders of our shares by reducing their percentage ownership. The shares may be sold at a time when the market price is low because we need the funds. This will dilute existing holders more than if our stock price was higher. In addition, equity financings normally involve shares sold at a discount to the current market price.

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

In the fiscal quarter ended October 31, 2009, we sold common stock and other securities in transactions in reliance upon exemptions from the registration requirements of the Securities Act.

During the three months ended October 31, 2009, we issued 12,000 shares of common stock to American Capital Ventures, Inc. pursuant to an agreement with us for financial services. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that American Capital Ventures, Inc. is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

During the three months ended October 31, 2009, we issued 37,500 shares of our restricted common stock as partial consideration for the provision of services by The Abajian Group, LLC under a consulting agreement with us. William Abajian, a Business Development Consultant to Generex, is a principal of The Abajian Group, LLC. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that

The Abajian Group, LLC. is an “accredited investor” as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

We have issued shares of our common stock to The Investor Relations Group, Inc., a consultant, pursuant to an agreement to provide us with investor relation. During the three months ended October 31, 2009, we issued 83,335 shares of common stock to The Investor Relations Group, Inc. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that The Investor Relations Group, Inc. is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

We have issued shares of our common stock to Ventures and Projects Management, Inc, a consultant, pursuant to an agreement to provide us with investor relation services through September 4, 2009. During the three months ended October 31, 2009, we issued 500,000 shares of common stock to Ventures and Projects Management, Inc, pursuant to this agreement. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Ventures and Projects Management, Inc, is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

We have issued shares of our common stock to Seahawk Capital Partners, Inc, a consultant, pursuant to an agreement to provide us with investor relation services until October 11, 2010. During the three months ended October 31, 2009, we issued 60,000 shares of common stock to Seahawk Capital Partners pursuant to this agreement. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Seahawk Capital Partners is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock included a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

We have issued shares of our common stock to Oceanus Capital LLC, a consultant, pursuant to an agreement to provide us with investor relation. During the three months ended October 31, 2009, we issued 250,000 shares of common stock to Oceanus Capital LLC. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Oceanus Capital LLC is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

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 October 31, 2009.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other Information.

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

Item 6. Exhibits.

Exhibits are incorporated herein by reference or are filed with this quarterly report as set forth in the Exhibit Index beginning after page 30 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: December 11, 2009	By:	/s/ Anna E. Gluskin Anna E. Gluskin President and Chief Executive Officer
Date: December 11, 2009	By:	/s/ Rose C. Perri Rose C. Perri Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description of Exhibit(1)
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)	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(ii)	Amended and Restated By-Laws of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3.2(ii) to Generex Biotechnology Corporation's Report on Form 8-K filed December 5, 2007)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Registration Statement on Form S-1 (File No. 333-82667) filed on July 12, 1999)
4.2.1	Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.2	Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.3	Form of Warrant granted to Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.3	Form of replacement Warrant issued to warrant holders exercising at reduced exercise price in May and June 2003 (incorporated by reference to Exhibit 4.13.7 to Generex Biotechnology Corporation's Report on Form 10-K for the period ended July 31, 2003 filed on October 29, 2003)
4.4.1	Securities Purchase Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)

4.4.2	Registration Rights Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.3	Form of Warrant issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.4.4	Form of Additional Investment Right issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
4.5.1	Securities Purchase Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.2	Registration Rights Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.3	Warrant issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.4	Additional Investment Right issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.1	Securities Purchase Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.2	Registration Rights Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.3	Warrant issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.4	Additional Investment Right issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.1	Securities Purchase Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.2	Registration Rights Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.10 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)

4.7.3	Warrant issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.11 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.4	Additional Investment Right issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.12 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.5	Escrow Agreement, dated February 26, 2004, by and among Generex Biotechnology Corporation, Eckert Seamans Cherin & Mellott, LLC and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.13 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.1	Securities Purchase Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.14 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.2	Registration Rights Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.15 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.3	Additional Investment Right issued in connection with Exhibit 4.8.1 (incorporated by reference to Exhibit 4.17 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.1	Securities Purchase Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.18 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.2	Registration Rights Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.19 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.3	Warrant issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.4	Additional Investment Right issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.21 Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.10.1	Securities Purchase Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.2	Registration Rights Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.3	Form of Warrant issued in connection with Exhibit 4.10.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.4	Form of Additional Investment Right issued in connection Exhibit 4.10.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)

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

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

Form of Amendment to Outstanding Warrants (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)

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

4.24.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.24.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)

4.25.1	Form of Securities Purchase Agreement, dated August 6, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.25.2	Form of Warrant issued in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.25.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.28 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.26.1	Form of Securities Purchase Agreement, dated September 11, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.2	Form of Warrant issued in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
9	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)
10.1	At Market Offering Issuance Agreement dated October 14, 2009 entered into between Generex Biotechnology Corporation and Wm Smith & Co, LLC (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on October 15, 2009)
10.2	Recombinant Human Insulin Active Ingredient Manufacturing and Supply Agreement entered into on December 7, 2009 by and between Generex Biotechnology Corporation and Sanofi-Aventis Deutschland GmbH (subject to request for confidential treatment)
31.1	Certification of 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 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.