GENEREX BIOTECHNOLOGY CORP Form 10-Q March 11, 2008

#### 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 January 31, 2008

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

For the transition period from\_\_\_\_\_\_ to \_\_\_\_\_

## **COMMISSION FILE NUMBER: 0-25169**

#### GENEREX BIOTECHNOLOGY CORPORATION

(Exact name of registrant as specified in its charter)

Delaware (State of other jurisdiction of incorporation or organization)

98-0178636

(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. xYes oNo

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 definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "	Accelerated filer x
Non-accelerated filer "	Smaller reporting company "

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

The number of outstanding shares of the registrant's common stock, par value \$.001, was 111,478,091 as of March 6, 2008.

# 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

	(UNA	AUDITED)	
	Jai	nuary 31, 2008	July 31, 2007
ASSETS			
Current Assets:			
Cash and cash equivalents	\$	2,519,987	\$ 21,026,067
Short-term investments		20,182,969	14,011,738
Accounts receivable		102,927	58,264
Inventory		382,512	123,931
Other current assets		442,432	469,210
Total Current Assets		23,630,827	35,689,210
Property and Equipment, Net		1,927,229	2,137,027
Assets Held for Investment, Net		3,882,590	3,693,183
Patents, Net		4,804,795	4,884,984
TOTAL ASSETS	\$	34,245,441	\$ 46,404,404
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current Liabilities:			
Accounts payable and accrued expenses	\$	5,801,032	\$ 7,156,709
Deferred revenue and rebate liability		103,199	33,314
Current maturities of long-term debt		704,822	84,503
Total Current Liabilities		6,609,053	7,274,526
Long-Term Debt, Net		2,614,450	3,059,286
Commitments and Contingencies			
Stockholders' Equity:			
Special Voting Rights Preferred Stock, \$.001 par value; authorized			
1,000 shares at January 31, 2008 and July 31, 2007; -0-shares			
issued and outstanding at January 31, 2008 and July 31, 2007			
Common stock, \$.001 par value; authorized 500,000,000			
shares at			
		111,453	109,616

January 31, 2008 and July 31, 2007; 111,453,633 and 109,616,518 shares issued and outstanding at January 31, 2008 and July 31, 2007, respectively		
Additional paid-in capital	249,656,127	247,079,439
Deficit accumulated during the development stage	(225,729,357)	(212,000,270)
Accumulated other comprehensive income	983,715	881,807
Total Stockholders' Equity	25,021,938	36,070,592
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 34,245,441	\$ 46,404,404

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 (UNAUDITED)

		For the Six Mo Januar 2008			For the Three Janua 2008			Cumulative From November 2, 1995 (Date of Inception) to January 31, 2008
Revenues	\$	65,331	\$	184,928 \$	18,904	¢	45,923 \$	2,442,056
Sales discounts	ψ	(1,991)	ψ	(502)	(277)		(502)	(4,222)
Net Revenue		63,340		184,426	18,627		45,421	2,437,834
		05,510		101,120	10,027		15,121	2,137,031
Cost of Goods Sold		25,585		52,981	5,654		21,466	87,208
Operating Expenses:								
Research and								
development		7,317,427		4,075,015	3,469,624		2,482,082	80,773,891
Research and								
development -								220.210
related party								220,218
Selling and marketing General and		651,918		13,399	284,498		13,399	1,401,255
administrative		6,602,793		5,501,690	3,086,873		3,006,951	96,642,211
General and		0,002,795		5,501,090	3,080,873		5,000,951	90,042,211
administrative -								
related party								314,328
Total Operating								011,020
Expenses		14,572,138		9,590,104	6,840,995		5,502,432	179,351,903
<b>F</b> F		,,		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	.,,		-,,	
Operating Loss		(14,534,383)		(9,458,659)	(6,828,022)	)	(5,478,477)	(177,001,277)
Other Income (Expense):								
Miscellaneous income								
(expense)								196,193
Income from Rental								
Operations, net		170,411		147,806	88,324		79,189	1,091,339
Interest income		751,507		1,204,897	291,472		601,125	7,093,965
Interest expense		(116,622)		(566,898)	(58,948)		(275,164)	(43,718,637)
Loss on extinguishment				(100 925)			(100.207)	(14.124.069)
of debt				(180,825)			(122,307)	(14,134,068)
Net Loss Before								
Undernoted		(13,729,087)		(8,853,679)	(6,507,174)		(5,195,634)	(226,472,485)

Minority Interest Share							
of Loss							3,038,185
Net Loss		(13,729,087)		(8,853,679)	(6,507,174)	(5,195,634)	(223,434,300)
Preferred Stock							
Dividend							2,295,057
Net Loss Available to							
Common							
Shareholders	\$	(13,729,087)	\$	(8,853,679)\$	(6,507,174) \$	(5,195,634)\$	(225,729,357)
Basic and Diluted Net							
Loss Per							
Common Share	\$	(.12)	\$	(.08)\$	(.06) \$	(.05)	
Weighted Average Numbe	r of Sl	hares					
of Common Stock							
Outstanding		110,502,721		107,884,535	110,945,413	108,160,528	
The Notes to Consolidated Financial Statements are an integral part of these statements.							

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

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

		Months Ended uary 31,	Cumulative From November 2, 1995 (Date of Inception) to January 31,
	2008	2007	2008
Cash Flows From Operating Activities:			
Net loss	\$ (13,729,087) \$	(8,853,679) \$	(223,434,300)
Adjustments to reconcile net loss to net cash used			
in operating activities:			
Depreciation and amortization	599,644	577,206	6,481,590
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		3,097	171,506
Loss on disposal of property and equipment			911
Loss on extinguishment of debt		180,826	14,134,069
Common stock issued as employee compensation	1,002,699	183,000	3,296,279
Common stock issued for services rendered	1,054,661	354,389	8,050,977
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			7,272,723
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			1,482,879
Amortization of discount on convertible debentures		435,087	18,930,427
Common stock issued as interest payment on			
convertible			
debentures		15,716	284,459
Interest on short-term advance			22,190
Founders' shares transferred for services rendered			353,506
Fees in connection with short-term refinancing of			

long-term debt			113,274
Changes in operating assets and liabilities (excluding			
the			
effects of acquisition):			
Accounts receivable	(51,281)	(110,104)	(107,961)
Miscellaneous receivables			43,812
Inventory	(247,815)	(44,087)	(365,317)
Other current assets	16,200	(177,291)	(112,513)
Accounts payable and accrued expenses	(922,649)	(341,258)	10,405,466
Deferred revenue	69,384	15,475	102,415
Other, net			110,317
Net Cash Used in Operating Activities	(12,208,244)	(7,761,623)	(130,096,521)

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

	For the Six M Januar 2008		Cumulative From November 2, 1995 (Date of Inception) to January 31, 2008
Cash Flows From Investing Activities:			
Purchase of property and equipment	(2,499)	(77,208)	(4,538,910)
Costs incurred for patents	(118,277)	(105,302)	(1,935,879)
Change in restricted cash			45,872
Proceeds from maturity of short term investments	11,829,420	17,488,782	169,912,229
Purchases of short-term investments	(18,000,651)	(11,413,110)	(190,095,198)
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	30,795	(176,092)	(672,495)
Change in notes receivable - common stock			(91,103)
Change in due from related parties			(2,222,390)
Other, net			89,683
Net Cash Provided by (Used in) Investing Activities	(6,261,212)	5,717,070	(30,584,116)
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	(44,056)	(34,773)	(1,896,425)
Change in due to related parties			154,541
Proceeds from exercise of warrants		125,000	44,015,049
Proceeds from exercise of stock options	49,290	176,983	4,603,416
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			20,254,930
Repayments of convertible debentures		(76,923)	(635,757)
Purchase of treasury stock			(483,869)
Proceeds from issuance of common stock, net			80,283,719
Purchase and retirement of common stock			(119,066)
Net Cash Provided by Financing Activities	5,234	190,287	163,213,042
Effect of Exchange Rates on Cash	(41,858)	(13,025)	(12,418)
Net Increase (Decrease) in Cash and Cash Equivalents	(18,506,080)	(1,867,291)	2,519,987
Cash and Cash Equivalents, Beginning of Period	21,026,067	38,208,493	
Cash and Cash Equivalents, End of Period	\$ 2,519,987	5 36,341,202 5	\$ 2,519,987

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

#### 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 six- and three-month periods 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 2008. 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 whose revenues is primarily comprised of \$1 million received in conjunction with the execution of a development agreement, grant revenue from government agencies related to Antigen's operations and \$50,000 in conjunction with the execution of a licensing agreement. The Company has realized minimal revenues to date from the sale of its commercial products, which currently consists of four commercially available products, including Glucose RapidSpray<sup>TM</sup>. 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.

While the Company believes that it will be successful in obtaining the necessary financing to fund its operations, 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.

## 2. Summary of Significant Accounting Policies

#### Reclassifications

Certain prior period balances have been reclassified in order to conform to the current period presentation. Such reclassifications have no effect on prior period's net loss.

## 3. Effects of Recent Accounting Pronouncements

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" ("FIN 48"), on August 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement 109 "Accounting for Income Taxes", and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition classification, interest and penalties accounting in interim periods disclosure and transition.

Based on our evaluation, we have concluded that there are no significant uncertain tax positions requiring recognition in our financial statements or adjustments to our deferred tax assets and related valuation allowance. Our evaluation was performed for the tax years ended July 31, 2007, 2006, 2005 and 2004, the tax years which remain subject to examination by major tax jurisdictions as of January 31, 2008.

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

The Company may from time to time be assessed interest or penalties by major tax jurisdictions, although such assessments historically have been minimal and immaterial to our financial results. If the Company receives an assessment for interest and/or penalties, it would be classified in the financial statements as general and administrative expense.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption. On February 12, 2008, the FASB delayed the effective date for non-financial assets and liabilities to fiscal years beginning after November 15, 2008; however, the effective date for financial assets remains intact. The Company is currently evaluating the impact of this statement on its results of operations or financial position.

In February 2007, the FASB issued SFAS No. 159, "Establishing the Fair Value Option for Financial Assets and Liabilities" ("SFAS 159") to permit all entities to choose to elect to measure eligible financial instruments and certain other items at fair value. The decision whether to elect the fair value option may occur for each eligible item either on a specified election date or according to a preexisting policy for specified types of eligible items. However, that decision must also take place on a date on which criteria under SFAS 159 occurs. Finally, the decision to elect the fair value option shall be made on an instrument-by-instrument basis, except in certain circumstances. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 applies to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS 157. The Company is currently evaluating this pronouncement in connection with SFAS 157.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS 141(R)"). This Statement replaces SFAS No. 141, "Business Combinations" ("SFAS 141"). This Statement retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. This Statement 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. SFAS 141(R) will apply 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. The Company is currently evaluating the impact of this statement on its results of operations or financial position.

In December 2007, the FASB issued SFAS No. 160, "Non-controlling Interests in Consolidated Financial Statements" ("SFAS 160"). This Statement amends ARB 51 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. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company is currently evaluating the impact of this statement on its results of operations or financial position.

## 4. Stock-Based Compensation

As of January 31, 2008, 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 10,000,000 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 January 31, 2008, there were 2,000,000, 2,643,490 and 8,012,000 shares of common stock reserved for future awards under the 2000 Plan, 2001 Plan and 2006 Plan, respectively.

The 2000, 2001 and 2006 Plans (collectively, 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 are Non-Qualified Options. In addition, the 2006 Plan also provides for restricted stock grants.

The following information relates to stock options that have been granted under the Company's stockholder-approved incentive plans. The stock option exercise price is typically granted at 100 percent of the fair market value on the date the options are granted. Options may be exercised for a period of five years commencing on the date of grant and vest from zero to two years from the date of grant.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. In the case of restricted stock grants under the 2006 Plan, fair market value of the shares is the market price.

No options were granted to employees during the six months ended January 31, 2008.

The summary of the stock option activity for the six months ended January 31, 2008 is as follows:

	Shares	Weighted Average Exercise Price Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, August 1, 2007	7,962,638	\$ 0.94		
Granted		\$ 		
Forfeited or expired	(1,490,000)	\$ 2.10		
Exercised	(31,000)	\$ 1.59		
Outstanding, January 31, 2008	6,441,638	\$ 0.67	1.70	\$ 4,670,131
Exercisable, January 31, 2008	6,441,638	\$ 0.67	1.70	\$ 4,670,131
Grant Date Fair Value of Forfeited				
or Expired Options				\$ 1.56
Total Intrinsic Value of Options				
Exercised				\$ 7,750

As of January 31, 2008, all stock options outstanding are vested. Accordingly, there was no unrecognized compensation related to non-vested stock options granted under the Company's stock option plans.

During the six month ended January 31, 2008, 396,000 shares of restricted and 150,000 shares of unrestricted common stock were granted to employees, consultants and advisors under the 2006 Plan fair valued at \$828,920 and has been included in the statement of operations (see Note 10). These shares were fully vested on the date of grant.

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 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 three months ended January 31, 2008:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested stock, August 1, 2007	\$	
Granted	550,000	1.51
Vested	(312,500)	1.51
Forfeited		

Non-vested stock, January 31, 2008

237,500 \$ 1.51

As of January 31, 2008, approximately \$235,000 of total unrecognized compensation costs related to unvested shares is expected to be recognized over the remaining service period of 1.75 years.

#### 5. Comprehensive Income/(Loss)

Comprehensive loss, which includes net loss and the change in the foreign currency translation account during the period, for the six months ended January 31, 2008 and 2007, was \$13,627,179 and \$8,952,888, respectively, and for the three months ended January 31, 2008 and 2007, was \$6,639,645 and \$5,312,527, respectively.

#### 6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	January 31, 2008	July 31, 2007
Accounts Payable	\$ 2,770,624	\$ 1,791,080
Research and Development	1,377,932	1,956,049
Executive Compensation	1,523,124	2,252,978
Financial Services	129,352	1,156,602
Total	\$ 5,801,032	\$ 7,156,709

#### 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 called 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. 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 EPS and Diluted EPS for the six and three months ended January 31, 2008 and 2007 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period. All outstanding warrants, options and non-vested restricted stock, approximately 20,758,296 incremental shares, at January 31, 2008 have been excluded from the computation of Diluted EPS as they are anti-dilutive. All outstanding warrants, options and shares issuable upon conversion of convertible debentures, approximately 23,647,730 incremental shares, at January 31, 2007 have been excluded from the computation of Diluted EPS as they are anti-dilutive.

### 9. Supplemental Disclosure of Cash Flow Information

	For the Six Months Ended January 31,				
	•			2007	
	2008			2007	
Cash paid during the period for:					
Interest	\$	116,666	\$	137,696	
Income taxes	\$		\$		
Disclosure of non-cash investing and financing activities:					
Issuance of common stock as satisfaction of accrued					
executive compensation	\$	471,875	\$		
Principal repayment of convertible debentures through the					
of common stock	\$		\$	384,616	
Issuance of common stock in conjunction with convertible					
debenture conversion	\$		\$	52,554	

#### 10. Stockholders' Equity

During the six months ended January 31, 2008, the Company issued 677,623 shares of common stock to various consultants for services rendered in the amount of \$1,054,661. The shares were valued at \$1.34 to \$1.84 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the six months ended January 31, 2008, the Company issued 578,492 shares of common stock valued at \$879,421 as employee compensation including 546,000 shares issued under 2006 Stock Option Plan (see Note 4). The shares were valued at \$1.36 to \$1.75 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the six months ended January 31, 2008, the Company issued 550,000 shares of restricted common stock valued at \$830,500 as executive compensation to officers of the Company, 312,500 shares of which were issued as satisfaction of accrued executive compensation amounting to \$471,875. The shares were valued at \$1.51 per share based on the quoted market price of the Company's common stock on the dates of the issuances. These shares vest over a period of two years from the date of the grant (see Note 4).

During the six months ended January 31, 2008, the Company received aggregate cash proceeds of \$49,290 from exercises of stock options. The Company issued 31,000 shares of common stock as a result of these transactions.

The issuances of common stock as described above are summarized as follow:

	Common Stock			Additional Paid-In	Total Stockholders'	
	Shares		Amount	Capital	Equity	
Issuance for services	677,623	\$	678 \$	1,053,983	\$ 1,054,661	
Issuance as employee						
compensation	578,492		578	878,843	879,421	
Issuance as executive						
compensation	550,000		550	(550)		
Stock-based executive						
compensation				123,276	123,276	
Issuance in satisfaction of accrued						
executive compensation				471,875	471,875	
Stocks options exercised for cash	31,000		31	49,259	49,290	
Total	1,837,115	\$	1,837 \$	2,576,686	\$ 2,578,523	

#### **11. Subsequent Events**

In February, 2008, a securities broker-dealer and investment bank filed a complaint against the Company in the Supreme Court of the State of New York alleging breach of a business advisory agreement and seeking cash, stock, and warrant compensation. The Company has not yet filed an answer to the complaint; we are 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.

### 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 six-month periods ended January 31, 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, 2007, as amended, and the information contained in *Part I, Item 1 - Financial Statements* and *Part II, Item 1A-Risk Factors* in this Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2008.

#### **Forward-Looking Statements**

We have made statements in this *Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations* and elsewhere in this Quarterly Report on Form 10-Q of Generex Biotechnology Corporation for the fiscal quarter ended January 31, 2008 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," "plans," "intends," "believes," "will," "estimates," "anticipates," "projects," "predicts," "foresees" 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:

- Ÿ our expectations concerning product candidates for our technologies;
- Ÿ our expectations concerning existing or potential development and license agreements for third-party collaborations and joint ventures;
- Ÿ our expectations of when different phases of clinical activity may commence and conclude;
- Ÿ our expectations of when regulatory submissions may be filed or when regulatory approvals may be received; and
- Ÿ 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:

- Ÿ the inherent uncertainties of product development based on our new and as yet not fully proven technologies;
- Ÿ the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when tested clinically;
- Ÿ the inherent uncertainties associated with clinical trials of product candidates;
- Ÿ the inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates;
- Ÿ the inherent uncertainties associated with commercialization of products that have received regulatory approval; and
- $\ddot{Y}$  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, 2007, as amended, and in *Part II, Item 1A. Risk Factors* of this Quarterly Report on Form 10-Q. We caution investors that the forward-looking statements contained in this Quarterly Report must be interpreted and understood in light of conditions and circumstances that exist as of the date of this Quarterly Report. We expressly disclaim any obligation or undertaking to update or revise forward-looking statements to reflect any changes in management's expectations resulting from future events or changes in the conditions or circumstances upon which such expectations are based.

## **Executive Summary**

### About the Company

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 Express, Inc., we are expanding our focus to include immunomedicines. We operate in only one segment: the research, development and commercialization of drug delivery systems and technologies for metabolic and immunological diseases.

We have a limited number of products that are ready for commercial marketing and sale: our oral insulin formulation, Generex Oral-lyn<sup>TM</sup>, has been approved for commercial marketing and sale in Ecuador and India; and our over-the-counter line glucose spray products utilizing our proprietary buccal delivery technology have been launched in retail outlets in the United States and Canada.

We have begun the regulatory approval process for six pharmaceutical products: our oral insulin formulation (late-stage), our oral morphine formulation (pre-clinical), the Antigen HER-2/neu positive breast cancer vaccine (Phase II), the Antigen avian influenza vaccine (Phase I), the Antigen prostate cancer vaccine (Phase I), and the Antigen RNAi immunotherapeutic technology for myelogenous leukemia (pre-clinical).

Our organizational structure consists of Generex Biotechnology Corporation and five wholly-owned subsidiaries: Generex Pharmaceuticals Inc., which is incorporated in Ontario, Canada and which performs all of our Canadian operations; Generex (Bermuda), Inc., which is incorporated in Bermuda and which currently does not conduct any business activities; Antigen Express, Inc., which is incorporated in Delaware and which we acquired in 2003; Generex Pharmaceuticals (USA) LLC, which we organized in North Carolina in February 2006 and which has not yet commenced any business operations; and Generex Marketing & Distribution Inc., which we organized in Ontario, Canada in September 2006 and which has not yet commenced any business operations.

We are a development stage company. From inception through the end of the year ended July 31, 2006, we have received only limited revenues from operations. Pursuant to a development and license agreement that we entered into with Eli Lilly and Company in September 2000 and terminated as of June 2003, we received a \$1,000,000 upfront payment. In the fiscal year ended July 31, 2007, we received approximately \$136,448 in revenues from sales of Glucose RapidSpray<sup>TM</sup>. In the six-month period ending January 31, 2008, we received approximately \$63,340 in revenues from sales of Glucose RapidSpray<sup>TM</sup>. This number does not reflect deferred sales to the customers during this period with the right of return.

#### Strategy

## Generex Oral-lyn<sup>TM</sup>

In fiscal 2008, our efforts will focus on enrolling patients and dosing of late-stage clinical trials of Generex Oral-lyn<sup>TM</sup> in the United States, Canada, Europe and certain countries in Eastern Europe including Russia, Ukraine, Bulgaria and Romania and assisting our Indian licensee with preparation for the commercialization of Generex Oral-lyn<sup>TM</sup> in India.

We have identified key vendors for the management of Phase III clinical trials of Generex Oral-lyn<sup>TM</sup> and have selected centers to conduct such trials in the United States, Canada, Europe and Eastern Europe. In anticipation of undertaking late-stage clinical trials globally, we have engaged consultants to assist with the design and implementation of clinical trials and regulatory strategies and have secured a manufacturer to produce clinical trial batches of Generex Oral-lyn<sup>TM</sup>. We have contracted with our third-party manufacturers for sufficient quantities of the RapidMist<sup>TM</sup> device components,

the insulin, and the formulary excipients that will be required for the production of clinical trial batches of Generex Oral-lyn<sup>TM</sup>. Patient enrollment has begun at some of the sites with the first dosing taking place in April 2008 and is expected expand to several global centers over the course of the study. The primary objective of the study is to compare the efficacy of Generex Oral-lyn<sup>TM</sup> and the RapidMist<sup>TM</sup> Diabetes Management System with that of standard regular injectable human insulin therapy as measured by HbA1c, in patients with Type-1 diabetes mellitus. We expect to use the data collected from these trials in the New Drug Submission that will be prepared concurrently with the progression of the late-stage trials for Health Canada, European Union (EMEA) and the U.S. Food and Drug Administration (FDA).

In early November 2007, Generex Oral-lyn<sup>™</sup> was approved for importation and commercial marketing and sale in India for the treatment of diabetes by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India, which is responsible for authorizing marketing approval of all new pharmaceutical products in India. In connection with this approval, we entered into a Product Licensing and Distribution Agreement with Shreya Life Sciences Pvt. Ltd., a leading Indian-based pharmaceutical company and the fourth largest distributor of insulin in the Indian insulin product market. We are working with Shreya to prepare for the commercial launch of Generex Oral-lyn<sup>™</sup> in India in the second calendar quarter of 2008. Preparations include marketing plans and post-approval clinical studies. We do not expect to receive revenues from the sale of this product in India in fiscal 2008.

In fiscal 2008, we also plan to continue with the commercialization of Generex Oral-lyn<sup>™</sup> in Ecuador and efforts to obtain regulatory approval of this product in other countries using the approved Ecuadorian dossier. Our business partner for the commercialization of Generex Oral-lyn<sup>™</sup> in Ecuador, PharmaBrand, S.A., expects additional commercial manufacturing runs of the product at its facilities in Quito, Ecuador later in 2008. We are also working with PharmaBrand to expand extant production facilities to meet the anticipated demand for the product in India and other jurisdictions where governmental approvals are pending. Currently, our relationship with PharmaBrand is governed by a letter of intent, and we are in the process of transitioning PharmaBrand's role into one of a third-party manufacturer with distribution rights for Ecuador. PharmaBrand has generated some commercial sales of Generex Oral-lyn<sup>™</sup> in Ecuador to date. While we expect to receive revenues from such sales sometime in fiscal 2008, we do not expect that such sales will be reflected in our financial statements until we have entered into a definitive licensing and distribution agreement with PharmaBrand.

Pursuant to a licensing and distribution agreement with a multinational distributor, we have submitted applications for registration of Generex Oral-lyn<sup>TM</sup> to some of the public health authorities in the Middle East, but no approvals have been forthcoming to date except for a limited, pharmacy specific importation license in the United Arab Emirates to import Generex Oral-lyn<sup>TM</sup> into Abu Dhabi. We terminated the licensing and distribution agreement with the Armenian Development Agency (the "ADA") and Canada Armenia Trading House Ltd. ("CATH") relating to the regulatory approval and commercialization of Generex Oral-lyn<sup>TM</sup> in Armenia, Georgia, and Kazakhstan as of January 16, 2008, but we are continuing to prosecute the registration submitted to public health authorities in Armenia.

We face competition from other providers of alternate forms of insulin. One of our most significant competitors, Pfizer, announced in October 2007 that it would no longer sell or produce its inhalable form of insulin, marketed as Exubera®, due to disappointing sales and failure to gain acceptance with patients and physicians. 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.

## Buccal Glucose and Energy Products - Glucose RapidSpray<sup>TM</sup>, BaBOOM! <sup>TM</sup> Energy Spray and GlucoBreak<sup>TM</sup>

With the recent launch of commercial sales of our over-the-counter oral glucose and energy spray products, GlucoBreak<sup>TM</sup> and BaBOOM!<sup>TM</sup> Energy Spray, in retail outlets in the United States and Canada, we expect to receive increased revenues from product sales in fiscal 2008. We plan to achieve this by increasing our over-the-counter product line to three products - the two products mentioned above and Glucose RapidSpray<sup>TM</sup> - and expanding our existing distribution channels. In addition, we will increase our advertising and marketing efforts of our products and expand the availability of our products from North America to the rest of the world. This strategy has already been implemented by the execution of licensing and distribution agreements with Leosons General Trading Company for the distribution and sale of our over-the-counter products in 15 Middle Eastern countries and Adcock Ingram LLP and Adcock Ingram Healthcare (Pty) Ltd. for the distribution and sale of Glucose RapidSpray <sup>TM</sup> in South Africa and six neighboring countries. In December 2007, we received a \$400,000 purchase order for our over-the-counter products, including Glucose Rapid Spray<sup>TM</sup>, from Leosons General Trading Company. We are currently in the process of filing the order.

#### Metformin Gum Product/Strategic Alliance

During fiscal 2008, we expect to continue joint development activities with Fertin Pharma A/S with respect to a metformin medicinal chewing gum for the treatment of Type-2 diabetes mellitus and obesity, which we anticipate to be a prospective companion product for Generex Oral-lyn<sup>TM</sup>. Fertin Pharma is in the process of producing clinical materials for a bioequivalence Phase I study which is expected to commence before the end of calendar year 2008.

#### Immunomedicine Technology and Products

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 stage II HER-2/neu positive breast cancer and patients with prostate cancer and against avian influenza. The Phase II clinical trial of the Antigen peptide vaccine in breast cancer patient commenced patient dosing in May 2007. This trial is being conducted with the United States Military Cancer Institute Clinical Trials Group under the direction of Colonel George Peoples, M.D. The trial will measure the rate of relapse after two years in breast cancer patients who have completed standard therapy for node-positive or high-risk node-negative breast cancer expressing at least low levels of the HER-2/neu oncogene and who are at increased risk for recurrence. Patient dosing for Phase I clinical trials with the same compound as an immunotherapeutic vaccine for prostate cancer is currently underway at two hospital sites in Athens, Greece. The Lebanese-Canadian Hospital in Beirut, Lebanon commenced a Phase I clinical trial of the Antigen synthetic avian influenza vaccine in April 2007 that is currently ongoing. In addition, Antigen entered into an agreement with Drs. Daopei Lu and Chunrong Tong and Beijing Daopei Hospital in Beijing, China to conduct a Phase I clinical study using Antigen's novel immunotherapeutic strategy involving RNA interference to develop a cancer cell vaccine for use in patients with acute myeloid leukemia. In February 2008, some preliminary pre-clinical work commenced under this clinical trial agreement.

#### Financing

We project that revenues generated from sales of both our glucose and energy spray products in the U.S. and Canada and sales of Generex Oral-lyn<sup>TM</sup> in Ecuador will not be sufficient for all of our cash needs during fiscal year 2008. In the past we were able to fund Antigen expenses with some revenue from research grants for Antigen's immunomedicine products. During the fiscal quarter ended January 31, 2008, we did not receive any of such research grants. We do not expect to receive such grants on a going forward basis.

We expect to satisfy the majority of our cash needs during the current year from previous capital raised through equity and debt financings with a limited group of investors. We believe that the terms of such financings were favorable to us. Through the financing transactions that we closed in the fiscal years ending July 31, 2005 and 2006, we believe that we have secured the funds necessary to continue in the short term to pursue late-stage clinical trials of Generex Oral-lyn<sup>TM</sup> in the United States, Canada and Europe, to pursue the commercialization of this product in Ecuador and India, and to seek regulatory approval for this product in certain other countries. We also project that we will have the funds to support further research and development and limited clinical testing of technology created by Antigen.

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 Food and Drug Administration or other regulatory approvals are obtained. Management may seek to meet all or some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments. 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. Management is actively pursuing industry collaboration activities, including product licensing and specific project financing. We are also looking into procurement of the reliable insulin supply for our

future commercial needs.

## 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<sup>TM</sup>), our buccal morphine product and Antigen's peptide immunotherapeutic vaccines.

During the last six months, we expended resources on the clinical testing and commercialization, of our buccal insulin product, Generex Oral-lyn<sup>TM</sup>. 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<sup>TM</sup>. 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<sup>TM</sup> was approved for commercial sale by drug regulatory authorities in Ecuador in May 2005. PharmaBrand handled the commercial launch of Generex Oral-lyn<sup>TM</sup> in Ecuador in June 2006. While we anticipate generating revenue from sales of Generex Oral-lyn<sup>TM</sup> in Ecuador, we do not expect that such revenues will be sufficient to sustain our research and development and regulatory activities.

Generex Oral-lyn<sup>TM</sup> 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 are working with Shreya to prepare for the commercial launch of the product in India. We do not expect to receive revenues from the sale of Generex Oral-lyn<sup>TM</sup> in India in fiscal 2008.

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 six months ended January 31, 2008, 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 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 six months ended January 31, 2008, approximately 82% of our \$7,317,427 in research expenses related to morphine, fentanyl or other buccal projects. During the six months ended January 31, 2007, approximately 69% of our \$4,075,015 in research expenses was attributable to insulin and platform technology development, and we did not have any research expenses, and we did not have any research expenses related to morphine, fentanyl or other buccal projects.

Approximately 18% or \$1,310,155 of our research and development expenses for the six months ended January 31, 2008 was related to Antigen's immunomedicine products compared to approximately 31% or \$1,242,950 for the six months ended January 31, 2007. 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. Because of 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.

## **Results of Operations**

#### Three Months Ended January 31, 2008 Compared to Three Months Ended January 31, 2007

Our net loss for the quarter ended January 31, 2008 was 6,507,174 versus 5,195,634 in the corresponding quarter of the prior fiscal year. The increase in net loss in this fiscal quarter versus the corresponding quarter of the prior fiscal year is primarily due to the increase in research and development activities in connection with preparations for global Phase III clinical trials of Generex Oral-lyn<sup>TM</sup> at sites in the United States, Canada, and Europe. Our operating loss for the quarter ended January 31, 2008 increased to 6,828,022 compared to 5,478,477 in the second fiscal quarter of 2007. The increase resulted from an increase in research and development expenses (to 3,469,624 from 2,482,082), an increase in selling and marketing expenses (to 284,498 from 13,399), and a slight increase in general and administrative expenses (to 3,086,873 from 3,006,951). Our revenues in the second quarter ended January 31, 2008 decreased to 18,627 from 45,421 for the quarter ended January 31, 2007.

The small increase in general and administrative expenses for the quarter ended January 31, 2008 is due primarily to a modest increase in accounting, financial and consulting expenses despite a modest decrease of legal expenses, advertising and sponsorship expenses and travel expenses. as compared to the same period last year

The increase in research and development expenses for the quarter ended January 31, 2008 reflects increased levels of research and development activities in connection with preparation for commencement of Phase III clinical trials of Generex Oral-lyn<sup>TM</sup> in Canada, the United States, Europe and Eastern Europe.

Our interest expense in the second fiscal quarter of 2008 decreased to \$58,948 compared to interest expense of \$275,164 in the second fiscal quarter of 2007 since all of our convertible debentures were repaid prior to the first fiscal quarter of 2008. Our loss on extinguishment of debt, also incurred in connection with convertible debentures, was \$0 in the second fiscal quarter of 2008 compared to \$122,307 in the same quarter for the last year. Our interest income decreased to \$291,472 in the second fiscal quarter of 2008 compared to \$601,125 in the same quarter for the last year primarily due to lower cash and short term investment balances during the current fiscal quarter and lower market interest rates. We received a slightly higher income from rental operations (net of expense) of \$88,324 in the second fiscal quarter of 2008 compared to \$79,189 in the same quarter for the last year.

#### Results of Operations Six Months Ended January 31, 2008 Compared to Six Months Ended January 31, 2007

Our net loss for the six months ended January 31, 2008 was \$13,729,087 versus \$8,853,679 in the corresponding six-month period of the prior fiscal year. The increase in net loss in this six-month period versus the corresponding six-month period of the prior fiscal year is primarily due to the increase in research and development expenses in connection with preparations for global Phase III clinical trials of Generex Oral-lyn<sup>TM</sup> at sites in the United States, Canada, and Europe. This increase was significantly reduced by the decrease in interest expense and loss on extinguishment of debt incurred in connection with convertible debentures entered into during the 2006 fiscal year. Our operating loss for the six months ended January 31, 2008 increased to \$14,534,383 compared to \$9,458,659 in the corresponding six-month period ended January 31, 2007. The increase resulted from an increase in research and development expenses (to \$7,317,427 from \$4,075,015) and increases in general and administrative expenses (to \$6,602,793 from \$5,501,690) and selling expenses (to \$651,918 from \$13,399). Our net revenues decreased to \$63,340 in the six months ended January 31, 2008 from \$184,426 in the six months ended January 31, 2007. The decrease in net revenue is attributable to grant revenue received by Antigen in 2007 and reduction in sales of Glucose RapidSpray<sup>TM</sup> in 2008 compared to stocking sales in the same period last year.

The increase in research and development expenses for the six-month period ended January 31, 2008 reflects an increased level of research and development of our oral insulin product and platform technology and additional clinical trials. The increase in general and administrative expenses reflects the increase in legal, financial, consulting expenses and an increase in executive compensation due to non-cash bonuses. The increase was offset by the reduction in accounting, advertising and travel expenses. The selling expenses are associated with the commercial sales of Glucose RapidSpray<sup>TM</sup> that began in fiscal 2007.

Our interest expense in the six-month period ended January 31, 2008 decreased to \$116,622 compared to interest expense of \$566,898 in the six-month period ended January 31, 2007 due to no convertible debentures outstanding during fiscal 2008. Our loss on extinguishment of debt, also incurred in connection with convertible debentures, was \$0 in the six-month period ended January 31, 2008 compared to \$180,825 in the six-month period ended January 31, 2007. Our interest income decreased to \$751,507 in the six-month period ended January 31, 2008 compared to \$1,204,897 in the same period in the last fiscal year primarily due to lower cash and short term investment balances during the current six-month period and lower interest rates. We received a slightly higher income from rental operations (net of expense) of \$170,411 in the six months ended January 31, 2008 compared to \$147,806 in the six months ended January 31, 2007.

## **Developments**

In November 2007, Generex Oral-lyn<sup>TM</sup> became the first non-injectable buccal insulin approved for importation and commercial marketing and sale in India for the treatment of diabetes.

## **Financial Condition, Liquidity and Resources**

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

During the fiscal quarter ended January 31, 2008, we did not engage in any capital-raising transactions. At January 31, 2008, we had cash and short-term investments of approximately \$22.7 million, a decrease of \$12.3 million from the balance as of the end of the prior fiscal year. As of January 31, 2008, 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 may require additional funds to support our working capital requirements or for other purposes. Management plans to meet our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments. Management is also actively pursuing industry collaboration activities, including product licensing and specific project financing. We are also looking into procurement of the reliable insulin supply for our future commercial needs. While we have generally been able to raise equity capital as required, our cash balances were very low during portions of fiscal 2005 and unforeseen problems with our clinical program, manufacturing and commercialization plans in Ecuador and India or materially 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. If we are unable to raise additional capital as needed, we could be required to "scale back" or otherwise revise our business plan. Any significant scale back of operations or modification of our business plan due to a lack of funding could be expected to affect our prospects materially and adversely.

At January 31, 2008, the following warrants issued under the auspices of the Securities Purchase Agreement dated November 10, 2004 and amendments thereto and the Securities Purchase Agreement dated June 1, 2006 were outstanding:

	Aggregate No. of	Exercise		
Date Issued	Shares Unexercised	Price*	Exercise Date	Expiration Date
			June 2,	July 22,
January 23, 2006	622,226 \$	1.60	2006	2011
			August	August
February 27, 2006	4,770,617 \$	3.00	27, 2006	27, 2011
			August	August
February 28, 2006	172,120 \$	1.25	31, 2006	31, 2011
			September	September
March 1, 2006	800,000 \$	3.00	6, 2006	6, 2011
			June 1,	June 1,
June 1, 2006	2,560,980 \$	2.45	2006	2011
			June 2,	June 2,
June 2, 2006	3,273,144 \$	2.35	2006	2011

\*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.

### **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:

<u>Revenue Recognition</u>. Net sales of Glucose RapidSpray<sup>TM</sup>, BaBOOM!<sup>TM</sup> Energy Spray and GlucoBreak<sup>TM</sup> 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.

<u>Inventory</u>.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.

<u>Impairment of Long-Lived Assets</u>. 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.

<u>Intangible Assets</u>. 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.

# **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.

# **Contractual Obligations**

The following table of contractual obligations as of January 31, 2008 includes interest obligations.

Payments Due by Period					
Contractual Obligations	Total	Less than 1 Year	1-3 years	3-5 years	More than 5 years
o Migarions	1000	I vui	1 o yours	e e jeurs	e years
Long-Term Debt	3,724,774	917,637	2,110,232	696,905	-
Obligations					
Capital Lease	-	-	-	-	-
Obligations					
Operating Lease	533,080	152,743	235,035	145,302	-
Obligations					

Purchase Obligations	-	-	-	-	-
Other Long-Term					
Liabilities Reflected					
on the					
Registrant's Balance					
Sheet under GAAP	-	-	-	-	-
Total	\$4,257,854	\$1,070,380	\$2,345,267	\$842,207	-
19					

#### **Certain Relationships and Related Transactions**

#### **Related Transactions**

Prior to January 1, 1999, a portion of our general and administrative expenses resulted from transactions with affiliated persons, and a number of capital transactions also involved affiliated persons. Although these transactions were not the result of "arms-length" negotiations, we do not believe that this fact had a material impact on our results of operations or financial position. Prior to December 31, 1998, we classified certain payments to executive officers for compensation and expense reimbursements as "Research and Development - related party" and "General and Administrative - related party" because the executive officers received such payments through personal services corporations rather than directly. After December 31, 1998, these payments have been and will continue to be accounted for as though the payments were made directly to the officers, and not as a related party transaction. With the exception of our arrangement with our management company described below, we do not foresee a need for, and therefore do not anticipate, any related party transactions in the current fiscal year.

On May 3, 2001, we advanced \$334,300 to each of three senior officers, who are also our stockholders, in exchange for promissory notes. These notes bore interest at 8.5% per annum and were payable in full on May 1, 2002. These notes were guaranteed by a related company owned by these officers and secured by a pledge of 2,500,000 shares of our common stock owned by this related company. On June 3, 2002, our Board of Directors extended the maturity date of the loans to October 1, 2002. The other terms and conditions of the loans and guaranty remained unchanged and in full force and effect. As of July 31, 2002, the balance outstanding on these notes, including accrued interest, was \$1,114,084. Pursuant to a decision made by the Compensation Committee as of August 30, 2002, these loans were satisfied through the application of 592,716 shares of pledged stock, at a value of \$1.90 per share, which represented the lowest closing price during the sixty days prior to August 30, 2002.

On December 9, 2005, our Board of Directors approved a one-time recompense payment in the aggregate amount of \$1,000,000 for each of Ms. Gluskin, our Chairwoman, Chief Executive Officer and President, and Ms. Rose Perri, our Chief Operating Officer, Chief Financial Officer, Treasurer and Secretary, in recognition of the company's failure to remunerate each of Ms. Gluskin and Ms. Perri in each of the fiscal years ended July 31, 1998, 1999, 2000 and 2001 in a fair and reasonable manner commensurate with comparable industry standards and Ms. Gluskin's and Ms. Perri's duties, responsibilities and performance during such years. The payment of such amount to each of Ms. Gluskin and Ms. Perri, as applicable, and/or (b) in shares of our common stock at such time or times as determined solely by Ms. Gluskin or Ms. Perri, as applicable, provided that the conversion price for any such shares shall be equal to the average closing price of our common stock on the NASDAQ Capital Market for the 20 successive trading days immediately preceding, but not including, December 9, 2005. The amounts were not paid as of March 11, 2008 with the exception of \$415,742.30 that was used by Ms. Perri to repay Note Receivable, Due from Related Party. The amount was due from EBI, Inc., a shareholder of the Company that is controlled by the estate of the Company's former Chairman of the Board, Mark Perri. The note was not interest bearing, unsecured and did not have any fixed terms of repayment. The note was extended to EBI, Inc. in May 1997.

*Real Estate Transactions*: On August 7, 2002, we purchased real estate with an aggregate purchase price of approximately \$1.6 million from an unaffiliated party. In connection with that transaction, Angara Enterprises, Inc., a licensed real estate broker that is an affiliate of Ms. Gluskin received a commission from the proceeds of the sale to the seller in the amount of 3% of the purchase price, or \$45,714. We believe that this is less than the aggregate commission which would have been payable if a commission had been negotiated with an unaffiliated broker on an arm's length basis.

On December 9, 2005, our Board of Directors approved the grant to Ms. Perri of a right of first refusal in respect of any sale, transfer, assignment or other disposition of either or both real properties municipally known as 1740 Sismet

Road, Mississauga, Ontario and 98 Stafford Drive, Brampton, Ontario (collectively, the "Properties"). We granted Ms. Perri this right in recognition of the fair market value transfer to us during the fiscal year ended July 31, 1998 by Ms. Perri (or parties related to her) of the Properties.

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 fiscal quarters ended January 31, 2008 and 2007, we paid the management company approximately \$13,141 and \$11,464, 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.

*Legal Fees.* David Wires, a former director, is a partner of the firm Wires Jolley LLP. Wires Jolley represents us in various matters. During fiscal 2007, we paid approximately \$95,000 in fees to Wires Jolley. We continue to use Wires Jolley and expect to pay legal fees in similar amounts to the firm in fiscal 2008. Mr. Wires elected not to stand for re-election at our annual meeting of stockholders which was held on May 29, 2007.

*Consulting Fees.* Peter Amanatides, one of our directors, is the Senior Vice-President and Chief Operating Officer of PharmaLogika, Inc., a private consulting firm in the pharmaceuticals regulatory field. During fiscal year 2007, Generex paid \$100,000 in fees to PharmaLogika for services rendered, and we owe a balance of \$50,000. We do not expect to pay any further fees to PharmaLogika going forward. Mr. Amanatides is neither a director nor a shareholder of PharmaLogika.

# **New Accounting Pronouncements**

We adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" ("FIN 48"), on August 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement 109 "Accounting for Income Taxes", and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition classification, interest and penalties accounting in interim periods disclosure and transition.

Based on our evaluation, we have concluded that there are no significant uncertain tax positions requiring recognition in our financial statements or adjustments to our deferred tax assets and related valuation allowance. Our evaluation was performed for the tax years ended July 31, 2007, 2006, 2005 and 2004, the tax years which remain subject to examination by major tax jurisdictions as of January 31, 2008.

We may from time to time be assessed interest or penalties by major tax jurisdictions, although such assessments historically have been minimal and immaterial to our financial results. In the event we have received an assessment for interest and/or penalties, it has been classified in the financial statements as general and administrative expense.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption. On November 15, 2007, the FASB granted a one year deferral for non-financial assets and liabilities to comply with SFAS No. 157, however, the effective date for financial assets remains intact. We are currently evaluating the impact of this statement on our results of operations or financial position.

In February 2007, the FASB issued SFAS No. 159, "Establishing the Fair Value Option for Financial Assets and Liabilities" ("SFAS 159") to permit all entities to choose to elect to measure eligible financial instruments at fair value. The decision whether to elect the fair value option may occur for each eligible item either on a specified election date or according to a preexisting policy for specified types of eligible items. However, that decision must also take place on a date on which criteria under SFAS 159 occurs. Finally, the decision to elect the fair value option shall be made on an instrument-by-instrument basis, except in certain circumstances. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 applies to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS 157. We are currently evaluating the impact of this statement on our results of operations or financial position.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS 141(R)"). This Statement replaces SFAS No. 141, "Business Combinations" ("SFAS 141"). This Statement retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. This Statement 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. SFAS 141(R) will apply 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. We are currently evaluating the impact of this statement on our results of operations or financial position.

In December 2007, the FASB issued SFAS No. 160, "Non-controlling Interests in Consolidated Financial Statements" ("SFAS 160"). This Statement amends ARB 51 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. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. We are currently evaluating the impact of this statement on our results of operations or financial position.

# Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks associated with changes in the exchange rates between U.S. and Canadian currencies and with changes in the interest rates related to our fixed rate debt. We do not believe that any of these risks will have a material impact on our financial condition, results of operations and cash flows.

At the present time, we maintain our cash in short-term government or government guaranteed instruments, short-term commercial paper, interest bearing bank deposits or demand bank deposits which do not earn interest. A substantial majority of these instruments and deposits are denominated in U.S. dollars, with the exception of funds denominated in Canadian dollars on deposit in Canadian banks to meet short-term operating needs in Canada. At the present time, with the exception of professional fees and costs associated with the preparation for commencement of clinical trials in the United States and Europe, substantially all of our operating expense obligations are denominated in Canadian dollars. We do not presently employ any hedging or similar strategy intended to mitigate against losses that could be incurred as a result of fluctuations in the exchange rates between U.S. and Canadian currencies.

As of January 31, 2008, we had fixed rate debt totaling \$3,319,272. This amount consists of the following:

	Interest Rate
Loan Amount	per Annum
468,991	6.82%
284,855	6.82%
704,901	7.60%
404,155	8.50%
217,465	10%
1,238,905	6.07%
3,319,272	Total

These debt instruments mature from August 2008 through June 2011. As our fixed rate debt instruments mature, we will likely refinance such debt at the existing market interest rates which may be more or less than interest rates on the maturing debt. Since this debt is fixed rate debt, if interest rates were to increase 100 basis points prior to maturity, there would be no impact on earnings or cash flows.

We have neither issued nor own any long-term debt instruments, or any other financial instruments, for trading purposes and as to which we would be subject to material market risks.

#### Item 4. Controls and Procedures.

#### Evaluation of disclosure controls and procedures

Prior to the filing of this Quarterly Report on Form 10-Q, an evaluation was performed under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on the evaluation our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report of Form 10-Q, the Company's disclosure controls and procedures were effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and is accumulated and communicated to the Company's management, as appropriate, to allow timely decisions regarding required disclosures.

#### Changes in internal control over financial reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# **PART II - OTHER INFORMATION**

#### Item 1. Legal Proceedings.

*Shemano Group, Inc.* On September 26, 2006, Shemano Group, Inc. initiated a National Association of Securities Dealers arbitration proceeding against us. Shemano claimed it was entitled to be paid fees pursuant to a finder's agreement in connection with certain private placements effected by us The arbitration hearing took place in June 2007. In July 2007, the arbitration panel awarded Shemano an aggregate of \$1,030,545 in cash in compensatory damages. A third party subsequently initiated an arbitration proceeding claiming an entitlement to 60% of the award. Consequently, we paid 40% of the award to Shemano in September 2007. After the remaining portion of the award (\$618,327) was paid in early November 2007 to Shemano, the arbitration proceedings were closed.

Subash Chandarana et al. v. Generex Biotechnology Corporation. In February 2001, a former business associate of Pankaj Modi ("Modi") (a former officer of the Company) and an entity called Centrum Technologies Inc. ("CTI") commenced an action in the Ontario Superior Court of Justice against us and Modi seeking, among other things, damages for alleged breaches of contract and tortious acts related to a business relationship between this former associate and Modi that ceased in July 1996. The plaintiffs' statement of claim also seeks to enjoin the use, if any, by us 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 our position that the buccal drug delivery technologies which are the subject matter of our research, development, and commercialization efforts, including Generex Oral-lyn<sup>TM</sup> and the RapidMist<sup>TM</sup> 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, we 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 us. Consequently, the shareholders of CBI are in a deadlock. The court granted our 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 Modi and us. We 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 Modi and us. A statement of claim was served in July 2004. Since that time, the plaintiffs have not taken any steps in furtherance of the proceeding. We are 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.

*Newbridge Securities Corporation v. Generex Biotechnology Corporation.* In February, 2008, a securities broker-dealer and investment bank filed a complaint against the Company in the Supreme Court of the State of New York alleging breach of a business advisory agreement and seeking cash, stock, and warrant compensation. The Company has not yet filed an answer to the complaint; we are 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.

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

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

# Item 1A. Risk Factors.

In addition to the other information included in this Quarterly Report on Form 10-Q, you should carefully review and consider the factors discussed in *Part I, Item 1A - Risk Factors* of our Annual Report on Form 10-K for the year ended July 31, 2007, 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 quarter ended January 31, 2008, we received nominal revenues from sales of Glucose RapidSpray<sup>TM</sup>. We did not recognize any revenue from the sale of our oral insulin product in Ecuador in fiscal 2007 and do not expect to receive any until we enter into a final agreement with PharmaBrand to manufacture commercial orders of Generex Oral-lyn<sup>TM</sup> and to continue its marketing and sales efforts in Ecuador in 2008 with a focus on that portion of the population with the newly identified condition closely related to diabetes known as Impaired Glucose Tolerance (IGT). Individuals with IGT usually do not meet the criteria for the diagnosis of diabetes mellitus but experience abnormally high blood glucose levels several hours after a meal. While Generex Oral-lyn<sup>TM</sup> was approved for importation and commercial marketing and sale in India in November 2007, we do not expect to receive any revenues from sales of the product in fiscal 2008. We have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor and have begun assisting them with preparations for commercial launch in India sometime in 2008. In January 2008, we commenced a marketing campaign with a presentation to key opinion leaders and endocrinologists at a meeting in Mumbai, India.

To date, we have not been profitable and our accumulated net loss was \$225,729,357 at January 31, 2008. 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<sup>TM</sup> which is currently available for sale in Ecuador and has been approved for sale in India and our over-the-counter glucose and energy spray products, Glucose RapidSpray<sup>TM</sup>, BaBOOM!<sup>TM</sup> Energy Spray and GlucoBreak<sup>TM</sup>, 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<sup>TM</sup> in countries outside of Ecuador and India. 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 Our Technologies

# Until we receive regulatory approval to sell our pharmaceutical products in additional countries, our ability to generate revenues from operations may be limited and those revenues may be insufficient to sustain operations. Many factors impact our ability to obtain approvals for commercially viable products.

Our only pharmaceutical product that has been approved for commercial sale by drug regulatory authorities is our oral insulin spray formulation, and that approval has been obtained in Ecuador and, recently, in India. We have begun the regulatory approval process for our oral insulin, buccal morphine and fentanyl products in other countries, and we expect to begin late stage clinical trials of Generex Oral-lyn<sup>™</sup> at some of our clinical trial sites according to the Phase III clinical plan in 2008.

Our immunomedicine products are in the pre-clinical stage of development, with the exception of a Phase II trial in human patients with stage II HER-2/neu positive breast cancer, a Phase I clinical trial in patients with prostate cancer, a Phase I trial in human volunteers of a peptide vaccine for use against the H5N1 avian influenza virus and Phase I trial of our experimental H5N1 prophylactic vaccine in Beirut, Lebanon.

Pre-clinical and clinical trials of our products, and the manufacturing and marketing of our technologies, are subject to extensive, costly and rigorous regulation by governmental authorities in the United States, Canada and other countries. The process of obtaining required regulatory approvals from the FDA and other regulatory authorities often takes many years, is expensive and can vary significantly based on the type, complexity and novelty of the product candidates. For these reasons, it is possible we will not receive regulatory approval for any prescription pharmaceutical product candidate in any country other than Ecuador and India.

In addition, we cannot be sure when or if we will be permitted by regulatory agencies to undertake additional clinical trials or to commence any particular phase of clinical trials. Because of this, statements in this Quarterly Report regarding the expected timing of clinical trials cannot be regarded as actual predictions of when we will obtain regulatory approval for any "phase" of clinical trials.

Delays in obtaining United States or other foreign approvals for our pharmaceutical products could result in substantial additional costs to us, and, therefore, could adversely affect our ability to compete with other companies. If regulatory approval is ultimately granted in any country other than Ecuador and India, the approval may place limitations on the intended use of the product we wish to commercialize, and may restrict the way in which we are permitted to market the product.

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

#### Unregistered Sales of Equity Securities

In the fiscal quarter ended January 31, 2008, we sold common stock and other securities in transactions in reliance upon exemptions from the registration requirements of the Securities Act.

We have issued shares of our common stock to CEOcast, Inc., a consultant, pursuant to an agreement to provide us with investor relation services until August 21, 2008. During the three months ended January 31, 2008, we issued 50,000 shares of common stock to CEOcast 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 CEOcast, 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 be legended 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 January 31, 2008, we issued 24,000 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 be legended 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 January 31, 2008, we issued 68,184 shares of common stock to Lyons Capital LLC 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 Lyons 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 be legended 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 January 31, 2008, 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 be legended 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.

In November 2007, we issued an aggregate of 326,255 shares of our restricted common stock to Nectid Inc. in consideration of the achievement of certain milestones pursuant to the terms of our consulting agreement dated as of July 26, 2007 with Nectid. Under this agreement, Nectid assisted us in early November 2007 in procuring governmental approval for the importation, marketing, distribution, and sale of Generex Oral-lyn in India. This agreement was terminated in accordance with its terms on December 1, 2007. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Nectid 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 be legended 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 we nor any affiliated purchaser (as defined in Section 240.10 b-18(a)(3) of the Exchange Act) purchased any of our equity securities during the fiscal quarter ended January 31, 2008.

# 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 *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.

Exhibit Number	Description of Exhibit <sup>(1)</sup>
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 3(II) to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 19, 2006)
3(ii)	Amended and Restated Bylaws of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3(ii) to Generex Biotechnology Corporation's Report on Form 8-K filed on 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 April 30, 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 April 30, 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 April 30, 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)
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	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)

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- 4.13.1 Amendment No. 4 to Securities Purchase Agreement and Registration Rights Agreement entered into by and between Generex Biotechnology Corporation and the Purchasers listed on the signature pages thereto on January 19, 2006 (incorporated by reference herein to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)

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- 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.

#### **SIGNATURES**

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

# **GENEREX BIOTECHNOLOGY CORPORATION**

(Registrant)

Date: March 11, 2008	By:	/s/ Anna E. Gluskin Anna E. Gluskin President and Chief Executive Officer
Date: March 11, 2008	By:	/s/ Rose C. Perri Rose C. Perri Chief Financial Officer
32		

**Generex Biotechnology Corporation** Form 10-Q January 31, 2008 Exhibit Index

Exhibit

- 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 3(II) to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 19, 2006)
- 3(ii) Amended and Restated Bylaws of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3(ii) to Generex Biotechnology Corporation's Report on Form 8-K filed on 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 April 30, 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 April 30, 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 April 30, 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)
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