

GENEREX BIOTECHNOLOGY CORP  
Form 10-Q  
June 11, 2012

**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 April 30, 2012

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

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

**COMMISSION FILE NUMBER: 0-25169**

**GENEREX BIOTECHNOLOGY CORPORATION**

**(Exact name of registrant as specified in its charter)**

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

**incorporation or organization)**

**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)**

Indicate by check mark whether the registrant: (1) has filed all reports required by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer 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 347,967,322 as of June 8, 2012.



**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**

	April 30, 2012 (Unaudited)	July 31, 2011
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 1,194,578	\$ 2,798,797
Accounts receivable	—	8,690
Inventory (Note 5)	—	717,442
Other current assets (Note 12)	296,290	225,052
Total Current Assets	1,490,868	3,749,981
Property and Equipment, Net	851,423	1,271,867
Assets Held for Investment, Net	886,927	3,634,929
Patents, Net	3,038,855	3,349,588
<b>TOTAL ASSETS</b>	<b>\$ 6,268,073</b>	<b>\$ 12,006,365</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIENCY</b>		
Current Liabilities:		
Accounts payable and accrued expenses (Note 6)	\$ 6,976,878	\$ 7,738,179
Deferred revenue	287,080	369,748
Current maturities of long-term debt	1,482,023	1,210,271
Total Current Liabilities	8,745,981	9,318,198
Long-Term Debt, Net	569,653	1,869,795
Derivative Warrant Liability (Note 11)	4,603,470	8,745,508
Derivative Additional Investment Rights Liability (Note 11)	437	515,000
Total Liabilities	13,919,541	20,448,501
Commitments and Contingencies (Notes 7 and 8)		

## Stockholders' Deficiency (Note 10):

Series A 9% Convertible Preferred Stock, \$1,000 par value; authorized 5,500 shares at April 30, 2012 and July 31, 2011, respectively ; -0- and 1,287 shares issued and outstanding at April 30, 2012 and July 31, 2011, respectively	—	—
Series B 9% Convertible Preferred Stock, \$1,000 par value; authorized 2,000 and -0- shares at April 30, 2012 and July 31, 2011, respectively ; 2,000 and -0- shares issued and outstanding at April 30, 2012 and July 31, 2011, respectively	—	—
Common stock, \$.001 par value; authorized 750,000,000 shares at April 30, 2012 and July 31, 2011, respectively; 346,678,800 and 308,519,768 shares issued and outstanding at April 30, 2012 and July 31, 2011, respectively	346,679	308,520
Additional paid-in capital	347,267,912	338,124,525
Deficit accumulated during the development stage	(356,035,942 )	(347,744,756)
Accumulated other comprehensive income	769,883	869,575
Total Stockholders' Deficiency	(7,651,468 )	(8,442,136 )
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIENCY</b>	<b>\$6,268,073</b>	<b>\$12,006,365</b>

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

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

	For the Nine Months Ended		For the Three Months Ended		Cumulative From
	April 30,	2011	April 30,	2011	November 2, 1995
	2012	(Unaudited)	2012	(Unaudited)	(Date of
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)	Inception)
					April 30,
					2012
					(Unaudited)
Revenues, net	\$21,901	\$269,086	\$7,012	\$65,583	\$ 5,104,034
Cost of Goods Sold	9,122	143,360	2,230	55,482	1,618,388
Gross profit	12,779	125,726	4,782	10,101	3,485,646
Operating Expenses:					
Research and development	3,835,715	7,859,382	1,127,047	1,754,325	130,824,443
Research and development - related party	—	—	—	—	220,218
Selling and marketing	167,316	806,798	18,258	207,848	9,335,355
General and administrative	3,732,027	10,262,883	1,325,747	3,109,887	146,645,004
General and administrative - related party	—	—	—	—	314,328
Total Operating Expenses	7,735,058	18,929,063	2,471,052	5,072,060	287,339,348
Operating Loss	(7,722,279 )	(18,803,337 )	(2,466,270 )	(5,061,959 )	(283,853,702 )
Other Income/(Expense):					
Miscellaneous income	—	488,959	—	—	686,303
Income from assets held for investment, net (Note 13)	1,928,850	236,732	1,148,526	70,450	4,056,891
Interest income	1,215	5,985	450	1,154	7,781,589
Interest expense	(518,506 )	(153,385 )	(423,674 )	(52,301 )	(68,934,663 )
Change in fair value of derivative liabilities (Note 11)	(1,603,720 )	1,993,920	2,608,825	925,703	(1,238,257 )
Loss on extinguishment of debt	—	—	—	—	(14,134,068 )
Net (Loss)/Income Before Undernoted	(7,914,440 )	(16,231,126 )	867,857	(4,116,953 )	(355,635,907 )
Minority Interest Share of Loss	—	—	—	—	3,038,185



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Net (Loss) /Income	(7,914,440 )	(16,231,126 )	867,857	(4,116,953 )	(352,597,722 )
Preferred Stock Dividend	376,746	—	376,746	—	3,438,220
Net (Loss)/Income Available to Common Stockholders	\$(8,291,186 )	\$(16,231,126 )	\$491,111	\$(4,116,953 )	\$(356,035,942 )
Net (Loss)/Income Per Common Share (Note 9)					
Basic	\$(.024 )	\$(.060 )	\$.003	\$(.010 )	
Diluted	\$(.024 )	\$(.060 )	\$.003	\$(.010 )	
Shares Used to Compute (Loss)/Earnings per Share (Note 9)					
Basic	326,340,807	279,968,884	345,539,723	292,370,915	
Diluted	326,340,807	279,968,884	345,543,799	292,370,915	

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

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

	For the Nine Months Ended April 30,		Cumulative From November 2, 1995 (Date of Inception) to April 30, 2012
	2012 (Unaudited)	2011 (Unaudited)	(Unaudited)
Cash Flows From Operating Activities:			
Net loss	\$(7,914,440)	\$(16,231,126)	\$ (352,597,722 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	472,146	561,304	9,768,028
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	88,582	—	1,001,778
Gain on disposal of property and equipment	(1,793,087)	—	(1,756,298 )
Loss on extinguishment of debt	—	—	14,134,069
Common stock issued as employee compensation	68,483	75,749	3,949,877
Amortization of options and option modifications as stock compensation	56,961	885,475	2,865,803
Common stock issued for services rendered	606,545	1,797,355	14,414,379
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	—	—	7,956,723
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	—	—	2,405,629
Amortization of discount on convertible debentures	—	—	38,345,592
Common stock issued for interest on convertible debentures & preferred stock	347,490	—	1,105,004
Interest on short-term advance	—	—	22,190
Founders' shares transferred for services rendered	—	—	353,506
Fees in connection with refinancing of debt	—	—	113,274
Warrant repricing costs	—	—	3,198,604
Change in fair value of derivative liabilities	1,603,720	(1,993,920 )	1,238,257

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Changes in operating assets and liabilities (excluding the effects of acquisition):

Accounts receivable	8,474	51,926	(15,043	)	
Miscellaneous receivables	—	—	43,812		
Inventory	716,415	443,626	(20,068	)	
Other current assets	(70,693	)	153,278	(274,587	)
Accounts payable and accrued expenses	(1,267,420)	336,322	14,975,136		
Deferred revenue	(81,634	)	(19,854	)	281,093
Other, net	—	—	110,317		
Net Cash Used in Operating Activities	(7,158,458)	(13,939,865)	(215,713,877	)	

Cash Flows From Investing Activities:

Purchase of property and equipment	(2,416	)	(52,160	)	(4,809,439	)
Proceeds from sale of property and equipment	4,614,057	—	4,614,057			
Costs incurred for patents	(110,929	)	(179,503	)	(2,777,200	)
Change in restricted cash	—	—	512,539			
Proceeds from maturity of short term investments	—	—	195,242,918			
Purchases of short-term investments	—	—	(195,242,918	)		
Cash received in conjunction with merger	—	—	82,232			
Advances to Antigen Express, Inc.	—	—	(32,000	)		
Increase in officers' loans receivable	—	—	(1,126,157	)		
Change in deposits	—	—	(652,071	)		
Change in notes receivable - common stock	—	—	(91,103	)		
Change in due from related parties	—	—	(2,222,390	)		
Other, net	—	—	89,683			
Net Cash Provided by/(Used in) Investing Activities	4,500,712	(231,663	)	(6,411,849	)	

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

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

	For the Nine Months Ended April 30,		Cumulative From November 2, 1995 (Date of Inception) to April 30, 2012
	2012 (Unaudited)	2011 (Unaudited)	(Unaudited)
<b>Cash Flows From Financing Activities:</b>			
Proceeds from short-term advance	—	—	325,179
Repayment of short-term advance	—	—	(347,369 )
Proceeds from issuance of long-term debt	3,566,088	—	5,571,697
Repayment of long-term debt	(4,488,539)	(86,016 )	(6,729,727 )
Repayment of obligations under capital lease	—	(7,818 )	(83,002 )
Change in due to related parties	—	—	154,541
Proceeds from exercise of warrants	30,000	—	45,728,281
Proceeds from exercise of stock options	—	577	5,002,493
Proceeds from minority interest investment	—	—	3,038,185
Proceeds from issuance of preferred stock	1,975,000	—	16,305,000
Redemption of SVR preferred stock	—	—	(100 )
Proceeds from issuance of convertible debentures, net	—	—	40,704,930
Payment of costs associated with convertible debentures	—	—	(722,750 )
Repayments of convertible debentures	—	—	(5,142,424 )
Purchase of treasury stock	—	—	(483,869 )
Proceeds from issuance of common stock, net	—	3,939,000	120,576,242
Purchase and retirement of common stock	—	—	(497,522 )
Net Cash Provided by Financing Activities	1,082,549	3,845,743	223,399,785
Effect of Exchange Rates on Cash	(29,022 )	10,399	(79,481 )
Net (Decrease)/Increase in Cash and Cash Equivalents	(1,604,219)	(10,315,386)	1,194,578
Cash and Cash Equivalents, Beginning of Period	2,798,797	13,880,870	—
Cash and Cash Equivalents, End of Period	\$ 1,194,578	\$ 3,565,484	\$ 1,194,578
<b>Supplemental Disclosure of Cash Flow Information:</b>			
Cash paid during the period for:			
Interest	\$ 518,506	\$ 153,385	
Income taxes	\$ —	\$ —	
<b>Disclosure of non-cash investing and financing activities:</b>			
	\$ —	\$ 1,008,220	

Issuance of common stock as satisfaction of accounts payable and accrued expenses

Par value of common stock issued in conjunction with cashless exercise of warrants	\$20,460	\$998
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Issuance of common stock as interest on convertible preferred stock	\$347,490	\$—
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The Notes to Consolidated Financial Statements are an integral part of these statements.

**GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**1. Basis of Presentation**

The accompanying unaudited interim consolidated financial statements (“interim statements”) have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by generally accepted accounting principles for complete financial statements are not included herein. The interim statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s latest Annual Report on Form 10-K. The results for the nine months ended April 30, 2012 may not be indicative of the results for the entire year.

Interim statements are subject to possible adjustments in connection with the annual audit of the Company’s accounts for fiscal year 2012. In the Company’s opinion, all adjustments necessary for a fair presentation of these interim statements have been included and are of a normal and recurring nature.

The Company is a development stage company, which has a limited history of operations and limited revenue to date. This revenue has been comprised mainly of the sale of our confectionary products, although the Company has recognized \$600,000 relating to upfront license fees for the signing of license and distribution agreements for Generex Oral-lyn™. Additionally, the Company has several product candidates that are in various research or early stages of pre-clinical and clinical development. There can be no assurance that the Company will be successful in obtaining regulatory clearance for the sale of existing or any future products or that any of the Company’s products will be commercially viable.

**Going Concern**

The accompanying interim statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has experienced negative cash flows from operations since inception and had an accumulated deficit at April 30, 2012 of approximately \$356 million. The Company has funded its activities to date almost exclusively from debt and equity financings, as well as the recent sales of non-essential real estate assets in August 2011.

The Company will continue to require substantial funds to continue research and development, including pre-clinical studies and clinical trials of its product candidates, and to commence sales and marketing efforts, if the FDA or other

regulatory approvals are obtained. Management's plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments. Management will be limited in the financing activities that the Company undertakes in the near future as the securities purchase agreement that the Company entered into on January 31, 2012 with certain investors prohibits the Company from (i) issuing additional equity securities until 60 days after the effective date of a registration statement covering the resale of the common stock issuable upon exercise of the warrants and conversion of the preferred stock sold in that transaction and (ii) issuing additional debt or equity securities with variable conversion or exercise prices until February 1, 2013. Management is also actively pursuing financial and strategic alternatives, including strategic investments and divestitures, industry collaboration activities and strategic partners. Management has sold, and is also seeking further sales of, non-essential real estate assets which are classified as Assets Held for Investment to augment its cash position.

There are no assurances that such additional funding will be achieved and that it will succeed in its future operations. The interim 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. The Company's inability to obtain required funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

## **2. Effects of Recent Accounting Pronouncements**

### *Recently Adopted Accounting Pronouncements*

In January 2010, the Financial Accounting Standards Board ("FASB") issued additional guidance on fair value measurements and disclosures which requires reporting entities to provide information about movements of assets among Levels 1 and 2 of the three-tier fair value hierarchy established by the existing guidance. The guidance was effective for our fiscal year beginning August 1, 2011. The adoption of this new accounting guidance did not have a material impact on the Company's interim statements.

In May 2011, the FASB issued further guidance on fair value measurements and disclosures which requires the categorization by level for items that are only required to be disclosed at fair value and information about transfers between Level 1 and Level 2. In addition, the update provides guidance on measuring the fair value of financial instruments managed within a portfolio and the application of premiums and discounts on fair value measurements. The guidance requires additional disclosure for Level 3 measurements regarding the sensitivity of fair value to changes in unobservable inputs and any interrelationships between those inputs. The guidance is effective for the Company's interim period ended April 30, 2012. The adoption of this new accounting guidance did not have a material impact on the Company's interim statements.

**GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES**

**(A DEVELOPMENT STAGE COMPANY)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

*Recently Issued Accounting Pronouncements*

In June 2011, the FASB issued guidance regarding the presentation of Comprehensive Income within financial statements. The guidance is effective for annual periods beginning after December 15, 2011 and subsequent interim periods. The Company is currently evaluating the impact of this new accounting guidance on its interim statements.

**3. Stock-Based Compensation**

As of April 30, 2012, the Company had three stockholder-approved stock incentive plans under which shares and options exercisable for shares of common stock have been or may be granted to employees, directors, consultants and advisors. A total of 2,000,000 shares of common stock are reserved for issuance under the 2000 Stock Option Plan (the “2000 Plan”), a total of 12,000,000 shares of common stock are reserved for issuance under the 2001 Stock Option Plan (the “2001 Plan”) and 30,000,000 shares of common stock are reserved for issuance under the 2006 Stock Plan (the “2006 Plan”). Restricted shares can only be issued under the 2006 Plan. At April 30, 2012, there were 2,000,000, 3,739,444 and 14,726,577 shares of common stock reserved for future awards under the 2000 Plan, 2001 Plan and 2006 Plan, respectively.

The 2000, 2001 and 2006 Plans (the “Plans”) are administered by the Board of Directors (the “Board”). The Board is authorized to select from among eligible employees, directors, advisors and consultants those individuals to whom options are to be granted and to determine the number of shares to be subject to, and the terms and conditions of the options. The Board is also authorized to prescribe, amend and rescind terms relating to options granted under the Plans. Generally, the interpretation and construction of any provision of the Plans or any options granted hereunder are within the discretion of the Board.

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



The fair value of each option granted is estimated on the grant date using the Black-Scholes option pricing model which takes into account as of the grant date the exercise price and expected life of the option, the current price of the underlying stock and its expected volatility, expected dividends on the stock and the risk-free interest rate for the term of the option.

In the case of restricted stock grants under the 2006 Plan, fair market value of the shares is established as the market price on the date of the stock grant.

The following is a summary of the common stock options granted, forfeited or expired and exercised under the Plans for the nine months ended April 30, 2012:

	Options	Weighted Average Exercise Price Share	Aggregate Intrinsic Value
Outstanding, August 1, 2011	7,340,182	\$ 0.465	
Granted	—	n/a	
Forfeited or expired	(327,250 )	0.716	
Exercised	—	n/a	
Outstanding, April 30, 2012	7,012,932	\$ 0.453	\$ 54,758
Exercisable, April 30, 2012	6,740,432	\$ 0.445	\$ 54,758

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

The 7,012,932 outstanding options at April 30, 2012 had a weighted average remaining contractual term of 3.8 years.

The following is a summary of the non-vested common stock options granted, vested and forfeited under the Plan for the nine months ended April 30, 2012:

	Options	Weighted Average Grant Date Fair Value
Outstanding, August 1, 2011	845,836	\$ 0.50
Granted	—	0.00
Vested	(470,836)	0.53
Forfeited	(102,500)	0.46
Outstanding, April 30, 2012	272,500	\$ 0.46

As of April 30, 2012, the Company had \$73,604 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of 1.45 years.

**4. Comprehensive Income and Loss**

Comprehensive income, which includes net income and the change in the foreign currency translation account, for the three months ended April 30, 2012, was \$853,204. Comprehensive loss, which includes net loss and the change in the foreign currency translation account, for the three months ended April 30, 2011, was \$4,041,033.

Comprehensive loss, which includes net loss and the change in the foreign currency translation account, for the nine months ended April 30, 2012, was \$8,014,132. Comprehensive loss, which includes net loss and the change in the foreign currency translation account, for the nine months ended April 30, 2011, was \$16,126,975.

**5. Inventory**

Inventory consists of the following:

	April 30, 2012	July 31, 2011
Raw materials	\$ —	\$502,195
Finished goods		— 215,247
Total	\$ —	\$717,442

At July 31, 2011, 70% of the inventory related to the Company's Oral-lyn™ product which was expected to be used primarily in future clinical trials, while the remainder at July 31, 2011 related to the Company's over-the-counter confectionary products. As the Company is no longer focusing resources on the sale of the over-the-counter confectionary products, the Company took a write-down of approximately \$207,000 in the nine months ended April 30, 2012 related to the remaining raw materials and finished goods pertaining to this product line which is included in research and development expenses. The Company took a write-down of approximately \$501,000 in the nine months ended April 30, 2012, pertaining to the remaining raw material inventory related to Oral-lyn™, as such inventory was not expected to be used up in clinical trials prior to its expiration date.

**6. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consist of the following:

	April 30, 2012	July 31, 2011
Accounts Payable & Accruals – General and Administrative	\$3,679,270	\$4,805,091
Accounts Payable & Accruals – Research and Development	2,088,101	2,151,333
Accounts Payable & Accruals – Selling and Marketing	298,802	434,265
Accrued Make Whole Payments on Convertible Preferred Stock (see Note 10)	540,000	347,490
Executive Compensation and Directors' Fees Payable	370,705	—
Total	\$6,976,878	\$7,738,179

## **GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES**

**(A DEVELOPMENT STAGE COMPANY)**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

#### **7. Pending Litigation**

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

In May 2011, Rose C. Perri, the Company’s former Chief Operating Officer and Chief Financial Officer, commenced two proceedings against the Company. On May 11, 2011, Ms. Perri filed a notice of application in the Ontario Superior Court of Justice, Commercial List, against the Company, two of its affiliates (1097346 Ontario, Inc. and Generex Pharmaceuticals Inc.), three of the Company’s independent directors (John P. Barratt, Nola Masterson and Brian T. McGee), the President and Chief Executive Officer (Mark A. Fletcher), the Chief Operating Officer (David Brusegard) and the Acting Chief Financial Officer (Stephen Fellows). The application has since been abandoned.

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

On June 1, 2011, Golden Bull Estates Ltd. filed a claim (subsequently amended) in the Ontario Superior Court of Justice, naming the Company, 1097346 Ontario, Inc. and Genex Pharmaceuticals Inc. as defendants. The plaintiff, Golden Bull Estates, is controlled by Ms. Perri. The plaintiff alleges damages in the amount of \$550,000 for breach of contract, \$50,000 for punitive damages, plus interest and costs. The plaintiff's claims relate to an alleged contract between the plaintiff and the Company for property management services for certain Ontario properties owned by the Company. The Company terminated the plaintiff's property management services in April 2011. Following the close of pleadings, the Company served a motion for summary judgment. The plaintiff responded by amending its statement of claim to include a claim to the Company's interest in certain of its real estate holdings. The plaintiff has brought a motion for leave to issue and register a Certificate of Pending Litigation in respect of this real estate. The Company has responded to the motion which was scheduled to be heard on March 22, 2012, but was postponed by the plaintiff and has not yet been rescheduled. 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.

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In August 2011, the estate of Antonio Perri, the late father of Ms. Perri, commenced an action against Genorex Pharmaceuticals, Inc., the law firm of Brans, Lehun, Baldwin LLP and William Lehun in the Ontario Superior Court of Justice claiming that the estate is entitled to the proceeds of sale (approximately \$1,730,000) received by the Company on its sale of two properties to Golden Bull Estates Ltd., a company controlled by Ms. Perri. The suit alleges that no consideration was received when the Company purchased the two properties from Antonio Perri in 1998. The Company has responded to this statement of claim and intends to defend this action vigorously. The Company is not able to predict the ultimate outcome of this legal proceeding at the present time or to estimate an amount or range of potential loss, if any, from this legal proceeding.

In December 2011, a vendor of the Company's commenced an action against the Company and its subsidiary, Genorex Pharmaceuticals, Inc., in the Ontario Superior Court of Justice claiming damages for unpaid invoices including interest in the amount of \$429,000, in addition to costs and further interest. The Company has responded to this statement of claim and intends to defend this action vigorously. The Company has also asserted a counterclaim in the proceeding for \$200,000 arising from the vendor's breach of contract and detinue, together with interest and costs. A hearing for the vendor's motion for summary judgment is scheduled for November 15, 2012. The Company will be responding to the motion. 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 consolidated financial position, operations or cash flows.

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

**8. Commitments**

On December 7, 2009, the Company entered into a long-term agreement with sanofi-aventis Deutschland GmbH ("sanofi"). Under this agreement, sanofi-aventis will manufacture and supply recombinant human insulin to the Company in the territories specified in the agreement. Through this agreement, the Company will procure

recombinant human insulin crystals for use in the production of Generex Oral-lyn™. The terms of the supply agreement require the Company to make certain minimum purchases of insulin from sanofi through the period ended December 31, 2011. To date, the Company has not met the minimum purchase commitments under this agreement. After December 31, 2011, sanofi may terminate the agreement due to the Company's failure to meet such purchase commitments. Upon termination, the Company would be obligated to pay sanofi for all materials and components that it has acquired or ordered to manufacture insulin based on the Company's forecasts or minimum purchase commitments, all related work-in-progress (at cost) and all finished insulin in inventory. To date, the Company has not provided forecasts to sanofi for the purchase of insulin and sanofi has not terminated the agreement.

### **9. Net (Loss)/Income Per Share ("EPS")**

Basic earnings per share ("EPS") and Diluted EPS for the three-month period ended April 30, 2012 have been computed by dividing the net income available to common stockholders for the period by the weighted average shares outstanding and the diluted weighted average shares outstanding during that period, respectively. Per the treasury method of calculating Diluted EPS, 4,076 shares representing outstanding stock options which have an exercise price lower than the average market price for the quarter ended April 30, 2012 are included in the calculation of EPS. All remaining outstanding stock options and warrants which have out-of-the-money exercise prices and common stock underlying convertible preferred stock, representing 95,111,892 incremental shares in aggregate, have been excluded from the April 30, 2012 computation of Diluted EPS, as they are anti-dilutive.

Basic EPS and Diluted EPS for the nine-month period ended April 30, 2012 and for the three- and nine-month periods ended April 30, 2011 have been computed by dividing the net loss available to common stockholders for the period by the weighted average shares outstanding during that period. All outstanding stock options, non-vested restricted stock, warrants and common stock underlying convertible preferred stock, representing 95,115,968 incremental shares at April 30, 2012 and 65,084,765 incremental shares at April 30, 2011, have been excluded from the respective computations of Diluted EPS as they are anti-dilutive, due to the losses generated during those periods.

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**10. Stockholders' Deficiency**

*Common Stock*

During the nine months ended April 30, 2012, the Company issued or committed to issue 4,618,390 shares of common stock to various consultants for services rendered in the amount of \$606,545. The shares were valued at \$0.09 to \$0.17 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the nine months ended April 30, 2012, the Company issued or committed to issue 494,626 shares of common stock valued at \$68,483 as employee compensation. The shares were valued at \$0.09 to \$0.15 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the nine months ended April 30, 2012, the Company issued 20,459,431 shares of common stock in conjunction with a cashless exercise of 49,663,260 warrants.

During the nine months ended April 30, 2012, the Company received aggregate cash proceeds of \$30,000 from exercises of warrants at \$0.15 per share. The Company issued 200,000 shares of common stock as a result of these exercises.

Stock option expense related to executive and employee options granted in October 2009, resulting in a charge to operations during the nine-month period ended April 30, 2012 of \$56,961.

During the nine months ended April 30, 2012, the Company issued 8,580,002 shares of common stock in conjunction with the conversion of 1,287 shares of Series A 9% Convertible Preferred Stock and 3,806,583 shares of common stock as dividend on Series A 9% Convertible Preferred Stock.



During the nine months ended April 30, 2012, the Company recognized an increase in equity of \$841,333 related to the partial exercise of the additional investment rights related to the Company's July 2011 convertible preferred stock financing.

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

	Common Stock Shares	Amount	Additional Paid-In Capital	Change to Stockholders' Equity
Issuance of common stock on conversion of convertible preferred stock	8,580,002	\$8,580	\$(8,580)	) \$ —
Issuance of common stock as dividend on convertible preferred stock	3,806,583	3,807	343,683	347,490
Issuance of common stock for services	4,618,390	4,618	601,927	606,545
Issuance of common stock in conjunction with cashless exercise of warrants	20,459,431	20,459	7,210,274	7,230,733
Warrants exercised for cash	200,000	200	29,800	30,000
Exercise of additional investment rights	—	—	841,333	841,333
Issuance of common stock as employee compensation	494,626	495	67,989	68,484
Amortization of stock options as employee compensation	—	—	56,961	56,961
Total	38,159,032	\$38,159	\$9,143,387	\$ 9,181,546

#### *Warrants*

The following is a summary of warrants issued, forfeited or expired and exercised for the nine months ended April 30, 2012:

	Warrants
Outstanding, August 1, 2011	99,955,190
Issued	24,777,773
Forfeited or expired	(100,000 )
Exercised	(49,863,260)
Outstanding, April 30, 2012	74,769,703

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The outstanding warrants at April 30, 2012 have a weighted average exercise price of \$0.33 per share and have a weighted average remaining life of 3.78 years.

As of April 30, 2012, the Company has 4,000,000 warrants with a current exercise price of \$0.15 and an expiry date of January 16, 2016, 29,027,322 warrants with a current exercise price of \$0.15 and an expiry date of March 31, 2016, 3,333,331 warrants with a current exercise price of \$0.15 and an expiry date of July 11, 2016, 5,454,544 warrants with a current exercise price of \$0.15 and an expiry date of September 30, 2016 and 13,333,333 warrants with a current exercise price of \$0.15 and an expiry date of February 2, 2017 (55,148,530 warrants in total), which have price protection provisions that allow for the reduction in the current exercise price upon the occurrence of certain events, including the Company's issuance of common stock or securities convertible into or exercisable for common stock, such as options and warrants, at a price per share less than the exercise price then in effect. For instance, if the Company issues shares of its common stock or options exercisable for or securities convertible into common stock at an effective price per share of common stock less than the exercise price then in effect, the exercise price will be reduced to the effective price of the new issuance. Simultaneously with any reduction to the exercise price, the number of shares of common stock that may be purchased upon exercise of each of these warrants shall be increased proportionately, so that after such adjustment the aggregate exercise price payable for the adjusted number of warrants shall be the same as the aggregate exercise price in effect immediately prior to such adjustment.

The Company's issuance of the following securities will not trigger the price protection provisions of the warrants described above that were issued in connection with the March 2008 private placement: (a) shares of common stock or standard options to the Company's directors, officers, employees or consultants pursuant to a board-approved equity compensation program or other contract or arrangement (up to an aggregate amount of 5,608,926, representing 5% of the common stock issued and outstanding immediately prior to March 31, 2008); (b) shares of common stock issued upon the conversion or exercise of any security, right or other instrument convertible or exchangeable into common stock (or securities exchangeable into common stock) issued prior to March 31, 2008; (c) the shares of common stock issued upon exercise of the warrants issued in March 2008; and (d) shares of common stock and warrants in connection with strategic alliances, acquisitions, mergers, and strategic partnerships, the primary purpose of which is not to raise capital, and which are approved in good faith by the Company's board of directors (up to an aggregate number of 11,217,852, representing 10% of the shares of common stock issued and outstanding immediately prior to March 31, 2008). On July 8, 2011, the Company's issuance of common stock triggered the price protection features of the warrants that were issued in March 2008 resulting in a decrease of the exercise price from \$0.25 to \$0.15 per share and an increase in the number of warrants from 21,784,410 to 36,307,350.

The Company's issuance of the following securities will not trigger the price protection provisions of the warrants issued on January 25, 2011 and in March and April 2011: (I) (a) shares of common stock or options to employees, officers, or directors of the Company pursuant to plans approved by a majority of the non-employee directors of the Company or pursuant to independent contractors pursuant to other agreements or arrangements in existence as of January 24, 2011, (b) securities issued upon the exercise or exchange of or conversion of any securities issued under the Securities Purchase Agreement dated January 24, 2011 and/or other securities exercisable or exchangeable for or convertible into shares of common stock issued and outstanding on January 24, 2011, provided that such securities have not been amended since their issue date through the date of conversion, exercise or exchange to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (except certain adjustments to warrants expiring in March 2016 and September 2016 are not prohibited), and (c) shares of common stock or warrants to trade vendors of the Company approved by a majority of the non-employee members of the Board of Directors; provided that (II) (i) the shares issued under paragraphs I(a) and I(c) shall not, in the aggregate exceed 1,500,000 shares in each 30-day period during the first 90 days after January 24, 2011, (ii) there is a reasonable relationship between the value of the common stock or options issued pursuant to paragraphs I(a) and I(c) and the value of services rendered or goods provided and (iii) the Company does not rely in whole or in part on the exemptions provided in Sections 3(a)(9) or 3(a)(10) of the Securities Act. On July 8, 2011, the Company's issuance of common stock triggered the price protection features of the warrants that were issued on January 25, 2011 and in March and April 2011 resulting in a decrease of the exercise price from \$0.25 to \$0.15 per share and an increase in the number of warrants from 16,056,000 to 26,760,001.

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The Company's issuance of the following securities will not trigger the price protection provisions of the warrants issued on July 8, 2011: (I)(a) shares of common stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose, (b) shares of common stock issued to the vendors identified in Securities Purchase Agreement dated July 8, 2011, in the periodic amounts set forth therein, (c) securities upon the exercise or exchange of or conversion of any Securities issued under the Securities Purchase Agreement dated July 8, 2011 and/or other securities exercisable or exchangeable for or convertible into shares of common stock issued and outstanding on July 8, 2011, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, and (d) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a person (or to the equityholders of a person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities. On February 1, 2012, the triggering of the price protection features of the warrants that were issued in July 2011 resulted in a decrease of the exercise price from \$0.25 to \$0.15 per share and an increase in the number of warrants from 17,166,666 to 28,611,106.

The Company's issuance of the following securities will not trigger the price protection provisions of the warrants issued on February 2, 2012: (I)(a) shares of common stock or options to employees, officers or directors of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose, (b) shares of common stock issued to the vendors identified in Securities Purchase Agreement dated January 31, 2012, in the periodic amounts set forth therein, (c) securities upon the exercise or exchange of or conversion of any Securities issued under the Securities Purchase Agreements dated July 8, 2011 and January 31, 2012 and/or other securities exercisable or exchangeable for or convertible into shares of common stock issued and outstanding on February 2, 2012, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities, and (d) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that any such issuance shall only be to a person (or to the equityholders of a person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

The Company accounts for the warrants with price protection provisions in accordance with FASB ASC Topic 815 as described in *Note 11 - Derivative Liabilities* below. As of April 30, 2012, there were a total of 55,148,530 warrants with an estimated fair value of \$4,603,470, which are identified on the consolidated balance sheet under the caption "Derivative Warrant Liability".

*Series A 9% Convertible Preferred Stock*

The Company has authorized 5,500 shares of Series A 9% Convertible Preferred Stock with a stated value of one thousand (\$1,000) per share. Pursuant to a securities purchase agreement dated July 8, 2011, the Company sold an aggregate of 2,575 shares of convertible preferred stock, as well as accompanying warrants to purchase 17,166,666 shares of common stocks. An aggregate of 17,166,666 shares of the Company's common stock were issuable upon conversion of the convertible preferred stock which was issued at the initial closing.

Subject to certain ownership limitations, the convertible preferred stock is convertible at the option of the holder at any time into shares of the Company's common stock at an effective conversion price of \$0.15 per share, and will accrue a 9% dividend until July 8, 2014 and, beginning on July 8, 2014 and on each one year anniversary thereafter, such dividend rate will increase by an additional 3%. The dividend is payable quarterly on September 30, December 31, March 31 and June 30, beginning on September 30, 2011 and on each conversion date in cash, or at the Company's option, in shares of common stock. In the event that the convertible preferred stock is converted prior to July 8, 2014, the Company will pay the holder of the converted preferred stock an amount equal to \$270 per \$1,000 of stated value of the convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. Such "make-whole payment" may be made in cash or, at the Company's option, in shares of its common stock. In addition, beginning July 8, 2014, the Company will pay dividends on shares of preferred stock equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, and if such dividends are paid. The Company will incur a late fee of 18% per annum on unpaid dividends.

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The conversion price of the convertible preferred stock is subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The conversion price will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then conversion price, except in the event of certain exempt issuances. In addition, the holders of convertible preferred stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had converted all of their shares of convertible preferred stock. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the holders of convertible preferred stock will be entitled to receive, upon conversion of their shares, any securities or other consideration received by the holders of the Company's common stock pursuant to the fundamental transaction.

The Company may become obligated to redeem the convertible preferred stock in cash upon the occurrence of certain triggering events, including the failure to provide an effective registration statement covering shares of common stock issuable upon conversion of the convertible preferred stock, material breach of certain contractual obligations to the holders of the convertible preferred stock, the occurrence of a change in control of the Company, the occurrence of certain insolvency events relating to the Company, or the failure of the Company's common stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges or regulated quotation service. Upon the occurrence of certain triggering events, each holder of convertible preferred stock will have the option to redeem such holder's shares of convertible preferred stock for a redemption price payable in shares of common stock or receive an increased dividend rate of 18% on all of such holder's outstanding convertible preferred stock.

In conjunction with the issuance of the Series A convertible preferred stock, the Company also issued 17,166,666 warrants to the investors. Subject to certain ownership limitations, the warrants will be exercisable at any time after their date of issuance and on or before the fifth-year anniversary thereafter at an exercise price of \$0.15 per share of common stock. The exercise price of the warrants and, in some cases, the number of shares issuable upon exercise, are subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The exercise price and number of shares of common stock issuable upon exercise will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then exercise price, except in the event of certain exempt issuances. In addition, the warrant holders will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had exercised all of their warrants. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or

recapitalizations, the warrant holders will be entitled to receive, upon exercise of their warrants, any securities or other consideration received by the holders of the Company's common stock pursuant to the fundamental transaction. These warrants have been classified as derivative liabilities and are described further in *Note 11 – Derivative Liabilities*.

In addition, until the first anniversary of date of the securities purchase agreement, each investor may, in its sole determination, elect to purchase, severally and not jointly with the other investors, in one or more purchases, in the ratio of such investor's original subscription amount to the original aggregate subscription amount of all investors, additional units consisting of convertible preferred stock and warrants at a purchase price of \$1,000 per unit with an aggregate subscription amount thereof of up to \$2,575,000, which units will have terms identical to the units of convertible preferred stock and warrants issued in connection with the July 2011 closing. These additional investment rights of the investors have been classified as derivative liabilities and are described further in *Note 11 – Derivative Liabilities*. On February 2, 2012, the investors exercised \$2,000,000 of the additional investment rights in the Series B 9% Convertible Preferred Stock financing described below.

As of April 30, 2012, 17,166,666 shares of common stock had been issued upon the conversion of 2,575 shares of Series A convertible preferred stock and 6,129,666 shares of common stock were issued as "make whole payments" on such conversions of the convertible preferred stock. As of April 30, 2012, all of the Series A 9% Convertible Preferred Stock had been converted. At July 31, 2011, there were 1,287 shares of Series A convertible preferred stock outstanding which were discounted at 100% of their face value of \$1,287,000 and were classified in equity on the consolidated balance sheet under the caption "Series A 9% Convertible Preferred Stock". At July 31, 2011, the "make whole payments" on the remaining Series A convertible preferred stock in the amount of \$347,490 are included in Accounts Payable and Accrued Expenses (see Note 6). The total make whole payments at the date of issuance, in the amount of \$695,250, were accrued on the issuance date, with such amount allocated as described directly below, when accounting for the initial proceeds from the convertible preferred stock financing. The September 30, 2011 quarterly dividend payment of \$12,383, as pro-rated for the period from July 8, to September 30, 2011, was paid in shares of the Company's common stock. There was no dividend payment on December 31, 2011, as all of the Series A convertible preferred stock had been converted prior to that date.

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*Series B 9% Convertible Preferred Stock*

The Company has authorized 2,000 shares of Series B 9% Convertible Preferred Stock with a stated value of one thousand (\$1,000) per share. Pursuant to a securities purchase agreement dated January 31, 2012, the Company sold an aggregate of 2,000 shares of Series B convertible preferred stock, as well as accompanying warrants to purchase 13,333,333 shares of common stocks. An aggregate of 13,333,333 shares of the Company's common stock were issuable upon conversion of the Series B convertible preferred stock which was issued at the initial closing.

Subject to certain ownership limitations, the convertible preferred stock is convertible at the option of the holder at any time into shares of the Company's common stock at an effective conversion price of \$0.15 per share, and will accrue a 9% dividend until February 1, 2015 and, beginning on February 2, 2015 and on each one year anniversary thereafter, such dividend rate will increase by an additional 3%. The dividend is payable quarterly on September 30, December 31, March 31 and June 30, beginning on March 31, 2012 and on each conversion date in cash, or at the Company's option, in shares of common stock. In the event that the convertible preferred stock is converted prior to February 1, 2015, the Company will pay the holder of the converted preferred stock an amount equal to \$270 per \$1,000 of stated value of the convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. Such "make-whole payment" may be made in cash or, at the Company's option, in shares of its common stock. In addition, beginning February 1, 2015, the Company will pay dividends on shares of preferred stock equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, and if such dividends are paid. The Company will incur a late fee of 18% per annum on unpaid dividends.

The conversion price of the convertible preferred stock is subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The conversion price will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then conversion price, except in the event of certain exempt issuances. In addition, the holders of convertible preferred stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had converted all of their shares of convertible preferred stock. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the holders of convertible preferred stock will be entitled to receive, upon conversion of their shares, any securities or other consideration received by the holders of the Company's common stock pursuant to the fundamental transaction.



The Company may become obligated to redeem the convertible preferred stock in cash upon the occurrence of certain triggering events, including the failure to provide an effective registration statement covering shares of common stock issuable upon conversion of the convertible preferred stock, material breach of certain contractual obligations to the holders of the convertible preferred stock, the occurrence of a change in control of the Company, the occurrence of certain insolvency events relating to the Company, or the failure of the Company's common stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges or regulated quotation service. Upon the occurrence of certain triggering events, each holder of convertible preferred stock will have the option to redeem such holder's shares of convertible preferred stock for a redemption price payable in shares of common stock or receive an increased dividend rate of 18% on all of such holder's outstanding convertible preferred stock.

In conjunction with the issuance of the Series B convertible preferred stock, the Company also issued 13,333,333 warrants to the investors. Subject to certain ownership limitations, the warrants will be exercisable at any time after their date of issuance and on or before the fifth-year anniversary thereafter at an exercise price of \$0.15 per share of common stock. The exercise price of the warrants and, in some cases, the number of shares issuable upon exercise, are subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The exercise price and number of shares of common stock issuable upon exercise will also be adjusted if the Company sells or grants any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then exercise price, except in the event of certain exempt issuances. In addition, the warrant holders will be entitled to receive any securities or rights to acquire securities or property granted or issued by the Company pro rata to the holders of its common stock to the same extent as if such holders had exercised all of their warrants. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the warrant holders will be entitled to receive, upon exercise of their warrants, any securities or other consideration received by the holders of the Company's common stock pursuant to the fundamental transaction. These warrants have been classified as derivative liabilities and are described further in *Note 11 – Derivative Liabilities*.

As of April 30, 2012, none of the Series B convertible preferred stock had been converted to common stock. The make whole payments at the date of issuance, in the amount of \$540,000, were accrued on the issuance date and are included in Accounts Payable and Accrued Expenses (see Note 6). The "make whole" amount was allocated as described directly below, when accounting for the initial proceeds from the Series B convertible preferred stock financing.

**GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES****(A DEVELOPMENT STAGE COMPANY)****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)***Accounting for proceeds from the Series A convertible preferred stock financing*

The net cash proceeds from the Series A convertible preferred stock financing were \$2,315,000. The proceeds from the financing were allocated first to the warrants that were issued in the financing, second to the additional investment rights associated with the financing and third to the make whole payments. As the assigned fair values were greater than the net cash proceeds from the transaction, the excess was treated as a “deemed dividend” for accounting purposes and is reported on the Company’s consolidated statement of operations for the year ended July 31, 2011 under the caption “Preferred Stock Dividend”. The calculation methodologies for the fair values of the derivative warrant liability and the derivative additional investment rights liability are described in *Note 11 – Derivative Liabilities* below. The fair values assigned to each component and the calculation of the amount of the deemed dividend are as follows:

Accounting allocation of initial proceeds	
Net proceeds	\$2,315,000
Derivative warrant liability fair value	(1,871,167)
Derivative additional investment rights fair value	(515,000 )
Make whole payments liability	(695,250 )
Deemed dividend	\$(766,417 )

*Accounting for proceeds from the Series B convertible preferred stock financing*

The net cash proceeds from the Series B convertible preferred stock financing were \$1,975,000. The proceeds from the financing were allocated first to the warrants that were issued in the financing and second to the make whole payments. As the assigned fair values were greater than the net cash proceeds from the transaction, the excess was treated as a “deemed dividend” for accounting purposes and is reported on the Company’s consolidated statements of operations for the three and nine-month periods ended April 30, 2012 under the caption “Preferred Stock Dividend”. The calculation methodologies for the fair values of the derivative warrant liability and the derivative additional investment rights liability are described in *Note 11 – Derivative Liabilities* below. The fair values assigned to each component and the calculation of the amount of the deemed dividend are as follows:

Accounting allocation of initial proceeds

Net proceeds	\$ 1,975,000
Derivative warrant liability fair value	(1,811,746)
Make whole payments liability	(540,000 )
Deemed dividend	\$ (376, 746)

**11. Derivative Liabilities**

*Derivative warrant liability*

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

**Accounting for Derivative Warrant Liability**

The Company's derivative warrant instruments have been measured at fair value at April 30, 2012 and July 31, 2011 using the binomial lattice model. The Company recognizes all of its warrants with price protection in its consolidated balance sheets as a liability. The liability is revalued at each reporting period and changes in fair value are recognized currently in the consolidated statements of operations. The initial recognition and subsequent changes in fair value of the derivative warrant liability have no effect on the Company's consolidated cash flows.

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

The derivative warrants outstanding at April 30, 2012 are all currently exercisable with a weighted-average remaining life of 4.2 years.

The revaluation of the warrants at each reporting period, as well as the charges associated with issuing additional warrants due to the price protection features, resulted in the recognition of loss of \$1,276,950 within the Company's consolidated statements of operations for the nine months ended April 30, 2012 and income of \$1,993,920 for the nine months ended April 30, 2011, which is included in the total under the caption "Change in fair value of derivative liabilities". The fair value of the warrants at April 30, 2012 and July 31, 2011 was \$4,603,470 and \$8,745,508, respectively, which is reported on the consolidated balance sheets under the caption "Derivative Warrant Liability". The following summarizes the changes in the value of the derivative warrant liability from August 1, 2010 until April 30, 2012:

	Value	No. of Warrants
Balance at August 1, 2010 – Derivative warrant liability	\$5,679,721	16,503,340
Additional warrants issued in January to April 2011 financings	3,415,536	16,056,000
Additional warrants issued in July 2011 financing	1,871,167	17,166,666
Additional warrants from price protection features of existing warrants	3,867,678	30,508,011
Decrease in fair value of derivative warrant liability	(6,088,594)	n/a
Balance at July 31, 2011 – Derivative warrant liability	8,745,508	80,234,017
Exercise of warrants classified as derivative liability	(7,230,734)	(49,863,260)
Additional warrants issued in February 2012 financing	1,811,746	13,333,333
Additional warrants from price protection features of existing warrants	1,548,813	11,444,440
Decrease in fair value of derivative warrant liability	(271,863 )	n/a
Balance at April 30, 2012 – Derivative warrant liability	\$4,603,470	55,148,530

**Fair Value Assumptions Used in Accounting for Derivative Warrant Liability**

The Company has determined its derivative warrant liability to be a Level 2 fair value measurement and has used the binomial lattice pricing model to calculate the fair value as of April 30, 2012 and July 31, 2011. The binomial lattice model requires six basic data inputs: the exercise or strike price, time to expiration, the risk free interest rate, the

current stock price, the estimated volatility of the stock price in the future, and the dividend rate. Because the warrants contain the price protection feature, the probability that the exercise price of the warrants would decrease as the stock price decreased was incorporated into the valuation calculations. The key inputs used in the April 30, 2012 and July 31, 2011 fair value calculations were as follows:

	April 30, 2012	July 31, 2011	
Current exercise price	\$0.15	\$0.15 and \$0.25	
Time to expiration	4.2 years	4.7 years	
Risk-free interest rate	0.60	1.23	%
Estimated volatility	106	108	%
Dividend	-0-	-0-	
Stock price at period end date	\$0.102	\$0.13	

#### *Derivative additional investment rights liability*

The benefit received by the participants in the July 2011 Series A 9% Convertible Preferred Stock transaction (see Note 10) in respect to the right to make an additional investment with the same terms as the July 2011 transaction was determined to be an embedded derivative instrument and has been measured at fair value using the binomial lattice model. The liability will be revalued at each subsequent reporting period prior to its expiry in July 2012 and any changes in fair value will be recognized in the consolidated statements of operations. The initial recognition and subsequent changes in fair value of the derivative additional investment rights liability have no effect on the Company's cash flows.

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

The Company has determined the derivative additional investment rights liability to be a Level 2 fair value measurement and has used the binomial lattice pricing model to measure the fair value. The fair value of the derivative liability associated with the additional investment rights was determined to be \$515,000 at July 31, 2011 and \$437 at April 30, 2012. The key inputs used in the fair value calculations were as follows:

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

	April 30, 2012	July 31, 2011		
Underlying number of units of convertible preferred stock	575	2,575		
Underlying number of warrants	3,833,333	17,166,667		
Current exercise price of warrants	\$0.15	\$0.25		
Current conversion price of preferred stock	\$0.15	\$0.15		
Time to expiration	0.19 years	1.0 years		
Risk-free interest rate	0.09	%	1.23	%
Estimated volatility	37	%	58	%
Dividend	-0-		-0-	
Stock price	\$0.102		\$0.13	

The revaluation of the additional investment rights at the April 30, 2012 reporting period, resulted in the recognition of a gain of \$326,770 within the Company's consolidated statements of operations for the nine months ended April 30, 2012, which is included in the total under the caption "Change in fair value of derivative liabilities". In addition, \$841,333 was transferred to equity, as a result of the partial exercise of the additional investment rights in the nine months ended April 30, 2012.

**12. Other Current Assets**

Other current assets consist of the following:

	April 30, 2012	July 31, 2011
Mortgage loan origination fees	\$102,895	\$—
Prepaid insurance, deposits and taxes	193,395	225,052
Total	\$296,290	\$225,052

The mortgage loan origination fees include legal and other lender fees related to the mortgage loan financing which closed on January 19, 2012, which have been capitalized and are being amortized over the twelve month term of the

loan to January 18, 2013.

### **13. Income from Assets Held for Investment, net**

In March and April, 2012, the Company sold nine commercial condominium units which were held for investment for gross proceeds after real estate commissions of \$2,865,682. These properties had a net book value of \$1,783,932, resulting in an accounting gain of \$1,081,750 which is included in income from assets held for investment, net on the consolidated statement of operations. The net proceeds after commissions and other expenses were used to discharge or partially discharge the first and second mortgages on the properties. There were two first mortgages on the properties, with combined remaining principals of CAD\$568,836, which were discharged completely upon sale. The remaining net proceeds of CAD\$2,180,051 after expenses and the discharge of the first mortgages was used to partially discharge the second mortgage and the Company did not receive any of the net proceeds from these property sales.

In August 2011, the Company sold two properties which were held for investment for gross proceeds after real estate commissions of \$1,669,115. These two properties had a net book value of \$1,029,435, resulting in an accounting gain of \$639,680 which is included in income from assets held for investment, net on the consolidated statement of operations. The two properties had mortgages of \$659,288 which were discharged upon sale, resulting in net cash proceeds to the Company of \$1,009,827.

The remaining income of \$207,420 in this category in the nine months ended April 30, 2012, pertains to rental income from properties held for investment, net of carrying and operating expenses, compared to \$236,732 in the prior year period.

### **14. Subsequent Events**

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

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

As used herein, the terms the "Company," "Generex," "we," "us," or "our" refer to Generex Biotechnology Corporation, a Delaware corporation. The following discussion and analysis by management provides information with respect to our financial condition and results of operations for the three and nine-month periods ended April 30, 2012 and 2011. 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, 2011, as amended, and the information contained in *Part I, Item 1 - Financial Statements* and *Part II, Item 1A - Risk Factors* in this Quarterly Report on Form 10-Q for the fiscal quarter ended April 30, 2012.

### 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 April 30, 2012 that may constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Act"). The Act limits our liability in any lawsuit based on forward-looking statements that we have made. All statements, other than statements of historical facts, included in this Quarterly Report that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. These statements can be identified by introductory words such as "may," "expects," "anticipates," "plans," "intends," "believes," "will," "estimates" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Our forward-looking statements address, among other things:

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

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may



differ materially from what is expressed or implied in our forward-looking statements. Among the factors that could affect future results are:

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

Additional factors that could affect future results are set forth in *Part I, Item 1A Risk Factors* of our Annual Report on Form 10-K for the year ended July 31, 2011, 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**

### ***Overview of Business***

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

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

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

### ***Financial Condition***

As of April 30, 2012, our current cash position is not sufficient to meet our working capital needs for the next twelve months. To continue operations, we will require additional funds to support our working capital requirements and any development activities, or will need to curtail our clinical trials and other planned activities or suspend operations. Management is seeking various alternatives to ensure that we can meet some of our operating cash flow requirements

through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. In addition, management is actively seeking strategic alternatives, including strategic investments and divestitures. Management has sold, and is also seeking further sales of, non-essential real estate assets which are classified as Assets Held for Investment to augment its cash position. We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations.

### *Generex Oral-lyn™*

#### *Regulatory Approvals and Clinical Trials*

To date, we have received regulatory approval in Ecuador, India (subject to further study), Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™. We have previously submitted regulatory dossiers for Generex Oral-lyn™ in a number of other countries, including Bangladesh, Kenya, Jordan and Armenia. While we believe these countries will ultimately approve our product for commercial sale, we do not anticipate recognizing revenues in any of these jurisdictions in the next twelve months. No dossier related activities or product shipments have taken place to these countries during 2011 or during 2012 to date, nor are any expected during the remainder of 2012.

In March 2008, we initiated Phase III clinical trials for this product in the U.S. with the first patient screening for such trials at a clinical study site in Texas in April 2008. Approximately 450 patients have been enrolled to date at approximately 70 clinical sites around the world, including sites in the United States, Canada, Bulgaria, Poland, Romania, Russia, Ukraine and Ecuador. The first Oral-lyn global Phase III trial initiated in April 2008 had a final patient visit date in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite metanalysis of all safety data. Following notification of the completion of their review, we will schedule a meeting with the FDA to arrive at a consensus for the pathway for regulatory approval, including any additional clinical or pharmacological studies that might be required to support regulatory approval or enhance marketing success.

### *Marketing*

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

In India, a marketing plan has been submitted by Shreya Life Sciences Pvt. Ltd., to Generex on the marketing strategy for the distribution of Oral Recosulin™, the trademark under which Shreya will market Generex Oral-lyn™ within India. The marketing plan also includes post-approval marketing studies. Per the requirements of the regulatory approval in India, an in-country clinical study must be completed in India with Oral Recosulin™ before commercial sales can commence. Completion of the study and regulatory agency approval is not currently expected until at least the third quarter of calendar year 2012, after which approval commercial sales may commence. We have not recognized any revenues from the sale of Generex Oral-lyn™ in India through the end of the 2011 fiscal year or in the first three quarters of the 2012 fiscal year.

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

### *Cancer and Immunotherapeutic Vaccine Platforms*

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

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

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

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

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

#### *Other Potential Buccal Products*

We have had discussions regarding possible research collaborations with various pharmaceutical companies concerning use of our large molecule drug delivery technology with other compounds, including monoclonal antibodies, human growth hormone, fertility hormone, estrogen and heparin, and a number of vaccines. We are currently pursuing development opportunities to complement our insulin therapy. Amaranthus BioSciences and Generex Biotechnology announced in June 2011 that they are working towards establishing a collaboration on cell therapy for late stage diabetes, but as of the date of this report, no definitive agreements have been signed.

In October 2008, we announced the enrollment of subjects in our bioequivalence clinical trial of MetControl™, our proprietary Metformin medicinal chewing gum product, conducted in the United States. The protocol for the study is an open-label, two-treatment, two-period, randomized, crossover study comparing MetControl™ and immediate release Metformin™ tablets in healthy volunteers. The study results that we received and analyzed in December 2008 demonstrated bioequivalence. We have, however, determined that the economics of proceeding with this product do not warrant the expenditure of further resources. We have not expended resources to further develop this product during the fiscal years ended July 31, 2011 and 2010 or in the first three quarters of fiscal 2012 and do not currently plan to expend any further resources on this product.

#### *Consumer/Over-the-Counter Glucose Product Line*

Using our buccal delivery technology, we have also launched a consumer/over-the-counter glucose spray called Glucose RapidSpray™. We do not plan to expend significant resources to market this product in the future. Revenues will not likely be significant unless we engage a major marketing partner to manufacture, distribute, market and sell this product. In fiscal 2011 and in the first three quarters of fiscal 2012, we received modest revenues from sales of our commercially available consumer/over-the-counter products. We are currently seeking a global purchaser or licensee for the Glucose Rapid Spray Product.

#### *Competition*

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

In May 2009, Mannkind Corporation submitted an NDA to the FDA requesting approval to market AFREZZA(R) (insulin human [rDNA origin]) Inhalation Powder, for the treatment of adult patients with Type 1 and Type 2 diabetes for the control of hyperglycemia, and the NDA is still currently under review by the FDA. In addition to other delivery systems for insulin, there are numerous products, such as sulfonylureas (Amaryl® and Glynase®), biguanides (branded and generic metformin products), thiazolidinediones (Avandia® and Actos®), glucagon-like peptide 1 (Byetta® and Victoza®), and dipeptidyl peptidase IV inhibitors (Januvia® and Onglyza™), which have been approved for use in the treatment of Type 2 diabetics in substitution of, or in addition to, insulin therapy. These products may also be considered competitive with insulin products.

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

#### *Brief Company Background*

We are a development stage company. From inception through the end of the quarter ended April 30, 2012, we have received only limited revenues from operations. In the nine months ended April 30, 2012 and in the fiscal year ended July 31, 2011, we generated \$21,901 and \$291,628 in revenue, respectively. The revenue in each of the fiscal periods pertained primarily to the sale of our consumer/over-the-counter products. These numbers do not reflect deferred sales to customers during the respective periods with the right of return.

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

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

## Accounting for Research and Development Projects

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

During the first nine months of the current fiscal year and during the last fiscal year, we expended resources on the clinical testing and results analysis of our buccal insulin product, Generex Oral-lyn™. In July 2007, we received no objection from the FDA to proceed with our long-term multi-center Phase III study protocol for Generex Oral-lyn™. The first Oral-lyn global Phase III trial initiated in April 2008 had a final patient visit date in August 2011. After appropriate validation, the data from approximately 450 patients was tabulated, reviewed and analyzed. Those results from the Phase III trial along with a comprehensive review and supplemental analyses of approximately 40 prior Oral-lyn clinical studies were compiled and submitted to the FDA in late December 2011 in a comprehensive package including a composite metanalysis of all safety data. Following notification of the completion of their review, we will schedule a meeting with the FDA to arrive at a consensus for the pathway for regulatory approval, including any additional clinical or pharmacological studies that might be required to support regulatory approval or enhance marketing success. 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.

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

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

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



products, as a significant portion of all research has involved improvements to the platform technology in connection with insulin, which may benefit all of our potential buccal products. During the nine months ended April 30, 2012, approximately 63% of our \$3,835,715 in research expenses was attributable to insulin and platform technology development, and we did not have any research expenses related to morphine, fentanyl or other buccal projects. During the nine months ended April 30, 2011, approximately 75% of our total \$7,859,382 in research expenses was attributable to insulin and platform technology development, and we did not have any research expenses related to morphine, fentanyl or other buccal projects.

During the nine months ended April 30, 2012, approximately 37% of our \$3,835,715 of research expenses was attributable to Antigen's immunomedicine compared to approximately 25% of our total \$7,859,382 of research and development expenses for the nine months ended April 30, 2011. Because these products are in initial phases of clinical trials or early, pre-clinical stage of development (with the exception of the Phase II clinical trials of Antigen HER-2/neu positive breast cancer vaccine that are underway), all of the expenses were accounted for as basic research and no distinctions were made as to particular products. Due to the early stage of development, we cannot predict the timing of completion of any products arising from this technology, or when products from this technology might begin producing revenues.

### **Critical Accounting Policies**

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

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

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

Revenue Recognition. Net sales of our over-the-counter confectionary products are generally recognized in the period in which the products are delivered. Delivery of the products generally completes the criteria for revenue recognition for us. In the event where the customers have the right of return, sales are deferred until the right of return lapses, the product is sold to a third party or a provision for returns can be reasonably estimated based on historical experience.

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

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

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

Estimating accrued liabilities, specifically litigation accruals. Management's current estimated range of liabilities related to pending litigation is based on management's best estimate of future costs. While the final resolution of the litigation could result in amounts different than current accruals, and therefore have an impact on our consolidated financial results in a future reporting period, management believes the ultimate outcome will not have a significant effect on our consolidated results of operations, financial position or cash flows.

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

Derivative warrant liability. FASB ASC 815, Derivatives and Hedging, requires all derivatives to be recorded on the balance sheet at fair value for fiscal years beginning after December 15, 2008. As a result, certain derivative warrant liabilities (namely those with a price protection feature) are now separately valued as of August 1, 2009 and accounted

for on our balance sheet, with any changes in fair value recorded in earnings. For our balance sheets as of April 30, 2012 and July 31, 2011, we used the binomial lattice model to estimate the fair value of these warrants. Key assumptions of the binomial lattice option-pricing model include the market price of our stock, the exercise price of the warrants, applicable volatility rates, risk-free interest rates, expected dividends and the instrument's remaining term. These assumptions require significant management judgment. In addition, changes in any of these variables during a period can result in material changes in the fair value (and resultant gains or losses) of this derivative instrument.

## Results of Operations

### Three Months Ended April 30, 2012 Compared to Three Months Ended April 30, 2011

We had net income for the quarter ended April 30, 2012 of \$491,111 versus a net loss of \$4,116,953 in the corresponding quarter of the prior fiscal year. The almost \$5 million improvement in net income in this fiscal quarter versus the net loss in the corresponding quarter of the prior fiscal year is primarily due to a \$2.6 million gain due to the change in fair value of the derivative liabilities in the current quarter, a \$2.6 million reduction in operating expenses in all major categories, as compared to the corresponding prior year quarter and a \$1.1 million gain on the sale of properties which were previously held for investment. Our operating loss for the quarter ended April 30, 2012 decreased to \$2,466,270 compared to \$5,061,959 in the same fiscal quarter of 2011. The decrease in operating loss resulted from a decrease in selling and marketing expense (to \$18,258 from \$207,848), a decrease in research and development expenses (to \$1,127,047 from \$1,754,325), and a decrease in general and administrative expenses (to \$1,325,747 from \$3,109,887). Our revenues in the quarter ended April 30, 2012 decreased to \$7,012 from \$65,583 for the quarter ended April 30, 2011 reflecting lower sales of our over-the-counter products, due to a decision not to focus resources on the sale of these products going forward.

The decrease in research and development expenses in the current fiscal quarter versus the comparative quarter in the previous fiscal year is primarily due to the field portion of the global Phase III clinical trials of our oral insulin product and platform technology being completed in August 2011, resulting in significantly lower costs on an ongoing basis related to this trial. Our efforts to significantly reduce expenses in all categories also contributed to the decrease in this category. The decrease in general and administrative expenses is primarily related to a decrease in professional services expenses including legal and consulting services of approximately \$526,000 in the quarter ended April 30, 2012, as compared to the previous year quarter ended April 30, 2011, as well as reductions of expenses in most other categories due to efforts to conserve cash until we complete the strategic development plan announced by management on March 30, 2011. We also incurred a charge in the previous fiscal year period of approximately \$692,000 related to the granting of options to the executives, key employees and the board members, which did not recur in the current year's quarter. The decrease in selling expenses for the quarter ended April 30, 2012 versus the prior year comparative quarter is associated with decreased advertising and promotion relating to our over-the-counter products.

Our interest expense in the third quarter of fiscal 2012 was \$423,674 compared to the previous year's fiscal quarter at \$52,301 due to the amortization of fees and costs associated with the January and February 2012 property financings, as well as penalties incurred upon the early discharge of mortgages on the properties held for investment which were sold in March and April 2012. Our interest income decreased slightly to \$450 in the third quarter of fiscal 2012, compared to \$1,154 in the same quarter for the last year, due to lower average cash balances. We recognized higher income from assets held for investment (net of expense) of \$1,148,526 in the third quarter of fiscal 2012 compared to \$70,450 in the same quarter of the previous fiscal year due to the almost \$1.1 million accounting gain on the aforementioned sale of properties held for investment. Change in fair value of derivative liabilities contributed a gain of \$2,608,825 in the third quarter of fiscal 2012 versus a gain of \$925,703 in the third fiscal quarter of fiscal 2011.

Our net income available to shareholders was decreased by \$376,746 in the third quarter of fiscal 2012 relating to a preferred stock dividend as a result of the accounting treatment of our convertible preferred stock financing in February 2012. This amount represents a deemed dividend to the investors as a result of this financing, as further described in Note 10 to the *Notes to Consolidated Financial Statements* included elsewhere in this Quarterly Report. There was no preferred stock dividend in the comparable period of fiscal 2011.

#### **Nine Months Ended April 30, 2012 Compared to Nine Months Ended April 30, 2011**

We had a net loss for the three quarters ended April 30, 2012 of \$7,914,440 versus a net loss of \$16,231,126 in the corresponding three quarters of the prior fiscal year. The \$8.3 million improvement in net loss in this fiscal year versus the corresponding period of the prior fiscal year is primarily due to an \$11.2 million reduction in operating expenses in all major categories, offset by a \$1.6 million loss due to the change in fair value of the derivative liabilities in the current fiscal year versus a gain of \$2.0 million in the prior fiscal year. Our operating loss for the three quarters ended April 30, 2012 decreased to \$7,722,279 compared to \$18,803,337 in the comparative three quarters of 2011. The decrease in operating loss resulted from a decrease in selling expense (to \$167,316 from 806,798), a decrease in research and development expenses (to \$3,835,715 from 7,859,382), and a decrease in general and administrative expenses (to \$3,732,027 from \$10,262,883). Our revenues in the three quarters ended April 30, 2012 decreased to \$21,901 from \$269,086 for the three quarters ended April 30, 2011 reflecting lower sales of our over-the-counter products due to a decision not to focus resources on the sale of these products going forward.

Similar to the above three month period, the decrease in research and development expenses in the current fiscal year period versus the comparative period in the previous fiscal year, is primarily due to the field portion of the global Phase III clinical trials of our oral insulin product and platform technology being completed in August 2011, resulting in significantly lower costs on an ongoing basis related to this trial. The company's efforts to significantly reduce expenses in all categories also contributed to the decrease in this category. The decrease in general and administrative expenses is primarily related to a decrease in professional services expenses including legal, accounting, consulting and financial services of over \$4.2 million in the three quarters ended April 30, 2012, as compared to the previous year period ended April 30, 2011, as well as reductions of expenses in most other categories due to management's efforts to reduce expenses and conserve cash. The decrease in selling expenses for the quarter ended April 30, 2012 versus the prior year comparative quarter is associated with decreased advertising and promotion relating to our

over-the-counter products.

Our interest expense in the first three quarters of fiscal 2012 increased to \$518,506, compared to interest expense of \$153,385 in the first three quarters of fiscal 2011, due to the amortization of fees and costs associated with the January and February 2012 property financings, as well as penalties incurred upon the early discharge of mortgages on the properties held for investment which were sold in March and April 2012. Our interest income decreased to \$1,215 in the first three quarters of fiscal 2012, compared to \$5,985 in the comparable period for last fiscal year, due to lower average cash balances. We recognized higher income from assets held for investment (net of expense) of \$1,928,850 in the first three quarters of fiscal 2012 compared to \$236,732 in the same quarter of the previous fiscal year due primarily to accounting gains related to the sale of the properties held for investment in August 2011 and March and April 2012 of approximately \$1.8 million, while rental income decreased slightly from the comparative prior fiscal year period. Change in fair value of derivative liabilities caused a loss of \$1,603,720 in the first three quarters of fiscal 2012 versus a gain of \$1,993,920 in the comparative prior fiscal year period. The change in fair value of the warrants carried as a derivative liability contributed a loss of \$1,276,950 in this category in the current year, compared to a gain of \$1,993,920 in the comparable period last year, while the change in fair value of the additional investment rights contributed a loss in fiscal 2012 only, of \$326,770.

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

### ***Sources of Liquidity***

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

As of April 30, 2012, our current cash position is not sufficient to meet our working capital needs for the next twelve months. Therefore, we will require additional funds to support our working capital requirements and any development or other activities, or will need to curtail our clinical trials and other planned activities or suspend operations.

While we have financed our development stage activities to date primarily through private placements of our common stock and securities convertible into our common stock and raised approximately \$6.5 million during fiscal 2011 and approximately \$4.0 million during fiscal 2012 (including the net proceeds from mortgage financings in January and February 2012), our cash balances have been extremely low thus far in fiscal 2012.

On March 30, 2011, our realigned management team announced its strategic development plan for Generex's future growth. The plan included the spin-out of Antigen Express, a reverse stock split for Generex and a rights offering to Generex stockholders. As proposed, we would spin out Antigen Express as a separate DTC-eligible company, register its shares with the Securities and Exchange Commission (the "SEC"), and seek to list its shares on a national securities exchange. Management believes that the spin-out would increase value for stockholders and provide Antigen Express with ready access to capital markets to finance its on-going clinical and regulatory initiatives. Management further believes that the spin-out would benefit Generex, by allowing Generex to hold a controlling interest in a publicly-traded company while continuing to focus on maximizing opportunities for its buccal drug delivery platform. The spin-out would be accomplished by the issuance of one or more dividends of Antigen Express stock to Generex stockholders. No determination has been made as to the timing of the proposed spin-out. *This Quarterly Report on Form 10-Q does not constitute an offer of any securities for sale or a solicitation of an offer to buy any securities.*

Although stockholders approved a reverse stock split proposal at the June 8, 2011 annual meeting of stockholders, our Board of Directors will only seek to implement a reverse stock split in conjunction with an effort to list our common stock on a national stock exchange. The terms of the securities purchase agreement that we entered into on January 31, 2012 also prohibit us from undertaking a reverse or forward stock split or reclassification of our common stock except for a reverse stock split made in conjunction with a listing of the common stock on a national securities exchange. As there are significant conditions, in addition to the minimum share price, which must be met before we can be considered for listing, management does not anticipate that the Board of Directors will move forward with a reverse stock split in the near future. Management's contemplated rights offering of common stock and warrants to our stockholders is contingent upon the occurrence of the reverse stock split and listing of our common stock.

Management may seek to meet all or some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. The securities purchase agreement that we entered into on January 31, 2012 with certain investors prohibits us from (i) issuing additional equity securities until 60 days after the effective date of a registration statement covering the resale of the common stock issuable upon exercise of the warrants and conversion of the preferred stock sold in that transaction and (ii) issuing additional debt or equity securities with variable a conversion or exercise price until February 1, 2013.

Through the shelf registration statement (File No. 333-164591) that we filed on January 29, 2010 and which was declared effective on February 9, 2010, we raised an aggregate of \$4,056,000 in gross proceeds between January and April 2011 and raised an additional \$2,575,000 in gross proceeds in July 2011 pursuant to a convertible preferred stock purchase agreement with takedowns from the shelf registration statement as described below. Upon the filing of our Annual Report on Form 10-K on October 14, 2011, we were no longer eligible to use the shelf registration statement as the aggregate market value of our outstanding voting and non-voting common equity held by non-affiliates is less than \$75 million. As we are required under the registration rights agreement that we entered into on January 31, 2012 with certain investors to register shares of our common stock issuable upon conversion or exercise of the securities purchased by the investors, we have filed a registration statement on Form S-1 (File No. 333-180170) which was declared effective April 9, 2012.

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

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

Unforeseen problems with the conduct or results of Phase III clinical trials for Oral-lyn™ or further negative developments in general economic conditions could interfere with our ability to raise additional capital as needed, or materially adversely affect the terms upon which such capital is available. We cannot provide any assurance that we will obtain the required funding. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and our strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected and we may have to cease operations.

### *Proceeds from Recent Financing*

On January 31, 2012, we entered into a securities purchase agreement with certain investors, pursuant to which we agreed to sell an aggregate of 2,000 shares of our newly designated non-voting Series B 9% Convertible Preferred Stock and warrants to purchase up to an aggregate of 100% of the shares of our common stock issuable upon conversion of the convertible preferred stock. The purchase closed on February 1, 2012. We sold the convertible preferred stock and warrants in units, with each unit consisting of one share of convertible preferred stock and a warrant to purchase 100% of the shares of our common stock issuable upon conversion of such share of convertible preferred stock. Each unit was sold at a negotiated price of \$1,000, for an aggregate purchase price of \$2,000,000. An aggregate of 26,666,666 shares of our common stock are issuable upon conversion of, or exercise of, the convertible preferred stock and warrants. We received net proceeds of approximately \$1,975,000 from this transaction, which will be reflected in the financial statements for the fiscal quarter ending April 30, 2012. We entered into this securities purchase agreement pursuant to the investors' additional investment rights existing under the securities purchase agreement dated July 8, 2011.

Subject to certain ownership limitations, the convertible preferred stock will be convertible at the option of the holder at any time into shares of our common stock at an effective conversion price of \$0.15 per share, and will accrue a 9% dividend until February 1, 2015 and, beginning on February 1, 2015 and on each one year anniversary thereafter, such dividend rate will increase by an additional 3%. The dividend will be payable quarterly on September 30, December 31, March 31 and June 30, beginning on the first such date after the original issue date and on each conversion date in cash, or at our option, in shares of common stock. In the event that the convertible preferred stock is converted prior to February 1, 2015, we will pay the holder of the converted preferred stock an amount equal to \$270 per \$1,000 of stated value of the convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. Such "make-whole payment" may be made in cash or, at our option, in shares of our common stock. In addition, beginning February 1, 2015, we will pay dividends on shares of preferred stock equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid. We will incur a late fee of 18% per annum on unpaid dividends.

The conversion price of the convertible preferred stock will be subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The conversion price will also be adjusted if we sell or grant any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then conversion price, except in the event of certain exempt issuances. In addition, the holders of convertible preferred stock will be entitled to receive any securities or rights to acquire securities or property granted or issued by us pro rata to the holders of our common stock to the same extent as if such holders had converted all of their shares of convertible preferred stock. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the holders of convertible preferred stock will be entitled to receive, upon conversion of their shares, any securities or other consideration received by the holders of our common stock pursuant to the fundamental transaction.



We may become obligated to redeem the convertible preferred stock in cash upon the occurrence of certain triggering events, including, material breach of certain contractual obligations to the holders of the convertible preferred stock, the occurrence of a change in control of Generex, the occurrence of certain insolvency events relating to Generex, or the failure of our common stock to continue to be listed or quoted for trading on one or more specified United States securities exchanges or regulated quotation service. Upon the occurrence of certain triggering events, each holder of convertible preferred stock will have the option to redeem such holder's shares of convertible preferred stock for a redemption price payable in shares of common stock or receive an increased dividend rate of 18% on all of such holder's outstanding convertible preferred stock. Late fees will apply on all redemption amounts not paid within five trading days of the payment date.

Subject to certain ownership limitations, the warrants will be exercisable at any time after their date of issuance and on or before the fifth-year anniversary thereafter at an exercise price of \$0.15 per share of common stock. The exercise price of the warrants and, in some cases, the number of shares issuable upon exercise, are subject to adjustment in the case of stock splits, stock dividends, combinations of shares, similar recapitalization transactions and certain pro-rata distributions to common stockholders. The exercise price and number of shares of common stock issuable upon exercise will also be adjusted if we sell or grant any shares of common stock or securities convertible into, or rights to acquire, common stock at an effective price per share that is lower than the then exercise price, except in the event of certain exempt issuances. In addition, the warrant holders will be entitled to receive any securities or rights to acquire securities or property granted or issued by us pro rata to the holders of our common stock to the same extent as if such holders had exercised all of their warrants. In the event of a fundamental transaction, such as a merger, consolidation, sale of substantially all assets and similar reorganizations or recapitalizations, the warrant holders will be entitled to receive, upon exercise of their warrants, any securities or other consideration received by the holders of common stock pursuant to the fundamental transaction.

With very limited exceptions, the investors will have a pro rata right of first refusal in respect of participation in any private debt or equity financings undertaken by us during the 12 months following the closing of the transaction.

We offered these securities privately pursuant to Rule 506 of Regulation D under the Securities Act of 1933. We entered into a registration rights agreement with the investors pursuant to which we agreed to file a registration statement with the SEC covering the public resale of the common stock issuable upon conversion of the preferred stock, issuable as dividends on the preferred stock, issuable upon exercise of the warrants and issued as a finders' fee. We have filed a registration statement on Form S-1 (File No. 333-180170) covering the public resale of these securities, which was declared effective April 9, 2012.

In addition, if, during the six-month period after the issuance of the warrants and continuing until such time that all of the securities may be sold without our meeting the current public information requirement under Securities Act rule 144(c)(1), we fail to meet such requirement, we will pay liquidate damages equal to 2.0% of the purchase price paid by each investor, payable in cash every 30 days until current public information for Generex is available or is no longer required for the investors to rely on Rule 144 to transfer the securities (including underlying securities) acquired under the securities purchase agreement.

Contemporaneous with entering into the securities purchase agreement, we and the investors also agreed to certain clarifications to the exercise price adjustment provisions under the outstanding warrants issued in July 2011. Under that agreement, the parties agreed to an exercise price of \$0.15 per share for the warrants to purchase 15,166,667 shares of common stock (25,277,775 shares after the anti-dilution adjustment required under the terms of the warrants), which were in the process of being exercised prior to the parties entering into the securities purchase agreement, and unexercised outstanding warrants to purchase 1,999,999 shares of common stock (3,333,331 shares following the required anti-dilution adjustment).

### ***Proceeds from Warrant Exercises***

We may receive additional proceeds from the exercise of warrants issued in the registered direct offerings conducted in June, August and September 2009, the sales to Seaside 88, LP in April, May and June 2010, the warrants issued in connection with the January 2011 registered direct offering and option thereunder and the warrants issued in July 2011 and February 2012 in connection with the issuance of the Series A 9% Convertible Preferred Stock and Series B 9% Convertible Preferred Stock, although some of the warrants include a cashless exercise feature.

In the transaction that closed on June 15, 2009, we sold shares of common stock and warrants exercisable for up to 8,600,000 shares of our common stock to investors and issued Midtown Partners & Co., LLC, our exclusive placement agent for the transaction, a warrant to purchase up to 244,926 shares of our common stock.

In the August 6, 2009 registered direct offering, we sold shares of common stock and warrants exercisable for up to 2,995,305 shares of our common stock to investors and issued a warrant to purchase 577,666 shares of our common stock to Midtown, which acted as our exclusive placement agent for the August 2009 transaction.

In the transaction that closed on September 14, 2009, we sold an aggregate of 15,312,500 shares of our common stock and warrants exercisable for up to 5,053,125 shares of our common stock to investors and issued warrants to purchase up to 969,526 shares of our common stock to the two placement agents and a consultant in relation to the transaction.

In the closings under the common stock purchase agreement that occurred in April, May and June 2010, we sold Seaside 12,000,000 shares of our common stock and issued to Midtown, as placement agent, warrants to purchase an aggregate of 300,000 shares of our common stock.

In connection with the securities purchase agreement dated January 24, 2011 and option thereunder, we sold an aggregate of 16,056,000 shares of our common stock and issued warrants exercisable for up to 16,056,000 shares of our common stock to investors.

In connection with the securities purchase agreement dated July 7, 2011 and option thereunder, we sold an aggregate of 2,575 shares of our Series A 9% Convertible Preferred Stock and issued warrants exercisable for up to 17,166,666 shares of our common stock to investors.

In connection with the securities purchase agreement dated January 31, 2012, we sold an aggregate of 2,000 shares of our Series B 9% Convertible Preferred Stock and issued warrants exercisable for up to 13,333,333 shares of our common stock to investors.

As of June 11, 2012 all of the warrants issued in the aforementioned registered direct offerings were exercisable. At June 11, 2012, outstanding warrants issued in connection with the June, August and September 2009 registered direct offerings, the April, May and June 2010 sales to Seaside and the January 2011 and July 2011 registered direct offering, as well as the February 2012 Series B 9% convertible preferred stock financing were as follows:

Date Issued	<i>Aggregate No. of Shares Unexercised</i>	<i>Exercise Price</i>	Expiration Date
June 15, 2009	8,844,926	0.76	December 15, 2014
August 6, 2009	3,572,971	0.79	February 4, 2015
September 14, 2009	6,022,651	1.00	March 15, 2015
April 8, 2010	50,000	0.47259	February 9, 2015
April 21, 2010	50,000	0.4258	February 9, 2015
April 30, 2010	50,000	0.415	February 9, 2015
May 14, 2010	50,000	0.3496	February 9, 2015
May 28, 2010	50,000	0.351	February 9, 2015
June 11, 2010	50,000	0.3543	February 9, 2015
January 25 – April 8, 2011*	4,000,000	0.15	January 25, 2016
July 7, 2011*	3,333,331	0.15	July 7, 2016
February 1, 2012*	13,333,333	0.15	January 31, 2017

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

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

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

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

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

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

The initial exercise price of each Series Warrant was \$1.21. The Series Warrants include a cashless exercise feature. The exercise price of the Series Warrants was subsequently reduced initially to \$0.50, then to \$0.33, to \$0.25 and currently to \$0.15 as a result of a price protection provision triggered by our offering of stock in private placements in May 2009 and January and July 2011. This price protection feature allows for the reduction in the exercise price of the Series Warrants in the event we subsequently issue common stock or securities convertible into or exercisable for common stock, such as options and warrants, at a price per share less than the Series Warrant exercise price then in effect. In addition, with any reduction to the Series Warrant exercise price, the number of shares of common stock that may be purchased upon exercise of each Series Warrant will be increased or decreased proportionately, so that after such adjustment the aggregate Series Warrant exercise price payable for the adjusted number of shares issuable upon exercise will be the same as the aggregate Series Warrant exercise price in effect immediately prior to such adjustment. We account for these warrants with price protection in accordance with ASC 815 as described in Note 11 to the *Notes to Consolidated Financial Statements* included elsewhere in this Quarterly Report.

As of June 11, 2012, outstanding Series Warrants were as follows:

Date Issued	<i>Aggregate No. of Shares Unexercised</i>	<i>Exercise Price*</i>	Expiration Date
March 31, 2008	29,027,322	\$ 0.15	March 31, 2016
March 31, 2008	5,454,544	\$ 0.15	September 30, 2016

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

#### ***Cash Flows for the Nine Months ended April 30, 2012***

For the nine months ended April 30, 2012, we used \$7,158,458 in cash to fund our operating activities. The use for operating activities included a net loss of \$7,914,440, changes to working capital including an increase related to other current assets of \$70,693, a decrease of \$81,634 in deferred revenue and a decrease related to accounts payable and accrued expenses of \$1,267,420, offset by a decrease of \$8,474 in accounts receivable, and a decrease of \$716,415 in inventory.

The use of cash was offset by non-cash expenses of \$472,146 related to depreciation and amortization, write-offs related to abandoned patents of \$88,582, stock-based compensation to employees of \$125,444, stock-based compensation issued in exchange for services rendered by consultants of \$606,545 and common stock issued for interest on our convertible preferred stock of \$347,490. There was also a year-to-date non-cash loss of \$1,603,720 related to the fair valuation of the derivative liabilities at April 30, 2012 and an accounting gain of \$1,793,087 related to the sale of property and equipment (primarily assets held for investment).

We had net cash provided by investing activities of \$4,500,712 in the nine months ended April 30, 2012, representing primarily the net proceeds after real estate commissions of \$4,534,797 related to the sale of properties held as investments, as well as sale of other fixed assets for \$79,260, offset by payments for property and equipment of \$2,416 and costs incurred for patents of \$110,929.

We had cash provided by financing activities in the nine months ended April 30, 2012 of \$1,082,549, which pertained to \$1,975,000 in net proceeds from sales of convertible preferred stock in February 2012 and \$3,566,088 raised from mortgage loans. This was offset by principal repayments related to our long-term mortgage debt of \$4,488,539, which related primarily to the discharge of mortgages related to the sale of properties held for investment, while the remainder pertained to regular monthly principal payments. There was also \$30,000 received for warrant exercises during the nine months ended April 30, 2012.

Our net working capital at April 30, 2012 decreased to negative \$7,255,113 from negative \$5,568,217 at July 31, 2011, which was attributed largely to our cash used in operations for the nine-month period ended April 30, 2012, offset by the net proceeds from the sale of two properties held for investment in August 2011, the series B convertible preferred stock financing in February 2012 and the mortgage financings in January and February 2012.

### ***Conversion of Outstanding Series A and B 9% Convertible Preferred Stock***

As of April 30, 2012, all outstanding shares of our Series A 9% Convertible Preferred Stock were converted into shares of our common stock. As of January 31, 2012, 17,166,666 shares of common stock had been issued upon the conversion of 2,575 shares of Series A convertible preferred stock. The Series A convertible preferred stock earned dividends at the rate of 9% per annum, payable quarterly on September 30, December 31, March 31 and June 30. Upon conversion, we paid the holders of the Series A converted preferred stock an amount equal to \$270 per \$1,000 of stated value of the Series A convertible preferred stock, less the amount of all prior quarterly dividends paid on such converted preferred stock before the relevant conversion date. We issued 6,129,666 additional shares of common stock on such conversions of the Series A convertible preferred stock. Dividends paid on the Series A Convertible Preferred Stock were \$12,383 during the nine months ended April 30, 2012.

None of the 2,000 shares of our Series B 9% Convertible Preferred Stock have been converted and no dividends have been paid through April 30, 2012.

### ***Funding Requirements and Commitments***

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

Under the long-term agreement that we signed with sanofi-aventis in December 2009, sanofi-aventis will manufacture and supply recombinant human insulin to us in the territories specified in the agreement. Through this agreement, we will procure recombinant human insulin crystals for use in the production of Generex Oral-lyn™. The terms of the supply agreement required us to make certain minimum purchases of insulin from sanofi-aventis through the period ended December 31, 2011, which minimum purchases we did not satisfy. Sanofi-aventis will be our exclusive supplier in certain countries and a non-exclusive supplier in some other countries. Sanofi-aventis may delete any territory from the agreement in which Generex Oral-lyn™ has not been approved for commercial sale by December 31, 2011. The prices under the supply agreement are subject to adjustment beginning after December 31, 2012. As we did not meet the minimum purchase requirements by December 31, 2011, sanofi-aventis may terminate the agreement. Upon termination, we would be obligated to pay sanofi-aventis for all materials and components that it has acquired or ordered to manufacture insulin based on our forecasts or minimum purchase commitments, all related work-in-progress (at cost) and all finished insulin in inventory. We did not provide any forecasts to sanofi-aventis and have not included any accruals related to the purchase commitments in our interim financial statements for the period ended April 30, 2012.

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

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

- the timing and amount of expense incurred to complete our clinical trials;
- the costs and timing of the regulatory process as we seek approval of our products in development;
- the advancement of our products in development;
- our ability to generate new relationships with industry partners throughout the world that will provide us with regulatory assistance and long-term commercialization opportunities;
- the timing, receipt and amount of sales, if any, from Generex Oral-lyn™ in India, Lebanon, Algeria and Ecuador;
- the cost of manufacturing (paid to third parties) of our licensed products, and the cost of marketing and sales activities of those products;
- the costs of prosecuting, maintaining, and enforcing patent claims, if any claims are made;



- our ability to maintain existing collaborative relationships and establish new relationships as we advance our products in development;
- our ability to obtain the necessary financing to fund our operations and effect our strategic development plan; and
- the receptivity of the financial market to biopharmaceutical companies.

### **Off-Balance Sheet Arrangements**

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

### **Certain Related Party Transactions**

See *Part III, Item 13 – Certain Relationships and Related Transactions, and Directors Independence* in our Annual Report on Form 10-K for the year ended July 31, 2011, as amended, for further descriptions of our transactions with related parties during the last fiscal year.

### **Recently Adopted Accounting Pronouncements**

In January 2010, the FASB issued additional guidance on fair value measurements and disclosures which requires reporting entities to provide information about movements of assets among Levels 1 and 2 of the three-tier fair value hierarchy established by the existing guidance. The guidance was effective for our fiscal year beginning August 1, 2011. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

In May 2011, the FASB issued further guidance on fair value measurements and disclosures which requires the categorization by level for items that are only required to be disclosed at fair value and information about transfers between Level 1 and Level 2. In addition, the update provides guidance on measuring the fair value of financial instruments managed within a portfolio and the application of premiums and discounts on fair value measurements. The guidance requires additional disclosure for Level 3 measurements regarding the sensitivity of fair value to changes in unobservable inputs and any interrelationships between those inputs. The guidance is effective for our interim period ended April 30, 2012. The adoption of this guidance did not have a significant impact on our consolidated financial statements.



### Recently Issued Accounting Pronouncements

In June 2011, the FASB issued guidance regarding the presentation of Comprehensive Income within financial statements. The guidance is effective for annual periods beginning after December 15, 2011 and subsequent interim periods. We are currently evaluating the impact of this new accounting guidance on our consolidated financial statements.

### 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, and 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. 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 April 30, 2012, we had fixed rate debt totaling \$2,051,676. This amount consists of the following:

Loan Amount	Interest Rate per Annum	
\$ 604,323	6.75	%
1,447,353	10.00	%
\$ 2,051,676	Total	

These debt instruments mature from January 2013 through May 2015. 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 to which we would be subject to material market risks.

We have warrants outstanding with price protection provisions that allow for the reduction in the exercise price of the warrants in the event we subsequently issue common stock or securities convertible into or exercisable for common stock, such as options and warrants, at a price per share less than the warrant exercise price then in effect. In addition, with any reduction to the warrant exercise price, the number of shares of common stock that may be purchased upon exercise of each warrant will be increased proportionately, so that after such adjustment the aggregate warrant exercise price payable for the adjusted number of shares issuable upon exercise will be the same as the aggregate warrant exercise price in effect immediately prior to such adjustment. We account for the warrants with price protection in accordance with FASB ASC 815. We recognize the warrants with price protection in our consolidated balance sheet as liabilities. The warrant liability is revalued at each reporting period and changes in fair value are recognized currently in the consolidated statements of operations under the caption *Change in fair value of derivative warrant liability*. While the change in fair value of the derivative warrant liability has no effect on our cash flows, the gains or losses can have a significant impact on non-operating income and expenses and thus the net income or loss. As of April 30, 2012, there were 55,148,530 warrants outstanding subject to price protection provisions with an estimated fair value of \$4,603,470 or \$0.084 per warrant. If the estimated fair value of the warrants increases, there will be a corresponding non-operating expense equal to the change in the value of the liability. Likewise, if the estimated fair value of the warrants decreases, there will be a corresponding non-operating gain equal to the change in the value of the liability. There is a directly proportional relationship between the fair value of the warrants and the market price of the stock; therefore increases or decreases in the market price will lead to corresponding increases or decreases in the value of the warrant liability and result in losses or gains, respectively, on our consolidated statements of operations.

#### **Item 4. Controls and Procedures**

##### *Evaluation of Disclosure Controls and Procedures*

Prior to the filing of this Quarterly Report on Form 10-Q, an evaluation was performed under the supervision of and with the participation of GenereX's management, including the Chief Executive Officer ("CEO") and acting Chief Financial Officer ("CFO"), of the effectiveness of GenereX's disclosure controls and procedures. Based on the evaluation, the CEO and CFO have concluded that, as of April 30, 2012, GenereX's disclosure controls and procedures are effective to ensure that information required to be disclosed by GenereX in reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to GenereX's management, as appropriate, to allow timely decisions regarding required disclosure.

##### *Changes in Internal Control over Financial Reporting*

During the fiscal quarter ended April 30, 2012, there were no changes in GenereX's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, GenereX's internal control over financial reporting.

#### **PART II - OTHER INFORMATION**

##### **Item 1. Legal Proceedings.**

See *Note 7 – Pending Litigation* of the Notes to the Consolidated Financial Statements set forth under Item 1 of Part I of this Quarterly Report for a description of legal proceedings in which we are currently involved.

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

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

### **Item 1A. Risk Factors.**

In addition to the other information included in this Quarterly Report on Form 10-Q, you should carefully review and consider the factors discussed in *Part I, Item 1A - Risk Factors* of our Annual Report on Form 10-K for the year ended July 31, 2011, as amended, certain of which have been updated below. These factors materially affect our business, financial condition or future results of operations. The risks, uncertainties and other factors described in our Annual Report on Form 10-K and below are not the only ones facing our company. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations, financial condition or operating results. Any of the risks, uncertainties and other factors could cause the trading price of our common stock to decline substantially.

#### ***Risks Related to Our Financial Condition***

##### ***We will require additional financing to continue our operations.***

As of April 30, 2012, our current cash position is not sufficient to meet our working capital needs for the next twelve months. To continue operations, we will require additional funds to support our working capital requirements and any development activities, or will need to curtail our clinical trials and other planned activities or suspend operations. Management is seeking various alternatives to ensure that we can meet some of our operating cash flow requirements through financing activities, such as private placement of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. The securities purchase agreement that we entered into on January 31, 2012 with certain investors limits the financing activities that we may undertake in the near future as it prohibits us from (i) issuing additional equity securities until 60 days after the effective date of a registration statement covering the resale of the common stock issuable upon exercise of the warrants and conversion of the preferred stock sold in that transaction and (ii) issuing additional debt or equity securities with variable a conversion or exercise price until February 1, 2013. In addition, management is actively seeking strategic alternatives, including strategic investments and divestitures. Management has sold, and is also seeking further sales of, non-essential real estate assets which are classified as Assets Held for Investment to augment its cash position.

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

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

We are a development stage company with a limited history of operations, and do not expect sufficient revenues to support our operation in the immediately foreseeable future. We do not expect to receive significant revenues in Ecuador, Algeria and Lebanon where we have been approved for commercial sale in the next twelve months. While we have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor, we do not anticipate recognizing significant revenue from sales of Generex Oral-lyn™ in India in 2012, as we have to complete an in-country clinical study before the product can be offered for commercial sale in India.

To date, we have not been profitable and our accumulated net loss available to shareholders was \$356,035,942 at April 30, 2012. Our losses have resulted principally from costs incurred in research and development, including clinical trials, and from general and administrative costs associated with our operations. While we seek to attain profitability, we cannot be sure that we will ever achieve product and other revenue sufficient for us to attain this objective.

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

#### ***Risks Related to the Market for Our Common Stock***

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

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

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



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

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

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

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

The equity financing transactions into which we have recently entered have and will dilute current stockholders. At April 30, 2012, there were 55,148,530 shares of common stock issuable upon exercise of the warrants that we issued in a private placement in March 2008, in the registered direct offerings conducted in June, August and September 2009, in connection with the sales to Seaside 88, LP in April, May and June 2010, in the registered direct offering in January to April 2011 and in the registered direct offering in July 2011. In addition, in connection with the private placement that closed on February 1, 2012, an additional 13,333,333 shares of common stock are issuable upon conversion of the recently issued Series B 9% Convertible Preferred Stock, as well as 13,333,333 shares of common stock issuable upon exercise of the warrants in connection with such preferred stock. Together the shares of common stock issuable upon exercise or conversion of the above-mentioned warrants and preferred stock represent approximately 25% of the shares of common stock currently outstanding. Assuming the holders of the warrants convert and exercise all of the warrants into shares of common stock, the number of shares of issued and outstanding common stock will increase significantly, and current stockholders will own a smaller percentage of the outstanding common stock of Generex. The issuance of shares of common stock pursuant to the warrants will also have a dilutive effect on earnings per share and may adversely affect the market price of the common stock.

In addition, the issuance of shares of common stock upon exercise of the warrants issued in the March 2008 private placement, the registered direct offerings in June, August and September 2009 and in connection with the sales to Seaside in April, May and June 2010, in the registered direct offering in January to April 2011, in the registered direct offering in July 2011 and in the private placement in February 2012, could have an anti-takeover effect because such issuance will make it more difficult for, or discourage an attempt by, a party to obtain control of Generex by tender offer or other means. The issuance of common stock upon the exercise of the warrants will increase the number of shares entitled to vote, increase the number of votes required to approve a change of control of the company, and dilute the interest of a party attempting to obtain control of the company.

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

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

In the fiscal quarter ended April 30, 2012, we sold, or have entered into commitments to issue, common stock and other securities in transactions in reliance upon exemptions from the registration requirements of the Securities Act.

We have issued or committed to issue shares of our common stock to Seahawk Capital Partners, Inc, a consultant, pursuant to an agreement to provide us with investor relation services through September 30, 2012, as well as in relation to a finder's fee for our February 2012 Series B convertible preferred stock financing. During the three months ended April 30, 2012, we issued or committed to issue 450,000 shares of common stock to Seahawk Capital Partners pursuant to the consulting agreement and 1,066,667 shares as the finder's fee. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Seahawk Capital Partners is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock included a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

*Issuer Purchases of Equity Securities*

Neither Generex nor any affiliated purchaser (as defined in Section 240.10 b-18(a)(3) of the Exchange Act) purchased any of its equity securities during the fiscal quarter ended April 30, 2012.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 5. Other Information.**

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

**Item 6. Exhibits.**

Exhibits are incorporated herein by reference or are filed with this quarterly report as set forth in the Exhibit Index beginning on page 36 hereof.

## SIGNATURES

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

GENEREX BIOTECHNOLOGY CORPORATION  
(Registrant)

Date: June 11, 2012 By: /s/ Mark A. Fletcher  
Mark A. Fletcher  
President and Chief Executive Officer

Date: June 11, 2012 By: /s/ Stephen Fellows  
Stephen Fellows  
Acting Chief Financial Officer

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit<sup>(1)</sup></b>
1	Amendment dated as of April 7, 2010 to Placement Agent Agreement Placement Agency Agreement, dated June 8, 2009, by and between Generex Biotechnology Corporation and Midtown Partners & Co., LLC and amendments dated August 5, August 18, and September 11, 2009 (incorporated by reference to Exhibit 1.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on April 8, 2010)
2	Agreement and Plan of Merger among Generex Biotechnology Corporation, Antigen Express, Inc. and AGEXP Acquisition Inc. (incorporated by reference to Exhibit 2.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 15, 2003)
3(i)(a)	Restated Certificate of Incorporation of Generex Biotechnology Corporation (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Post-Effective Amendment No. 1 to the Registration Statement on Form S-8 filed on October 26, 2009)
3(i)(b)	Certificate of Designation of Preferences, Rights and Limitations of Series A 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
3(i)(c)	Certificate of Designation of Preferences, Rights and Limitations of Series B 9% Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Generex Biotechnology Corporation's Current Report on form 8-K filed on February 1, 2012)
3(ii)	Amended and Restated By-Laws of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3.2(ii) to Generex Biotechnology Corporation's Report on Form 8-K filed December 5, 2007)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Registration Statement on Form S-1 (File No. 333-82667) filed on July 12, 1999)
4.2.1	Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.2	Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.3	

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Form of Warrant granted to Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)

4.3 Form of replacement Warrant issued to warrant holders exercising at reduced exercise price in May and June 2003 (incorporated by reference to Exhibit 4.13.7 to Generex Biotechnology Corporation's Report on Form 10-K for the period ended July 31, 2003 filed on October 29, 2003)

4.4.1 Securities Purchase Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)

4.4.2 Registration Rights Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)

- 4.4.3 Form of Warrant issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
- 4.4.4 Form of Additional Investment Right issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)
  - Securities Purchase Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and
  - 4.5.1 ICN Capital Limited (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
    - Registration Rights Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and
    - 4.5.2 ICN Capital Limited (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
  - 4.5.3 Warrant issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
  - 4.5.4 Additional Investment Right issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
    - Securities Purchase Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and
    - 4.6.1 Vertical Ventures, LLC (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
      - Registration Rights Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and
      - 4.6.2 Vertical Ventures, LLC (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
    - 4.6.3 Warrant issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
    - 4.6.4 Additional Investment Right issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
      - Securities Purchase Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation
      - 4.7.1 and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
        - Registration Rights Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation
        - 4.7.2 and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.10 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
      - 4.7.3 Warrant issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.11 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
      - 4.7.4 Additional Investment Right issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.12 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
      - 4.7.5

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Escrow Agreement, dated February 26, 2004, by and among GenereX Biotechnology Corporation, Eckert Seamans Cherin & Mellott, LLC and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.13 to GenereX Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)

4.8.1 Securities Purchase Agreement, dated February 11, 2004, by and between GenereX Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.14 to GenereX Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)

4.8.2 Registration Rights Agreement, dated February 11, 2004, by and between GenereX Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.15 to GenereX Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)



- 4.8.3 Additional Investment Right issued in connection with Exhibit 4.8.1 (incorporated by reference to Exhibit 4.17 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
- 4.9.1 Securities Purchase Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.18 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
- 4.9.2 Registration Rights Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.19 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
- 4.9.3 Warrant issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
- 4.9.4 Additional Investment Right issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.21 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
- 4.10.1 Securities Purchase Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
- 4.10.2 Registration Rights Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
- 4.10.3 Form of Warrant issued in connection with Exhibit 4.10.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
- 4.10.4 Form of Additional Investment Right issued in connection with Exhibit 4.10.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
- 4.11.1 Securities Purchase Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
- 4.11.2 Form of 6% Secured Convertible Debenture issued in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
- 4.11.3 Registration Rights Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
- 4.11.4 Form of Voting Agreement entered into in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
- 4.12 Warrant issued to The Aethena Group, LLC on April 28, 2005 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)

- 4.13.1 Amendment No. 4 to Securities Purchase Agreement and Registration Rights Agreement entered into by and between Generex Biotechnology Corporation and the Purchasers listed on the signature pages thereto on January 19, 2006 (incorporated by reference herein to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
- 4.13.2 Form of Additional AIRs issued in connection with Exhibit 4.13.1 (incorporated by reference herein to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
- 4.14 Form of Warrant issued by Generex Biotechnology Corporation on January 23, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 24, 2006)
- 4.15.1 Agreement to Amend Warrants between Generex Biotechnology Corporation and Cranshire Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).

4.15.2 Agreement to Amend Warrants between Genorex Biotechnology Corporation and Omicron Master Trust dated February 27, 2006 (incorporated by reference to Exhibit 4.2 to Genorex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).

4.15.3 Agreement to Amend Warrants between Genorex Biotechnology Corporation and Iroquois Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.3 to Genorex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).

4.15.4 Agreement to Amend Warrants between Genorex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 27, 2006 (incorporated by reference to Exhibit 4.4 to Genorex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).

4.15.5 Form of Warrant issued by Genorex Biotechnology Corporation on February 27, 2006 (incorporated by reference to Exhibit 4.26 to Genorex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)

4.16.1 Agreement to Amend Additional Investment Right between Genorex Biotechnology Corporation and Cranshire Capital, L.P. dated February 28, 2006 (incorporated by reference to Exhibit 4.1 to Genorex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).

4.16.2 Agreement to Amend Additional Investment Right between Genorex Biotechnology Corporation and Omicron Master Trust dated February 28, 2006 (incorporated by reference to Exhibit 4.2 to Genorex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).

4.16.3 Agreement to Amend Additional Investment Right between Genorex Biotechnology Corporation and Iroquois Capital LP dated February 28, 2006 (incorporated by reference to Exhibit 4.3 to Genorex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).

4.16.4 Agreement to Amend Additional Investment Right between Genorex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 28, 2006 (incorporated by reference to Exhibit 4.4 to Genorex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).

4.16.5 Form of Additional AIR Debenture issued by Genorex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.31 to Genorex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)

4.16.6 Form of Additional AIR Warrant issued by Genorex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.32 to Genorex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)

4.17.1 Form of Agreement to Amend Warrants between Genorex Biotechnology Corporation and the Investors dated March 6, 2006 (incorporated by reference to Exhibit 4.1 to Genorex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006).

4.17.2 Form of Warrant issued by Genorex Biotechnology Corporation on March 6, 2006 (incorporated by reference to Exhibit 4.2 to Genorex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006)

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Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.33 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006)

4.19 Form of Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to certain employees (incorporated by reference to Exhibit 4.34 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006).

4.20.1 Securities Purchase Agreement entered into by and between Generex Biotechnology Corporation and four Investors on June 1, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)

4.20.2 Form of Warrant issued by Generex Biotechnology Corporation on June 1, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)

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

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

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- 4.25.1 Form of Securities Purchase Agreement, dated August 6, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
- 4.25.2 Form of Warrant issued in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
- 4.25.3 Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.28 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
- 4.26.1 Form of Securities Purchase Agreement, dated September 11, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)

- 4.26.2 Form of Warrant issued in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
- 4.26.3 Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
- 4.27.1 Common Stock Purchase Agreement dated April 7, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
- 4.27.2 First Amendment to Common Stock Purchase Agreement dated April 28, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 29, 2010)
- 4.27.3 Form of Warrant issued to Midtown Partners & Co., LLC in connection with the Placement Agency Agreement and in connection with Exhibit 4.27.1 hereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
- 4.28.1 Form of Securities Purchase Agreement, dated January 24, 2011, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 25, 2011)
- 4.28.2 Form of Warrant issued in connection with Exhibit 4.28.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 25, 2011)
- 4.28.3 Amendment to Purchase Agreement dated March 25, 2011 (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on March 30, 2011).
- 4.28.4 Second Amendment to Purchase Agreement dated April 13, 2011 (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on April 14, 2011).
- 4.29.1 Form of Securities Purchase Agreement, dated July 8, 2011, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
- 4.29.2 Form of Common Stock Warrant issued in connection with Exhibit 4.29.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on July 11, 2011).
- 4.30.1 Form of Securities Purchase Agreement, dated January 31, 2012, by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on February 1, 2012).
- 4.30.2 Form of Common Stock Warrant issued in connection with Exhibit 4.30.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 1, 2012).
- 4.30.3 Form of Registration Rights Agreement by and among Generex Biotechnology Corporation and the purchaser(s) listed on the signature pages thereto (incorporated by reference to Exhibit 4.3 to Generex

Biotechnology Corporation's Report on Form 8-K filed on February 1, 2012)

- 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.

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