GENEREX BIOTECHNOLOGY CORP
Form 10-Q
December 10, 2010

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

FORM 10-Q

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

For the quarterly period ended October 31, 2010

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 0-25169

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

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

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

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

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

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

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

Large accelerated filer ¨ Accelerated filer 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 274,748,993 as of December 8, 2010.

GENEREX BIOTECHNOLOGY CORPORATION

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	October 31, 2010 (Unaudited)	July 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,596,871	$ 13,880,870
Accounts receivable, net	95,161	70,585
Inventory (see Note 5)	1,762,901	1,911,883
Other current assets	453,917	333,456
Total Current Assets	9,908,850	16,196,794
Property and Equipment, Net	1,360,588	1,341,408
Assets Held for Investment, Net	3,513,759	3,503,110
Patents, Net	3,477,228	3,533,688
TOTAL ASSETS	$ 18,260,425	$ 24,575,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses (see Note 6)	$ 6,166,898	$ 6,554,714
Deferred revenue	387,351	396,195
Current maturities of long-term debt	1,158,065	1,141,861
Current maturities of obligations under capital lease	—	7,818
Total Current Liabilities	7,712,314	8,100,588
Long-Term Debt, Net	1,818,163	1,824,071
Derivative Warrant Liability (see Note 11)	4,810,189	5,679,721
Total Liabilities	14,340,666	15,604,380
Commitments and Contingencies (see Notes 7 and 8)		
Stockholders' Equity (see Note 10):		
Preferred Stock, $.001 par value; authorized 1,000,000 shares at October 31, 2010 and July 31, 2010; -0- shares issued and outstanding at October 31, 2010 and July 31, 2010	—	—
Common stock, $.001 par value; authorized 750,000,000 shares at October 31, 2010 and July 31, 2010; 274,538,494 and 269,599,615 shares issued and outstanding at October 31, 2010 and July 31, 2010, respectively	274,538	269,600
Additional paid-in capital	335,021,183	333,219,309
Deficit accumulated during the development stage	(332,179,739)	(325,302,472)

Accumulated other comprehensive income		803,777		784,183
Total Stockholders' Equity		3,919,759		8,970,620
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$	18,260,425	$	24,575,000

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

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

	For the Three Months Ended October 31, 2010 (Unaudited)	2009 (Unaudited)	Cumulative From November 2, 1995 (Date of Inception) to October 31, 2010 (Unaudited)
Revenues, net	$ 173,943	$ 97,542	$ 4,964,448
Cost of Goods Sold	64,112	79,237	1,517,759
Gross Profit	109,831	18,305	3,446,689
Operating Expenses:			
Research and development	2,878,000	3,075,769	119,616,331
Research and development - related party	—	—	220,218
Selling and marketing	404,487	1,298,704	8,546,752
General and administrative	4,601,164	3,825,265	134,121,221
General and administrative - related party	—	—	314,328
Total Operating Expenses	7,883,651	8,199,738	262,818,850
Operating Loss	(7,773,820)	(8,181,433)	(259,372,161)
Other Income (Expense):			
Miscellaneous income	—	500	197,011
Income from rental operations, net	74,330	84,593	1,852,913
Interest income	3,231	10,085	7,777,150
Interest expense	(50,540)	(52,401)	(68,257,791)
Change in fair value of derivative warrant liability	869,532	2,996,271	(985,921)(1)
Loss on extinguishment of debt	—	—	(14,134,068)
Net Loss Before Undernoted	(6,877,267)	(5,142,385)	(332,922,867)
Minority Interest Share of Loss	—	—	3,038,185
Net Loss	(6,877,267)	(5,142,385)	(329,884,682)
Preferred Stock Dividend	—	—	2,295,057
Net Loss Available to Common Stockholders	$ (6,877,267)	$ (5,142,385)	$ (332,179,739)
Basic and Diluted Net Loss Per Common Share (see Note 9)	$ (0.03)	$ (0.02)	
Weighted Average Number of Shares of Common Stock Outstanding - basic and diluted (Note 9)	270,553,982	233,991,319	

(1) - includes $5,981,403 as adjustment related to the adoption of FASB ASC Topic 815 in "Cumulative from November 2, 1995 (Date of Inception) to October 31, 2010" column. See Note 11 - Derivative Warrant Liability.

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

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

	For the Three Months Ended October 31,		Cumulative From November 2, 1995 (Date of Inception) to October 31,
	2010 (Unaudited)	2009 (Unaudited)	2010 (Unaudited)
Cash Flows From Operating Activities:			
Net loss	$ (6,877,267)	$ (5,142,385)	$ (329,884,682)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	186,492	199,702	8,739,413
Minority interest share of loss	--	--	(3,038,185)
Reduction of notes receivable - common stock in exchange for services rendered	--	--	423,882
Write-off of uncollectible notes receivable - common stock	--	--	391,103
Write-off of deferred offering costs	--	--	3,406,196
Write-off of abandoned patents	--	--	913,196
Loss on disposal of property and equipment	--	--	911
Loss on extinguishment of debt	--	--	14,134,069
Common stock issued as employee compensation	25,250	28,986	3,805,645
Amortization of options and option modifications as stock compensation	72,438	884,653	1,944,815
Common stock issued for services rendered	1,486,704	639,224	13,304,533
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 as interest payment on convertible debentures	--	--	757,514
Interest on short-term advance	--	--	22,190
Founders' shares transferred for services rendered	--	--	353,506
Fees in connection with refinancing of debt	--	--	113,274
Warrant repricing costs	--	--	3,198,604
Change in fair value of derivative warrant liability	(869,532)	(2,996,271)	985,921(1)
Changes in operating assets and liabilities (excluding the effects of acquisition):			
Accounts receivable	(24,469)	(26,542)	(110,186)

Miscellaneous receivables	--	--	43,812
Inventory	150,442	(145,862)	(1,783,809)
Other current assets	(117,692)	(238,187)	(437,757)
Accounts payable and accrued expenses	(181,097)	1,168,647	14,250,339
Deferred revenue	(9,056)	(33,702)	381,823
Other, net	--	--	110,317
Net Cash Used in Operating Activities	(6,157,787)	(5,661,737)	(197,781,838)
Cash Flows From Investing Activities:			
Purchase of property and equipment	(51,703)	(132,646)	(4,806,343)
Costs incurred for patents	(47,032)	(42,237)	(2,478,319)
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 Used in Investing Activities	(98,735)	(174,883)	(10,723,929)
Cash Flows From Financing Activities:			
Proceeds from short-term advance	--	--	325,179
Repayment of short-term advance	--	--	(347,369)
Proceeds from issuance of long-term debt	--	--	2,005,609
Repayment of long-term debt	(27,654)	(23,492)	(2,152,210)
Repayment of obligations under capital lease	(7,818)	(10,403)	(83,002)
Change in due to related parties	--	--	154,541
Proceeds from exercise of warrants	--	1,517,940	45,698,281
Proceeds from exercise of stock options	--	--	5,001,916
Proceeds from minority interest investment	--	--	3,038,185
Proceeds from issuance of preferred stock	--	--	12,015,000
Redemption of SVR preferred stock	--	--	(100)
Proceeds from issuance of convertible debentures, net	--	--	40,704,930
Payment of costs associated with convertible debentures	--	--	(722,750)
Repayments of convertible debentures	--	--	(5,142,424)
Purchase of treasury stock	--	--	(483,869)
Proceeds from issuance of common stock, net	--	16,400,671	116,637,242
Purchase and retirement of common stock	--	--	(497,522)
Net Cash (Used in)/Provided by Financing Activities	(35,472)	17,884,716	216,151,637
Effect of Exchange Rates on Cash	7,995	16,996	(48,999)
Net (Decrease)/Increase in Cash and Cash Equivalents	(6,283,999)	12,065,092	7,596,871
Cash and Cash Equivalents, Beginning of Period	13,880,870	14,197,048	--
Cash and Cash Equivalents, End of Period	$ 7,596,871	$ 26,262,140	$ 7,596,871

(1) includes $5,981,403 as adjustment related to the adoption of FASB ASC Topic 815 in "Cumulative from
- November 2, 1995 (Date of Inception) to October 31, 2010" column. See Note 11 - Derivative Warrant Liability.

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 financial statements and notes thereto included in the Company's latest Annual Report on Form 10-K. The results for the three months ended October 31, 2010 may not be indicative of the results for the entire year.

Interim statements are subject to possible adjustments in connection with the annual audit of the Company's accounts for the fiscal year 2011. In the Company's opinion, all adjustments necessary for a fair presentation of these interim statements have been included and are of a normal and recurring nature.

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

Going Concern

The accompanying unaudited interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has experienced negative cash flows from operations since inception and had an accumulated deficit at October 31, 2010 of approximately $332 million. The Company has funded its activities to date almost exclusively from debt and equity financings.

The Company will continue to require substantial funds to continue research and development, including preclinical studies and clinical trials of its product candidates, and to support sales and marketing efforts, if the U.S. Food and Drug Administration ("FDA") or other regulatory approvals are obtained. Management's plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings and issuance of debt and convertible debt instruments. Management is also actively pursuing industry collaboration activities including product licensing and specific project financing.

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

2. Effects of Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board ("FASB") issued guidance on multiple deliverable revenue arrangements which eliminates the residual method of allocation and requires the relative selling price method when

allocating deliverables of a multiple-deliverable revenue arrangement. The determination of the selling price for each deliverable requires the use of a hierarchy designed to maximize the use of available objective evidence including, vendor specific objective evidence, third party evidence of selling price, or estimated selling price. This guidance is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, and must be adopted in the same period using the same transition method. If adoption is elected in a period other than the beginning of a fiscal year, the amendments in these standards must be applied retrospectively to the beginning of the fiscal year. This guidance was effective for the Company's current fiscal year beginning August 1, 2010. The adoption of this guidance did not have a significant impact on the Company's interim statements.

Recently Issued 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 is effective for any fiscal year that begins after December 15, 2010, and it should be used for quarterly and annual filings. We are currently evaluating the impact of this new accounting guidance on our consolidated financial statements.

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

3. Stock-Based Compensation

As of October 31, 2010, the Company had three stockholder-approved stock incentive plans under which shares and options exercisable for shares of common stock have been or may be granted to employees, directors, consultants and advisors. A total of 2,000,000 shares of common stock are reserved for issuance under the 2000 Stock Option Plan (the "2000 Plan"), a total of 12,000,000 shares of common stock are reserved for issuance under the 2001 Stock Option Plan (the "2001 Plan") and 30,000,000 shares of common stock are reserved for issuance under the 2006 Stock Plan (the "2006 Plan"). Restricted shares can only be issued under the 2006 Plan. At October 31, 2010, there were 2,000,000, 4,048,490 and 18,302,523 shares of common stock reserved for future awards under the 2000 Plan, 2001 Plan and 2006 Plan, respectively.

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

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

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

In the case of restricted stock grants under the 2006 Plan, fair market value of the shares is 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 three months ended October 31, 2010:

	Options	Weighted Average Exercise Price Share	Aggregate Intrinsic Value
Outstanding, August 1, 2010	7,465,638	$ 0.49	
Granted	—	—	
Forfeited or expired	(166,667)	0.64	
Exercised	—	—	

Outstanding, October 31, 2010	7,298,971	$	0.48	$ 770,886
Exercisable, October 31, 2010	6,241,051	$	0.46	$ 770,886

The 7,298,971 outstanding options at October 31, 2010 had a weighted average remaining contractual term of 5.12 years.

Grant Date Fair Value of Options Granted	$	n/a
Grant Date Fair Value of Options Forfeited or Expired	$	0.58
Total Intrinsic Value of Options Exercised	$	n/a

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

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

	Options	Weighted Average Grant Date Fair Value
Outstanding, August 1, 2010	2,021,669	$ 0.53
Granted	—	—
Vested	(797,082)	0.55
Forfeited	(166,667)	0.58
Outstanding, October 31, 2010	1,057,920	$ 0.51

As of October 31, 2010, the Company had $419,919 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 2.3 years.

4. Comprehensive Loss

Comprehensive loss, which includes net loss and the change in the foreign currency translation account, for the three months ended October 31, 2010 and 2009, was $6,857,673 and $5,103,555, respectively.

5. Inventory

Inventory consists of the following:

	October 31, 2010	July 31, 2010
Raw materials	$ 960,143	$ 962,035
Finished goods	802,758	949,848
Total	$ 1,762,901	$ 1,911,883

At October 31 and July 31, 2010, approximately 59% and 60%, respectively, of the inventory related to the Company's Oral-lyn™ product, while the remainder in each period related to the Company's over-the-counter confectionary products.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	October 31, 2010	July 31, 2010
Accounts Payable & Accruals – General and Administrative	$ 4,107,628	$ 3,480,340
Accounts Payable & Accruals – Research and Development	1,579,410	2,621,514
Accounts Payable & Accruals – Selling and Marketing	329,489	415,166
Executive Compensation	150,371	37,694
Total	$ 6,166,898	$ 6,554,714

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.

GENEREX BIOTECHNOLOGY CORPORATION AND SUBSIDIARIES
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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On April 6, 2010, the Company commenced legal proceedings against TheStreet.com, Inc. and Adam Feuerstein in the Supreme Court of the State of New York (New York, NY) seeking $250,000,000 in damages for business defamation, product disparagement, and injurious falsehood. The claims arise out of articles authored by Mr. Feuerstein and published on TheStreet.com website on March 19 and March 26, 2010. In the complaint, the Company contends that the articles disseminate numerous defamatory statements about the Company, its management, and its flagship product, Generex Oral-lyn™, and that the articles put forward several ostensible statements of fact that are, in truth, misleading or outright misstatements made with malicious intent or with a reckless disregard for the truth. Defendants have filed an answer denying the claims in the complaint and have served discovery requests on the Company. 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 damages recovered, 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-aventis"). Under this agreement, sanofi-aventis will manufacture and supply recombinant human insulin to the Company in the territories specified in the agreement. Through this agreement, the Company will procure recombinant human insulin crystals for use in the production of Generex Oral-lyn™. The terms of the supply agreement require the Company to make certain minimum purchases of insulin from sanofi-aventis through the period ending December 31, 2011.

On October 8, 2010, the Company entered into a purchase agreement with Global Medical Direct, LLC, a Kansas limited liability company ("GMD"), and all of the members of GMD, pursuant to which Generex will acquire fifty-one percent (51%) of the issued and outstanding equity interests of GMD. Pursuant to the terms of the purchase agreement, Generex has agreed to pay to the members of GMD an aggregate amount of (i) $20,000,000 in cash and (ii) $5,000,000 payable in shares of restricted common stock of Generex, subject to the terms and conditions of the purchase agreement. The closing is subject to the satisfaction or waiver of certain conditions, including Generex having secured the acquisition financing, the parties agreeing upon the amended terms of an operating agreement for GMD, the parties entering into a registration rights agreement with respect to the registration of the shares of Generex common stock issued as consideration and other customary closing conditions. The purchase agreement contains certain termination rights of the parties, including the right of any party to terminate the purchase agreement if the parties cannot reach agreement on employment and consulting agreements and the amendment of the operating agreement of GMD and if the closing has not occurred by January 31, 2011 or such later date as the parties may agree upon.

9. Net Loss Per Share

Basic earnings per share ("EPS") and Diluted EPS for the three-month periods ended October 31, 2010 and 2009 have been computed by dividing the net loss available to common stockholders for each respective period by the weighted

average shares outstanding during that period. All outstanding stock options, non-vested restricted stock and warrants, representing approximately 43,725,716 and 49,049,654 incremental shares, have been excluded from the October 31, 2010 and 2009 computations of Diluted EPS as they are anti-dilutive, due to the losses generated during the respective periods.

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

10. Stockholders' Equity

During the three months ended October 31, 2010, the Company issued 3,348,144 shares of common stock to various consultants for services rendered in the amount of $1,486,704. The shares were valued at $0.36 to $0.45 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the three months ended October 31, 2010, the Company issued 532,389 shares of common stock to various vendors as satisfaction of accounts payable and accrued expenses in the amount of $222,421. The shares were valued at $0.36 to $0.49 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

During the three months ended October 31, 2010, the Company issued 60,228 shares of common stock valued at $25,250 as employee compensation. The shares were valued at $0.36 to $0.50 per share based on the quoted market price of the Company's common stock on the dates of the issuances.

Stock option expense related to employee options granted in October 2009, resulting in a charge to operations during the three month period ended October 31, 2010 of $24,766. Stock option expense related to executive options granted in March 2010 resulted in a charge to operations during the three-month period ended October 31, 2010 of $47,672.

During the three months ended October 31, 2010, the Company issued 998,118 shares of common stock in conjunction with cashless exercises of 1,000,000 warrants.

The following is a summary of warrants issued, forfeited or expired and exercised for the three months ended October 31, 2010:

	Warrants
Outstanding, August 1, 2010	37,426,745
Issued	—
Forfeited or expired	—
Exercised	(1,000,000)
Outstanding, October 31, 2010	36,426,745

The outstanding warrants at October 31, 2010 have a weighted average exercise price of $0.62 per share.

Certain of the warrants above have been reclassified from equity to liability in accordance with FASB Accounting Standards Codification ("ASC") 815 and are not included in stockholders' equity. The Company has 13,931,027 warrants with a current exercise price of $0.33 and an expiry date of March 31, 2016 and 2,572,313 warrants with a current exercise price of $0.33 and an expiry date of September 30, 2016 (16,503,340 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 certain securities will not trigger the price protection provisions of these warrants described above. These "excluded" issuances include the Company's issuance of: (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 Warrant Shares; 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).

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

The Company accounts for the warrants with price protection provisions in accordance with FASB ASC Topic 815 as described in Note 11 - Derivative Warrant Liability below. As of October 31, 2010, there were a total of 16,503,340 warrants with an estimated fair value of $4,810,189 which are identified on the balance sheet under the caption “Derivative Warrant Liability”.

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

	Common Stock		Additional Paid-In	Total Stockholders’
	Shares	Amount	Capital	Equity
Issuance of common stock for services	3,348,144	$ 3,348	$ 1,483,355	$ 1,486,703
Issuance of common stock as employee compensation	60,228	60	25,190	25,250
Stock-based executive compensation	—	—	47,672	47,672
Issuance of common stock as satisfaction of accounts payable and accrued expenses	532,389	533	221,889	222,422
Issuance of common stock in conjunction with cashless exercise of warrants	998,118	998	(998)	—
Amortization of stock options as employee compensation	—	—	24,766	24,766
Total	4,938,879	$ 4,939	$ 1,801,874	$ 1,806,813

11. 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. As of August 1, 2009, the Company accounted for its warrants with price protection in accordance with FASB ASC Topic 815.

Accounting for Derivative Warrant Liability

The Company’s derivative warrant instruments have been measured at fair value at October 31 and July 31, 2010 using the binomial lattice model. The Company recognizes all of its warrants with price protection in its consolidated balance sheets as liabilities. 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.

The derivative warrants outstanding at October 31, 2010 are all currently exercisable with a weighted-average remaining life of 5.50 years.

The revaluation of the warrants at each reporting period resulted in the recognition of income of $869,532 and $2,996,271 within the Company's consolidated statements of operations for the quarters ended October 31, 2010 and 2009, respectively, under the caption "Change in fair value of derivative warrant liability". The fair values of the warrants at October 31, 2010 and July 31, 2010 were $4,810,189 and $5,679,721, respectively which are reported on the consolidated balance sheet under the caption "Derivative Warrant Liability". The following summarizes the changes in the value of the derivative warrant liability from the date of the Company's adoption of the provisions of FASB ASC Topic 815 on August 1, 2009 until October 31, 2010:

Balance at August 1, 2009– Derivative warrant liability	$ 19,825,865
Exercise of warrants classified as derivative warrant liabilities	(10,020,554)
Decrease in fair value of derivative warrant liability	(4,125,590)
Balance at July 31, 2010 – Derivative warrant liability	5,679,721
Exercise of warrants classified as derivative warrant liabilities	-0-
Decrease in fair value of derivative warrant liability	(869,532)
Balance at October 31, 2010 – Derivative warrant liability	$ 4,810,189

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

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 used the Black-Scholes pricing model to calculate the fair value at the date of adoption and for the first, second and third quarters of the fiscal year ended July 31, 2010. This model was used because of its wide acceptance by the investment community, relative simplicity and its emphasis on observable inputs. Key assumptions used in the Black-Scholes fair value calculation were as follows:

	April 30, 2010	January 31, 2010	October 31, 2009	August 1, 2009
Expected term (years)	5.92	6.17	6.42	6.67
Volatility	99.5%	98.5%	98.0%	96.9%
Risk-free interest rate	0.21%	0.16%	0.16%	0.16%
Dividend yield	-0-	-0-	-0-	-0-

In the fourth quarter ended July 31, 2010, the Company determined that due to the existence of the price protection provisions, the binomial lattice model valuation method would likely provide a better estimate of the fair value of these warrants. We engaged a valuation firm to estimate the fair value of these warrants using the binomial lattice model.

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 July 31 and October 31, 2010 fair value calculations were as follows:

	October 31, 2010	July 31, 2010
Current exercise price	$ 0.33	$ 0.33
Time to expiration (years)	5.49	5.75
Risk-free interest rate	1.35%	1.87%
Estimated volatility	105%	104%
Dividend yield	-0-	-0-
Current stock price	$ 0.344	$ 0.40

In accordance with the provisions of FASB ASC Topic 250 (Accounting Changes and Error Corrections) as they pertain to a change in accounting estimate due to a change in valuation technique, the binomial lattice valuation method has been applied on a prospective basis beginning in the fourth quarter of our fiscal year ended July 31, 2010.

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

10

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-month periods ended October 31, 2010 and 2009. 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, 2010, 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 October 31, 2010.

Forward-Looking Statements

We have made statements in this Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Quarterly Report on Form 10-Q of Generex Biotechnology Corporation for the fiscal quarter ended October 31, 2010 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 volatility of, and recent decline in, our stock price;
- our recent delisting from NASDAQ for failure to satisfy the minimum bid price requirement; and
- our ability to obtain the necessary financing to fund our operations.

Additional factors that could affect future results are set forth in Part I, Item 1A Risk Factors of our Annual Report on Form 10-K for the year ended July 31, 2010, 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, development and commercialization of drug delivery systems and technologies. Our primary focus at the present time is our proprietary technology for the administration of formulations of large molecule drugs to the oral (buccal) cavity using a hand-held aerosol applicator. Through our wholly-owned subsidiary, Antigen Express, Inc., we have expanded our focus to include immunomedicines incorporating proprietary vaccine formulations.

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

Generex Oral-lyn™

Regulatory Approvals and Clinical Trials

To date, we have received regulatory approval in Ecuador, India, Lebanon and Algeria for the commercial marketing and sale of Generex Oral-lyn™, although as per the terms and conditions of the regulatory approval in India, a local clinical study must be conducted before the product can be offered for commercial sale in that country.

In March 2008, we initiated Phase III clinical trials for this product in the U.S. with the first patient screening for such trials at a clinical study site in Texas. The patient screening at other participating clinical sites in the U.S. and Canada is ongoing. To date, over 450 patients have been enrolled in 70 clinical sites around the world, including sites in the United States, Canada, Ecuador, Bulgaria, Poland, Romania, Russia and Ukraine.

In November 2008, we submitted our product dossier to the Ministry of Health in Damascus, Syria through Generex MENA, our branch office in Dubai. The dossier includes Generex Oral-lyn™. We also submitted a file to register our proprietary over-the-counter products, including Glucose RapidSpray™, 7-Day Diet Aid Spray™ (marketed as Crave-Nx™ in the United States and Canada) and BaBOOM!™ Energy Spray. The Syrian Ministry of Health has reviewed the dossier for Generex Oral-lyn™ and has approved a four month in-country clinical trial, for which patient recruitment has commenced and which trial is expected to begin early in calendar year 2011. Upon successful completion of this trial, we anticipate that regulatory approval will follow shortly thereafter. We do not anticipate significant revenues to be recognized from this approval in the 2011 fiscal year.

We have also submitted regulatory dossiers for Generex Oral-lyn™ in a number of other countries including Bangladesh, Kenya, Yemen, Iraq, Iran, Libya and Sudan. While we believe these countries will ultimately approve our product for commercial sale, it could be some time before these approvals are received and as such we do not anticipate recognizing any revenues for these jurisdictions until the latter part of the 2011 calendar year, at the earliest.

Special Access Programs

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

life-threatening or otherwise serious conditions.

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

Marketing

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, including:

- Shreya Life Sciences Pvt. Ltd. for India, Pakistan, Bangladesh, Nepal, Bhutan, Sri Lanka, and Myanmar;
- Adcock Ingram Limited and Adcock Ingram Healthcare (Pty) Ltd. for South Africa, Lesotho, Swaziland, Botswana, Namibia, Mozambique and Zimbabwe;

- E&V Alca Distribution Corp. for Albania, Montenegro, and Kosovo;
- Medrey S.A.L. (formerly MedGen Corp.) and Benta S.A.L. for Lebanon;
- SciGen, Ltd. for China, Hong Kong, Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam;
- Pharmaris Perus S.A.C. for Peru;
- MediPharma SA for Argentina
- PMG S.A. for Chile; and
- Dong Sung Pharm. Co. Ltd. for South Korea.

In August 2008, we entered into a product licensing and distribution agreement with Dong Sung Pharm Co. Ltd. for the importation, marketing, distribution and sale of Generex Oral-lyn™ in South Korea. Under the seven-year agreement, Dong-Sung will have an exclusive license. Per the terms of the agreement, they paid us a USD $500,000 non-refundable license fee upon execution and will pay us a USD $500,000 non-refundable license fee at such time as governmental approval for the importation, marketing, distribution and sale of the product in South Korea is obtained. Under this agreement, we are responsible for procuring such governmental approval. In addition, when it places its first purchase order, Dong-Sung will make a pre-payment to us in the amount of USD $500,000, which will be applied against product purchase orders.

Our Generex MENA office, located in Dubai Healthcare City, has filed submissions of the Generex Oral-Lyn™ dossier with regulatory agencies throughout the Middle East and North Africa and has established a distribution network in over 20 countries. This distribution network is responsible for following up with dossiers submitted in their specific regions and has also been actively purchasing and distributing the company's confectionary line of products.

In India, a marketing plan has already been submitted by Shreya Life Sciences Pvt. Ltd., to Generex on the marketing strategy for the distribution of Oral Recosulin™, which is the trademark under which Shreya will market Generex Oral-lyn™ within India. 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.

Over-The-Counter Glucose Product Line

Using our buccal delivery technology, we have also launched a line of over-the-counter glucose and energy sprays , including Glucose RapidSpray™, a fat-free, low-calorie glucose formulation, Crave-NX™ 7-day Diet Aid Spray, a fat-free glucose spray to aid in dieting, and BaBOOM!™ Energy Spray, a flavored glucose "energy" spray supplemented with vitamins. We believe these products will complement Generex Oral-lyn™ and may provide us with an additional revenue stream prior to the commercialization of Generex Oral-lyn™ in other major jurisdictions. To date, we have received modest revenues from sales of these products. All three products are available in retail stores and independent pharmacies in the United States and Canada. In addition, the products are being distributed in the Middle East through our Generex MENA office in Dubai. We expect other distribution territories for these products to include South Africa, India, South America and other jurisdictions worldwide. We are currently pursuing European registrations for these products.

Other Product Candidates

In October 2008, we announced the enrollment of subjects in our bioequivalence clinical trial of MetControl™, our proprietary Metformin medicinal chewing gum product, conducted in the United States. Fertin Pharma A/S, a leading Danish manufacturer of medicinal chewing gum, produced clinical materials for the trial. The protocol for the study is an open-label, two-treatment, two-period, randomized, crossover study comparing MetControl™ and immediate release Metformin™ tablets in healthy volunteers. The study results that we received and analyzed in December 2008 demonstrated bioequivalence and will allow us to proceed with additional research and developmental initiatives and to consider regulatory agency registration applications. We are compiling the data from this study and may run

similar studies, which will allow us to file a marketing application with various global regulatory agencies, including the United States, in the latter part of the 2011 calendar year.

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

Competition

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

Brief Company Background

We are a development stage company. From inception through the end of the fiscal quarter ended October 31, 2010, we have received only limited revenues from operations. In the first quarter of fiscal 2011 and cumulatively since inception in November 1995, we have received $173,943 and $4,964,448, respectively in revenue. This revenue has been comprised mainly of the sale of our confectionary products, although we have recognized $600,000 relating to upfront license fees for the signing of license and distribution agreements for Generex Oral-lyn™. These numbers do not reflect deferred sales to customers during the respective periods with the right of return.

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

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

Accounting for Research and Development Projects

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

During the first quarter of the current fiscal year and during the last fiscal year, we expended resources on the clinical testing and commercialization, of our buccal insulin product, Generex Oral-lyn™. In July 2007, we received no objection from the FDA to proceed with our long-term multi-center Phase III study protocol for Generex Oral-lyn™, which study is ongoing. 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.

While Generex Oral-lyn™ has received regulatory approval in Ecuador, India (subject to the completion of an in-country study), Lebanon and Algeria, we have not recognized any revenue from sales of Generex Oral-lyn™ in Ecuador, India or Algeria to date and only modest revenues in Lebanon. We do not expect that the near-term revenues from the sales of Generex Oral-lyn™ in the countries where we currently have regulatory approval will be sufficient to sustain our research and development and regulatory activities.

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

During the first quarter 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. Preliminary pre-clinical work has commenced with respect to the experimental vaccine for patients with acute myeloid leukemia at Beijing Daopei Hospital in China.

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

Most of our buccal delivery research and development activities to date have involved developing our platform technology for use with insulin. Insubstantial amounts have been expended on projects with other drugs, including morphine and fentanyl, and those projects involved a substantial amount of platform technology development. As a result, we have not made significant distinctions in the accounting for research and development expenses among products, as a significant portion of all research has involved improvements to the platform technology in connection with insulin, which may benefit all of our potential buccal products. During the three months ended October 31, 2010, approximately 82% of our total $2,878,000 in research expenses was attributable to insulin and platform technology development, and we did not have any research expenses related to morphine, fentanyl or other buccal projects. During the three months ended October 31, 2009, approximately 85% of our $3,075,769 in research expenses was attributable to insulin and platform technology development, and we did not have any research expenses related to morphine, fentanyl or other buccal projects.

Approximately 18%, or $505,696, of our research and development expenses for the three months ended October 31, 2010 was related to Antigen's immunomedicine products compared to approximately 15%, or $446,346, of our research and development expenses for the three months ended October 31, 2009. Because these products are in initial phases of clinical trials or early, pre-clinical stage of development (with the exception of the Phase II clinical trials of Antigen HER-2/neu positive breast cancer vaccine that are underway), all of the expenses were accounted for as basic research and no distinctions were made as to particular products. Due to the early stage of development, we cannot predict the timing of completion of any products arising from this technology, or when products from this technology might begin producing revenues.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements which have been prepared in conformity with accounting principles generally accepted in the United States of America. 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 accompanying financial statements, we have not been profitable and have reported recurring losses from operations. These factors raise substantial doubt about our ability to continue to operate in the normal course of business. The accompanying financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Revenue Recognition. Net sales of Glucose RapidSpray™, BaBOOM!™ Energy Spray and Crave-NX™ 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 sheet as of July 31, 2010 and October 31, 2010, 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. Prior to the adoption of the binomial lattice method, we used the Black-Scholes option-pricing model to estimate the fair value of these warrants. The binomial lattice model was adopted as management determined that it may provide a better estimate of the fair value of these warrants. The binomial lattice model was adopted for the July 31, 2010 valuation date and was applied on a prospective basis.

Results of Operations
Three Months Ended October 31, 2010 Compared to Three Months Ended October 31, 2009

Our net loss for the quarter ended October 31, 2010 was $6,877,267 versus $5,142,385 in the corresponding quarter of the prior fiscal year. The increase in net loss in this fiscal quarter versus the corresponding quarter of the prior fiscal year is primarily due to the gain on revaluation of the derivative warrant liability in the current year's quarter of only $869,532 versus a gain of $2,996,271 in the corresponding prior year quarter. The increase in net loss for the current year's quarter was offset by a decrease in operating loss due to decreases in our selling and marketing expenses and research and development expenses versus the comparative prior year quarter, which were partially offset by an increase in general and administrative expenses. Our operating loss for the quarter ended October 31, 2010 decreased to $7,773,820 compared to $8,181,433 in the first fiscal quarter of 2010. The decrease in operating loss resulted from a decrease in selling expense (to $404,487 from $1,298,704) and a decrease in research and development expenses (to $2,878,000 from $3,075,769), offset by an increase in general and administrative expenses (to $4,601,164 from $3,825,265). Our revenues in the quarter ended October 31, 2010 increased to $173,943 from $97,542 for the quarter ended October 31, 2009 reflecting primarily the sales of our over-the-counter products.

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 timing differences related to the clinical costs associated with the global Phase III clinical trials of our oral insulin product and platform technology, as well as the timing of earlier stage (pre-clinical, Phase I and Phase II) clinical trials related to the Antigen immunotherapy products versus the previous fiscal year's quarter. Generally, costs relating to the Phase III oral insulin clinical studies have been decreasing as we progress closer to the conclusion of the study, while costs relating to the Antigen Phase II breast cancer trials are increasing as we progress further in to the studies and enroll more patients. The increase in general and administrative expenses is primarily related to an increase in financial services and consulting expenses in the quarter ended October 31, 2010, as compared to the previous year quarter ended October 31, 2009. The decrease in selling expenses for the quarter ended October 31, 2010 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 quarter of fiscal 2011 decreased to $50,540, compared to interest expense of $52,401 in the first quarter of fiscal 2010. Our interest income decreased slightly to $3,231 in the first quarter of fiscal 2011, compared to $10,085 in the same quarter for the last year, due to lower average cash balances. We received a slightly lower income from rental operations (net of expense) of $74,330 in the first quarter of fiscal 2011 compared to $84,593 in the same quarter of the previous fiscal year. The change in fair value of the warrants carried as a derivative liability contributed a gain of $869,532 in the current quarter, compared to a gain of $2,996,271 in the comparable quarter last year.

Financial Condition, Liquidity and Resources

Sources of Liquidity

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

As of October 31, 2010, we expect that our current cash position will not be sufficient to meet our working capital needs for the next twelve months based on the pace of our planned activities. Therefore, we will require additional funds to support our working capital requirements and any expansion or other activities, or will need to significantly reduce our clinical trials and other planned activities.

While we have financed our development stage activities to date primarily through private placements of our common stock and securities convertible into our common stock and while we raised over $36 million during fiscal 2010 and the fourth quarter of fiscal 2009 combined, our cash balances were very low during portions of fiscal 2009. Unforeseen problems with our clinical program, manufacturing and commercialization plans in Ecuador and India, volatility or a significant decline in our stock price following our delisting from NASDAQ, or further negative developments in general economic conditions could interfere with our ability to raise additional equity capital as needed, or materially adversely affect the terms upon which such capital is available. Our inability to obtain required funding will have a material adverse effect on one or more of our research or development programs and curtail some of our commercialization efforts.

Management may seek to meet all or some of our operating cash flow requirements through financing activities, such as private placement of our common stock, at-market stock issuance programs, preferred stock offerings and offerings of debt and convertible debt instruments, as well as through merger or acquisition opportunities. On January 29, 2010, we filed a new shelf registration statement (File No. 333-164591) with the Securities and Exchange Commission ("SEC") to renew and replace the prior shelf registration statement (File No. 333-139637), filed in December 2006, pursuant to which we registered an indeterminate number of shares of common stock and preferred stock and an indeterminate number of warrants and units with an aggregate initial offering price of up to $150,000,000. The new shelf registration statement is intended to renew and replace the prior registration statement. The new registration statement was declared effective on February 9, 2010 and covers offerings of shares of our common stock, preferred stock, warrants and/or units with a maximum aggregate offering price of $150,000,000, which includes the $116,110,920 of securities remaining unsold under the prior registration statement. In May, June, August and September 2009, we conducted offerings pursuant to the prior registration statement and raised an aggregate of $32,335,164 in net proceeds. In April, May and June 2010, we raised a further $4,499,618 in net proceeds pursuant to a common stock purchase agreement with takedowns from the new shelf registration statement.

In addition, management is actively pursuing industry collaboration activities, including product licensing, specific project financing, and potential strategic partners in the consumer market for diabetes-related products.

We believe that our current progress in the Phase III clinical trial trials for Oral-lyn™ in the United States and Canada represents a significant milestone event. We also anticipate that the commercial launch of Oral-lyn™ in countries where it has been approved may provide us with revenue in 2011. 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, and to commence sales and marketing efforts if the FDA or other regulatory approvals are obtained.

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 and the sales to Seaside 88, LP in April, May and June 2010, 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.

As of December 10, 2010, all of the warrants issued in the June, August and September 2009 registered direct offerings were exercisable. At December 10, 2010, outstanding warrants issued in connection with the June, August and September 2009 registered direct offerings and April, May and June 2010 sales to Seaside were as follows:

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

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 and then to $0.33 as a result of a price protection provision triggered by our offering of stock in a private placement in May 2009. 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 December 10, 2010, outstanding Series Warrants were as follows:

Date Issued	Aggregate No. of Shares Unexercised	Exercise Price*	Expiration Date
March 31, 2008	13,931,027	$ 0.33	March 31, 2016
March 31, 2008	2,572,313	$ 0.33	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 Three Months Ended October 31, 2010

For the three months ended October 31, 2010, we used $6,157,787 in cash to fund our operating activities. The use for operating activities included a net loss of $6,877,267, an increase of $24,469 in accounts receivable, an increase in other current assets of $117,692, a decrease of $9,056 in deferred revenue and a decrease of $181,097 related to accounts payable and accrued expenses, offset by a decrease of $150,442 in inventory.

The use of cash was offset by non-cash expenses of $186,492 related to depreciation and amortization, $72,438 in stock-based compensation to employees and $1,511,954 in stock and warrant-based compensation issued in exchange for services rendered by consultants. There was also a year-to-date non-cash gain of $869,532 related to the fair valuation of the derivative warrant liability at October 31, 2010.

We had net cash outflows from investing activities of $98,735 in the three months ended October 31, 2010, representing payments for property and equipment of $51,703 and costs incurred for patents of $47,032.

We had cash outflows from financing activities in the three months ended October 31, 2010 of $35,472, which pertained to principal payments related to our capital leases in the amount of $7,818 and long-term debt in the amount of $27,654. There were no cash inflows related to issuances of common stock or warrant exercises during the three months ended October 31, 2010.

Our net working capital at October 31, 2010 decreased to $2,196,536 from $8,096,206 at July 31, 2010, which was attributed largely to our net loss for the three-month period ended October 31, 2010.

Funding Requirements and Commitments

We expect to devote substantial resources to obtaining regulatory approval of Generex Oral-lyn™ in the U.S., Canada and Europe and to commercializing Generex Oral-lyn™ in India, Lebanon, Ecuador and Algeria. We also will devote resources to obtaining approval for the importation, marketing and commercialization of Generex Oral-lyn™ in other countries where we have licensed distributors.

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 require us to make certain minimum purchases of insulin from sanofi-aventis through the period ended December 31, 2011. Sanofi-aventis will be our exclusive supplier in certain countries and a non-exclusive supplier 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.

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.

We also will require funding to complete our acquisition of a majority interest in Global Medical Direct, LLC (“GMD”), durable medical equipment and pharmaceutical provider specializing in direct-to-consumer diabetes supplies and medications. Pursuant to the Limited Liability Company Ownership Interest Purchase Agreement dated as of October 8, 2010 (the “Purchase Agreement”) that we entered into with GMD and all of the members of GMD, we agreed to pay to the members of GMD an aggregate amount of (i) $20,000,000 in cash and (ii) $5,000,000 payable in shares of restricted common stock, calculated based on the value weighted average closing prices per share of our common stock on the then principal trading market for each of the last 20 trading days prior to the closing date, subject to the terms and conditions of the Purchase Agreement. The consummation of the transactions contemplated by the Purchase Agreement is subject to the satisfaction or waiver of closing conditions, including our having secured the acquisition financing, the parties agreeing upon the amended terms of the operating agreement for GMD, the parties entering into a registration rights agreement with respect to the registration of the shares of our common stock issued as consideration, and other customary closing conditions. The Purchase Agreement contains certain termination rights of the parties, including the right of any party to terminate the Purchase Agreement if the parties cannot reach agreement on employment and consulting agreements and the amendment of the operating agreement of GMD and if the closing has not occurred by January 31, 2011 or such later date as the parties may agree upon.

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 timing, receipt and amount of sales, if any, from our over-the-counter products;
- the cost of manufacturing (paid to third parties) of our licensed products, and the cost of marketing and sales activities of those products;
- the costs of prosecuting, maintaining, and enforcing patent claims, if any claims are made;
- our ability to maintain existing collaborative relationships and establish new relationships as we advance our products in development; and
- the receptivity of the financial market to biopharmaceutical companies.

Off-Balance Sheet Arrangements

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

Certain Related Party Transactions

We utilize a management company to manage all of our real properties. The property management company is owned by Ms. Perri, Ms. Gluskin, a director and former Chief Executive Officer and President, and the estate of Mark Perri, a former Chairman of the Board. In the three month period ended October 31, 2010 and the fiscal year ended July 31, 2010, we paid the management company approximately $14,407 and $55,691, respectively, in management fees. We believe that the amounts paid to the management company approximate the rates that would be charged by a non-affiliated property management company.

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, 2010, as amended, for further descriptions of our transactions with related parties during the last fiscal year.

Recently Adopted Accounting Pronouncements

In October 2009, the FASB issued guidance related to revenue recognition with multiple deliverable revenue arrangements. This guidance eliminates the residual method of allocation and requires the relative selling price method when allocating deliverables of a multiple-deliverable revenue arrangement. The determination of the selling price for each deliverable requires the use of a hierarchy designed to maximize the use of available objective evidence including, vendor specific objective evidence, third party evidence of selling price, or estimated selling price. This guidance is effective on a prospective basis for revenue arrangements entered into or materially modified in our fiscal year beginning August 1, 2010. The adoption of this guidance did not have a significant impact on our consolidated financial statements.

Recently Issued 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 is effective for any fiscal year that begins after December 15, 2010, and it should be used for quarterly and annual filings. 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 October 31, 2010, we had fixed rate debt totaling $2,976,228. This amount consists of the following:

	Loan Amount	Interest Rate per Annum
$	1,100,796	5.91%
	627,896	6.75%
	670,001	6.82%
	392,600	8.50%
	184,935	10.00%
$	2,976,228	Total

These debt instruments mature from June 2011 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 and as 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 October 31, 2010, there were 16,503,340 warrants outstanding subject to price protection provisions with an estimated fair value of $4,810,189 or $0.291 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 Interim Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of Generex's disclosure controls and procedures. Based on the evaluation, the CEO and CFO have concluded that, as of October 31, 2010, Generex's disclosure controls and procedures are effective to ensure that information required to be disclosed by Generex in reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to Generex's management, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended October 31, 2010, 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, 2010, certain of which have been updated below. These factors materially affect our business, financial condition or future results of operations. The risks, uncertainties and other factors described in our Annual Report on Form 10-K and below are not the only ones facing our company. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations, financial condition or operating results. Any of the risks, uncertainties and other factors could cause the trading price of our common stock to decline substantially.

Risks Related to Our Financial Condition

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

We are a development stage company with a limited history of operations, and do not expect sufficient revenues to support our operation in the immediately foreseeable future. In the three months ended October 31, 2010, we received revenues of $173,943 which were primarily from sales of our over-the-counter confectionary products. In the fiscal year ended July 31, 2010, we received modest revenues of approximately $1,172,611 which were also primarily from sales of our over-the-counter confectionary products. We have not recognized any revenue from the sale of our oral insulin product in Ecuador, Algeria or India to date, including during the first three months of fiscal 2011, although we have recognized $600,000 in licensing fee revenue relating to the signing of licensing and distribution agreements for the sale of Generex Oral-lyn™. We do not expect to receive any revenues in Ecuador until we enter into a definitive manufacturing and distribution agreement with our business partner there. While we have entered into a licensing and distribution agreement with a leading Indian-based pharmaceutical company and insulin distributor, we do not anticipate recognizing revenue from sales of Generex Oral-lyn™ in India until at least the latter part of calendar year 2011, as we have to complete an in-country clinical study before the product can be offered for commercial sale in India. We have entered in to a subdistribution agreement in Lebanon, but do not expect any significant revenue from the launch of the product in that country in fiscal year 2011.

To date, we have not been profitable and our accumulated net loss available to shareholders was $332,179,739 at October 31, 2010. 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, and our over-the-counter glucose and energy spray products, Glucose RapidSpray™, BaBOOM!™ Energy Spray and Crave-NX™, our product candidates are in research or early stages of pre-clinical and clinical development. We will need to conduct substantial additional research, development and clinical trials. We will also need to receive necessary regulatory clearances both in the United States and foreign countries and obtain meaningful patent protection for and establish freedom to commercialize each of our product candidates. We must also complete further clinical trials and seek regulatory approvals for Generex Oral-lyn™ in countries outside of Ecuador, India, Lebanon and Algeria. We cannot be sure that we will obtain required regulatory approvals, or successfully research, develop, commercialize, manufacture and market any other product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses for the foreseeable future.

Risks Related to the Market for Our Common Stock

If our common stock becomes subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

Following the delisting of our common stock by the NASDAQ Stock Market, if, at any time, we have net tangible assets of $5,000,000 or less and our common stock has a market price per share of less than $5.00, transactions in our common stock will be subject to the SEC's "penny stock" rules. If our common stock becomes subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected.

Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser's written agreement to the transaction prior to sale;
- provide the purchaser with risk disclosure documents which identify certain risks associated with investing in "penny stocks" and which describe the market for these "penny stocks" as well as a purchaser's legal remedies; and
- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a "penny stock" can be completed.

As a result, if our common stock becomes subject to the penny stock rules, the market price of our securities may be depressed, and you may find it more difficult to sell our securities.

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 possible quarterly fluctuations in our financial results, 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. Currently approximately 35,609,513 shares of common stock are 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 and in connection with the sales to Seaside 88, LP in April, May and June 2010, which represents approximately 13% 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 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 need the funds. This will dilute existing holders more than if our stock price was higher. In addition, equity financings normally involve shares sold at a discount to the current market price.

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

In the fiscal quarter ended October 31, 2010, we sold common stock and other securities in transactions in reliance upon exemptions from the registration requirements of the Securities Act.

During the three months ended October 31, 2010, we issued 12,000 shares of common stock to American Capital Ventures, Inc. pursuant to an agreement with us for financial services. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that American Capital Ventures, Inc. is an “accredited investor” as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

During the three months ended October 31, 2010, we issued 150,000 shares of our restricted common stock as partial consideration for the provision of services by Dr. Craig Eagle under a consulting agreement with us. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Dr. Eagle is an “accredited investor” as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

During the three months ended October 31, 2010, we issued 300,000 shares of our restricted common stock as partial consideration for the financial services provided to us by Moscato Marsh & Partners, Inc. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Moscato Marsh & Partners, Inc. is an “accredited investor” as that term is defined in Rule 501(a) of Regulation D under the

Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

During the three months ended October 31, 2010, we issued 73,000 shares of our restricted common stock as partial consideration for the financial services provided to us by Market Update Network Corp. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Market Update Network Corp. is an “accredited investor” as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

We have issued shares of our common stock to Seahawk Capital Partners, Inc, a consultant, pursuant to an agreement to provide us with investor relation services through October 11, 2010. During the three months ended October 31, 2010, we issued 120,000 shares of common stock to Seahawk Capital Partners pursuant to this agreement. We also have issued shares of our common stock to Seahawk Capital Partners pursuant to a new agreement to provide us with investor relation services through September 30, 2011. During the three months ended October 31, 2010, we issued 2,650,000 shares of common stock to Seahawk Capital Partners pursuant to this agreement. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Seahawk Capital Partners is an “accredited investor” as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock included a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

We have issued shares of our common stock to Beckerman Public Relations, a consultant, pursuant to an agreement to provide us with investor relation services. During the three months ended October 31, 2010, we issued 43,144 shares of common stock to Beckerman Public Relations. The sale of such shares was exempt from registration under the Securities Act in reliance upon Section 4(2) thereof. We believe that Beckerman Public Relations is an "accredited investor" as that term is defined in Rule 501(a) of Regulation D under the Securities Act. The certificates issued for the shares of common stock will include a legend to indicate that they are restricted. The sales of such securities did not involve the use of underwriters, and no commissions were paid in connection therewith.

Issuer Purchases of Equity Securities

Neither Generex nor any affiliated purchaser (as defined in Section 240.10 b-18(a)(3) of the Exchange Act) purchased any of its equity securities during the fiscal quarter ended October 31, 2010.

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 27 hereof.

SIGNATURES

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

GENEREX BIOTECHNOLOGY CORPORATION
(Registrant)

Date: December 10, 2010	By:	/s/ Mark A. Fletcher Mark A. Fletcher Interim President and Chief Executive Officer
Date: December 10, 2010	By:	/s/ Rose C. Perri Rose C. Perri Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description of Exhibit(1)
1	Amendment dated as of April 7, 2010 to Placement Agent Agreement Placement Agency Agreement, dated June 8, 2009, by and between Generex Biotechnology Corporation and Midtown Partners & Co., LLC and amendments dated August 5, August 18, and September 11, 2009 (incorporated by reference to Exhibit 1.2 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on April 8, 2010)
2	Agreement and Plan of Merger among Generex Biotechnology Corporation, Antigen Express, Inc. and AGEXP Acquisition Inc. (incorporated by reference to Exhibit 2.1 to Generex Biotechnology Corporation's Current Report on Form 8-K filed on August 15, 2003)
3(i)	Restated Certificate of Incorporation of Generex Biotechnology Corporation (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Post-Effective Amendment No. 1 to the Registration Statement on Form S-8 filed on October 26, 2009)
3(ii)	Amended and Restated By-Laws of Generex Biotechnology Corporation (incorporated by reference to Exhibit 3.2(ii) to Generex Biotechnology Corporation's Report on Form 8-K filed December 5, 2007)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Registration Statement on Form S-1 (File No. 333-82667) filed on July 12, 1999)
4.2.1	Form of Securities Purchase Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.2	Form of Registration Rights Agreement entered into with Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.2.3	Form of Warrant granted to Cranshire Capital, L.P.; Gryphon Partners, L.P.; Langley Partners, L.P.; Lakeshore Capital, Ltd.; LH Financial; Omicron Capital; Photon Fund, Ltd.; Howard Todd Horberg and Vertical Ventures, LLC dated May 29, 2003 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 10-Q/A for the quarter ended October 31, 2003 filed on August 13, 2003)
4.3	Form of replacement Warrant issued to warrant holders exercising at reduced exercise price in May and June 2003 (incorporated by reference to Exhibit 4.13.7 to Generex Biotechnology Corporation's Report on Form 10-K for the period ended July 31, 2003 filed on October 29, 2003)
4.4.1	Securities Purchase Agreement, dated December 19, 2003, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex

Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)

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

4.4.3 Form of Warrant issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)

4.4.4 Form of Additional Investment Right issued in connection with Exhibit 4.4.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K/A filed on March 24, 2004)

4.5.1 Securities Purchase Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)

4.5.2	Registration Rights Agreement, dated January 7, 2004, by and between Generex Biotechnology Corporation and ICN Capital Limited (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.3	Warrant issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.5.4	Additional Investment Right issued in connection with Exhibit 4.5.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.1	Securities Purchase Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.2	Registration Rights Agreement, dated January 9, 2004, by and between Generex Biotechnology Corporation and Vertical Ventures, LLC (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.3	Warrant issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.6.4	Additional Investment Right issued in connection with Exhibit 4.6.1 (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.1	Securities Purchase Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.2	Registration Rights Agreement, dated February 6, 2004, by and between Generex Biotechnology Corporation and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.10 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.3	Warrant issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.11 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.4	Additional Investment Right issued in connection with Exhibit 4.7.1 (incorporated by reference to Exhibit 4.12 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.7.5	Escrow Agreement, dated February 26, 2004, by and among Generex Biotechnology Corporation, Eckert Seamans Cherin & Mellott, LLC and Alexandra Global Master Fund, Ltd. (incorporated by reference to Exhibit 4.13 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.1	Securities Purchase Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.14 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.8.2	Registration Rights Agreement, dated February 11, 2004, by and between Generex Biotechnology Corporation and Michael Sourlis (incorporated by reference to Exhibit 4.15 to Generex Biotechnology

Corporation's Report on Form 8-K filed on March 1, 2004)

4.8.3 Additional Investment Right issued in connection with Exhibit 4.8.1 (incorporated by reference to Exhibit 4.17 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)

4.9.1 Securities Purchase Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.18 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)

4.9.2 Registration Rights Agreement, dated February 13, 2004, by and between Generex Biotechnology Corporation and Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.19 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)

4.9.3	Warrant issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.9.4	Additional Investment Right issued in connection with Exhibit 4.9.1 (incorporated by reference to Exhibit 4.21 Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2004)
4.10.1	Securities Purchase Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.2	Registration Rights Agreement, dated June 23, 2004, by and among Generex Biotechnology Corporation and the investors (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.3	Form of Warrant issued in connection with Exhibit 4.10.1 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.10.4	Form of Additional Investment Right issued in connection Exhibit 4.10.1 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on July 14, 2004)
4.11.1	Securities Purchase Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.2	Form of 6% Secured Convertible Debenture issued in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.3	Registration Rights Agreement, dated November 10, 2004, by and among Generex Biotechnology Corporation and the investors named therein (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.11.4	Form of Voting Agreement entered into in connection with Exhibit 4.11.1 (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on November 12, 2004)
4.12	Warrant issued to The Aethena Group, LLC on April 28, 2005 (incorporated by reference to Exhibit 4.20 to Generex Biotechnology Corporation's Quarterly Report on Form 10-Q filed on June 14, 2005)
4.13.1	Amendment No. 4 to Securities Purchase Agreement and Registration Rights Agreement entered into by and between Generex Biotechnology Corporation and the Purchasers listed on the signature pages thereto on January 19, 2006 (incorporated by reference herein to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
4.13.2	Form of Additional AIRs issued in connection with Exhibit 4.13.1 (incorporated by reference herein to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 20, 2006)
4.14	Form of Warrant issued by Generex Biotechnology Corporation on January 23, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on January 24, 2006)

4.15.1	Agreement to Amend Warrants between Generex Biotechnology Corporation and Cranshire Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.2	Agreement to Amend Warrants between Generex Biotechnology Corporation and Omicron Master Trust dated February 27, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.3	Agreement to Amend Warrants between Generex Biotechnology Corporation and Iroquois Capital L.P. dated February 27, 2006 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).
4.15.4	Agreement to Amend Warrants between Generex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 27, 2006 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on February 28, 2006).

4.15.5	Form of Warrant issued by Generex Biotechnology Corporation on February 27, 2006 (incorporated by reference to Exhibit 4.26 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
4.16.1	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Cranshire Capital, L.P. dated February 28, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.2	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Omicron Master Trust dated February 28, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.3	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Iroquois Capital LP dated February 28, 2006 (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.4	Agreement to Amend Additional Investment Right between Generex Biotechnology Corporation and Smithfield Fiduciary LLC dated February 28, 2006 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 1, 2006).
4.16.5	Form of Additional AIR Debenture issued by Generex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.31 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
4.16.6	Form of Additional AIR Warrant issued by Generex Biotechnology Corporation on February 28, 2006 (incorporated by reference to Exhibit 4.32 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 16, 2006)
4.17.1	Form of Agreement to Amend Warrants between Generex Biotechnology Corporation and the Investors dated March 6, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006).
4.17.2	Form of Warrant issued by Generex Biotechnology Corporation on March 6, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on March 7, 2006)
4.18	Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to Zapfe Holdings, Inc. (incorporated by reference to Exhibit 4.33 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006)
4.19	Form of Warrant issued by Generex Biotechnology Corporation on April 17, 2006 to certain employees (incorporated by reference to Exhibit 4.34 to Generex Biotechnology Corporation's Report on Form 10-Q filed on June 14, 2006).
4.20.1	Securities Purchase Agreement entered into by and between Generex Biotechnology Corporation and four Investors on June 1, 2006 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)
4.20.2	Form of Warrant issued by Generex Biotechnology Corporation on June 1, 2006 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2,

2006)

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

4.21.2 Form of Warrant issued by Generex Biotechnology Corporation on June 1, 2006 in connection with Exhibit 4.39 (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 2, 2006)

4.22.1 Securities Purchase Agreement, dated as of March 31, 2008 among the Registrant and each of the purchasers named therein (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)

4.22.2 Form of 8% Secured Convertible Note, as amended (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Registration Statement (333-150562) on Form S-3 filed on October 31, 2008)

4.22.3 Form of Series A Warrant, as amended (incorporated by reference to Exhibit 4.3 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)

4.22.4	Form of Series A-1 Warrant, as amended (incorporated by reference to Exhibit 4.4 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)
4.22.5	Form of Series B Warrant, as amended (incorporated by reference to Exhibit 4.5 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)
4.22.6	Form of Series C Warrant, as amended (incorporated by reference to Exhibit 4.6 to Generex Biotechnology Corporation's Registration Statement on Form S-3 (333-150562) filed on October 31, 2008)
4.22.7	Registration Rights Agreement, dated March 31, 2008, among Registrant and each of the purchasers under Securities Purchase Agreement (incorporated by reference to Exhibit 4.7 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.8	Security Agreement (incorporated by reference to Exhibit 4.8 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.22.9	Form of Guaranty (incorporated by reference to Exhibit 4.9 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 2, 2008)
4.23.1	Form of Securities Purchase Agreement, dated May 15, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 1.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on May 18, 2009)
4.24.1	Form of Securities Purchase Agreement, dated June 15, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.24.2	Form of Warrant issued in connection with Exhibit 4.24.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.24.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.24.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on June 16, 2009)
4.25.1	Form of Securities Purchase Agreement, dated August 6, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.25.2	Form of Warrant issued in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.25.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.25.1 (incorporated by reference to Exhibit 4.28 to Generex Biotechnology Corporation's Report on Form 8-K filed on August 6, 2009)
4.26.1	

	Form of Securities Purchase Agreement, dated September 11, 2009, entered into between Generex Biotechnology Corporation and each investor in the offering (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.2	Form of Warrant issued in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.26.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with Exhibit 4.26.1 (incorporated by reference to Exhibit 4.2 to Generex Biotechnology Corporation's Report on Form 8-K filed on September 15, 2009)
4.27.1	Common Stock Purchase Agreement dated April 7, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
4.27.2	First Amendment to Common Stock Purchase Agreement dated April 28, 2010 by and between Generex Biotechnology Corporation and Seaside 88, LP. (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 29, 2010)

4.27.3	Form of Warrant issued to Midtown Partners & Co., LLC in connection with the Placement Agency Agreement and in connection with Exhibit 4.27.1 hereto (incorporated by reference to Exhibit 4.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on April 8, 2010)
10.1	Summary of Compensation Arrangements with Executive Officers
10.2	Amendment to the Employment Terms for Mark A. Fletcher, dated September 29, 2010 (incorporated by reference to Exhibit 10.46 to Generex Biotechnology Corporation's Report on Form 10-K filed on October 14, 2010)
10.3	Limited Liability Company Ownership Interest Purchase Agreement by and among Generex Biotechnology Corporation, Global Medical Direct, LLC and Joseph Corso, Jr., Robert S. Shea and Mark Franz (incorporated by reference to Exhibit 10.1 to Generex Biotechnology Corporation's Report on Form 8-K filed on October 12, 2010)
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.