



NORTHWEST BIOTHERAPEUTICS INC

FORM 10-Q

(Quarterly Report)

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

FORM 10-Q

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

For the quarterly period ended September 30, 2012

OR

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

For the transition period from ____ to ____

Commission file number 000-33393

Northwest Biotherapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware

94-3306718

(State or other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

4800 Montgomery Lane, Suite 800
Bethesda, Maryland 20814

20814
(Zip Code)

(Address of Principal Executive Offices)

(240) 497-9024

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒
(do not check if a smaller reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes ☐ No ☒

As of November 13, 2012, the total number of shares of common stock, par value \$0.001 per share, outstanding was 13,342,041.

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Part I - Financial Information

NORTHWEST BIOTHERAPEUTICS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 111	\$ 24
Prepaid expenses and other current assets	186	94
Total current assets	<u>297</u>	<u>118</u>
Property and equipment:		
Laboratory equipment	60	29
Office furniture and other equipment	171	172
	<u>231</u>	<u>201</u>
Less accumulated depreciation and amortization	(133)	(123)
Property and equipment, net	98	78
Deposit and other non-current assets	33	16
Total assets	<u>\$ 428</u>	<u>\$ 212</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable (includes related party of \$4,503 and \$1,589 in 2012 and 2011, respectively)	\$ 8,173	\$ 3,808
Accrued expenses (includes related party of \$5,844 and \$630 in 2012 and 2011, respectively)	8,186	2,815
Notes payable (includes related party of \$2,177 and \$2,056 in 2012 and 2011, respectively)	4,662	5,205
Convertible notes, net (includes related party of \$6,382 and \$3,588 in 2012 and 2011, respectively)	15,114	8,420
Embedded derivative liability	18	601
Liability for reclassified equity contracts	-	29,903
Total current liabilities	<u>36,153</u>	<u>50,752</u>
Long term liabilities:		
Notes payable	100	200
Convertible notes payable, net	2,279	1,433
Total long term liabilities	<u>2,379</u>	<u>1,633</u>
Total liabilities	<u>38,532</u>	<u>52,385</u>
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 40,000,000 shares authorized and none issued and outstanding		
Common stock, \$0.001 par value; 450,000,000 and 150,000,000 shares authorized, and 11,827,595 and 9,334,101 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	194	150
Additional paid-in capital	250,467	199,605
Deficit accumulated during the development stage	(288,575)	(251,778)
Cumulative translation adjustment	(190)	(150)
Total stockholders' equity (deficit)	<u>(38,104)</u>	<u>(52,173)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 428</u>	<u>\$ 212</u>

See accompanying notes to the condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from March 18 1996 (Inception) to September 30, 2012
	2012	2011	2012	2011	
Revenues:					
Research material sales	\$ -	\$ 10	\$ -	\$ 10	\$ 580
Contract research and development from related parties	-	-	-	-	1,128
Research grants and other	120	-	450	-	1,511
Total revenues	120	10	450	10	3,219
Operating cost and expenses:					
Cost of research material sales	-	-	-	-	382
Research and development	9,944	3,565	20,533	11,474	110,828
General and administration	3,913	2,804	8,152	10,675	83,445
Depreciation and amortization	5	2	10	6	2,372
Loss on facility sublease	-	-	-	-	895
Asset impairment loss and other (gain) loss	-	-	-	-	2,445
Total operating costs and expenses	13,862	6,371	28,695	22,155	200,367
Loss from operations	(13,742)	(6,361)	(28,245)	(22,145)	(197,149)
Other income (expense):					
Valuation of reclassified equity instruments	-	8,875	491	7,413	16,071
Conversion inducement expense	-	-	-	(125)	(18,234)
Derivative valuation gain/(loss)	35	338	583	29	1,366
Gain on sale of intellectual property and property and equipment	-	-	-	-	3,664
Interest expense	(2,788)	(2,370)	(9,626)	(5,426)	(51,190)
Interest income and other	-	-	-	-	1,707
Net income (loss)	(16,495)	482	(36,797)	(20,254)	(243,765)
Issuance of common stock in connection with elimination of Series A and Series A-1 preferred stock preferences	-	-	-	-	(12,349)
Modification of Series A preferred stock warrants	-	-	-	-	(2,306)
Modification of Series A-1 preferred stock warrants	-	-	-	-	(16,393)
Series A preferred stock dividends	-	-	-	-	(334)
Series A-1 preferred stock dividends	-	-	-	-	(917)
Warrants issued on Series A and Series A-1 preferred stock dividends	-	-	-	-	(4,664)
Accretion of Series A preferred stock mandatory redemption obligation	-	-	-	-	(1,872)
Series A preferred stock redemption fee	-	-	-	-	(1,700)
Beneficial conversion feature of Series D preferred stock	-	-	-	-	(4,274)
Net income (loss) applicable to common stockholders	<u>\$ (16,495)</u>	<u>\$ 482</u>	<u>\$ (36,797)</u>	<u>\$ (20,254)</u>	<u>(288,575)</u>
Net income (loss) per share applicable to common stockholders - basic	<u>\$ (1.50)</u>	<u>\$ 0.08</u>	<u>\$ (3.59)</u>	<u>\$ (3.78)</u>	
Weighted average shares used computing basic income (loss) per share	<u>11,029</u>	<u>5,945</u>	<u>10,258</u>	<u>5,355</u>	
Net income (loss) per share applicable to common stockholders - diluted	<u>\$ (1.50)</u>	<u>\$ 0.06</u>	<u>\$ (3.59)</u>	<u>\$ (3.78)</u>	
Weighted average shares used computing diluted income (loss) per share	<u>11,029</u>	<u>7,696</u>	<u>10,258</u>	<u>5,355</u>	

See accompanying notes to the condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/LOSS
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from March 18, 1996 (Inception) to September 30,
	2012	2011	2012	2011	2012
Net income (loss)	\$ (16,495)	\$ 482	\$ (36,797)	\$ (20,254)	\$ (243,765)
Other comprehensive loss					
Foreign currency translation adjustment	-	79	(40)	(44)	(190)
Total comprehensive income (loss)	<u>\$ (16,495)</u>	<u>\$ 561</u>	<u>\$ (36,837)</u>	<u>\$ (20,298)</u>	<u>\$ (243,955)</u>

See accompanying notes to the condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)
(Unaudited)

	Nine Months Ended September 30, 2012
Common stock:	
Balance, beginning of the period	\$ 150
Notes payable conversions / stock issuances for cash and services	44
Balance, end of the period	<u>\$ 194</u>
Additional paid-in-capital:	
Balance, beginning of the period	\$ 199,605
Stock issuances for cash	1,479
Notes payable conversions	7,797
Modifications / reclassifications of equity instruments	29,412
Stock based compensation	2,574
Debt discounts/beneficial conversion features of securities	7,885
Stock issuance for services	1,715
Balance, end of the period	<u>\$ 250,467</u>
Deficit accumulated during development stage:	
Balance, beginning of the period	\$ (251,778)
Net loss	(36,797)
Balance, end of the period	<u>\$ (288,575)</u>
Cumulative translation adjustment:	
Balance, beginning of the period	\$ (150)
Foreign currency translation adjustment	(40)
Balance, end of the period	<u>\$ (190)</u>
Total stockholders' equity (deficit)	<u>\$ (38,104)</u>

See accompanying notes to the condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(Unaudited)

	Nine Months Ended September 30,		Period from March 18, 1996 (Inception) to September 30,
	2012	2011	2012
Cash Flows from Operating Activities:			
Net Loss	\$ (36,797)	\$ (20,254)	\$ (243,765)
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization	10	6	2,373
Amortization of deferred financing costs	-	-	320
Amortization debt discount	8,692	4,058	38,917
Derivative valuation (gain) loss	(583)	(29)	(1,365)
Accrued interest converted to stock	-	-	260
Accreted interest on convertible promissory note	-	-	1,484
Stock-based compensation costs	2,574	7,354	22,433
Stock and warrants issued for services and other expenses	1,714	3,470	21,983
Loan conversion inducement	-	125	10,415
Valuation of reclassified equity contracts	(491)	(7,413)	(16,070)
Asset impairment loss and loss (gain) on sale of properties	-	-	(936)
Loss on facility sublease	-	-	895
Increase (decrease) in cash resulting from changes in assets and liabilities:			
Prepaid expenses and other current assets	(92)	(84)	524
Accounts payable and accrued expenses	10,485	2,615	30,700
Deposits and other non-current assets	(17)	-	(17)
Accrued loss on sublease	-	-	(265)
Deferred rent	-	-	410
Net Cash used in Operating Activities	(14,505)	(10,152)	(131,705)
Cash Flows from Investing Activities:			
Purchase of property and equipment, net	(31)	(31)	(5,124)
Proceeds from sale of property and equipment	-	-	258
Proceeds from sale of intellectual property	-	-	1,816
Proceeds from sale of marketable securities	-	-	2,000
Refund of security deposit	-	-	(3)
Transfer of restricted cash	-	-	(1,035)
Net Cash used in Investing Activities	(31)	(31)	(2,088)
Cash Flows from Financing Activities:			
Proceeds from issuance of notes payable	-	6,272	19,230
Proceeds from issuance of convertible notes payable	13,181	500	38,414
Repayment of note payable to related parties	-	-	(8,050)
Repayment of convertible promissory note	-	-	(1,069)
Borrowing under line of credit, Northwest Hospital	-	(399)	2,834
Repayment of line of credit, Northwest Hospital	-	-	(2,834)
Payment on capital lease obligations	-	-	(323)
Payments on note payable	-	-	(420)
Proceeds from issuance preferred stock, net	-	-	28,708
Proceeds from exercise of stock options and warrants	-	-	228
Proceeds from issuance common stock, net	1,482	5,340	60,557
Proceeds from sale of stock warrant	-	4	90
Payment of preferred stock dividends	-	-	(1,251)
Series A preferred stock redemption fee	-	-	(1,700)
Deferred financing costs	-	-	(320)
Net Cash provided by Financing Activities	14,663	11,717	134,094
Effect of exchange rates on cash and cash equivalents	(40)	(44)	(190)
Net increase (decrease) in cash and cash equivalents	87	1,490	111
Cash and cash equivalents at beginning of period	24	153	-
Cash and cash equivalent at end of period	\$ 111	\$ 1,643	\$ 111

See accompanying notes to the condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(Unaudited)

	Nine Months Ended September 30,		Period from March 18, 1996 (Inception) to September 30,
	2012	2011	2012
Supplemental disclosure of cash flow information - Cash paid during the period for interest	\$ -	\$ -	\$ 1,879
Supplemental schedule of non-cash financing activities:			
Equipment acquired through capital leases	\$ -	\$ -	\$ 285
Issuance of common stock in connection with elimination of Series A and Series A-1 preferred stock preferences	-	-	12,349
Issuance of common stock in connection with conversion of liabilities	7,785	2,790	26,840
Modification of Series A preferred stock warrants	-	-	2,306
Modification of Series A-1 preferred stock warrants	-	-	16,393
Warrants issued on Series A and Series A-1 preferred stock dividends	-	-	4,664
Liability for reclassified equity contracts	29,412	-	29,412
Accretion of mandatorily redeemable Series A preferred stock redemption obligation	-	-	1,872
Debt discount on promissory notes	7,885	4,891	27,386
Conversion of convertible promissory notes and accrued interest to Series D preferred stock	-	-	5,324
Conversion of convertible promissory notes and accrued interest to Series A-1 preferred stock	-	-	7,707
Conversion of convertible promissory notes and accrued interest to common stock	-	-	269
Issuance of Series C preferred stock warrants in connection with lease agreement	-	-	43
Issuance of common stock or notes to settle accounts payable	-	-	4
Liability for and issuance of common stock and warrants to Medarex	-	-	840
Issuance of common stock to landlord	-	-	35
Deferred compensation on issuance of stock options and restricted stock grants	-	-	759
Cancellation of options and restricted stock	-	-	849
Financing of prepaid insurance through note payable	-	-	491
Stock subscription receivable	-	-	480

See accompanying notes to the condensed consolidated financial statements

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Northwest Biotherapeutics, Inc. and its subsidiaries, NW Bio Europe S.A.R.L. and NW Bio GmbH (collectively, the “Company”, “we”, “us”, and “our”). All material intercompany balances and transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (“GAAP”). All normal recurring adjustments which are necessary for the fair presentation of the results for the interim periods are reflected herein. Operating results for the three month and nine month periods ended September 30, 2012 and 2011 are not necessarily indicative of results to be expected for a full year.

Effective September 25, 2012, all shares of the Company’s common stock issued and outstanding were combined and reclassified on a one-for-sixteen basis. The effect of this reverse stock split has been retroactively applied to all periods presented.

The Company has experienced recurring losses from operations. Net cash outflows from operations were \$6.1 million for the three months ended September 30, 2012, and \$14.5 million for the nine months ended September 30, 2012.

The independent registered public accounting firm’s report on the financial statements for the fiscal year ended December 31, 2011 states that because of recurring operating losses, net operating cash flow deficits, and a deficit accumulated during the development stage, there is substantial doubt about the Company’s ability to continue as a going concern. A “going concern” opinion indicates that the financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

The Company implemented the following accounting policies during the period ended September 30, 2012.

Revenue recognition. In various situations, the Company receives certain payments from patients. These are generally non-refundable, and are not dependent on the Company’s ongoing future performance. The Company has adopted a policy of recognizing these payments as revenue when received.

Accounts Receivable. The accounts receivable balances may include balances due from research grants and other services. We record an allowance for doubtful accounts for our best estimate of the amount of probable credit losses in our existing accounts receivable. We determine the allowance for doubtful accounts based primarily on historical write-off experience. Account balances that are deemed uncollectible, are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. As of September 30, the Company had a full valuation allowance on accounts receivable of \$195,000.

In September 2011, the Financial Accounting Standards Board issued ASU No. 2011-05, Comprehensive Income, or ASU 2011-05. The guidance in ASU 2011-05 revises the manner in which entities present comprehensive income in their financial statements. An entity is required to report the components of comprehensive income in either one or two consecutive financial statements:

- A single, continuous statement must present the components of net income and total net income, the components of other comprehensive income and total other comprehensive income, and a total for comprehensive income; or
- In a two-statement approach, an entity must present the components of net income and total net income in the first statement. That statement must be immediately followed by a financial statement that presents the components of other comprehensive income, a total for other comprehensive income, and a total for comprehensive income.

ASU 2011-05 does not change the items that must be reported in other comprehensive income. The amendments in ASU 2011-05 are effective for fiscal years beginning after December 15, 2011. The Company adopted this guidance, and implemented the two-statement approach.

The other significant accounting policies used in the preparation of the Company’s condensed consolidated financial statements are disclosed in Note 3 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011.

3. Stock-Based Compensation

Compensation expense for all stock-based awards is measured at the grant date based on the fair value of the award and is recognized as an expense, on a straight-line basis, over the employee’s requisite service period (generally the vesting period of the equity award). The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Stock-based compensation expense is recognized only for those awards that are expected to vest using an estimated forfeiture rate. We estimate pre-vesting option forfeitures at the time of grant and reflect the impact of estimated pre-vesting option forfeitures in compensation expense recognized. For options and warrants issued to non-employees, the Company recognizes stock compensation costs utilizing the fair value methodology over the related period of benefit.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

A summary of stock options activity for 2012 is as follows (shares in thousands):

	Number of Options	Weighted Average Exercise Price	Average Grant Date Fair Value	Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2011	1,574	\$ 10.56	\$ 10.56		
2012 activity	-	\$ -	\$ -		
Outstanding at September 30, 2012	1,574	\$ 10.56	\$ 10.56	5.8 years	\$ -

Stock-based compensation expense was as follows for the three months and nine months ended September 30, 2012 and 2011 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	\$ 91	\$ 226	\$ 380	\$ 2,172
General and administrative	586	1,178	2,194	5,182
Total stock-based compensation expense	\$ 677	\$ 1,404	\$ 2,574	\$ 7,354

There were no options to purchase common stock granted during the three month and nine month periods ended September 30, 2012, although certain options previously granted were vested. At September 30, 2012, the unrecognized compensation expense related to stock options was \$2.6 million which is to be recognized over a weighted average period of approximately 2.8 years.

4. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three tier fair value hierarchy which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The Company's liability for reclassified equity contracts was measured using significant unobservable (Level 3) inputs.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

In 2011, as a result of the Company entering into convertible promissory notes and issuing warrants to purchase common stock, the Company's total potential outstanding common stock exceeded the Company's authorized shares by approximately 6.8 million shares as of December 31, 2011, as also discussed in Note 7. As a result, the Company was required to value a number of shares equal to the excess issuable on exercise of warrants and options and on conversion of convertible notes and recognize the value as a liability. Effective February 6, 2012, the Company's stockholders approved an increase in the number of authorized shares sufficient to cover the excess. At that time, the liability was re-measured, with changes in value included in other income/(expense), and then reclassified to additional paid-in capital (thereby removing it from the Company's liabilities).

The following table represents the activity for the Company's liability for reclassified equity contracts for the three month and nine month periods ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Beginning balance	\$ -	\$ -	\$ 29,903,000	\$ -
Liabilities reclassified	-	5,446,000	693,000	23,975,000
Change in value of reclassified liabilities	-	(8,875,000)	(491,000)	(7,413,000)
Liabilities reclassified to equity	-	-	(30,105,000)	-
Ending balance	<u>\$ -</u>	<u>\$ (3,429,000)</u>	<u>\$ -</u>	<u>\$ 16,562,000</u>

The Company concluded that certain conversion features and warrant agreements included down-round provisions and were not indexed to the Company's stock (and are therefore recorded as derivative liabilities). The Company recognizes the derivative liabilities at their respective fair values using a binomial model adjusted for the probability of issuance using a Monte Carlo simulation. Changes in the fair value are recorded in "Derivative valuation gain (loss)" in the condensed consolidated statements of operations. Key assumptions for determining fair values during the periods presented included expected terms ranging from between 3 and 15 months, volatility ranging from between 95% and 190% and risk-free interest rate of 0.18%.

The Company's embedded derivative liability was measured using significant unobservable (Level 3) inputs. The following table represents the Company's embedded derivative liability activity for the three months and nine months ended September 30, 2012 and 2011:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Beginning balance	\$ 53,000	\$ 2,368,000	\$ 601,000	\$ 839,000
Reclassification to stockholders' equity upon conversion and expiration of derivative	-	(212,000)	-	(381,000)
Embedded derivative liability recognized	-	-	-	1,389,000
Net change in fair value of embedded derivative liabilities	(35,000)	(338,000)	(583,000)	(29,000)
Ending balance	<u>\$ 18,000</u>	<u>\$ 1,818,000</u>	<u>\$ 18,000</u>	<u>\$ 1,818,000</u>

5. Liquidity and Going Concern

The Company has experienced recurring losses from operations. Net cash outflows from operations were \$6.1 million for the three months ended September 30, 2012, and \$14.5 million nine months ended September 30, 2012, respectively. The Company had a working capital deficit of \$35.9 million at September 30, 2012.

The Company had a deficit accumulated during the development stage of \$288.6 million, which included \$131.7 million for operating cash flows.

Since 2004, Toucan Capital Fund II, L.P. ("Toucan Capital"), Toucan Partners LLC ("Toucan Partners"), entities controlled by Ms. Linda Powers, the managing director of Toucan Capital and managing member of Toucan Partners, and Ms. Linda Powers (collectively "Toucan") have provided substantial funding to the Company. During the period from 2004 to 2007, the funding consisted of various loans and purchases of common stock. Under a Conversion Agreement during 2007, all loans payable to Toucan outstanding at the time were converted to preferred stock and the preferred stock was subsequently converted to common stock. As a result of additional loans, as of September 30, 2012, notes payable and accrued interest include \$5.2 million convertible notes payable to Toucan. The notes payable to Toucan outstanding as of September 30, 2012, are convertible in accordance with their terms at \$3.20.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

The Company utilizes the services of Cognate BioServices, Inc., an entity controlled by Toucan, for manufacturing DCVax product candidates, regulatory advice, research and development preclinical activities, and managing certain aspects of clinical trials. Accounts payable to Cognate BioServices, Inc. amounted to \$4.8 million as of September 30, 2012.

The Company received proceeds of \$0.7 million in 2011 on an operational loan basis, from Artecel, Inc. Repayment terms as well as warrant coverage were agreed in August 2012. The note carries original issue discount of ten percent, an interest rate of ten percent, and a nine-month maturity. The note is convertible at 90% of the average of the lowest five days' closing prices of the Company's common stock in the twenty trading days prior to conversion. The note carries one hundred percent warrant coverage, with an exercise price of \$6.40, and an exercise period of five years. The Company and Artecel have entered into three extensions of this note. In consideration of the extensions, the Company agreed to issue warrants to Artecel on the same basis as warrants have been issued to unrelated investors for note extensions.

As of September 30, 2012, Toucan, beneficially owned (including common stock issuable upon exercise of exercisable warrants and options) approximately 4.7 million shares of common stock.

In addition to financing obtained from Toucan and related entities, the Company has raised additional capital by issuing common stock and debt securities. As of September 30, 2012 the Company had approximately \$0.1 million of cash and cash equivalents on hand. The Company will need to raise additional capital in the near future to continue to fund its clinical trials and other operating activities and there can be no assurance that its efforts to seek such funding will be successful. The Company may seek funding from Toucan Capital or Toucan Partners or their affiliates or other third parties. Such parties are under no obligation to provide the Company with any additional funds, and any such funding may be dilutive to stockholders and may contain restrictive covenants. The Company is currently exploring additional financings with several other parties; however, there can be no assurance that the Company will be able to complete any such financings or that the terms of such financings will be attractive to the Company. If the Company's capital raising efforts are unsuccessful, its inability to obtain additional cash as needed could have a material adverse effect on the Company's financial position, results of operations and the Company's ability to continue its existence.

During October 2012, the Company signed agreements to retire \$28.4 million of convertible notes, notes and other payables by entering into Conversion Agreements with non-affiliated and affiliated note holders and creditors of the Company, including certain of directors and executive officers. This aggregate debt amount will be converted into 8,125,494 common shares and warrants exercisable for 3,624,436 shares of common stock, effective upon the closing of a public offering which has not yet occurred prior to the date of this report. The warrants will have an exercise period of five years from the date of issuance and an exercise price of \$6.40 per share.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

6. Notes Payable

Notes payable consist of the following at September 30, 2012 and December 31, 2011(in thousands):

	September 30, 2012	December 31, 2011
Notes payable - current		
12% unsecured originally due July 2011	\$ 934	\$ 935
6% unsecured due May 16, 2013 (net of discount of \$0 in 2012 and \$236 in 2011)	1,450	1,764
12% unsecured originally due March 2011	100	450
	<u>\$ 2,484</u>	<u>\$ 3,149</u>
Notes payable related parties - current		
12% unsecured due June 2012 and within six months (net of discount of \$0 in 2012 and \$21 in 2011)	\$ 2,177	\$ 2,056
Convertible notes payable, net - current		
6% unsecured due between March 2011 and February 2012 (net of discount of \$0 in 2012 \$34 in 2011)	\$ 2,020	\$ 2,676
0% unsecured due between December 2012 and February 2013 (net of discount of \$1,463 in 2012)	1,323	-
10% unsecured due between April 2011 and February 2012 (net of discount of \$0 in 2012 \$38 in 2011)	50	150
10% unsecured convertible note due November 2012 (net of discount of \$333 in 2012 and \$1,833 in 2011)	2,667	1,167
6% unsecured due June 2012 (net of discount of \$0 in 2012 and \$182 in 2011)	-	839
8% unsecured convertible note due April 2013 (net of discount of \$753 in 2012)	2,672	-
	<u>\$ 8,732</u>	<u>\$ 4,832</u>
Convertible Notes payable related party, net - current		
10% unsecured due within 6 months (net of discount of \$46 in 2012)	\$ 4,429	\$ -
12% unsecured due June 2012	-	2,430
6% due July 2011 and November 2011 and on demand (net of discount of \$0 in 2012 and \$92 in 2011)	1,953	1,158
	<u>\$ 6,382</u>	<u>\$ 3,588</u>
Long term notes payable		
6% unsecured note due October 2012	\$ 100	\$ 200
Long term convertible notes, net		
4% unsecured due November 15, 2013 (net of discount of \$0 in 2012 and \$42 in 2011)	\$ -	\$ 402
4% unsecured due June 30, 2013 (net of discount of \$9 in 2011)	-	67
6% due April 2014 and May 2014 (net of discount of \$142 in 2012)	1,382	-
4% unsecured due Sept, 2014 (net of discount of \$458 in 2012)	375	-
11% unsecured convertible note due December 2013 (net of discount of \$32 in 2012 and \$321 in 2011)	135	964
10% unsecured convertible note due May 2015 (net of discount of \$611 in 2012)	388	-
	<u>\$ 2,279</u>	<u>\$ 1,433</u>
Total notes payable, net	<u>\$ 22,155</u>	<u>\$ 15,258</u>

The holders of notes payable with an aggregate principal balance of \$7.9 million converted the notes into approximately 2.0 million shares of common stock during the nine months ended September 30, 2012.

The holders of notes payable with an aggregate principal balance of \$1.1 million converted the notes into 0.3 million shares of common stock during the October 2012.

The Company received aggregate proceeds of \$13.2 million in connection with issuing various notes during the nine months ended September 30, 2012. Warrants for the purchase of approximately 1.5 million shares of common stock were also issued in connection with the notes. The notes are payable on various dates through May 2015 and have interest rates between 0% and 11%.

The conversion prices of the notes, with fixed terms, range between \$5.28 and \$6.40. The Company is currently negotiating the repayment terms for notes payable which are past due.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

7. Reclassified Equity Contracts

The Company accounts for potential shares that can be converted to common stock and that if converted, will be in excess of authorized shares, as a liability that is recorded on the balance sheet (at fair value) only until the authorized number of shares is increased (at which time the whole liability will be re-measured, with changes in value included in other income/ (expense), and then reclassified to additional paid-in capital). The value of the liability was computed by valuing the securities that management believed were most likely to be converted. This liability is revalued at each reporting date with any change in value included in other income/ (expense) until such time as enough shares are authorized to cover all potentially convertible instruments.

In 2011, as a result of the Company entering into convertible promissory notes and issuing stock options, and warrants to purchase common stock, the Company's total potential outstanding common stock exceeded the Company's authorized shares by approximately 6.8 million shares at December 31, 2011. During 2012, the number of potential shares in excess of authorized shares increased to approximately 7 million. Effective February 6, 2012, the number of authorized common shares was increased and the liability for potential shares in excess of total authorized shares was revalued at that date. This valuation resulted in non- cash gain of approximately \$0.5 million during the nine months ended September 30, 2012. The liability that was reclassified to additional paid in capital (and thereby removed from the Company's liabilities) during the nine months ended September 30, 2012 amounted to approximately \$30 million.

8. Net Income (Loss) Per Share Applicable to Common Stockholders

For the three months ended September 30, 2011, options and warrants to purchase 0.4 million shares of common stock were included in the computation of diluted net income (loss) per share because they were dilutive. Convertible debt having a face value of \$5.4 million is also considered dilutive for purposes of computing diluted net income (loss) per share. The conversion of the convertible debt increases the number of shares outstanding for purposes of computing diluted net income (loss) per share by 1.3 million shares for the three month period ended September 30, 2011. In determining the amount of net income used to compute diluted earnings per share, the Company applied the "if converted method." Accordingly, net income for the three months ended September 30, 2011, has been increased by approximately \$54,000, representing interest expense that would have been avoided if the debt had been converted as of July 1, 2011. Options, warrants, and convertible debt outstanding were all considered anti-dilutive for the three and nine months ended September 30, 2012, and for the nine months ended September 30, 2011, due to net losses.

The following securities were not included in the diluted net income (loss) per share calculation because their effect was antidilutive as of the periods presented (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,	September 30,	September 30,	September 30,
	2012	2011	2012	2011
Common stock options	1,574	1,574	1,574	1,574
Common stock warrants	5,437	3,038	5,437	3,326
Convertible notes	2,627	757	2,627	1,978
Excluded potentially dilutive securities	<u>9,638</u>	<u>5,369</u>	<u>9,638</u>	<u>6,878</u>

9. Related Party Transactions

Cognate BioServices

In April, 2011, the Company entered into a new service agreement with Cognate Therapeutics, Inc. ("Cognate"), a contract manufacturing and services organization in which Toucan Capital has a majority interest. In addition, two of the principals of Toucan Capital are members of Cognate's board of directors and Linda Powers who is a director of Cognate and managing director of Toucan Capital is Chairperson of the Company's Board of Directors and Chief Executive Officer of the Company. This agreement replaces the agreement dated May 17, 2007 between the Company and Cognate, which had expired. Under the service agreement, the Company agreed to continue to utilize Cognate's services, for certain consulting and manufacturing services to the Company for its ongoing DCVax®-Brain Phase III clinical trial. The scope of services are comparable to the prior agreement, and the structure and process for payments are simplified. Under the terms of the current agreement the Company pays Cognate a monthly facility fee and a fixed fee (in lieu of cost-plus charges) for each patient in the study, subject to specified minimum number of patients per month, plus charges for certain patient and product data services if such services are requested by the Company. The current service agreement will expire on March 31, 2016.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

During the three months ended September 30, 2012 and 2011, the Company recognized approximately \$3.9 million and \$2.4 million, respectively, of research and development costs related to these service agreements. During the nine months ended September 30, 2012 and 2011, the Company recognized approximately \$9.9 million and \$5.8 million, respectively, of research and development costs related to these service agreements. As of September 30, 2012 and December 31, 2011, the Company owed Cognate approximately \$4.8 million and \$0.6 million, respectively.

During 2009, the Company and Cognate agreed that some or most of the accounts payable owed by the Company to Cognate, will be converted into shares of common stock instead of paid in cash. The conversion price and terms will be no less favorable than the conversion price and terms applied to any other creditor of the Company. The Company will recognize the value of common stock issued in excess of the amount of accounts payable converted, if any, as a charge to operations when the conversion takes place.

Toucan Capital and Toucan Partners

In accordance with a recapitalization agreement between the Company and Toucan Capital, as amended, pursuant to which Toucan Capital agreed to recapitalize the Company by making loans to the Company, Toucan Capital, Toucan Partners and Linda Powers paid certain of the Company's operating costs on the Company's behalf. Pursuant to the terms of the Conversion Agreement discussed above, the recapitalization agreement ended in late 2007. Subsequent to the ending of the recapitalization agreement, Toucan Capital continued to pay certain of the Company's operating costs, including, among others, fees and costs for the CRO (contract research organization) managing the Company's clinical trials, legal fees and filing fees for the Company's patents, equipment and supplies, rent, payroll for personnel, travel expenses and other costs for the Company's operations, product pipeline and international expansion efforts.

During 2009, the Company agreed with Toucan Capital, Toucan Partners and Linda Powers that some or all of the payables owed by the Company to these parties for expense reimbursements will be converted into shares of common stock instead of paid in cash. The conversion price and terms will be no less favorable than the conversion price and terms applied to any other creditor of the Company.

In November 2012, the Company agreed to reimburse Toucan for \$4.6 million of these expenses previously incurred by Toucan for the Company. Toucan agreed to receive such reimbursement in the form of stock rather than cash. Pursuant to the prior agreement of the parties, Toucan was entitled to receive conversion terms no less favorable than had been provided to any non-affiliated creditor; however, Toucan agreed instead to accept the median terms provided to non-affiliated creditors over the preceding six months. The reimbursements are payable in approximately 1.7 million shares of common stock and 0.8 million warrants. The reimbursement and the conversion terms were approved by the Company's Board of Directors. The Company will recognize the fair value of the common stock and warrants to the extent, if any that they are in excess of the \$4.6 million of accrued expenses, as a charge to operations. The reimbursements of these expenses were accrued as of September 30, 2012. Accordingly, accounts payable to Toucan amounted to \$4.6 million at September 30, 2012 and \$0.6 million at December 31, 2011.

In November, 2011, Toucan provided the collateral required by an unrelated investor for a loan of \$2 million to the Company. The investor required that Toucan place in escrow, as collateral to secure repayment of the loan and accumulated interest, approximately 406,250 million shares of common stock of the Company owned by Toucan. Toucan placed such shares in escrow as required. The investor's loan had a maturity of six months, expiring in May, 2012. The Company did not repay the investor's loan at its maturity, and had not repaid the loan as of the date of this report. The investor has continued to retain Toucan's shares of Company stock as security for the loan. In August, 2012, the Company agreed to indemnify and compensate Toucan for providing the loan collateral by issuing to Toucan warrants equal to fifty percent of the number of shares provided as collateral by Toucan, with an exercise price of \$6.40 and an exercise term of five years. The Company recorded additional expenses of \$0.8 million and issued 203,125 warrants during the 3rd quarter of 2012 related to this transaction.

The Company terminated its sub-lease of office space with Toucan Capital on December 31, 2009. Under the sub-lease, the Company was responsible for its portion of the lease obligations with the landlord, on a straight pass-through basis. Those obligations included rent payments to the landlord for the remaining unused term of the lease. Pursuant to an extended payment arrangement with the landlord, those payments are to be made over a number of years. The Company's obligation will be approximately \$127,000 in 2012.

Notes Payable - Related Parties

Al Rajhi converted the note payable with a principal balance of \$2,523,201 into 4,426,670 shares of common stock on February 9, 2012.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The Company received proceeds of \$1.3 million in connection with issuing a convertible note to Toucan Partners in July, 2007. The note carried ten percent original issue discount and an interest rate of ten percent. The note is convertible at a fixed price of \$3.20 per share. The note had a 2-year maturity, and was due in July 2011. The note carried one hundred percent warrant coverage, with the warrants exercisable at the same price as the conversion price, and an exercise period of five years. The Company did not repay the note at its maturity and the note was still outstanding as of September 30, 2012. The Company and Toucan have agreed to extensions on the same terms as extensions have been provided to unrelated investors whose notes have not been repaid.

The Company received proceeds of \$1.5 million in connection with issuing a convertible note to Toucan Partners on February 9, 2012. The note carried 100% warrant coverage. The exercise price of the warrants is \$6.40. The note is unsecured, but will become secured if the Company enters into any secured financing or if there is an event of default, as defined. The note is payable on demand with 14 days written notice and carried an original issue discount of 10% and a one-time interest charge of 10%. The conversion price of the note is 95% of the average of the lowest five days' closing prices of the Company's common stock in the twenty trading days prior to conversion.

The Company received proceeds of \$1.3 million in connection with issuing unsecured convertible notes to Toucan Partners on dates between January 3, 2012 and March 6, 2012. The notes carried 100% warrant coverage. The exercise price of the warrants is \$6.40. The notes are payable on demand with between 7 and 14 days written notice and carried an original issue discount of 10% and a one-time interest charge of 10%. The conversion prices of the notes are 95% of the average of the lowest five days' closing prices of the Company's common stock in the twenty trading days prior to conversion.

The Company received proceeds of \$0.7 million from an operational loan from Artecetel, Inc. in 2011. Artecetel is controlled by Toucan Capital. Repayment terms as well as warrant coverage were agreed in August 2012. The note carries original issue discount of ten percent, an interest rate of ten percent, and a nine-month maturity. The note is convertible at 90% of the average of the lowest five days' closing prices of the Company's common stock in the twenty trading days prior to conversion. The note carries 100% warrant coverage. The warrants have an exercise price of \$6.40, and an exercise period of five years. The Company and Artecetel have entered into three extensions of this note. In consideration of the extensions, the Company agreed to issue warrants to Artecetel on the same basis as warrants have been issued to unrelated investors for note extensions.

Other Related Parties

The Company received proceeds of \$0.2 million in connection with issuing an unsecured convertible note to an officer of the Company on January 3, 2012. The notes carried 100% warrant coverage. The exercise price of the warrants is \$6.40, and the exercise period is 5 years. The note is payable on demand with 7 days written notice and carried an original issue discount of 10% and a one-time interest charge of 10%. The conversion price of the note is 95% of the average of the lowest five days' closing prices of the Company's common stock in the twenty trading days prior to conversion.

The Company received proceeds of \$0.3 million in connection with issuing an unsecured convertible demand note to an officer of the Company on June 29, 2012. The conversion price was \$5.28 and the interest rate was 10%. The notes carried 100% warrant coverage. The exercise price is \$5.60 and the exercise period of the warrants is five years.

During 2010, 2011 and 2012 year to date, a Board member of the Company arranged multiple financings for the Company, totaling approximately \$8.0 million. The Company agreed to compensate the Board member at a rate below the usual fees of investment banks for such transactions, by paying the Board member 63 thousand shares of common stock valued at \$0.3 million during the third quarter of 2012.

During 2008, 2009 and 2010, the Company received approximately \$1.0 million in proceeds in connection with issuing unsecured notes. The fixed conversion fixed prices range from \$3.20 to \$8.00 and interest rates range from 6% to 12%.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

10. Stockholders' Equity (Deficit)

Common Stock Issuances

Issuances of common stock during 2012 were as follows (shares and dollars in thousands):

Description	Shares Issued	Purchase/Conversion Price	Fair Value/ Proceeds/Debt Conversion
Issuance of shares to private investors	14	\$ 5.28	\$ 75
Issuance of shares to private investors	14	4.32	65
Conversion of notes payable	590	6.24	3,700
Conversion of accounts payable	3	5.12	15
Total 1st Quarter 2012	621		3,855
Issuance of shares to private investors	56	3.68	207
Conversion of notes payable	23	2.24	66
Conversion of notes payable	300	2.88	866
Shares issued for consulting services	1	4.00	3
Total 2nd Quarter 2012	380		1,142
Issuance of shares to private investors	222	5.11	1,135
Conversion of notes payable	1,080	2.94	3,172
Shares issued for consulting services	190	4.76	905
Total 3rd Quarter 2012	1,492		5,212
Total Nine Months Ended September 30, 2012	2,493		\$ 10,209

Stock Purchase Warrants

Through September 30, 2012, the Company has issued warrants to strategic partners, consultants and investors with exercise prices ranging from \$2.40 to \$51.84 and exercise periods ranging from three to five years. The following is a summary of warrant activity for the nine months ended September 30, 2012:

	Number of Warrants	Weighted Average Exercise Price
Outstanding as of December 31, 2011	3,568,308	\$ 8.96
Issued	1,868,550	7.14
Outstanding as of September 30, 2012	5,436,858	\$ 8.30

11. Subsequent Events

During October 2012, the Company signed agreements to retire \$28.4 million of convertible notes, notes and other payables by entering into Conversion Agreements with non-affiliated and affiliated note holders and creditors of the Company, including certain of directors and executive officers. This aggregate debt amount will be converted into 8,125,494 common shares and warrants exercisable for 3,624,436 shares of common stock, effective upon the closing of a public offering. The warrants will have an exercise period of five years from the date of issuance and an exercise price of \$6.40 per share.

During October and November 2012, the Company issued 1.0 million shares of common stock and received \$5 million in private placement transactions. In addition, the holders of notes payable with an aggregate principal balance of \$1.1 million converted the notes into 0.3 million of common stock during October 2012.

In November 2012, the Company agreed to reimburse Toucan for \$4.6 million of Company operations expenses previously incurred. Toucan agreed to receive such reimbursement in the form of stock rather than cash. Pursuant to the prior agreement of the parties, Toucan was entitled to receive conversion terms no less favorable that had been provided to any non-affiliated creditor. However, Toucan agreed instead to accept the median terms provided to non-affiliated creditors over the preceding six months. The reimbursements of such expenses are payable in approximately 1.7 million shares of common stock and 0.8 million warrants. The Company will recognize the fair value of the common stock and warrants in excess of the \$4.6 million of accrued expenses, if any, as a charge to operations. Pursuant to the prior agreement of the parties, Toucan was entitled to receive conversion terms no less favorable that had been provided to any non-affiliated creditor; however, Toucan agreed instead to accept the median terms provided to non-affiliated creditors over the preceding six months. The reimbursement of such expenses and the terms were approved by the Board of Directors. These expenses were accrued as of September 30, 2012.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes to those statements included with this report. In addition to historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected. The words "believe," "expect," "intend," "anticipate," and similar expressions are used to identify forward-looking statements, but some forward-looking statements are expressed differently. Many factors could affect our actual results, including those factors described under "Risk Factors" elsewhere in this report. These factors, among others, could cause results to differ materially from those presently anticipated by us. You should not place undue reliance on these forward-looking statements.

Overview

We are a development stage biotechnology company focused on discovering, developing and commercializing immunotherapy products to generate and enhance immune system responses to treat cancer. Data from our clinical trials suggest that our cancer therapies significantly extend both the time to tumor recurrence and patient survival time, while providing a superior quality of life with no debilitating side effects when compared with current therapies.

Our financing activities are described below under "- Liquidity and Capital Resources". We will need to raise additional capital to fund our operations, including our Phase III DCVax ® -L clinical trial. If the results of our Phase III trial are positive, we plan to seek early product approval for DCVax®-L.

The Company has experienced recurring losses from operations. Net cash outflows from operations were \$6.1 million for the three months ended September 30, 2012, and \$14.5 million for the nine months ended September 30, 2012.

We have experienced recurring losses from operations and as of September 30, 2012 we have a deficit accumulated during the development stage of \$288.6 million, which includes \$131.7 million of operating cash flows.

In addition, our independent registered public accounting firm's report on the financial statements for the year ended December 31, 2011, states that because of recurring operating losses, net operating cash flow deficits, and a deficit accumulated during the development stage, there is substantial doubt about the Company's ability to continue as a going concern.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2011. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

Recent Accounting Pronouncements

See Note 2 to Condensed Consolidated Financial Statements in this Form 10-Q.

Results of Operations

Operating costs:

Operating costs and expenses consist primarily of research and development expenses, including clinical trial expenses which increase when we are actively participating in clinical trials (and are especially high when we are in a phase III trial, as we now are), and general and administrative expenses.

Research and development:

Discovery and preclinical research and development expenses include scientific personnel-related salary and benefit expenses, costs of laboratory supplies used in our internal research and development projects, travel, regulatory compliance, and expenditures for preclinical and clinical trial operation and management when we are actively engaged in clinical trials.

Because we are a development stage company, we do not allocate research and development costs on a project basis. We adopted this policy, in part, due to the unreasonable cost burden associated with accounting at such a level of detail and our limited number of financial and personnel resources.

General and administrative:

General and administrative expenses include administrative personnel related salary and benefit expenses, cost of facilities, insurance, travel, legal support, property and equipment and amortization of stock options and warrants.

Three Months Ended September 30, 2012 and 2011

We recognized a net loss of \$16.5 million for the three months ended September 30, 2012 compared to a net income of \$0.5 million for the three months ended September 30, 2011. This net loss included \$6.1 million in total net cash outlays, as well as certain non-cash charges related to financing transactions. The increase in the net loss for the three months ended September 30, 2012 over the 2011 period was primarily attributable to the gain on valuation of reclassified equity instruments during 2011 and increased clinical development expenses incurred during the 3rd quarter of 2012 due to increased number of clinical trial sites open and recruiting across the United States in our ongoing Phase III clinical trial of DCVax®-L immune therapy for Glioblastoma multiforme (GBM), the most lethal form of brain cancer.

Research and Development Expense. Research and development expense was \$9.9 million for the three months ended September 30, 2012 compared to \$3.6 million for the three months ended September 30, 2011. The increase was primarily attributable to increased clinical development expenses incurred during the 3rd quarter of 2012 due to increased number of clinical trial sites open and recruiting across the United States in our ongoing Phase III clinical trial of DCVax®-L immune therapy for GBM, as well as expansion of the trial into Europe.

As of September 30, 2012 we had 41 clinical trial sites in operation in the U.S., compared to 16 clinical trial sites at September 30, 2011.

General and Administrative Expense. General and administrative expense was \$3.9 million for the three months ended September 30, 2012 compared to \$2.8 million for the three months ended September 30, 2011. These G&A expenses included \$1.7 million fees related to financing transactions and \$0.6 related to non-cash stock based compensation amortization. The increase was primarily due to incremental consulting expenses related to financing transactions. Such fees were paid in common stock and warrants.

Valuation of reclassified equity contracts. During the three months ended September 30, 2012, we did not recognize a non-cash gain from the valuation of reclassified equity contracts because there were no contracts required to be accounted for as liabilities during the 3rd quarter of 2012. There was a non-cash gain of \$8.9 million in reclassified equity contracts during the three months ended September 30, 2011.

Derivative valuation gain and loss. During the three months ended September 30, 2012 we recognized a gain on derivative liabilities of \$0.04 million due to the decrease in term remaining on this liability based financial instrument. We recognized a \$0.4 million loss in the three months ended September 30, 2011.

Interest (Expense). Interest expense (including amortization of debt discount) was \$2.8 million for the three months ended September 30, 2012 and \$2.4 million for the three months ended September 30, 2011. The increase in interest expense is related to the increase in notes payable, net balance from \$12.3 million as of September 30, 2011 to \$22.2 million as of September 30, 2012.

Nine Months Ended September 30, 2012 and 2011

We recognized a net loss of \$36.8 million for the nine months ended September 30, 2012 compared to a net loss of \$20.2 million for the nine months ended September 30, 2011. This net loss included \$14.5 million in total net cash outlays, as well as certain non-cash charges related to financing transactions.

Research and Development Expense. Research and development expense was \$20.5 million for the nine months ended September 30, 2012 compared to \$11.5 million for the nine months ended September 30, 2011. The increase was primarily attributable to increased number of clinical trial sites open and recruiting across the United States in our ongoing Phase III clinical trial of DCVax®-L immune therapy for GBM, as well as expansion of the trial into Europe.

General and Administrative Expense. General and administrative expense was \$8.2 million for the nine months ended September 30, 2012 compared to \$10.7 million for the nine months ended September 30, 2011. These G&A expenses included non-cash fees related to stock based compensation amortization and fees related to financing transactions. The decrease was primarily due to an incremental \$3.0 million of stock compensation expense primarily related to the grant of stock options to the new management team in September 2011.

Valuation of reclassified equity contracts. During the nine months ended September 30, 2012, the Company recognized a non-cash gain amounting to \$0.5 million from the decrease in value of reclassified equity contracts. There was a non-cash gain of \$7.4 million in reclassified equity contracts during the nine months ended September 30, 2011.

Derivative valuation gain and loss. During the nine months ended September 30, 2012 we recognized a gain on derivative liabilities of \$0.6 million due to the change in value of the financial instruments. We recognized a \$0.03 million gain in the nine months ended September 30, 2011.

Interest (Expense). Interest expense (including amortization of debt discount) increased to \$9.6 million for the nine months ended September 30, 2012 from \$5.4 million for the nine months ended September 30, 2011. Interest expense increased for the nine month period ended September 30, 2012 primarily related to the increase in notes payable, net balance from \$12.3 million as of September 30, 2011 to \$22.2 million as of September 30, 2012.

Liquidity and Capital Resources

The Company has experienced recurring losses from operations. Net cash outflows from operations were \$6.1 million for the three months ended September 30, 2012, and \$14.5 million for the nine months ended September 30, 2012.

At September 30, 2012, cash and cash equivalents totaled \$0.1 million, compared to \$0.02 million at December 31, 2011. Working capital was a deficit of \$35.9 million at September 30, 2012, compared to a deficit of \$50.6 million at December 31, 2011. The working capital deficit decreased as of September 30, 2012 as compared to December 31, 2011 primarily due to the decrease in the liability for reclassified equity contracts in 2012.

The change in cash for the periods presented was comprised of the following (in thousands):

	Nine Months Ended September 30,		
	2012	2011	Change
Net cash provided by (used in):			
Operating activities	\$ (14,505)	\$ (10,152)	\$ (4,353)
Investing activities	(31)	(31)	-
Financing activities	14,663	11,717	2,946
Effect of exchange rates on cash and cash equivalents	(40)	(44)	4
Increase in cash and cash equivalents	<u>\$ 87</u>	<u>\$ 1,490</u>	<u>\$ (1,403)</u>

Operating Activities

We used \$14.5 million in cash for operating activities during the nine months ended September 30, 2012. The increase in cash used in operating activities was primarily attributable to increased number of clinical trial sites open and recruiting across the United States, and expansion of the trial into Europe, in our ongoing Phase III clinical trial of DCVax®-L immune therapy for GBM.

Investing Activities

Investing activities for the periods presented are not material.

Financing Activities

During the nine months ended September 30, 2012, our financing activities consisted of net proceeds from notes payable amounting to \$13.2 million and proceeds from the issuance of common stock amounting to \$1.5 million. The increase in our financing activities was primarily attributable to raising financing to support the increased number of clinical trial sites open and recruiting across the U.S. in our ongoing Phase III clinical trial of DCVax®-L immune therapy for GBM.

In order to continue with our current activities under our DCVax- ®- -L program, we will have to obtain substantial amounts of further funding. Our ongoing funding requirements will depend on many factors, including the number of staff we employ, the pace of patient enrollment in our brain cancer trial, the cost of establishing clinical studies and compassionate use/named patient programs in other countries, and unanticipated developments. Without additional capital, we will not be able to continue significant enrollment in our DCVax®-L clinical trial or move forward with compassionate use/named patients programs or with any of our other product candidates for which investigational new drug applications have been cleared by the FDA. We will also be constrained in developing improved manufacturing processes.

The additional funding will be required in the near future and there can be no assurance that our efforts to seek such funding will be successful. If our capital raising efforts are unsuccessful, our inability to obtain additional cash as needed could have a material adverse effect on our financial position, results of operations and our ability to continue our existence. We may seek additional funds through the issuance of additional common stock or other securities (equity or debt) convertible into shares of common stock, which could dilute the ownership interest of our stockholders. We may seek funding from Toucan Capital or Toucan Partners or their affiliates or other third parties. Such parties are under no obligation to provide us any additional funds, and any such funding may be dilutive to stockholders and may contain restrictive covenants that could limit our ability to take certain actions.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive, financial and accounting officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our principal executive, financial and accounting officer concluded that, as of September 30, 2012, in light of the material weaknesses identified in our management report on internal controls and procedures contained in our Form 10-K for the fiscal year ended December 31, 2011, Item 9A filed on April 13, 2012, our disclosure controls and procedures were not effective to ensure that the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to management, including our chief executive officer, financial and accounting officer, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods prescribed by the SEC.

Changes in Internal Control over Financial Reporting

There has been no change in our internal controls over financial reporting that occurred during the fiscal quarter ended September 30, 2012, that has materially affected, or is reasonably expected to materially affect, our internal controls over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

From time to time, we are involved in claims and suits that arise in the ordinary course of our business. Although management currently believes that resolving any such claims against us will not have a material adverse impact on our business, financial position or results of operations, these matters are subject to inherent uncertainties and management's view of these matters may change in the future.

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

On July 30, 2012, we issued 82,386 shares of common stock to a private investor at \$5.28 per share for net proceeds of \$435,000.

On September 5, 2012, we issued 35,714 shares of common stock to a private investor at \$5.60 per share for net proceeds of \$200,000.

On September 28, 2012, we issued 104,167 shares of common stock to a private investor at \$4.80 per share for net proceeds of \$500,000.

In October 2012, we issued an aggregate 833,333 shares of common stock to private investors at \$4.80 per share for net proceeds of \$4,000,000.

In November 2012, we issued 208,333 shares of common stock to a private investor at \$4.80 per share for net proceeds of \$1,000,000.

The sales of the securities identified above were made pursuant to privately negotiated transactions that did not involve a public offering of securities and, accordingly, we believe that these transactions were exempt from the registration requirements of the Securities Act pursuant to Section 4(2) of the Securities Act and Rule 506 of Regulation D. The agreements executed in connection with these sales contain representations to support the Company's reasonable belief that the Investors had access to information concerning the Company's operations and financial condition, that the Investors acquired the securities for their own account and not with a view to the distribution thereof in the absence of an effective registration statement or an applicable exemption from registration, and that the Investors are sophisticated within the meaning of Section 4(2) of the Securities Act and are "accredited investors" (as defined by Rule 501 under the Securities Act). In addition, the issuances did not involve any public offering; the Company made no solicitation in connection with the sale other than communications with the Investor; the Company obtained representations from the Investor regarding their investment intent, experience and sophistication; and the Investor either received or had access to adequate information about the Company in order to make an informed investment decision. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

Item 6. Exhibits

- 31.1 Certification of President (Principal Executive Officer and Principal Financial and Accounting Officer), Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of President, Chief Executive Officer and Principal Financial and Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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.

NORTHWEST BIOTHERAPEUTICS, INC

Dated: November 12, 2012

By: /s/ Linda M. Powers

Name: Linda M. Powers

Title: President and Chief Executive Officer

Principal Executive Officer

Principal Financial and Accounting Officer