

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 June 30, 2009

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
  
Commission file number 000-33393

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

Delaware  
(State or other Jurisdiction of Incorporation or Organization)

I.R.S. Employer Identification No. 94-3306718

7600 Wisconsin Avenue, Suite 750  
Bethesda, Maryland 20814  
(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 the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒

(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 August 12, 2009, the total number of shares of common stock, par value \$0.001 per share, outstanding was 45,069,872.

TABLE OF CONTENTS

NORTHWEST BIOTHERAPEUTICS, INC.

	Page
<b>PART I — FINANCIAL INFORMATION</b>	<b>3</b>
Item 1. Financial Statements	3
Condensed Consolidated Balance Sheets as of December 31, 2008 and June 30, 2009 (unaudited)	3
Condensed Consolidated Statements of Operations (unaudited) for the three and six months ended June 30, 2008 and 2009 and the period from March 18, 1996 (inception) to June 30, 2009	4
Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2008 and 2009 and the period from March 18, 1996 (inception) to June 30, 2009	5-6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3. Quantitative and Qualitative Disclosures About Market Risk	29
Item 4. Controls and Procedures	30
<b>PART II — OTHER INFORMATION</b>	<b>31</b>
Item 1. Legal Proceedings	31
Item 1A. Risk Factors	34
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	44
Item 3. Defaults Upon Senior Securities	46
Item 4. Submission of Matters to a Vote of Security Holders	46
Item 5. Other Information	46
Item 6. Exhibits	47
<b>SIGNATURES</b>	<b>48</b>
<b>INDEX TO EXHIBITS</b>	<b>49</b>

NORTHWEST BIOTHERAPEUTICS, INC. (A Development Stage Company)		
Condensed Consolidated Balance Sheets (in thousands)		
	December 31, 2008	June 30, 2009 (Unaudited)
<b>Assets</b>		
Current assets:		
Cash	\$ 16	\$ 50
Accounts receivable	1	1
Prepaid expenses and other current assets	1,057	136
<b>Total current assets</b>	<b>1,074</b>	<b>187</b>
Property and equipment:		
Laboratory equipment	29	29
Office furniture and other equipment	82	82
Construction in progress	387	389
	498	500
Less accumulated depreciation and amortization	(104)	(493)
	394	7
Deposit and other non-current assets	12	2
<b>Total assets</b>	<b>\$ 1,480</b>	<b>\$ 196</b>
<b>Liabilities And Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 3,420	\$ 3,626
Accounts payable, related party	656	3,536
Accrued expenses	1,298	1,390
Accrued expense, related party	905	1,535
Notes payable, net of warrant related discount (\$603 and \$0 at December 31, 2008 and June 30, 2009)	2,047	2,650
Note payable to related parties, net of warrant related discount (\$46 and \$0 at December 31, 2008 and June 30, 2009)	5,454	5,500
<b>Total current liabilities</b>	<b>13,780</b>	<b>18,237</b>
Long term liabilities		
Convertible notes payable, net of discount (\$64 at June 30, 2009)	—	696
<b>Total long term liabilities</b>	<b>—</b>	<b>696</b>
<b>Total liabilities</b>	<b>13,780</b>	<b>18,933</b>
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 20,000,000 shares authorized and none issued and outstanding		
Common stock, \$0.001 par value; 100,000,000 shares authorized at December 31, 2008 and June 30, 2009 and 42,492,853 and 45,069,872 shares issued and outstanding at December 31, 2008 and June 30, 2009, respectively	42	45
Additional paid-in capital	152,308	154,524
Deficit accumulated during the development stage	(164,626)	(173,297)
Cumulative translation adjustment	(24)	(9)
<b>Total stockholders' equity (deficit)</b>	<b>(12,300)</b>	<b>(18,737)</b>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 1,480</b>	<b>\$ 196</b>

See accompanying notes to condensed consolidated financial statements.

<p style="text-align: center;"><b>NORTHWEST BIOTHERAPEUTICS, INC.</b> (A Development Stage Company)</p> <p style="text-align: center;"><b>Condensed Consolidated Statements of Operations</b> (in thousands, except per share data) (Unaudited)</p>					
	Three Months Ended June 30,		Six Months Ended June 30,		Period from March 18, 1996 (inception) to June 30, 2009
	2008	2009	2008	2009	
<b>Revenues:</b>					
Research material sales	\$ —	\$ —	\$ —	\$ —	\$ 550
Contract research and development from related parties	—	—	—	—	1,128
Research grants and other	—	—	—	—	1,061
Total revenues	—	—	—	—	2,739
<b>Operating cost and expenses:</b>					
Cost of research material sales	—	—	—	—	382
Research and development	3,143	2,480	6,205	4,972	62,297
General and administrative	2,855	786	5,458	2,119	51,163
Depreciation and amortization	—	—	22	—	2,344
Loss on facility sublease	—	—	—	—	895
Asset impairment loss	—	389	—	389	2,445
Total operating costs and expenses	5,998	3,655	11,685	7,480	119,526
Loss from operations	(5,998)	(3,655)	(11,685)	(7,480)	(116,787)
<b>Other income (expense):</b>					
Warrant valuation	—	—	—	—	6,759
Gain on sale of intellectual property	—	—	—	—	3,664
Interest expense	(69)	(440)	(81)	(1,191)	(23,342)
Interest income and other	17	—	91	—	1,218
<b>Net loss</b>	(6,050)	(4,095)	(11,675)	(8,671)	(128,488)
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 loss applicable to common stockholders	<u>\$ (6,050)</u>	<u>\$ (4,095)</u>	<u>\$ (11,675)</u>	<u>\$ (8,671)</u>	<u>\$ (173,297)</u>
Net loss per share applicable to common stockholders — basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.09)</u>	<u>\$ (0.28)</u>	<u>\$ (0.20)</u>	
Weighted average shares used in computing basic and diluted net loss per share	<u>42,376</u>	<u>45,069</u>	<u>42,361</u>	<u>44,232</u>	

See accompanying notes to condensed consolidated financial statements.

<p style="text-align: center;"><b>NORTHWEST BIOTHERAPEUTICS, INC.</b> (A Development Stage Company)</p> <p style="text-align: center;"><b>Condensed Consolidated Statements of Cash Flows</b> (in thousands) (Unaudited)</p>			
	<p style="text-align: center;">Six Months Ended June 30,</p>		<p style="text-align: center;">Period from March 18, 1996 (Inception) to June 30, 2009</p>
	2008	2009	2009
<b>Cash Flows from Operating Activities:</b>			
<b>Net Loss</b>	\$ (11,675)	\$ (8,671)	\$ (128,488)
<b>Reconciliation of net loss to net cash used in operating activities:</b>			
Depreciation and amortization	22	—	2,344
Amortization of deferred financing costs	—	—	320
Amortization of debt discount	—	659	19,023
Accrued interest converted to preferred stock	—	—	260
Accreted interest on convertible promissory note	—	—	1,484
Stock-based compensation costs	2,214	658	7,450
Warrant valuation	—	—	(6,759)
Asset impairment and loss (gain) on sale of properties	—	389	(936)
Loss on facility sublease	—	—	895
<b>Increase (decrease) in cash resulting from changes in assets and liabilities:</b>			
Accounts receivable	—	—	(1)
Prepaid expenses and other current assets	(576)	931	588
Accounts payable and accrued expenses	94	391	5,031
Related party accounts payable and accrued expenses	(459)	3,510	5,071
Accrued loss on sublease	—	—	(265)
Deferred rent	—	—	410
Net Cash used in Operating Activities	(10,380)	(2,133)	(93,573)
<b>Cash Flows from Investing Activities:</b>			
Purchase of property and equipment, net	(240)	(2)	(5,003)
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	(240)	(2)	(1,967)
<b>Cash Flows from Financing Activities:</b>			
Proceeds from issuance of note payable	—	—	2,650
Proceeds from issuance of convertible notes payable	—	760	760
Proceeds from issuance of note payable to related parties	4,000	—	11,250
Repayment of note payable to stockholder	—	—	(6,700)
Proceeds from issuance of convertible promissory note and warrants, net of issuance costs	—	—	13,099
Repayment of convertible promissory note	—	—	(119)
Borrowing under line of credit, Northwest Hospital	—	—	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 of Series A cumulative preferred stock, net	—	—	28,708
Proceeds from exercise of stock options and warrants	—	—	228
Proceeds from issuance of common stock, net	—	1,394	49,737
Payment of preferred stock dividends	—	—	(1,251)
Mandatorily redeemable Series A preferred stock redemption fee	—	—	(1,700)
Deferred financing costs	—	—	(320)
Net Cash provided by Financing Activities	4,000	2,154	95,599

	Six Months Ended June 30,		Period from March 18, 1996 (Inception) to June 30, 2009
	2008	2009	
Effect of exchange rates on cash	(36)	15	(9)
Net increase (decrease) in cash	(6,656)	34	50
Cash at beginning of period	7,861	16	—
<b>Cash at end of period</b>	<b>\$ 1,205</b>	<b>\$ 50</b>	<b>\$ 50</b>
Supplemental disclosure of cash flow information — Cash paid during the period for interest	<u>\$ 12</u>	<u>—</u>	<u>\$ 1,879</u>
Supplemental schedule of non-cash financing activities:			
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
Warrants issued on Series A and Series A-1 preferred stock dividends	—	—	4,664
Equipment acquired through capital leases	—	—	285
Common stock warrant liability	—	—	11,841
Accretion of mandatorily redeemable Series A preferred stock redemption obligation	—	—	1,872
Beneficial conversion feature of convertible promissory notes	—	73	8,332
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 for license rights	—	—	4
Issuance of common stock and warrants to Medarex	—	—	840
Issuance of common stock to landlord	—	—	35
Issuance of common stock for finders fee	—	93	93
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	<u>—</u>	<u>—</u>	<u>480</u>

See accompanying notes to condensed consolidated financial statements.

**Northwest Biotherapeutics, Inc.**  
**(A Development Stage Company)**

**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 subsidiary, NW Bio Europe Sarl (collectively, the “Company”). 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 the Company’s Annual Report on Form 10-K for the year ended December 31, 2008. 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 and six month periods ended June 30, 2009 and 2008 are not necessarily indicative of results to be expected for a full year.

The independent registered public accounting firm’s report on the financial statements for the fiscal year ended December 31, 2008 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 significant accounting policies used in the preparation of the Company’s condensed consolidated financial statements are disclosed in Note 3 to the consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2008. Certain amounts in the 2008 Financial Statements have been reclassified to conform to the 2009 Financial Statement presentation.

***Impairment of long-lived assets***

In accordance with the provisions of Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), long-lived assets including property and equipment are reviewed for possible impairment whenever significant events or changes in circumstances, including changes in our business strategy and plans, indicate that an impairment may have occurred. An impairment is indicated when the sum of the expected future undiscounted net cash flows identifiable to that asset or asset group is less than its carrying value. Long-lived assets to be held and used, including assets to be disposed of other than by sale, for which the carrying amount is not recoverable are adjusted to their estimated fair value at the date an impairment is indicated, which establishes a new basis for the assets for depreciation purposes. Long-lived assets to be disposed of by sale are reported at the lower of carrying amount or fair value less cost to sell. Impairment losses are determined from actual or estimated fair values, which are based on market values, net realizable values or projections of discounted net cash flows, as appropriate.

During 2009, the Company determined that the carrying value of its construction in progress was not recoverable, and recorded an impairment charge of \$389,000 to reduce the carrying value to \$0. Property and equipment are stated at cost, as adjusted for any prior impairments. Property and equipment are depreciated or amortized over their estimated useful lives using the straight-line method.

***Recent Accounting Pronouncements***

In December 2007, the Financial Accounting Standards Board (“FASB”) ratified the consensus reached by the Emerging Issues Task Force (“EITF”) on Issue No. 07-1 (“EITF 07-1”), *Accounting for Collaborative Arrangements*. EITF 07-1 was effective for the Company beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The Company adopted EITF 07-1 effective January 1, 2009 which had no effect on the consolidated financial statements.

In February 2008, the FASB issued FASB Staff Position (“FSP No. 157-1”) which excludes SFAS No. 13, *Accounting for Leases* and certain other accounting pronouncements that address fair value measurements under SFAS 13, from the scope of SFAS 157 *Fair Value Measurements* . In February 2008, the FASB issued FSP No. 157-2 (“FSP FAS 157-2”), which provides a one-year delayed application of SFAS 157 *Fair Value Measurements* for nonfinancial assets and liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Therefore the Company was required to adopt SFAS 157 as amended by FSP FAS 157-1 and FSP FAS 157-2 on January 1, 2009, the beginning of the Company’s fiscal year, as related to nonfinancial assets and liabilities, which did not have an impact on the Company’s consolidated financial statements.

On April 9, 2009 the FASB issued several Staff Positions, as listed below, relating to fair value accounting, impairment of securities, and disclosures. All of these FSP’s are effective for interim and annual periods ending after June 15, 2009; entities may early adopt the FSP’s for the interim and annual periods ended after March 15, 2009. The Company did not early adopt any of these FSP’s and the adoption on April 1, 2009 did not have a material impact on the Company’s consolidated financial statements.

- FSP FAS 157-4 *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions that are Not Orderly.*
- FSP FAS 115-2 *Recognition and Presentation of Other-Than-Temporary Impairments*; and
- FSP FAS 107-1, *Interim Disclosures about Fair Value of Financial Statements.*

In May 2008, the FASB issued Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments that may be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (“FSP APB 14-1”). FSP APB 14-1 states that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of Accounting Principles Board Opinion No. 14 and that issuers of such instruments should account separately for the liability and equity components of the instrument in a manner that will reflect the entity’s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 was effective for financial statements issued for fiscal years beginning after December 15, 2008, and must be applied retrospectively to all periods presented. The Company adopted this standard on January 1, 2009 which had no effect on the consolidated financial statements.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity’s Own Stock* (“EITF 07-5”). EITF 07-5 provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument’s contingent exercise and settlement provisions. EITF 07-5 was effective for fiscal years beginning after December 15, 2008. The Company adopted EITF 07-5 effective January 1, 2009, which had no effect on the consolidated financial statements.

In June 2008, the FASB issued EITF Issue No. 08-4, *Transition Guidance for Conforming Changes to Issue No. 98-5* (“EITF 08-4”). The objective of EITF 08-4 is to provide transition guidance for conforming changes made to EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios that result from EITF Issue No. 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments, and SFAS Issue No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. EITF 08-4 was effective for financial statements issued for fiscal years ending after December 15, 2008. The Company adopted EITF 08-4 effective January 1, 2009, which had no effect on the consolidated financial statements.

In June 2008, the FASB issued FSP EITF Issue No. 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (“FSP EITF 03-6-1”) . FSP EITF 03-6-1 provides that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP EITF 03-6-1 was effective for fiscal years beginning after December 15, 2008. The Company adopted EITF 03-6-1 effective January 1, 2009, which had no effect on the consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165 *Subsequent Events* (“SFAS 165”) , which provides guidance to establish general standards of accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 is effective for interim or fiscal periods ending after June 15, 2009. Accordingly, the Company adopted the provisions of SFAS 165 on April 1, 2009. The adoption of this guidance did not have a material impact on our consolidated financial statements. However, the provisions of SFAS 165 result in additional disclosures with respect to subsequent events. See note 10, Subsequent Events, for this additional disclosure.



In April 2009, FASB issued FSP 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, which amends SFAS No.107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as annual financial statements. This standard is effective for periods ending after June 15, 2009. Accordingly, the Company adopted the provisions of FSP FAS 107-1 and APB 28-1 on April 1, 2009. The adoption of this guidance did not have a material impact on our consolidated financial position, results of operations or cash flows. However, the provisions of FSP FAS 107-1 and APB 28-1 result in additional disclosures with respect to the fair value of the Company’s financial instruments.

3. Fair Value Measurements

The Company adopted SFAS 157 which applies to certain accounting standards that require or permit fair value measurements on January 1, 2008.

SFAS 157 defines fair value, establishes a consistent framework for measuring fair value and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions, SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1:** Observable market inputs such as quoted prices in active markets.
- Level 2:** Observable market inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3:** Unobservable inputs where there is little or no market data, which require the reporting entity to develop its own

As of June 30, 2009, the Company did not hold any assets and liabilities which were required to be measured at fair value.

The Company adopted SFAS no. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities*”, which provides entities the option to measure many financial instruments and certain other items at fair value. The Company has currently chosen not to elect the fair value option for any option for any items that are not already required to be measured at fair value in accordance with generally accepted accounting principles.

The Company adopted the provisions of FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments on April 1, 2009*, which require disclosures about the fair value of financial instruments in interim as well as annual financial statements. The following table summarizes the carrying value of the Company's financial instruments as of June 30, 2009 (in thousands):

	June 30, 2009	
	Carrying Amount	Fair Value
<u>Assets</u>		
Cash	\$ 50	\$ 50
Accounts receivable	1	1
<u>Liabilities</u>		
Accounts payable	3,626	3,626
Accounts payable , related party	3,536	3,536
Accrued expenses	1,390	1,390
Accrued expenses, related parties	1,535	1,535
Notes payable, net	2,650	2,650
Notes payable to related parties, net	5,500	5,500
Convertible notes payable	696	696

For cash, accounts payable and accrued expenses, the carrying amount approximates fair value because of the relative short maturity of these instruments. There are no direct market comparables for the notes payable, notes payable related parties or the convertible notes. Due to the short term nature of the notes payable and notes payable related parties management believes that their fair value equates to the carrying value. In determining the fair value of the convertible notes payable management has considered both their net present value and the conversion price of the notes relative to the current market price for the Company’s stock and concluded that as the conversion price is below the current price of the Company’s carrying value of the notes equates to fair market value.

**4. Stock-Based Compensation Plans**

The Company has share-based compensation plans under which employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. Stock-based compensation cost is measured by the Company at the grant date, based on the fair value of the award, and is recognized as an expense over the requisite service period which is generally the service period. For options and warrants issued to non-employees, the Company recognizes stock compensation costs utilizing the fair value methodology prescribed in SFAS 123 (revised 2004), *Share Based Payment* (“SFAS 123(R)”), over the related period of benefit.

The stock-based compensation expense related to stock-based awards under SFAS 123(R) totaled approximately \$468,300 and \$1,117,200 for the three months ended June 30, 2009 and 2008, respectively. The stock-based compensation expense related to stock-based awards under SFAS 123(R) totaled approximately \$658,000 and \$2,213,900 for the six months ended June 30, 2009 and 2008, respectively. As of June 30, 2009, the Company had \$3.8 million of total unrecognized compensation cost related to non-vested stock-based awards granted under all equity compensation plans.

Options to purchase 870,000 shares of the Company’s common stock were granted to employees in April and May 2008. No options to purchase the Company’s common stock were granted during the six month period ended June 30, 2009. The fair value of each option grant is estimated on the grant date using the Black-Scholes option pricing model.

***Stock Option Plans***

The Company established a stock option plan, which became effective on June 22, 2007 (the “2007 Stock Option Plan”). In April 2008, the Company increased the number of shares reserved for issuance under the 2007 Stock Option Plan by 519,132 shares of its common stock for an aggregate of 6,000,000 shares of its common stock, par value \$0.001 per share (“Common Stock”), reserved for issue in respect of options granted under the plan. The plan provides for the grant to employees of the Company, its parents and subsidiaries, including officers and employee directors, of “incentive stock options” within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended, and for the grant of non-statutory stock options to the employees, officers, directors, including non-employee directors, and consultants of the Company, its parents and subsidiaries. To the extent an optionee would have the right in any calendar year to exercise for the first time one or more incentive stock options for shares having an aggregate fair market value, under all of the Company’s plans and determined as of the grant date, in excess of \$100,000, any such excess options will be treated as non-statutory options.

**5. Liquidity**

The Company has experienced recurring losses from operations, and, as of June 30, 2009, had a working capital deficit of \$18.1 million and a deficit accumulated during the development stage of \$173.3 million.

Between 2004 and 2009, the Company has undergone a significant recapitalization through the transactions described below.

***Toucan Capital and Toucan Partners***

Toucan Capital Fund II, L.P. (“Toucan Capital”) loaned the Company an aggregate of \$6.75 million during 2004 and 2005. In April 2006, the \$6.75 million of notes payable plus all accrued interest due to Toucan Capital were converted into shares of the Company’s Series A-1 cumulative convertible Preferred Stock (the “Series A-1 Preferred Stock”). In connection with these loans the Company issued Toucan Capital a warrant to purchase 6,471,333 shares of Series A-1 Preferred Stock.

On January 26, 2005, the Company entered into a securities purchase agreement with Toucan Capital pursuant to which it purchased 32.5 million shares of the Company’s Series A cumulative convertible preferred stock (the “Series A Preferred Stock”) at a purchase price of \$0.04 per share, for a net purchase price of \$1.276 million. In connection with these loans the Company issued Toucan Capital a warrant to purchase 2,166,667 shares of Series A Preferred Stock.

From November 14, 2005 through March 9, 2006, Toucan Partners, LLC (“Toucan Partners”) loaned the Company \$4.825 million. In connection with these loans the Company issued a warrant to purchase 3,198,555 shares of Series A-1 Preferred Stock. In April 2007 this amount was converted into convertible demand notes (the “2007 Convertible Notes”) and related warrants (the “2007 Warrants”) carrying an interest rate of 10% per annum. The notes and related interest were repaid in full in the fourth quarter of 2007.

In May 2007 Toucan Partners loaned the Company an aggregate amount of \$725,000, and issued warrants to purchase shares of the Company’s capital stock to Toucan Partners in connection with the notes. These notes and warrants are on the same terms as the 2007 Convertible Notes and 2007 Warrants. The notes and related interest were repaid in full in the fourth quarter of 2007.

On June 1, 2007, the Company, Toucan Capital, and Toucan Partners entered into a conversion agreement (“Conversion Agreement”) which became effective on June 22, 2007 upon the admission of the Company’s Common Stock to trade on Alternative Investment Market (“AIM”) of the London Stock Exchange (“Admission”). Under the conversion agreement Toucan Capital and Toucan Partners agreed to eliminate a number of rights, preferences and protections associated with the Series A Preferred Stock and the Series A-1 Preferred Stock in exchange for 4,287,851 and 2,572,710 shares of common stock, respectively and Toucan Capital converted its preferred shares into 15,011,635 shares of common stock. Additionally under the conversion agreement the Company exchanged the warrants issued to purchase Series A-1 Preferred Stock and Series A Preferred Stock (discussed above) for warrants to purchase common stock of the Company. As a result of the conversion Toucan Capital now holds warrants to purchase 14,150,732 shares of Common Stock at an exercise price of \$0.60 per share and 7,884,357 shares of Common Stock at an exercise price of \$0.15 per share and Toucan Partners holds warrants to purchase 8,831,541 shares of Common Stock at an exercise price of \$0.60 per share.

On August 19, 2008, the Company entered into a loan agreement with Toucan Partners, under which Toucan Partners provided the Company with debt financing in the amount of \$1.0 million (the “Toucan Loan”). Under the terms of the Toucan Loan, the Company received \$1.0 million in return for an unsecured promissory note in the principal amount of \$1,060,000 (reflecting an original issue discount of six percent, or \$60,000). The Toucan Loan had a term of six months. On February 19, 2009, Toucan Partners agreed to extend the term of the loan. The terms and period of the extension are currently being negotiated by management. The note may be paid at any time without a prepayment penalty and the term may be extended in Toucan Partners discretion upon the Company’s request. Since February 20, 2009 the Company has been accruing interest related to the Toucan Loan on the same terms as those included in the original agreement. At June 30, 2009, the carrying value (inclusive of interest accrued to June 30, 2009) of the Loan was \$1,135,598. The Company amortizes the discount using the effective interest method over the term of the loan. During the three and six month periods ended June 30, 2009, the Company recorded interest expense related to the amortization of the discount of \$44,836 and \$89,179 respectively. Toucan Partners may elect to have the original issue discount amount paid at maturity in shares of common stock, at a price per share equal to the average closing price of the Company’s common stock on the NASD Over-The-Counter Bulletin Board during the ten trading days prior to the execution of the loan agreement. The intrinsic value of the Toucan Loan did not result in a beneficial conversion feature.

On December 22, 2008, the Company entered into a Loan Agreement and Promissory Note with Toucan Partners. Under the Note, Toucan has loaned the Company \$500,000 (the “Toucan December Loan”). The Note is an unsecured obligation of the Company and accrues interest at the rate of 12% per year. The term of the Note is six months, with a maturity date of June 22, 2009. Toucan Partners have agreed to extend the term of the loan. The terms and period of the extension are currently being negotiated by management. The Note may be prepaid without the consent of Toucan. The Note contains customary representations and warranties, and affirmative and negative covenants regarding the operation of the Company’s business during the term of the Note. In connection with the Note, the Company issued to Toucan Partners a warrant to purchase 132,500 shares of the Company’s common stock at an exercise price equal to \$0.40 per share, which was the closing price of the Company’s Common Stock on the NASD Over-The-Counter Bulletin Board on December 22, 2008. The warrant expires 5 years from the date of issuance.

Upon issuing the Note to Toucan Partners, the Company recognized the note and warrants based on their relative fair values of \$453,000 and \$47,000, respectively, in accordance with APB Opinion No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants* (“APB 14”). The fair value of the note was determined using the Black-Scholes option pricing model. The relative fair value of the warrants was classified as a component of additional paid-in capital in accordance with SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (“SFAS 150”) and EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* ("EITF 00-19"), with the corresponding amount reflected as a contra-liability to the debt. The fair value of the warrants was determined using the Black Scholes model, assuming a term of five years, volatility of 197%, no dividends, and a risk-free interest rate of 1.53%.

As a result of the financings described above, as of June 30, 2009, Toucan Capital held:

- an aggregate of 19,299,486 shares of Common Stock;
- warrants to purchase 14,150,732 shares of Common Stock at an exercise price of \$0.60 per share; and
- warrants to purchase 7,884,357 shares of Common Stock at an exercise price of \$0.15 per share.

As a result of the financings described above, as of June 30, 2009, Toucan Partners and its managing member Ms. Linda Powers held:

- an aggregate of 2,572,710 shares of Common Stock;
- warrants to purchase 8,832,541 shares of Common Stock at an exercise price of \$0.60 per share; and
- warrants to purchase 132,500 shares of common stock at an exercise price of \$0.40.

As of June 30, 2009, Toucan Capital, including the holdings of Toucan Partners, held 21,872,196 shares of the Company’s capital stock, representing approximately 48.5% of the outstanding Common Stock. Further, as of June 30, 2009, Toucan Capital, including the holdings of Toucan Partners, beneficially owned (including unexercised warrants) 52,872,326 shares of the Company’s capital stock, representing a beneficial ownership interest of approximately 69.5%.

***Private Placement***

On March 30, 2006, the Company entered into a securities purchase agreement (the “Purchase Agreement”) with a group of accredited investors pursuant to which the Company agreed to sell an aggregate of approximately 2.6 million shares of its Common Stock, at a price of \$2.10 per share, and to issue, for no additional consideration, warrants to purchase up to an aggregate of approximately 1.3 million shares of the Company’s Common Stock. The PIPE Financing closed and stock was issued to the new investors and the Company received gross proceeds of approximately \$5.5 million, before cash offering expenses of approximately \$442,000. The total cost of the offering recorded, including both cash and non-cash costs, was approximately \$837,000. The relative fair value of the Common Stock was estimated to be approximately \$3.7 million and the relative fair value of the warrants was estimated to be \$1.8 million as determined based on the relative fair value allocation of the proceeds received. The warrants were valued using the Black-Scholes option pricing model.

In connection with the securities purchase agreement, the Company issued approximately 67,000 warrants to its investment bank valued at approximately \$395,000. The fair value of the warrants issued to the investment bank was determined using the Black-Scholes option pricing model based on the following assumptions: risk free interest rate of 4.8%, contractual life of five years, expected volatility of 382% and a dividend yield of 0%.

The warrants expire five years after issuance, and are initially exercisable at a price of \$2.10 per share, subject to adjustments under certain circumstances.

On January 16, 2009 the Company received \$700,000 from Al Rajhi Holdings through the purchase of 1,000,000 shares of its common stock at \$0.70 per share. The Company granted Al Rajhi Holdings piggyback registration rights for the shares issued under the sale of securities. The Securities Purchase Agreement contains the usual representations, warranties and covenants.

On March 27, 2009, the Company entered into a securities purchase agreement (the “2009 Purchase Agreement”) with a group of accredited investors pursuant to which the Company agreed to sell an aggregate of approximately 1.4 million shares of its common stock, at a price of \$0.53 per share, and to issue, for no additional consideration, warrants to purchase up to an aggregate of approximately 207,000 shares of the Company’s common stock. The financing closed and stock was issued to the new investors and the Company received gross proceeds of approximately \$0.7 million, before cash offering expenses of approximately \$36,000. The total cost of the offering recorded, including both cash and non-cash costs, was approximately \$176,000. The relative fair value of the common stock was estimated to be approximately \$0.6 million and the relative fair value of the warrants was estimated to be \$140,000 as determined based on the relative fair value allocation of the proceeds received. The warrants were valued using the Black-Scholes option pricing model.

***Placement of Common Stock with Foreign Institutional Investors***

On June 22, 2007, the Company placed 15,789,473 shares of its Common Stock with foreign institutional investors at a price of £0.95 per share. The gross proceeds from the placement were approximately £15.0 million, or \$29.9 million, while net proceeds from the offering, after deducting commissions and expenses, were approximately £13.0 million, or \$25.9 million. The net proceeds from the placement were used to fund clinical trials, product and process development, working capital needs and repayment of certain existing debt.

***Shareholder Loan***

On May 12, 2008, the Company entered into a loan agreement with Al Rajhi, under which Al Rajhi provided the Company with debt financing in the amount of \$4.0 million (the “Loan”). Under the terms of the Loan, the Company received \$4.0 million in return for an unsecured promissory note in the principal amount of \$4,240,000 (reflecting an original issue discount of six percent, or \$240,000). The Loan had an original term of six months. On November 14, 2008 Al Rajhi agreed to extend the term of the Loan on terms that are currently being negotiated. Since November 14, 2008 and until the terms of negotiation and execution of necessary documents are complete the Company has been accruing costs related to the Loan on the same terms as those included in the original loan agreement. The note may be paid at any time without a prepayment penalty and the term may be extended in Al Rajhi’s discretion upon the Company’s request. At June 30, 2009, the carrying value (inclusive of interest accrued through June 30, 2009) of the Loan was \$4,560,884. During the three and six month periods ended June 30, 2009, the Company recorded interest expense including amortization of the original issue discount of \$120,663 and \$240,000 respectively. Al Rajhi may elect to have the original issue discount amount paid at maturity in shares of Common Stock, at a price per share equal to the average closing price of the Company’s Common Stock on the NASD Over-The-Counter Bulletin Board during the ten trading days prior to the execution of the Loan agreement. The intrinsic value of the Loan did not result in a beneficial conversion feature on the maturity date of the Loan.

***Other Loans***

On October 1, 2008, the Company entered into a Loan Agreement (the “SDS Loan”) and Promissory Note (the “Note”) with SDS. Under the Note, SDS loaned the Company \$1.0 million. The Note is an unsecured obligation of the Company and accrues interest at the rate of 12% per year. The term of the Note is six months, with a maturity date of April 1, 2009. In April 2009, SDS agreed to extend the term of the Note on terms that are currently being negotiated. Since April 2, 2009 the Company has been accruing interest related to the SDS Loan on the same terms as those included in the original agreement. The Note may not be prepaid without the consent of SDS. The Note contains customary representations and warranties, and affirmative and negative covenants regarding the operation of the Company’s business during the term of the Note. In connection with the Note, the Company issued to SDS a warrant (the “Investment Warrant”) to purchase 299,046 shares of the Company’s common stock at an exercise price equal to \$0.53 per share, which was the closing price of the Company’s Common Stock on the AIM on October 1, 2008. The Investment Warrant expires 5 years from the date of issuance.

In addition to the Investment Warrant, under the terms of the Note, the Company issued SDS an additional warrant as a placement fee (the “Placement Warrant”) to purchase 398,729 shares of the Company’s Common Stock at an exercise price equal to \$0.53 per share. The Placement Warrant, which is in substantially the same form as the Investment Warrant, also expires 5 years after issuance.

Upon issuing the note to SDS, the Company recognized the note and warrants based on their relative fair values of \$625,000 and \$375,000, respectively, in accordance with APB 14. The fair value of the note was determined using the Black-Scholes option pricing model. The relative fair value of the warrants was classified as a component of additional paid-in capital in accordance with SFAS No. 150, and EITF 00-19, with the corresponding amount reflected as a contra-liability to the debt. The fair value of the warrants was determined using the Black Scholes model, assuming a term of five years, volatility of 194%, no dividends, and a risk-free interest rate of 2.87%.

On dates between October 21, 2008 and November 6, 2008, the Company entered into Loan Agreements (the “Private Investor Loans”) and Promissory Notes (the “Private Investor Promissory Notes”) with SDS and a group of private investors (the “Private Investors”). Under the Private Investor Promissory Notes, SDS loaned the Company \$1 million and the Private Investors loaned the Company \$650,000 for an aggregate of \$1.65 million. The Private Investor Promissory Notes are unsecured obligations of the Company and accrue interest at the rate of 12% per year. The term of the Private Investor Promissory Notes is six months, with maturity dates in April 2009. In April 2009, the Private Investors agreed to extend the term of the Note on terms that are currently being negotiated. Since the maturity dates of the Notes the Company has been accruing interest related to the Private Investor Loans on the same terms as those included in the original agreements. The Private Investor Promissory Notes may be prepaid at the discretion of the Company any time prior to maturity. The Private Investor Promissory Notes contain customary representations and warranties, and affirmative and negative covenants regarding the operation of the Company’s business during the term of the Private Investor Promissory Notes. The Company granted SDS and the Private Investors piggyback registration rights for any shares of the Company’s Common Stock issued to such investors upon exercise of the warrants issued to them in connection with the Private Investor Promissory Notes. Additionally, SDS received certain rights relating to subsequent financings, subject to the Company’s right to pre-pay SDS and avoid the rights being triggered.

In connection with the Private Investor Promissory Notes, the Company issued to SDS and the Private Investors warrants to purchase, in the aggregate, 2,132,927 shares of the Company’s Common Stock at an exercise price of \$0.41 per share. The Warrants expire three years from the date of issuance.

Upon issuing the notes to SDS, the Company recognized the note and warrants based on their relative fair values of \$1,053,000 and \$597,000, respectively, in accordance with APB 14. The fair value of the notes and warrants was determined using the Black-Scholes option pricing model. The relative fair value of the warrants was classified as a component of additional paid-in capital in accordance with SFAS 150 and EITF 00-19, with the corresponding amount reflected as a contra-liability to the debt. The fair value of the warrants was determined using the Black Scholes model, assuming a term of three years, volatility of 158%, no dividends, and a risk-free interest rate of 1.86%.

During March 2009, the Company entered into convertible Loan Agreements and Promissory Notes with a group of private lenders (“Private Lenders”). Under the Notes the Private Lenders have loaned the Company \$650,000. The Notes are unsecured obligations of the Company and accrue interest at the rate of 6% per year. The term of the Notes is two years, with a maturity dates in March 2011. The Notes may not be prepaid without the consent of Private Lenders. The Notes contain customary representations and warranties, and affirmative and negative covenants regarding the operation of the Company’s business during the term of the Notes. The conversion feature of the Loan Agreements allows the holder to receive shares of the Company’s common stock and not cash or other consideration. The Private Lenders may elect to have the total principal and accrued interest or any fraction thereof paid at maturity in shares of Common Stock, at a price per share equal to the average closing price of the Company’s Common Stock on the NASD Over-The-Counter Bulletin Board during the five trading days prior to the execution of the Loan agreement. The intrinsic value of the Loans resulted in a beneficial conversion feature with a relative fair value of \$73,000 attributable to the beneficial conversion feature.

On March 26, 2009, the Company entered into convertible Loan Agreement and Promissory Note with a private lender (“Private Lender”). Under the Note the Private Lender has loaned the Company \$110,000. The Note is an unsecured obligation of the Company and accrues interest at the rate of 6% per year. The term of the Note is two years, with a maturity date of March 25, 2011. The Note may not be prepaid without the consent of Private Lender. The Note contains customary representations and warranties, and affirmative and negative covenants regarding the operation of the Company’s business during the term of the Note. Upon receiving a request from the Private Lender for conversion the Company may elect to settle the instrument in cash or pay the total principal and accrued interest or any fraction thereof at maturity in shares of Common Stock, at a price per share equal to the average closing price of the Company’s Common Stock on the NASD Over-The-Counter Bulletin Board during the five trading days prior to the execution of the Loan agreement. The Company has assessed the note under the terms of FASB Staff Position No. APB 14-1 and concluded that the amount of the loan attributable to equity is immaterial. The intrinsic value of the note did not result in a material beneficial conversion feature.

Short-term debt consists of the following at December 31, 2008 and June 30, 2009 (in thousands):

	December 31, 2008	June 30, 2009
Unsecured note payable to SDS, interest rate 12% per annum	\$ 1,000	\$ 1,000
Unsecured notes payable to SDS and Private Investors, interest rate 12% per annum (net of warrant related discount \$603 and \$0 December 31, 2008 and June 30, 2009)	1,047	1,650
<b>Total notes payable (net)</b>	<b>\$ 2,047</b>	<b>\$ 2,650</b>
Notes payable to Al Rajhi, interest rate 12% per annum	\$ 4,000	\$ 4,000
Notes payable to Toucan Partners, interest rate 12% per annum	1,000	1,000
Note payable Toucan Partners, interest rate 12% per annum (net of warrant related discount \$46 and \$0 at December 31, 2008 and June 30,2009)	454	500
<b>Total notes payable related parties (net)</b>	<b>\$ 5,454</b>	<b>\$ 5,500</b>

Long-term debt consists of the following at December 31, 2008 and June 30,2009 (in thousands):

	December 31, 2008	June 30, 2009
Unsecured convertible notes payable to Private Lenders, interest rate 6% per annum, maturing on March 25, 2011, convertible into the Company’s common stock (net of discount related to beneficial conversion feature (\$64 at June 30, 2009)	\$ –	\$ 586
Unsecured convertible note payable to Private Lender, interest rate 6% per annum, matures March 25, 2011, convertible into the Company’s common stock at Company’s option	–	110
<b>Total -long-term debt (net)</b>	<b>\$ –</b>	<b>\$ 696</b>

Going Concern

As of August 12, 2009, the Company had approximately \$265,000 of cash on hand. Management estimates that the available cash is sufficient to support day to day operations through the end of September. Management is in discussions with multiple parties regarding potential funding transactions. However, these parties are not obligated to provide such financing.

The Company will require additional funding before the Company achieves profitability and there can be no assurance that its efforts to seek such funding will be successful. The Company may raise additional funds by issuing additional common stock or securities (equity or debt) convertible into shares of Common Stock, in which case, the ownership interest of the Company’s stockholders will be diluted. Any debt financing, if available, is likely to include restrictive covenants that could limit its ability to take certain actions. Further, 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 any additional funds, and any such funding may be dilutive to stockholders and may contain restrictive covenants. The Company currently is exploring additional financings with several other parties; however, there can be no assurance that the Company will be able to complete any such financing, or that the terms of such financings will be attractive to us. 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 its ability to continue in existence. Its independent registered public accounting firm has indicated in its report on the Company’s consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2008 that there is substantial doubt about its ability to continue as a going concern.

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

Effective June 19, 2007, all shares of Common Stock issued and outstanding were combined and reclassified on a one-for-fifteen basis (the “Reverse Stock Split”). The effect of the Reverse Stock Split has been retroactively applied to prior periods.



For the three and six months ended June 30, 2009 and 2008, respectively, options to purchase 2,400,000 and 5,600,000 shares of Common Stock and warrants to purchase 35 million and 32 million shares of Common Stock respectively were not included in the computation of diluted net loss per share because they were antidilutive.

7. Related Party Transactions

*Cognate Agreement*

On July 30, 2004, the Company entered into a service agreement with Cognate Therapeutics, Inc. (now known as Cognate BioServices, Inc., or 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, on May 17, 2007, the managing director of Toucan Capital was appointed to serve as a director of the Company and to serve as the non-executive Chairperson of the Company’s Board of Directors. Under the service agreement, the Company agreed to utilize Cognate’s services for an initial two-year period, related primarily to manufacturing DCVax® product candidates, regulatory advice, research and development preclinical activities and managing clinical trials. The agreement expired on July 30, 2006; however, the Company continued to utilize Cognate’s services under the same terms as set forth in the expired agreement. On May 17, 2007, the Company entered into a new service agreement with Cognate pursuant to which Cognate will provide certain consulting and, when needed, manufacturing services to the Company for its DCVax®-Brain Phase II clinical trial. Under the terms of the new contract, the Company paid a non-refundable contract initiation fee of \$250,000 and committed to pay budgeted monthly service fees of \$400,000, subject to quarterly true-ups, and monthly facility fees of \$150,000. The Company may terminate this agreement with 180 days notice and payment of all reasonable wind-up costs and Cognate may terminate the contract in the event that the brain cancer clinical trial fails to complete enrollment by July 1, 2009. As of August 14, 2009 Cognate has not terminated the service agreement. However, if such termination by the Company occurs at any time prior to the earlier of the submission of an FDA biological license application/new drug application on the Company’s brain cancer clinical trial or July 1, 2010 or, such termination by Cognate results from failure of the brain cancer clinical trial to complete patient enrollment by July 1, 2009, the Company is obligated to make an additional termination fee payment to Cognate equal to \$2 million.

During the three months ending June 30, 2009 and 2008, the Company recognized approximately \$2.0 million and \$2.3 million, respectively, of research and development costs related to these service agreements. During the six months ending June 30, 2009 and 2008, respectively, the Company recognized approximately \$4.0 million and \$4.1 million of research and development costs related to these service agreements. As of June 30, 2009 and December 31, 2008, the Company owed Cognate approximately \$3.2 and \$1.1 million, respectively.

*Toucan Capital*

In accordance with a recapitalization agreement dated April 26, 2004 between the Company and Toucan Capital, as amended and restated on July 30, 2004 and further amended ten times between October 22, 2004 and November 14, 2005, pursuant to which Toucan Capital agreed to recapitalize the Company by making loans to the Company, the Company accrued and paid certain legal and other administrative costs on Toucan Capital’s behalf. Pursuant to the terms of the Conversion Agreement discussed above, the recapitalization agreement was terminated on June 22, 2007. Subsequent to the termination of the recapitalization agreement, Toucan Capital continues to incur costs on behalf of the Company. These costs primarily relate to consulting costs and travel expenses incurred in support of the Company’s international expansion efforts. In addition, since July 1, 2007, the Company has paid and recorded rent expense due to Toucan Capital Corporation, an affiliate of Toucan Capital and Toucan Partners, for its office space in Bethesda, Maryland.

During the three months ending June 30, 2009 and 2008, respectively, the Company recognized approximately \$102,000 and \$148,000 of general and administrative costs related to the recapitalization agreement, rent expense, as well as legal, travel and other costs incurred by Toucan Capital on the Company’s behalf. At June 30, 2009 and December 31, 2008, accrued expense payable to Toucan Capital amounted to \$150,000 and \$50,000, respectively, and are included in the accompanying consolidated balance sheets.

*Toucan Partners*

See “Toucan Capital and Toucan Partners” in Note 5 above.

*Al Rajhi*

See “Shareholder Loan” in Note 5 above.

8. Contingencies

Private Placement

On March 30, 2006, the Company entered into a securities purchase agreement (the “Purchase Agreement”) with a group of accredited investors pursuant to which the Company sold an aggregate of approximately 2.63 million shares of its Common Stock, at a price of \$2.10 per share (the “PIPE Shares”), and issued, for no additional consideration, warrants to purchase up to an aggregate of approximately 1.3 million shares of Company’s Common Stock (the “Warrant Shares”).

Under the Purchase Agreement, the Company agreed to register for resale under the Securities Act of 1933, as amended (the “Securities Act”), both the PIPE Shares and the Warrant Shares. The Company also agreed to other customary obligations regarding registration, including matters relating to indemnification, maintenance of the registration statement, payment of expenses, and compliance with state “blue sky” laws. The Company may be liable for liquidated damages if the registration statement (after being declared effective) ceases to be effective in a manner, and for a period of time, that violates the Company’s obligations under the Purchase Agreement. The amount of the liquidated damages payable to the investors is, in aggregate, one percent (1%) of the aggregate purchase price of the shares per month, subject to a cap of ten percent (10%) of the aggregate purchase price of the shares.

As of April 30, 2009, the Company’s registration statement ceased to be effective. The Company has not yet filed a post-effective amendment to the registration statement. Liquidated damages will accrue at a rate of approximately \$550 per day until a post effective registration statement is filed and becomes effective. Liquidated damages accrued through June 30, 2009 for previous periods during which the registration statement was not effective amount to the aggregate of approximately \$215,000.

Legal Proceedings

Soma Arbitration

The Company signed an engagement letter, dated October 15, 2003, with Soma Partners, LLC, or Soma, a New Jersey-based investment bank, pursuant to which the Company engaged them to locate potential investors. Pursuant to the terms of the engagement letter, any disputes arising between the parties would be submitted to arbitration in the New York metropolitan area. A dispute arose between the parties. Soma filed an arbitration claim against us with the American Arbitration Association in New York, NY claiming unpaid commission fees of \$186,000 and seeking declaratory relief regarding potential fees for future transactions that may be undertaken by the Company with Toucan Capital. The Company vigorously disputed Soma’s claims on multiple grounds. The Company contended that it only owed Soma approximately \$6,000.

Soma subsequently filed an amended arbitration claim, claiming unpaid commission fees of \$339,000 and warrants to purchase 6% of the aggregate securities issued to date, and seeking declaratory relief regarding potential fees for future financing transactions which may be undertaken by the Company with Toucan Capital and others, which could potentially be in excess of \$4 million. Soma also requested the arbitrator award its attorneys’ fees and costs related to the proceedings. The Company strongly disputed Soma’s claims and defended ourselves.

The arbitration proceedings occurred from March 8-10, 2005 and on May 24, 2005, the arbitrator ruled in the Company’s favor and denied all claims of Soma. In particular, the arbitrator decided that the Company did not owe Soma the fees and warrants sought by Soma, that the Company would not owe Soma fees in connection with future financings, if any, and that the Company had no obligation to pay any of Soma’s attorneys’ fees or expenses. The arbitrator agreed that the only amount owed Soma was \$6,702.87, the payment of which was made on May 27, 2005.

On August 29, 2005, Soma filed a notice of petition to vacate the May 24, 2005 arbitration award with the Supreme Court of the State of New York. On December 30, 2005, the Supreme Court of the State of New York dismissed Soma’s petition.

On February 3, 2006, Soma filed another notice of appeal with the Supreme Court of the State of New York. On December 6, 2006, the Company filed its brief for this appeal and on December 12, 2006, Soma filed its reply brief. On June 19, 2007, the Appellate Division, First Department of the Supreme Court of the State of New York, reversed the December 30, 2005 decision and ordered a new arbitration proceeding. On July 26, 2007, the Company filed a Motion for Leave to Appeal with the Court of Appeals of the State of New York and on August 3, 2007 Soma filed its reply brief. On October 16, 2007, the Court of Appeals of the State of New York denied our motion to appeal. The Company intends to continue to vigorously defend against Soma’s claims. A new arbitration hearing was held New York for May 13-15, 2009 and June 24, 2009. We are continuing to vigorously defend against the claims of Soma, which we believe are unfounded.

***Lonza Patent Infringement Claim***

No change from previous filings.

***Stockholder Class Action Lawsuits***

On August 13, 2007, a complaint was filed in the U.S. District Court for the Western District of Washington naming the Company, the Chairperson of its Board of Directors, Linda F. Powers, and its Chief Executive Officer, Alton L. Boynton, as defendants in a class action for violation of federal securities laws. After this complaint was filed, five additional complaints were filed in other jurisdictions alleging similar claims. The complaints were filed on behalf of purchasers of the Company’s Common Stock between July 9, 2007 and July 18, 2007 and allege violations of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder. The complaints seek unspecified compensatory damages, costs and expenses. On December 18, 2007, a consolidated complaint was filed in the U.S. District Court for the Western District of Washington consolidating the stockholder actions previously filed. The putative securities class action lawsuit, *In re Northwest Biotherapeutics, Inc. Securities Litigation* , No. C-07-1254-RAJ was settled with prejudice January 8, 2009. The Company has agreed to pay in settlement US\$1 million. In accordance with the stipulation the insurance company has directly deposited the \$1,000,000 in a court controlled escrow account. The settlement must be approved by the Court. Management is unable to determine when the Court will approve the settlement. Additional details about the settlement can be found in the formal settlement documents, which are available from the United States District Court for the Western District of Washington. The case alleged that the Company misrepresented certain facts that resulted in the artificial inflation of the price of Northwest Biotherapeutics publicly-traded common stock between April 17, 2007 and July 18, 2007. The Company disputes the allegations of the lawsuit, and denies that there was any such misrepresentation or that the shares of Northwest Biotherapeutics common stock were artificially inflated. Nevertheless the Company is settling the lawsuit to avoid potentially expensive and protracted litigation. The Class Action Lawsuit final settlement was approved by the Court, and the case was dismissed with prejudice on June 16, 2009. Additional details about the settlement can be found in the formal settlement documents, which are available from the United States District Court for the Western District of Washington.

**9. Common Stock**

During the six months ended June 30, 2008, the Company issued 24,578 shares of common stock upon the cashless exercise of options to purchase 33,334 shares of common stock.

On June 17, 2008, the Company issued 122,190 shares of common stock pursuant to a letter agreement under which it received an exclusive right to negotiate the terms of a potential transaction in which the Company would obtain the rights, title and interest to and under a certain license agreement. The fair value of the stock issued amounting to \$225,000 was expensed on March 31, 2009 as the Company had failed to negotiate a transaction in the time frame specified in the letter agreement.

**10. Subsequent Events**

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* ( “SFAS 165”), which provides guidance to establish general standards of accounting for, and disclosures of, events that occur after the balance sheet date but before financial statements are issued or available to be issued. SFAS 165 is effective for interim or fiscal periods ending after June 15, 2009. Accordingly, the Company adopted the provisions of SFAS 165 on April 1, 2009. The Company has evaluated subsequent events for the period from June 30, 2009, the date of these financial statements, through August 14, 2009, which represents the date these financial statements are being filed with the SEC. Pursuant to the requirements of SFAS 165, there are no events or transactions occurring during this subsequent event reporting period which require recognition or disclosure in the financial statements except as described below. With respect to this disclosure, the Company has not evaluated subsequent events occurring after August 14, 2009.

In July 2009, the Company received \$1,250,000 from Toucan Partners on the condition that the funds be held under restriction until matching funds are raised for purposes establishing named patient or compassionate use activities in several foreign countries. The terms of the short term loan are currently being negotiated with Toucan Partners and with other investors. The Company is also exploring additional financing transactions with several other parties, which it hopes to complete during 2009. However, there can be no assurance that the Company will be able to complete any of the financings, or that the terms for such financings will be favorable to the Company.

On July 23, 2009 the Company announced that it will seek shareholder approval for the Company to cancel its listing on the London Stock Exchange’s Alternative Investment Market (“AIM”) (“the De-listing”). The Company is recommending that, at the Annual Meeting of Shareholders scheduled to be held on September 4, 2009, shareholders to approve this action based on the following factors:

- The high cost of maintaining the Company’s AIM listing;
- The operational and legal difficulties of being subject to two different regulatory regimes in two different countries, under which the Company has faced conflicting requirements on an ongoing basis;
- The management time taken up with the Company’s AIM listing; and
- The ability to continue the Company’s U.S. listing is unaffected by the De-listing from the AIM

**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**

Northwest Biotherapeutics, Inc. was formed in 1996 and incorporated in Delaware in July 1998. We are a development stage biotechnology company focused on discovering, developing, and commercializing immunotherapy products that safely generate and enhance immune system responses to effectively treat cancer. Currently approved cancer treatments are frequently ineffective, can cause undesirable side effects and provide marginal clinical benefits. Our approach in developing cancer therapies utilizes our expertise in the biology of dendritic cells, which are a type of white blood cell that activate the immune system. Our primary activities since incorporation have been focused on advancing proprietary dendritic cell immunotherapies for prostate and brain cancer, together with strategic and financial planning, and raising capital to fund our operations.

We have two basic technology platforms applicable to cancer therapeutics: dendritic cell-based cancer vaccines, which we call DCVax®, and monoclonal antibodies for cancer therapeutics. DCVax® is our registered trademark. Our DCVax® dendritic cell-based cancer vaccine program is our main technology platform.

We completed an initial public offering of our common stock on the NASDAQ Stock Market (“NASDAQ”) in December 2001 and an initial public offering of our common stock on the Alternative Investment Market (“AIM”) of the London Stock Exchange in June 2007.

As described in further detail elsewhere in this report, since 2004 we have undergone a significant recapitalization pursuant to which (i) Toucan Capital Fund II, L.P. (“Toucan Capital”) loaned us an aggregate of \$6.75 million, which notes payable and accrued interest thereon were converted into shares of our Series A-1 cumulative convertible preferred stock (the “Series A-1 Preferred Stock”) in April 2006 and subsequently converted into common stock in June 2007; and (ii) Toucan Partners, LLC (“Toucan Partners”) loaned us an aggregate of \$4.825 million (excluding \$225,000 in proceeds from a demand note that was received on June 13, 2007 and repaid on June 27, 2007), which borrowings have, in a series of transactions, been converted into convertible notes with an aggregate outstanding principal of \$4.825 million and related warrant coverage. In the fourth quarter of 2007, we repaid all of the remaining outstanding principal and accrued interest pursuant to these convertible notes in the aggregate amount of \$5.3 million to Toucan Partners.

In addition, on January 26, 2005, Toucan Capital purchased 32.5 million shares of our Series A cumulative convertible preferred stock (the “Series A Preferred Stock”) at a purchase price of \$0.04 per share, for a net purchase price of \$1.276 million, net of offering related costs of approximately \$24,000. In June 2007, this Series A Preferred Stock was converted into common stock.

On March 30, 2006, we sold approximately 2.6 million shares of common stock at a purchase price of \$2.10 per share and raised aggregate gross proceeds of approximately \$5.5 million in a closed equity financing with unrelated investors (the “PIPE Financing”) The total cost of the offering recorded, including both cash and non-cash costs, was approximately \$837,000.

On June 22, 2007, we placed 15,789,473 shares of our common stock with foreign institutional investors at a price of £0.95 per share. The gross proceeds from the placement were approximately £15.0 million, or \$29.9 million, while net proceeds from the offering, after deducting commissions and expenses, were approximately £13.0 million, or \$25.9 million.

On May 9, 2008 the Company entered into a loan agreement with Al Rajhi Holdings, under which the Company received \$4.0 million in return for an unsecured promissory note in the principal amount of \$4,240,000 (reflecting an original issue discount of six percent, or \$240,000) for a period of six (6) months.

On August 19, 2008, the Company entered into a loan agreement with Toucan Partners, under which the Company received \$1.0 million in return for an unsecured promissory note in the principal amount of \$1,060,000 (reflecting an original issue discount of six percent, or \$60,000) for a period of six months.

On October 1, 2008 we entered into a loan agreement with SDS Capital for \$1.0 million for a term of six (6) months at 12%. In connection with the loan the Company issued SDS warrants to purchase shares of the Company’s common stock. The warrants have a term of five years from the issuance date.

On October 22, 2008 we entered into a loan agreement with a group of private investors and SDS Capital for \$1.65 million for a term of six (6) months at 12%. In connection with the loan the Company issued the private investors and SDS warrants to purchase shares of the Company’s common stock. The warrants have a term of five years from the issuance date.

On December 22, 2008, we entered into a loan agreement with Toucan Partners for \$500,000 with a term of six months at 12% interest. In connection with the loan the Company issued Toucan Partners warrants to purchase shares of the Company’s common stock. The warrants have a term of five years from the issuance date.

On January 16, 2009 we entered into a securities purchase agreement for \$700,000 with Al Rajhi Holdings who purchased 1,000,000 shares of our common stock at \$0.70 per share.

During March 2009, we entered into loan agreements with a group of private lenders for \$760,000 for a term of two years at 6% per annum.

On March 27, 2009, we sold approximately 1.4 million shares of common stock at a purchase price of \$0.53 per share and raised aggregate gross proceeds of approximately \$0.7 million in a closed equity financing with unrelated investors.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. The critical accounting policies that involve significant judgments and estimates used in the preparation of our financial statements are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008.

Recent Accounting Pronouncements

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

Results of Operations

Operating expenses:

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 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. We shifted our focus, starting in 2002, from discovering, developing, and commercializing immunotherapy products to conserving cash and primarily concentrating on securing new working capital to re-activate our two DCVax® clinical trial programs.

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 June 30, 2008 and 2009

We recognized a net loss of \$4.1 million for the three months ended June 30, 2009 compared to a net loss of \$6.1 million for the three months ended June 30, 2008. The decrease in net loss for the three months ended June 30, 2009 was primarily attributable to a decrease in research and development and general and administrative expenses offset by an increase in interest expense compared to the same period in 2008.

*Research and Development Expense.* Research and development expense decreased from \$3.1 million for the three months ended June 30, 2008 to \$2.5 million for the three months ended June 30, 2009. This decrease was primarily due to:

- reduced personnel costs; and
- reduced activity in Switzerland as we await a decision from Swissmedic related to the Market Authorization for DCVax®-Brain.

*General and Administrative Expense.* General and administrative expense decreased from \$2.9 million for the three months ended June 30, 2008 to \$0.8 million for the three months ended June 30, 2009. This decrease was primarily due to:

- reduced staffing costs; and
- reduced legal costs due to settlement of litigation;

*Asset Impairment Loss*– In July 2009 the Company’s contract manufacturer, Cognate Bioservices, Inc., consolidated its Sunnyvale, California and Memphis, Tennessee manufacturing facilities and closed the Sunnyvale facility housing the Company’s clean room. As the clean room cannot be relocated the Company provided an impairment allowance of \$389,000 reducing the carrying value of the clean room to \$0. The clean room will be written off when the Sunnyvale facility closes during the third quarter of 2009.

*Total Other Income (Expense), Net.* Interest expense net of interest income increased from \$52,000 for the three months ended June 30, 2008 to \$440,000 for the three months ended June 30, 2009. Interest expense for the three-month period ended June 30, 2009 increased over the same period in 2008 was due to higher average balances of notes payable and convertible notes payable.

**Six Months Ended June 30, 2008 and 2009**

We recognized a net loss of \$8.7 million for the six months ended June 30, 2009 compared to a net loss of \$11.7 million for the six months ended June 30, 2008. The decrease in net loss for the six months ended June 30, 2009 was primarily attributable to reductions in research and development and general and administrative expenses offset by increased interest costs compared to the same period in 2008.

*Research and Development Expense.* Research and development expense decreased from \$6.2 million for the six months ended June 30, 2008 to \$5.0 million for the six months ended June 30, 2009. This decrease was primarily due to:

- reduced activity in Switzerland as we await a decision from Swissmedic related to the Market Authorization for DCVax®-Brain; and
- reduced personnel costs.

*General and Administrative Expense.* General and administrative expense decreased from \$5.5 million for the six months ended June 30, 2008 to \$2.1 million for the six months ended June 30, 2009. This decrease was primarily due to:

- reduced staffing costs associated with expansion of our business activities in the United States and internationally; and
- reduced legal costs due to settlement of litigation.

*Asset Impairment Loss*– In July 2009 the Company’s contract manufacturer, Cognate Bioservices, Inc., consolidated its Sunnyvale, California and Memphis, Tennessee manufacturing facilities and closed the Sunnyvale facility housing the Company’s clean room. As the clean room cannot be relocated the Company provided an impairment allowance of \$389,000 reducing the carrying value of the clean room to \$0. The clean room will be written off when the Sunnyvale facility closes during the third quarter of 2009.

*Depreciation and Amortization.* Depreciation and amortization decreased from \$22,000 during the six months ended June 30, 2008 to \$0 for the six months ended June 30, 2009. This decrease was due to assets reaching the end of their useful lives.

*Total Other Income (Expense), Net.* Net interest expense increased from (\$10,000) for the six months ended June 30, 2008 to \$1,191,000 for the six months ended June 30, 2009 The increase over the same period in 2008 was due to higher average balances of notes payable and convertible notes payable.

**Liquidity and Capital Resources**

*Toucan Capital and Toucan Partners*

Toucan Capital loaned the Company an aggregate of \$6.75 million during 2004 and 2005. In April 2006, the \$6.75 million of notes payable plus all accrued interest due to Toucan Capital were converted into shares of the Company’s Series A-1 cumulative convertible Preferred Stock (the “Series A-1 Preferred Stock”).

On January 26, 2005, the Company entered into a securities purchase agreement with Toucan Capital pursuant to which it purchased 32.5 million shares of the Company’s Series A cumulative convertible preferred stock (the “Series A Preferred Stock”) at a purchase price of \$0.04 per share, for a net purchase price of \$1.276 million.

On June 1, 2007, the Company, Toucan Capital, and Toucan Partners entered into a conversion agreement (“Conversion Agreement”) which became effective on June 22, 2007 upon the admission of the Company’s Common Stock to trade on Alternative Investment Market (“AIM”) of the London Stock Exchange (“Admission”). Under the conversion agreement Toucan Capital and Toucan Partners agreed to eliminate a number of rights, preferences and protections associated with the preferred stock in exchange for 4,287,851 and 2,572,710 shares of common stock, respectively and Toucan Capital converted its preferred shares into 15,011,635 shares of common stock. Additionally in connection with the conversion agreement the Company exchanged warrants issued to purchase Series A-1 Preferred Stock and Series A Preferred Stock for warrants to purchase common stock of the Company. As a result of the conversion Toucan Capital now holds warrants to purchase 14,150,732 shares of Common Stock at an exercise price of \$0.60 per share and 7,884,357 shares of Common Stock at an exercise price of \$0.15 per share and Toucan Partners holds warrants to purchase 8,831,541 shares of Common Stock at an exercise price of \$0.60 per share.

From November 14, 2005 through March 9, 2006, Toucan Partners loaned the Company \$4.825 million. In April 2007 this amount was converted into convertible demand notes (the “2007 Convertible Notes”) and related warrants (the “2007 Warrants”) carrying an interest rate of 10% per annum. The notes and related interest were repaid in full in the fourth quarter of 2007.

In May 2007 Toucan Partners loaned the Company an aggregate amount of \$725,000, and issued warrants to purchase shares of the Company’s capital stock to Toucan Partners in connection with this loan. These notes and warrants are on the same terms as the 2007 Convertible Notes and 2007 Warrants. The notes and related interest were repaid in full in the fourth quarter of 2007.



On August 19, 2008, the Company entered into a loan agreement with Toucan Partners, under which Toucan Partners provided the Company with debt financing in the amount of \$1.0 million (the “Toucan Loan”). Under the terms of the Toucan Loan, the Company received \$1.0 million in return for an unsecured promissory note in the principal amount of \$1,060,000 (reflecting an original issue discount of six percent, or \$60,000). The Toucan Loan had a term of six months. On February 19, 2009, Toucan Partners agreed to extend the term of the loan. The terms and period of the extension are currently being negotiated by management. The note may be paid at any time without a prepayment penalty and the term may be extended in Toucan Partners discretion upon the Company’s request. Since February 20, 2009 the Company has been accruing interest related to the Toucan Loan on the same terms as those included in the original agreement. At June 30, 2009, the carrying value of the Loan was \$1,135,598. The Company amortizes the discount using the effective interest method over the term of the loan. During the three and six month periods ended June 30, 2009, the Company recorded interest expense related to the amortization of the discount of \$44,836 and \$89,179 respectively. Toucan Partners may elect to have the original issue discount amount paid at maturity in shares of common stock, at a price per share equal to the average closing price of the Company’s common stock on the NASD Over-The-Counter Bulletin Board during the ten trading days prior to the execution of the loan agreement. The intrinsic value of the Toucan Loan did not result in a beneficial conversion feature.

On December 22, 2008, the Company entered into a Loan Agreement and Promissory Note with Toucan Partners. Under the Note, Toucan has loaned the Company \$500,000 (the “Toucan December Loan”). The Note is an unsecured obligation of the Company and accrues interest at the rate of 12% per year. The term of the Note is six months, with a maturity date of June 22, 2009. Toucan Partners have agreed to extend the term of the loan. The terms and period of the extension are currently being negotiated by management. The Note may be prepaid without the consent of Toucan. The Note contains customary representations and warranties, and affirmative and negative covenants regarding the operation of the Company’s business during the term of the Note. In connection with the Note, the Company issued to Toucan Partners a warrant to purchase 132,500 shares of the Company’s common stock at an exercise price equal to \$0.40 per share, which was the closing price of the Company’s Common Stock on the NASD Over-The-Counter Bulletin Board on December 22, 2008. The warrant expires 5 years from the date of issuance.

Upon issuing the Note to Toucan Partners, the Company recognized the note and warrants based on their relative fair values of \$453,000 and \$47,000, respectively, in accordance with APB Opinion No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants* (“APB 14”). The fair value of the note was determined using the Black-Scholes option pricing model. The relative fair value of the warrants was classified as a component of additional paid-in capital in accordance with SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (“SFAS 150”) and EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* ("EITF 00-19"), with the corresponding amount reflected as a contra-liability to the debt. The fair value of the warrants was determined using the Black Scholes model, assuming a term of five years, volatility of 197%, no dividends, and a risk-free interest rate of 1.53%.

As a result of the financings described above, as of June 30, 2009, Toucan Capital held:

- an aggregate of 19,299,486 shares of common stock;
- warrants to purchase 14,150,732 shares of common stock at an exercise price of \$0.60 per share; and
- warrants to purchase 7,884,357 shares of common stock at an exercise price of \$0.15 per share.

As a result of the financings described above, as of June 30, 2009, Toucan Partners and its managing member Ms. Linda Powers held:

- an aggregate of 2,572,710 shares of common stock;
- warrants to purchase 8,832,541 shares of common stock at an exercise price of \$0.60 per share; and
- warrants to purchase 132,500 shares of common stock at an exercise price of \$0.40 per share.

The investments made by Toucan Capital and Toucan Partners were made pursuant to the terms and conditions of a Recapitalization Agreement originally entered into on April 26, 2004 with Toucan Capital (the “Recapitalization Agreement”). The Recapitalization Agreement originally contemplated the investment of up to \$40 million through the issuance of new securities to Toucan Capital and a syndicate of other investors to be determined.

We and Toucan Capital amended the Recapitalization Agreement in conjunction with each successive loan agreement. The amendments generally (i) updated certain representations and warranties of the parties made in the Recapitalization Agreement, and (ii) made certain technical changes in the Recapitalization Agreement in order to facilitate the bridge loans described therein.

In accordance with the Recapitalization Agreement, we accrued and paid certain legal and other administrative costs on Toucan Capital’s behalf. During the three months ending June 30, 2009 and 2008, respectively, the Company recognized approximately \$0 and \$148,000 of general and administrative costs related to the recapitalization agreement, rent expense, as well as legal, travel and other costs incurred by Toucan Capital on the Company’s behalf. During the six months ending June 30, 2009 and 2008, respectively, the Company recognized approximately \$0 and \$298,000 of general and administrative costs related to the recapitalization agreement, rent expense, as well as legal, travel and other costs incurred by Toucan Capital on the Company’s behalf.

As of June 30, 2009, Toucan Capital and Toucan Partners collectively, held 21,872,196 shares of our common stock, representing approximately 48.5% of our outstanding common stock. Further, as of June 30, 2009, Toucan Capital and Toucan Partners collectively, beneficially owned (including unexercised warrants) 52,872,326 shares of our common stock, representing a beneficial ownership interest of approximately 69.5%.

***Other Financings***

On November 13, 2003, we borrowed an aggregate of \$335,000 from certain members of our current and former management. These notes were either repaid or converted into common stock prior to December 31, 2006.

On March 30, 2006, we completed the PIPE Financing pursuant to which we raised aggregate gross proceeds of approximately \$5.5 million.

On June 22, 2007, we placed 15,789,473 shares of our common stock with foreign institutional investors at a price of £0.95 per share. The gross proceeds from the placement were approximately £15.0 million, or \$29.9 million, while net proceeds from the offering, after deducting commissions and expenses, were approximately £13.0 million, or \$25.9 million. The net proceeds from the placement are being used to fund clinical trials, product and process development, working capital needs and repayment of certain existing debt.

On May 9, 2008 the Company entered into a loan agreement with Al Rajhi Holdings, under which the Company received \$4.0 million in return for an unsecured promissory note in the principal amount of \$4,240,000 (reflecting an original issue discount of six percent, or \$240,000) for a period of six (6) months.

On August 19, 2008, the Company entered into a loan agreement with Toucan Partners, under which the Company received \$1.0 million in return for an unsecured promissory note in the principal amount of \$1,060,000 (reflecting an original issue discount of six percent, or \$60,000) for a period of six months.

On October 1, 2008 we entered into a loan agreement with SDS Capital for \$1.0 million for a term of six (6) months at 12%. In connection with the loan the Company issued SDS warrants to purchase shares of the Company’s common stock. The warrants have a term of five years from the issuance date.

On October 22, 2008 we entered into a loan agreement with a group of private investors and SDS Capital for \$1.65 million for a term of six (6) months at 12%. In connection with the loan the Company issued the private investors and SDS warrants to purchase shares of the Company’s common stock. The warrants have a term of five years from the issuance date.

On December 22, 2008, we entered into a loan agreement with Toucan Partners for \$500,000 with a term of six months at 12% interest. In connection with the loan the Company issued Toucan Partners warrants to purchase shares of the Company’s common stock. The warrants have a term of five years from the issuance date.

On January 16, 2009 we entered into a securities purchase agreement for \$700,000 with Al Rajhi Holdings who purchased 1,000,000 shares of our common stock at \$0.70 per share.

During March 2009, we entered into loan agreements with a group of private lenders for \$760,000 for a term of two years at 6% per annum.

On March 27, 2009, we sold approximately 1.4 million shares of common stock at a purchase price of \$0.53 per share and raised aggregate gross proceeds of approximately \$0.7 million in a closed equity financing with unrelated investors.

As of August 12, 2009, we had approximately \$265,000 of cash on hand. We need to raise additional capital to fund our clinical trials and other operating activities. We are exploring additional financing transactions with several other parties, which we hope to complete later this year. However, there can be no assurance that we will be able to complete any of the financings, or that the terms for such financings will be favorable to us.

We are seeking 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. 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. Our independent registered public accounting firm has indicated in its report on our financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2008 that there is substantial doubt about our ability to continue as a going concern.

*Sources of Cash*

During the six months ending June 30, 2009, we received \$2.2 million in equity infusions and loan advances from both related party and third party investors.

*Uses of Cash*

We used \$2.1 million in cash for operating activities during the six months ended June 30, 2009, compared to \$10.4 million for the six months ended June 30, 2008. The decrease in cash used in operating activities was a result of reduced activity in the U.S. and Switzerland due to reduced staffing and cash resources.

We utilized \$2,000 in cash for investing activities during the six months ended June 30, 2009 compared to \$240,000 used in investing activities during the six months ended June 30, 2008. The cash utilized during the six-month periods ended June 30, 2008 and 2009 consisted of purchases of property and equipment primarily required to expand production capacity.

On March 21, 2008, we executed a sublease agreement with Toucan Capital Corporation, an affiliate of Toucan Capital and Toucan Partners, for our corporate headquarters located at 7600 Wisconsin Avenue, Suite 750, Bethesda, Maryland 20814. This sublease agreement was effective as of July 1, 2007 and expires on October 31, 2016, unless sooner terminated according to its terms. Previously, we had been occupying our Bethesda headquarters under an oral arrangement with Toucan Capital Corporation, whereby we were required to pay base rent of \$32,949 per month through December 31, 2007. Under the sublease agreement, we are required to pay base rent of \$34,000 per month during 2008, which monthly amount increases by \$1,000 on an annual basis, to a maximum of \$42,000 per month during 2016, the last year of the term of the lease. In addition to monthly base rent, we are obligated to pay operating expenses allocable to the subleased premises under Toucan Capital Corporation’s master lease. During the six months ended June 30, 2008 and 2009, the Company incurred expense of \$404,000 and \$210,000 respectively to Toucan Capital Corporation pursuant to this sublease agreement.

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

Market Interest Rate Risk

Our exposure to market risk is presently limited to the interest rate sensitivity of our cash which is affected by changes in the general level of U.S. and Swiss interest rates. We are exposed to interest rate changes primarily as a result of our investment activities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. To minimize risk, we maintain our cash in interest-bearing instruments, primarily money market funds. Due to the short-term nature of our cash, we believe that our exposure to market interest rate fluctuations is minimal. A hypothetical 10% change in short-term interest rates from those in effect at June 30, 2009 would not have a significant impact on our financial position or our expected results of operations. Our interest rate risk management objective with respect to our borrowings is to limit the impact of interest rate changes on earnings and cash flows. Our debt is carried at a an annual rate of interest between 6 and 12 percent. We do not have any foreign currency or other derivative financial instruments.

Foreign Currency Exchange Rate Risk

As a corporation with contractual arrangements overseas, we are exposed to changes in foreign exchange rates. These exposures may change over time and could have a material adverse impact on our financial results. At this time we do not have a program to hedge this exposure.

**Item 4. Controls and Procedures**

**Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating these disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**Evaluation of disclosure controls and procedures**

We evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q are recorded, processed, summarized and reported within the time periods specified by the SEC. Disclosure controls are also designed to ensure that such information is accumulated and communicated to our management as appropriate, to allow timely decisions regarding required disclosure.

Based on the evaluation, our President and Chief Executive Officer after evaluating the effectiveness of our “disclosure controls and procedures” (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), have concluded that, subject to the inherent limitations noted in this Part II, Item 4, as of June 30, 2009, our disclosure controls and procedures were not effective due to the existence of several material weaknesses in our internal control over financial reporting, as discussed below.

**Material Weaknesses Identified**

In connection with the preparation of our financial statements for the year ended December 31, 2008, certain significant deficiencies in internal control became evident to management that, in the aggregate, represent material weaknesses, including:

- (i) Lack of a sufficient number of independent directors for our board and audit committee. We currently only have one independent director on our board, which is comprised of two directors, and on our audit committee, which is comprised of one director. Although we are considered a controlled company, whereby a group holds more than 50% of the voting power, and as such are not required to have a majority of our board of directors be independent. It is our intention to have an majority of independent directors in due course.
- (ii) Lack of a financial expert on our audit committee. We currently do not have an audit committee financial expert, as defined by SEC regulations on our audit committee.
- (iii) Insufficient segregation of duties in our finance and accounting functions due to limited personnel. During the six month period ended June 30, 2009, we had one person on staff that performed nearly all aspects of our financial reporting process, including, but not limited to, access to the underlying accounting records and systems, the ability to post and record journal entries and responsibility for the preparation of the financial statements. This creates certain incompatible duties and a lack of review over the financial reporting process that would likely result in a failure to detect errors in spreadsheets, calculations, or assumptions used to compile the financial statements and related disclosures as filed with the SEC. These control deficiencies could result in a material misstatement to our interim or annual consolidated financial statements that would not be prevented or detected.
- (iv) Insufficient corporate governance policies. Although we have a code of ethics which provides broad guidelines for corporate governance, our corporate governance activities and processes are not always formally documented. Specifically, decisions made by the board to be carried out by management should be documented and communicated on a timely basis to reduce the likelihood of any misunderstandings regarding key decisions affecting our operations and management.
- (v) Inadequate approval and control over transactions and commitments made on our behalf by related parties. Specifically, during the year certain related party transactions were not effectively communicated to all internal personnel who needed to be involved to account for and report the transaction in a timely manner. This resulted in material adjustments during the quarterly reviews and annual audit, respectively, that otherwise would have been avoided if effective communication and approval processes had been maintained.

As part of the communications by Peterson Sullivan, LLP, (“Peterson Sullivan”), with our Audit Committee with respect to Peterson Sullivan’s audit procedures for fiscal 2008, Peterson Sullivan informed the audit committee that these deficiencies constituted material weaknesses, as defined by Auditing Standard No. 5, “An Audit of Internal Control Over Financial Reporting that is Integrated with an Audit of Financial Statements and Related Independence Rule and Conforming Amendments,” established by the Public Company Accounting Oversight Board (“PCAOB”).

*Plan for Remediation of Material Weaknesses*

We intend to take appropriate and reasonable steps to make the necessary improvements to remediate these deficiencies. We intend to consider the results of our remediation efforts and related testing as part of our year-end 2009 assessment of the effectiveness of our internal control over financial reporting.

We have implemented certain remediation measures and are in the process of designing and implementing additional remediation measures for the material weaknesses described in this Quarterly Report on Form 10-Q. Such remediation activities include the following:

- We plan to recruit one or more additional independent board members to join our board of directors in due course. Such recruitment will include at least one person who qualifies as an audit committee financial expert to join as an independent board member and as an audit committee member.
- We are attempting to hire additional qualified and experienced accounting personnel to perform the month-end review and closing processes as well as provide additional oversight and supervision within the accounting department. We are in the process of establishing more rigorous review procedures. In addition, we have changed our accounting system to make it simpler and more appropriate for a company our size.
- We are initiating a formal commitment review process to establish and document the accounting events and methodology at the time the transactions are entered into, so that there is a clear understanding of what events will trigger an accounting event and establish the amounts to be recognized for each event.
- We are initiating a formal monthly reporting and approval process with our related parties to ensure timely provision of information affecting our quarterly and annual consolidated financial statements.

In addition to the foregoing remediation efforts, we will continue to update the documentation of our internal control processes, including formal risk assessment of our financial reporting processes.

*Changes in Internal Controls over Financial Reporting*

There were no significant changes in internal control over financial reporting during the six months ended June 30, 2009 that materially affected, or are reasonably likely to materially affect, our internal control over financing 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. In addition to any such claims and suits, we are involved in the following legal proceedings.

**SOMA Arbitration**

We signed an engagement letter, dated October 15, 2003, with Soma Partners, LLC, or Soma, a New Jersey-based investment bank, pursuant to which we engaged them to locate potential investors. Pursuant to the terms of the engagement letter, any disputes arising between the parties would be submitted to arbitration in the New York metropolitan area. A dispute arose between the parties. Soma filed an arbitration claim against us with the American Arbitration Association in New York, NY claiming unpaid commission fees of \$186,000 and seeking declaratory relief regarding potential fees for future transactions that may be undertaken by us with Toucan Capital. We vigorously disputed Soma’s claims on multiple grounds. We contended that we only owed Soma approximately \$6,000.

Soma subsequently filed an amended arbitration claim, claiming unpaid commission fees of \$339,000 and warrants to purchase 6% of the aggregate securities issued to date, and seeking declaratory relief regarding potential fees for future financing transactions which may be undertaken by us with Toucan Capital and others, which could potentially be in excess of \$4 million. Soma also requested the arbitrator award its attorneys’ fees and costs related to the proceedings. We strongly disputed Soma’s claims and defended ourselves.

The arbitration proceedings occurred from March 8-10, 2005 and on May 24, 2005; the arbitrator ruled in our favor and denied all claims of Soma. In particular, the arbitrator decided that we did not owe Soma the fees and warrants sought by Soma, that we would not owe Soma fees in connection with future financings, if any, and that we had no obligation to pay any of Soma’s attorneys’ fees or expenses. The arbitrator agreed with us that the only amount we owed Soma was \$6,702.87, which payment we made on May 27, 2005.

On August 29, 2005, Soma filed a notice of petition to vacate the May 24, 2005 arbitration award with the Supreme Court of the State of New York. On December 30, 2005, the Supreme Court of the State of New York dismissed Soma’s petition.

On February 3, 2006, Soma filed another notice of appeal with the Supreme Court of the State of New York. On December 6, 2006, we filed our brief for this appeal and on December 12, 2006, Soma filed its reply brief. On June 19, 2007, the Appellate Division, First Department of the Supreme Court of the State of New York, reversed the December 30, 2005 decision and ordered a new arbitration proceeding. On July 26, 2007, we filed a Motion for Leave to Appeal with the Court of Appeals of the State of New York and on August 3, 2007 Soma filed its reply brief. On October 16, 2007, the Court of Appeals of the State of New York denied our motion to appeal. A new arbitration hearing was held New York for May 13-15, 2009and June 24, 2009. We are continuing to vigorously defend against the claims of Soma, which we believe are unfounded.

**Lonza Patent Infringement Claim**

No change from previous filings.

**Stockholder Class Action Lawsuits**

On August 13, 2007, a complaint was filed in the U.S. District Court for the Western District of Washington naming the Company, the Chairperson of its Board of Directors, Linda F. Powers, and its Chief Executive Officer, Alton L. Boynton, as defendants in a class action for violation of federal securities laws. After this complaint was filed, five additional complaints were filed in other jurisdictions alleging similar claims. The complaints were filed on behalf of purchasers of the Company’s Common Stock between July 9, 2007 and July 18, 2007 and allege violations of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder. The complaints seek unspecified compensatory damages, costs and expenses. On December 18, 2007, a consolidated complaint was filed in the U.S. District Court for the Western District of Washington consolidating the stockholder actions previously filed. The putative securities class action lawsuit, *In re Northwest Biotherapeutics, Inc. Securities Litigation* , No. C-07-1254-RAJ was settled with prejudice January 8, 2009. The Company has agreed to pay in settlement US\$1 million. In accordance with the stipulation the insurance company has directly deposited the \$1,000,000 in a court controlled escrow account. The settlement must be approved by the Court. Management is unable to determine when the Court will approve the settlement. Additional details about the settlement can be found in the formal settlement documents, which are available from the United States District Court for the Western District of Washington. The case alleged that the Company misrepresented certain facts that resulted in the artificial inflation of the price of Northwest Biotherapeutics publicly-traded common stock between April 17, 2007 and July 18, 2007. The Company disputes the allegations of the lawsuit, and denies that there was any such misrepresentation or that the shares of Northwest Biotherapeutics common stock were artificially inflated. Nevertheless the Company is settling the lawsuit to avoid potentially expensive and protracted litigation. The Class Action Lawsuit final settlement was approved by the Court, and the case was dismissed with prejudice on June 16, 2009. Additional details about the settlement can be found in the formal settlement documents, which are available from the United States District Court for the Western District of Washington.

We have no other legal proceedings pending at this time.



**Item 1A. Risk Factors**

Our business, operations and financial condition are subject to various risks and uncertainties, including those described below and elsewhere in this Quarterly Report on Form 10-Q. This section discusses factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. Our business, operations or financial condition could be materially adversely affected by the occurrence of any of these risks.

**We will need to raise additional capital, which may not be available.**

As of August 12, 2009, we had approximately \$265,000 of cash on hand. We will need additional capital to support and fund the research, development and commercialization of our product candidates and to fund our other operating activities. We are negotiating additional financing with several other parties, which we hope to complete later this year. There can be no assurance that we will be able to complete any of the financings, or that the terms for such financings will be attractive. If we are unable to obtain additional funds on a timely basis or on acceptable terms, we may be required to curtail or cease certain of our operations. We may raise additional funds by issuing additional common stock or securities (equity or debt) convertible into shares of common stock, in which case, the ownership interest of our stockholders will be diluted. Any financing, if available, is likely to include restrictive covenants that could limit our ability to take certain actions. Further, 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. If we are unable to obtain sufficient additional capital in the near term, we may cease operations at any time.

**We are likely to continue to incur substantial losses, and may never achieve profitability.**

We have incurred net losses every year since our formation in March 1996 and had a deficit accumulated during the development stage of approximately \$173.3 million as of June 30, 2009. We expect that these losses will continue and anticipate negative cash flows from operations for the foreseeable future. Despite the receipt of approximately \$25.9 million of net proceeds from an offering of our common stock on AIM in June 2007, receipt of loan proceeds between May 2008 and March 2009 of \$8.9 million and equity infusions in 2009 of \$1.1 million we will need additional funding, and over the medium term we will need to generate revenue sufficient to cover operating expenses, clinical trial expenses and some research and development costs to achieve profitability. We may never achieve or sustain profitability.

**Our auditors have issued a “going concern” audit opinion.**

Our independent auditors have indicated in their report on our December 31, 2008 financial statements that there is substantial doubt about our ability to continue as a going concern. A “going concern” opinion indicates that the financial statements have been prepared assuming we 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. Therefore, you should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to stockholders, in the event of liquidation.

**As a company in the early stage of development with an unproven business strategy, our limited history of operations makes an evaluation of our business and prospects difficult.**

We have had a limited operating history and we are at an early stage of development. We may not be able to achieve revenue growth in the future. We have generated the following limited revenues: \$529,000 in 2003; \$390,000 in 2004; \$124,000 in 2005; \$80,000 in 2006; \$10,000 in 2007; \$10,000 in 2008; and \$0 in 2009. We have derived most of these limited revenues from the sale of research products to a single customer, contract research and development for related parties, research grants and royalties from licensing fees generated from a licensing agreement. Our limited operating history makes it difficult to assess our prospects for generating revenues.

**We may not be able to retain existing personnel.**

We employ four full-time employees. The uncertainty of our business prospects and the volatility in the price of our common stock may create anxiety and uncertainty, which could adversely affect employee morale and cause us to lose employees whom we would prefer to retain. To the extent that we are unable to retain existing personnel, our business and financial results may suffer.

**We may not be able to attract expert personnel.**

In order to pursue our product development and marketing plans, we will need additional management personnel and personnel with expertise in clinical testing, government regulation, manufacturing and marketing. Attracting and retaining qualified personnel, consultants and advisors will be critical to our success. There can be no assurance that we will be able to attract personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. The failure to attract any of these personnel could impede the achievement of our development objectives.

**We must rely at present on a single relationship with a third-party contract manufacturer, which will limit our ability to control the availability of our product candidates in the near-term.**

We rely upon a single contract manufacturer, Cognate. The majority owner of Cognate is Toucan Capital, one of our majority stockholders. Cognate provides consulting services and is the manufacturer of our product candidates. We have an agreement in place with Cognate pursuant to which Cognate has agreed to provide manufacturing and other services in connection with our pivotal Phase II clinical trial for DCVax<sup>®</sup>-Brain. The agreement requires us to make minimum monthly payments to Cognate irrespective of whether any DCVax<sup>®</sup> products are manufactured. The agreement does not extend to providing services in respect of commercialization of the DCVax<sup>®</sup>-Brain product, nor for other clinical trials or commercialization of any of our other product candidates. If and to the extent we wish to engage Cognate to manufacture our DCVax<sup>®</sup>-Brain for commercialization or any of our other product candidates (including DCVax<sup>®</sup>-Prostate) for clinical trials or commercialization, we will need to enter into a new agreement with Cognate or another third-party manufacturer which might not be feasible on a timely or favorable basis. The failure to timely enroll patients in our clinical trials will have an adverse impact on our financial results due, in part, to the minimum monthly payments that we make to Cognate.

Problems with our contract manufacturer’s facilities or processes could result in a failure to produce, or a delay in production, of adequate supplies of our product candidates. Any prolonged interruption in the operations of our contract manufacturer’s facilities could result in cancellation of shipments or a shortfall in availability of a product candidate. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in FDA regulatory requirements or standards that require modifications to our manufacturing processes, action by the FDA or by us that results in the halting or slowdown of production of components or finished products due to regulatory issues, the contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. Difficulties or delays in our contract manufacturer’s manufacturing and supply of components could delay our clinical trials, increase our costs, damage our reputation and, if our product candidates are approved for sale, cause us to lose revenue or market share if it is unable to timely meet market demands.

**Our success partly depends on existing and future collaborators.**

We work with scientists and medical professionals at academic and other institutions, including UCLA, the University of Pennsylvania, M.D. Anderson Cancer Centre and the H. Lee Moffitt Cancer Centre, among others, some of whom have conducted research for us or have assisted in developing our research and development strategy. We do not employ these scientists and medical professionals. They may have commitments to, or contracts with, other businesses or institutions that limit the amount of time they have available to work with us. We have little control over these individuals. We can only expect that they devote time to us as required by our license, consulting and sponsored research agreements. In addition, these individuals may have arrangements with other companies to assist in developing technologies that may compete with our products. If these individuals do not devote sufficient time and resources to our programs, or if they provide substantial assistance to our competitors, our business could be seriously harmed.

The success of our business strategy may partially depend upon our ability to develop and maintain our collaborations and to manage them effectively. Due to concerns regarding our ability to continue our operations or the commercial feasibility of our personalized DCVax<sup>®</sup> product candidates, these third parties may decide not to conduct business with us or may conduct business with us on terms that are less favorable than those customarily extended by them. If either of these events occurs, our business could suffer significantly.

We may have disputes with our collaborators, which could be costly and time consuming. Failure to successfully defend our rights could seriously harm our business, financial condition and operating results. We intend to continue to enter into collaborations in the future. However, we may be unable to successfully negotiate any additional collaboration and any of these relationships, if established, may not be scientifically or commercially successful.

**We are involved in legal proceedings that could result in an adverse outcome, or that could otherwise harm our business. In addition, future litigation could be costly to defend or pursue and uncertain in its outcome.**

We are party to various legal actions, as more fully described above under “Legal Proceedings.” These pending legal proceedings include a dispute with Soma Partners, LLC, an investment bank, regarding certain fees Soma claims it is entitled to under an engagement letter with us. The patent infringement claim filed against us by Lonza Group AG alleging infringement of certain patents relating to recombinant DNA methods, sequences, vectors, cell lines and host cells was settled May 6, 2008. In addition, a consolidated class action complaint has been filed against us alleging violations of Section 10(b) of the Exchange Act, and Rule 10b-5 thereunder, based on certain of our public announcements regarding the status of certain regulatory approvals for our DCVax<sup>®</sup>-Brain vaccine in Switzerland was also settled and more fully described above. We also cooperated in a formal SEC investigation into the same matter which after thorough investigation by the SEC was closed by the SEC without action. We can provide no assurances as to the outcome of the pending Soma Partners legal proceedings.

The defense of these or future legal proceedings could divert management’s attention and resources from the needs of our business. We may be required to make substantial payments or incur other adverse effects, in the event of adverse judgments or settlements of any such claims, investigations, or proceedings. Any legal proceeding, even if resolved in our favor, could result in negative publicity or cause us to incur significant legal and other expenses. Actual costs incurred in any legal proceedings may differ from our expectations and could exceed any amounts for which we have made reserves.

**Clinical trials for our product candidates are expensive and time consuming and their outcome is uncertain.**

The process of obtaining and maintaining regulatory approvals for new therapeutic products is expensive, lengthy and uncertain. It can vary substantially, based upon the type, complexity and novelty of the product involved. Accordingly, any of our current or future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval, either of which could reduce our anticipated revenues and delay or terminate the potential commercialization of our product candidates.

**We have limited experience in conducting and managing clinical trials.**

We rely on third parties to assist us in managing and monitoring all our clinical trials. Our reliance on these third parties may result in delays in completing, or failure to complete, these trials if the third parties fail to perform under the terms of our agreements with them. We may not be able to find a sufficient alternative supplier of these services in a reasonable time period, or on commercially reasonable terms, if at all. If we were unable to obtain an alternative supplier of these services, we might be forced to curtail our Phase II clinical trial for DCVax<sup>®</sup>-Brain.

**Our product candidates will require a different distribution model than conventional therapeutic products.**

The nature of our product candidates means that different systems and methods will need to be followed for the distribution and delivery of the products than is the case for conventional therapeutic products. The personalized nature of these products, the need for centralized storage, and the requirement to maintain the products in frozen form may mean that we are not able to take advantage of distribution networks normally used for conventional therapeutic products. If our product candidates are approved, it may take time for hospitals and physicians to adapt to the requirements for handling and storage of these products, which may adversely affect their sales.

**We lack sales and marketing experience and as a result may experience significant difficulties commercializing our research product candidates.**

The commercial success of any of our product candidates will depend upon the strength of our sales and marketing efforts. We do not have a sales force and have no experience in sales, marketing or distribution. To fully commercialize our product candidates, we will need a substantial marketing staff and sales force with technical expertise and the ability to distribute these products. As an alternative, we could seek assistance from a third party with a large distribution system and a large direct sales force. We may be unable to put either of these plans in place. In addition, if we arrange for others to market and sell our products, our revenues will depend upon the efforts of those parties. Such arrangements may not succeed.

Even if one or more of our product candidates is approved for marketing, if we fail to establish adequate sales, marketing and distribution capabilities, independently or with others, our business will be seriously harmed.

**Competition in the biotechnology and biopharmaceutical industry is intense and most of our competitors have substantially greater resources than us.**

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Several companies, such as Dendreon Corporation, Immuno-Designed Molecules, Inc., Celldex Therapeutics, Inc., Ark Therapeutics plc, Oxford Biomedica plc, Argos Therapeutics, Inc. and Antigenics, are actively involved in the research and development of immunotherapies or cell-based cancer therapeutics. Of these companies, we believe that only Dendreon and Ark Therapeutics are carrying-out Phase III clinical trials with a cell-based therapy. To our knowledge no DC-based therapeutic product is currently approved for commercial sale. Additionally, several companies, such as Medarex, Inc., Amgen, Inc., Agensys, Inc., and Genentech, Inc., are actively involved in the research and development of monoclonal antibody-based cancer therapies. Currently, at least seven antibody-based products are approved for commercial sale for cancer therapy. Genentech is also engaged in several Phase III clinical trials for additional antibody-based therapeutics for a variety of cancers, and several other companies are in early stage clinical trials for such products. Many other third parties compete with us in developing alternative therapies to treat cancer, including: biopharmaceutical companies; biotechnology companies; pharmaceutical companies; academic institutions; and other research organizations.

Most of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing than we do. In addition, many of these competitors are actively seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

We expect that our ability to compete effectively will be dependent upon our ability to: obtain additional funding; successfully complete clinical trials and obtain all requisite regulatory approvals; maintain a proprietary position in our technologies and products; attract and retain key personnel; and maintain existing or enter into new partnerships.

Our competitors may develop more effective or affordable products, or achieve earlier patent protection or product marketing and sales. As a result, any products developed by us may be rendered obsolete and non-competitive.

**Our intellectual property rights may not provide meaningful commercial protection for our research products or product candidates, which could enable third parties to use our technology, or very similar technology, and could reduce our ability to compete in the market.**

We rely on patent, copyright, trade secret and trademark laws to limit the ability of others to compete with us using the same or similar technology in the United States and other countries. However, as described below, these laws afford only limited protection and may not adequately protect our rights to the extent necessary to sustain any competitive advantage we may have. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

We have 33 issued and licensed patents (9 in the United States and 23 in other jurisdictions) and 134 patent applications pending (19 in the United States and 115 in other jurisdictions) which cover the use of dendritic cells in DCVax<sup>®</sup> as well as targets for either our dendritic cell or fully human monoclonal antibody therapy candidates. The issued patents expire at various dates from 2015 to 2026.

We will only be able to protect our technologies from unauthorized use by third parties to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent positions of companies developing novel cancer treatments, including our patent position, generally are uncertain and involve complex legal and factual questions, particularly concerning the scope and enforceability of claims of such patents against alleged infringement. Recent judicial decisions in the United States are prompting a reinterpretation of the limited case law that exists in this area, and historical legal standards surrounding questions of infringement and validity may not apply in future cases. A reinterpretation of existing U.S. law in this area may limit or potentially eliminate our patent position and, therefore, our ability to prevent others from using our technologies. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or the interpretations of patent laws in the United States and other countries may, therefore, diminish the value of our intellectual property.

We own or have rights under licenses to a variety of issued patents and pending patent applications. However, the patents on which we rely may be challenged and invalidated, and our patent applications may not result in issued patents. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from using our technologies or from developing competing products. We also face the risk that others may independently develop similar or alternative technologies or design around our patented technologies.

We have taken security measures to protect our proprietary information, especially proprietary information that is not covered by patents or patent applications. These measures, however, may not provide adequate protection for our trade secrets or other proprietary information. We seek to protect our proprietary information by entering into confidentiality agreements with employees, partners and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to protect our trade secrets in a meaningful way. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

**Our success will depend substantially on our ability to operate without infringing or misappropriating the proprietary rights of others.**

Our success will depend to a substantial degree upon our ability to develop, manufacture, market and sell our research products and product candidates without infringing the proprietary rights of third parties and without breaching any licenses entered into by us regarding our product candidates.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert management’s attention from our core business. For example, Lonza Group AG filed a complaint against us in the United States District Court for the District of Maryland alleging patent infringement which was recently settled with prejudice without any monetary consideration (more detailed description under Legal Proceedings). In addition, we may be exposed to future litigation by third parties based on claims that our products infringe their intellectual property rights. This risk is exacerbated by the fact that there are numerous issued and pending patents in the biotechnology industry and the fact that the validity and breadth of biotechnology patents involve complex legal and factual questions for which important legal principles remain unresolved.

Competitors may assert that our products and the methods we employ are covered by U.S. or foreign patents held by them. In addition, because patents can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our products may infringe. There could also be existing patents of which we are not aware that one or more of our products may inadvertently infringe.

If we lose a patent infringement claim, we could be prevented from selling our research products or product candidates unless we can obtain a license to use technology or ideas covered by such patent or we are able to redesign our products to avoid infringement. A license may not be available at all or on terms acceptable to us, or we may not be able to redesign our products to avoid infringement. If we are not successful in obtaining a license or redesigning our products, we may be unable to sell our products and our business could suffer.

**We may not receive regulatory approvals for our product candidates or there may be a delay in obtaining such approvals.**

Our products and our ongoing development activities are subject to regulation by governmental and other regulatory authorities in the countries in which we or our collaborators and distributors wish to test, manufacture or market our products. For instance, the FDA will regulate the product in the U.S. and equivalent authorities, such as the European Medicines Agency (“EMA”), will regulate in other jurisdictions. Regulatory approval by these authorities will be subject to the evaluation of data relating to the quality, efficacy and safety of the product for its proposed use.

The time taken to obtain regulatory approval varies between countries. Different regulators may impose their own requirements and may refuse to grant, or may require additional data before granting, an approval, notwithstanding that regulatory approval may have been granted by other regulators. Regulatory approval may be delayed, limited or denied for a number of reasons, including insufficient clinical data, the product not meeting safety or efficacy requirements or any relevant manufacturing processes or facilities not meeting applicable requirements.

**Further trials and other costly and time-consuming assessments of the product may be required to obtain or maintain regulatory approval.**

Medicinal products are generally subject to lengthy and rigorous pre-clinical and clinical trials and other extensive, costly and time-consuming procedures mandated by regulatory authorities. We may be required to conduct additional trials beyond those currently planned, which could require significant time and expense. For example, the field of cancer treatment is evolving, and the standard of care for a particular cancer could change while we are in the process of conducting the clinical trials for our product candidates. Such a change in standard of care could make it necessary for us to conduct additional clinical trials, which could delay our opportunities to obtain regulatory approval of our product candidates.

As for all biological products, we may need to provide pre-clinical and clinical data evidencing the comparability of products before and after any changes in manufacturing process both during and after product approval. Regulators may require that we generate data to demonstrate that products before or after any change are of comparable safety and efficacy if we are to rely on studies using earlier versions of the product. DCVax<sup>®</sup>-Brain has been the subject of process changes during the early clinical phase of its development and regulators may require comparability data unless they are satisfied that changes in process do not affect the quality, and hence efficacy and safety, of the product.

We plan to rely on our current DCVax<sup>®</sup>-Brain Phase II clinical trial as a single study in support of regulatory approval. While under certain circumstances, both EMEA and the FDA will accept a Phase II study as a single study in support of approval, it is not yet known whether they will do so in this case. If the regulators do not consider the Phase II study adequate on its own to support a finding of efficacy, we may be required to perform additional clinical trials in DCVax<sup>®</sup>-Brain. There is some possibility that changes requested by the FDA could complicate the licensing application process.

Only the data for DCVax<sup>®</sup>-Brain has been discussed with European regulators. On an informal basis, a number of European national regulators have indicated that additional pre-clinical and clinical data could be required before the DCVax<sup>®</sup>-Brain product would be approved. However, it is not clear whether such data will be required until formal scientific advice is sought from the EMEA, which is the regulator that will ultimately review any application for approval of this product. Unless the EMEA grants a deferral or a waiver, we may also be obliged to generate clinical data in pediatric populations.

The FDA previously identified a number of deficiencies regarding the design of our original proposed Phase III clinical trial for DCVax<sup>®</sup>-Prostate. We believe we remedied these deficiencies in the new trial design for a 600-patient Phase III clinical trial, which was cleared by the FDA in January 2005. However, we now intend to split this single 600-patient Phase III trial into two separate 300-patient Phase III trials. These revisions in trial design may cause delay in the development process for DCVax<sup>®</sup>-Prostate. It is not yet known whether the FDA will consider the two-trial design sufficient for marketing approval, or whether the agency will require us to design and carry out additional studies. If, after the Phase III studies are carried out, the FDA is not satisfied that its concerns were adequately addressed, those studies could be insufficient to demonstrate efficacy and additional clinical studies could be required at that time.

Any delay in completing sufficient trials or other regulatory requirements will delay our ability to generate revenue from product sales and we may have insufficient capital resources to support its operations. Even if we do have sufficient capital resources, our ability to generate meaningful revenues or become profitable may be delayed.

**Regulatory approval may be withdrawn at any time.**

After regulatory approval has been obtained for medicinal products, the product and the manufacturer are subject to continual review and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions, or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if we do not comply. Extensive post-approval safety studies are likely to be a condition of the approval and will commit us to significant time and expense.

**We may fail to comply with regulatory requirements.**

Our success will be dependent upon our ability, and our collaborative partners’ abilities, to maintain compliance with regulatory requirements, including regulators’ current good manufacturing practices (“cGMP”) and safety reporting obligations. The failure to comply with applicable regulatory requirements can result in, among other things, fines, injunctions, civil penalties, total or partial suspension of regulatory approvals, refusal to approve pending applications, recalls or seizures of products, operating and production restrictions and criminal prosecutions.

**We may be subject to sanctions if we are determined to be promoting our investigational products prior to regulatory approval or for unapproved uses.**

Laws in both the U.S. and Europe prohibit us from promoting any product that has not received approval from the appropriate regulator, or from promoting a product for an unapproved use. If any regulator determines that we have engaged in such pre-approval, or off-label promotion, through our website, press releases, or other communications, the authority could require us to change the content of those communications and could also take regulatory enforcement action, including the issuance of a warning letter, requirements for corrective action, civil fines, and criminal penalties. In the event of a product liability lawsuit, materials that appear to promote a product for unapproved uses may increase our product liability exposure.

**We may not obtain or maintain orphan drug status and the associated benefits, including marketing exclusivity.**

We may not receive the benefits associated with orphan drug designation. This may result from a failure to achieve or maintain orphan drug status or the development of a competing product that has an orphan designation for the same indication. In Europe, the orphan status of DCVax<sup>®</sup>-Brain will be reassessed shortly prior to the product receiving any regulatory approval. The EMEA will need to be satisfied that there is evidence that DCVax<sup>®</sup>-Brain offers a significant benefit relative to existing therapies for the treatment of glioma if DCVax<sup>®</sup>-Brain is to maintain its orphan drug status.

**New legislation may have an adverse effect on our business.**

Changes in applicable legislation and/or regulatory policies or discovery of problems with the product, production process, site or manufacturer may result in delays in bringing products to market, the imposition of restrictions on the product’s sale or manufacture, including the possible withdrawal of the product from the market, or may otherwise have an adverse effect on our business.

**The availability and amount of reimbursement for our product candidates and the manner in which government and private payers may reimburse for our potential products is uncertain.**

In many of the markets where we intend to operate, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms.

We expect that many of the patients in the United States who may seek treatment with our products that may be approved for marketing will be eligible for coverage under Medicare, the federal program that provides medical coverage for the aged and disabled. Other patients may be covered by private health plans or may be uninsured. The Medicare program is administered by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services. Coverage and reimbursement for products and services under Medicare are determined pursuant to regulations promulgated by CMS and pursuant to CMS’s subregulatory coverage and reimbursement determinations. It is difficult to predict how CMS will apply those regulations and subregulatory determinations to novel products such as ours.

Moreover, the methodology under which CMS makes coverage and reimbursement determinations is subject to change, particularly because of budgetary pressures facing the Medicare program. For example, the Medicare Prescription Drug, Improvement, and Modernization Act (the “Medicare Modernization Act”), enacted in 2003, provided for a change in reimbursement methodology that has reduced the Medicare reimbursement rates for many drugs, including oncology therapeutics. Even if our product candidates are approved for marketing in the U.S., if we are unable to obtain or retain coverage and adequate levels of reimbursement from Medicare or from private health plans, our ability successfully to market such products in the U.S. will be adversely affected. The manner and level at which the Medicare program reimburses for services related to our product candidates (e.g., administration services) also may adversely affect our ability to market or sell any of our product candidates that may be approved for marketing in the U.S.

In the U.S., efforts to contain or reduce health care costs have resulted in many legislative and regulatory proposals at both the federal and state level, and it is difficult to predict which, if any, of these proposals will be enacted, and, if so, when. Cost control initiatives by governments or third party payers could decrease the price that we receive for any one or all of our potential products or increase patient coinsurance to a level that makes our product candidates unaffordable for patients. In addition, government and private health plans are more persistently challenging the price and cost-effectiveness of therapeutic products. If third-party payers were to determine that one or more of our product candidates is not cost-effective, this could result in refusal to cover those products or in coverage at a low reimbursement level. Any of these initiatives or developments could prevent us from successfully marketing and selling any of our potential products.

In the E.U. governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the role of the National Institute for Health and Clinical Excellence in the U.K. which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

**DCVax<sup>®</sup> is our only technology in clinical development.**

Unlike many pharmaceutical companies that have a number of products in development and which utilize many technologies, we are dependent on the success of our DCVax<sup>®</sup> platform and, potentially, our CXCR4 antibody technology. While DCVax<sup>®</sup> technology has a number of potentially beneficial uses, if that core technology is not commercially viable, we would have to rely on the CXCR4 technology, which is at an early pre-clinical stage of development, for our success. If the CXCR4 technology also fails, we currently do not have other technologies to fall back on and our business could fail.

**We may be prevented from using the DCVax<sup>®</sup> name in Europe.**

The EMEA has indicated that DCVax<sup>®</sup> may not be an acceptable name because of the suggested reference to a vaccine. Failure to obtain the approval for the use of the DCVax<sup>®</sup> name in Europe would require us to market our potential products in Europe under a different name which could impair the successful marketing of our product candidates and may have a material adverse effect on our results of operations and financial condition.

**Competing generic medicinal products may be approved.**

In the E.U., there exists a process for the approval of generic biological medicinal products once patent protection and other forms of data and market exclusivity have expired. If generic medicinal products are approved, competition from such products may reduce sales of our products. Other jurisdictions, including the U.S., are considering adopting legislation that would allow the approval of generic biological medicinal products.

**We may be exposed to potential product liability claims, and insurance against these claims may not be available to us at a reasonable rate in the future, if at all.**

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing, marketing and sale of therapeutic products. Our insurance coverage may not be adequate to cover claims against us or may not be available to us at an acceptable cost, if at all. Regardless of their merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to our reputation, withdrawal of clinical trial volunteers and loss of revenues. Thus, whether or not we are insured, a product liability claim or product recall may result in losses that could be material.

We store, handle, use and dispose of controlled hazardous, radioactive and biological materials in our business. Our current use of these materials generally is below thresholds giving rise to burdensome regulatory requirements. Our development efforts, however, may result in our becoming subject to additional requirements, and if we fail to comply with applicable requirements we could be subject to substantial fines and other sanctions, delays in research and production, and increased operating costs. In addition, if regulated materials were improperly released at our current or former facilities or at locations to which we send materials for disposal, we could be liable for substantial damages and costs, including cleanup costs and personal injury or property damages, and incur delays in research and production and increased operating costs.



Insurance covering certain types of claims of environmental damage or injury resulting from the use of these materials is available but can be expensive and is limited in its coverage. We have no insurance specifically covering environmental risks or personal injury from the use of these materials and if such use results in liability, our business may be seriously harmed.

**Toucan Capital and Toucan Partners beneficially own a majority of our shares of common stock and, as a result, the trading price for our common stock may be depressed and these stockholders can take actions that may be adverse to the interests of other investors.**

As of August 14, 2009, Toucan Capital, its affiliate, Toucan Partners and its managing member, Ms. Linda Powers, collectively beneficially owned an aggregate of 21,872,196 shares of our common stock, representing approximately 48.5 percent of our outstanding common stock. In addition, as of August 14, 2009, Toucan Capital may acquire an aggregate of approximately 22.0 million shares of common stock upon exercise of warrants and Toucan Partners may acquire an aggregate of approximately 9.0 million shares of common stock upon the exercise of warrants. This significant concentration of ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. Toucan Capital has the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, a managing member of Toucan Capital is a member of the Board. In light of the foregoing, Toucan Capital can significantly influence the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination that could be favorable to investors.

**Our Certificate of Incorporation and Bylaws and stockholder rights plan may delay or prevent a change in our management.**

Our Seventh Amended and Restated Certificate of Incorporation, as amended (the “Certificate of Incorporation”), Third Amended and Restated Bylaws (the “Bylaws”) and stockholder rights plan contain provisions that could delay or prevent a change in our management team. Some of these provisions:

- authorize the issuance of preferred stock that can be created and issued by the Board without prior stockholder approval, commonly referred to as “blank check” preferred stock, with rights senior to those of the common stock;
- allow the Board to call special meetings of stockholders at any time but restrict the stockholders from calling special meetings;
- authorize the Board to issue dilutive common stock upon certain events; and
- provide for a classified Board.

These provisions could allow our Board to affect the rights of an investor since the Board can make it more difficult for holders of common stock to replace members of the Board. Because the Board is responsible for appointing the members of the management team, these provisions could in turn affect any attempt to replace the current management team.

**There may not be an active, liquid trading market for our common stock.**

Our common stock is currently listed on the Over-The-Counter Bulletin Board, or OTCBB, and on AIM, which are generally recognized as being less active markets than NASDAQ, the stock exchange on which our common stock previously was listed. You may not be able to sell your shares at the time or at the price desired. There may be significant consequences associated with our stock trading on the OTCBB rather than a national exchange. The effects of not being able to list our securities on a national exchange include:

- limited release of the market price of our securities;

- limited news coverage;
- limited interest by investors in our securities;
- volatility of our stock price due to low trading volume;
- increased difficulty in selling our securities in certain states due to “blue sky” restrictions; and
- limited ability to issue additional securities or to secure additional financing.

**The resale, or the availability for resale, of the shares placed in the PIPE Financing could have a material adverse impact on the market price of our common stock.**

The PIPE Financing, completed in March 2006, included the private placement of an aggregate of approximately 2.6 million shares of common stock and accompanying warrants to purchase an aggregate of approximately 1.3 million shares of common stock. In connection with the PIPE Financing, we agreed to register, and subsequently did register, the resale of the shares of common stock sold in the PIPE Financing and the shares underlying the warrants issued in the PIPE Financing. The resale of a substantial number of the shares placed in the PIPE Financing or even the availability of these shares for resale could have a material adverse impact on our stock price.

**Because our common stock is subject to “penny stock” rules, the market for the common stock may be limited.**

Because our common stock is 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. Under the “penny stock” rules promulgated under the Exchange Act, 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 a 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 of these rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our common stock may be adversely affected. As a result, the market price of our common stock may be depressed, and stockholders may find it more difficult to sell our common stock.

**The price of our common stock may be highly volatile.**

The share price of publicly traded biotechnology and emerging pharmaceutical companies, particularly companies without earnings and consistent product revenues, can be highly volatile and are likely to remain highly volatile in the future. The price at which our common stock is quoted and the price which investors may realize in sales of their shares of our common stock will be influenced by a large number of factors, some specific to us and our operations and some unrelated to our operating performance. These factors could include the performance of our marketing programs, large purchases or sales of the shares, currency fluctuations, legislative changes and general economic conditions. In the past, share class action litigation has often been brought against companies that experience volatility in the market price of their shares. Whether or not meritorious, litigation brought against us following fluctuations in the trading price of our common stock could result in substantial costs, divert management’s attention and resources and harm our financial condition and results of operations.

**Our business could be adversely affected by animal rights activists.**

Our business activities have involved animal testing. These types of activities have been the subject of controversy and adverse publicity. Some organizations and individuals have attempted to stop animal testing by pressing for legislation and regulation in these areas. To the extent the activities of such groups are successful; our business could be adversely affected. Negative publicity about us, our pre-clinical trials and our product candidates could have an adverse impact on our sales and profitability.

**The requirements of the Sarbanes-Oxley Act of 2002 and other U.S. securities laws reporting requirements impose cost and operating challenges on us.**

We are subject to certain of the requirements of the Sarbanes-Oxley Act of 2002 in the U.S. and the reporting requirements under the Exchange Act. These laws require, among other things, an attestation report of our independent auditor on the effectiveness of our internal control over financial reporting, currently expected to begin with our annual report for the year ended December 31, 2009, as well as the filing of annual reports on Form 10-K, quarterly reports on Form 10-Q and periodic reports on Form 8-K following the happening of certain material events. To meet these compliance deadlines, we will need to have our internal controls designed, tested and operational by early 2009 to ensure compliance with applicable standards. We initiated the process of documenting and evaluating our internal controls and financial reporting procedures in early 2008. This process is ongoing and will continue to likely be time consuming and will result in us having to significantly change our controls and reporting procedures due to our small number of employees and lack of governance controls. Most similarly-sized companies registered with the SEC have had to incur significant costs to ensure compliance. Moreover, any failure by us to comply with such provisions would be required to be disclosed publicly, which could lead to a loss of public confidence in our internal controls and could harm the market price of our common stock.

**Our management has identified significant internal control deficiencies, which management and our independent auditor believe constitute material weaknesses.**

In connection with the preparation of our financial statements for the year ended December 31, 2008, certain significant internal control deficiencies became evident to management that, in the aggregate, represents material weaknesses, including:

- lack of a sufficient number of independent directors on our audit committee;
- lack of a financial expert on our audit committee
- insufficient segregation of duties in our finance and accounting function due to limited personnel;
- insufficient corporate governance policies; and
- inadequate approval and control over transactions and commitments made on our behalf by related parties.

As part of the communications by our independent auditors with our audit committee with respect to audit procedures for the year ended December 31, 2008, our independent auditors informed the audit committee that these deficiencies constituted material weaknesses, as defined by Auditing Standard No. 5, “An Audit of Internal Control Over Financial Reporting that is Integrated with an Audit of Financial Statements and Related Independence Rule and Conforming Amendments,” established by the Public Company Accounting Oversight Board, or PCAOB. We intend to take appropriate and reasonable steps to make the necessary improvements to remediate these deficiencies but we cannot be certain that we will have the necessary financing to address these deficiencies or that we will be able to attract qualified individuals to serve on our Board and to take on key management roles within the Company. Our failure to successfully remediate these issues could lead to heightened risk for financial reporting mistakes and irregularities and a further loss of public confidence in our internal controls that could harm the market price of our common stock.

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

On June 17, 2008, the Company issued 122,190 shares of common stock pursuant to a letter agreement under which we received an exclusive right to negotiate the terms of a potential transaction in which we would obtain the rights, title and interest to and under a certain license agreement.

On January 16, 2009 we entered into a securities purchase agreement for \$700,000 with Al Rajhi Holdings who purchased 1,000,000 shares of our common stock at \$0.70 per share.

On March 27, 2009, we sold approximately 1.4 million shares of common stock at a purchase price of \$0.53 per share and raised aggregate gross proceeds of approximately \$0.7 million in a closed equity financing with unrelated investors.

The Company claimed exemption from registration under the Securities Act for the issuance of such shares of common stock under Section 4(2) of the Securities Act and/or Regulation D thereunder, as a transaction not involving any public offering. The acquirer of the unregistered shares for which the Company relied on Section 4(2) and/or Regulation D represented to the Company that it was an accredited investor, as defined under the Securities Act. The Company claimed such exemption on the basis that (i) the acquirer represented that it intended to acquire the shares for investment only and not with a view to the distribution thereof and that it either received adequate information about the Company or had access to such information and (ii) appropriate legends were affixed to the stock certificates issued in such transaction.

**Item 3. Defaults upon Senior Securities**

None

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

None

**Item 5. Other Information**

None

Item 6. Exhibits

- 3.1 Seventh Amended and Restated Certificate of Incorporation (3.1)(1)
- 3.2 Third Amended and Restated Bylaws (3.1)(2)
- 3.3 Amendment to the Seventh Amended and Restated Certificate of Incorporation (3.2)(2)
- 3.4 Amendment to Seventh Amended and Restated Certificate of Incorporation (3.4)(3)
- \*31.1 Certification of President and Chief Executive Officer (Principal executive officer and principal financial 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 and Chief Executive Officer (Principal executive officer and principal financial officer) Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- 
- (1) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Registrant’s Registration Statement on Form S-1 (File No. 333-67350) on July 17, 2006.
  - (2) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Registrant’s Current Report on Form 8-K on June 22, 2007.
  - (3) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Post-Effective Amendment No. 2 to the Registrant’s Registration Statement on Form S-1 (File No. 333-134320) on January 28, 2008.
  - (4) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Registrant’s Current Report on Form 8-K on May 15, 2008.
  - \* Filed herewith.

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: August 14, 2009

By: /s/ Alton L. Boynton  
Alton L. Boynton  
President and Chief Executive Officer  
(Principal Executive, Financial and Accounting Officer)

NORTHWEST BIOTHERAPEUTICS, INC.  
(A Development Stage Company)

EXHIBIT INDEX

3.1	Seventh Amended and Restated Certificate of Incorporation (3.1)(1)
3.2	Third Amended and Restated Bylaws (3.1)(2)
3.3	Amendment to the Seventh Amended and Restated Certificate of Incorporation (3.2)(2)
3.4	Amendment to Seventh Amended and Restated Certificate of Incorporation (3.4)(3)
*31.1	Certification of President and Chief Executive Officer (Principal executive officer and principal financial 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 and Chief Executive Officer (Principal executive officer and principal financial officer) Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

---

(1) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Registrant’s registration statement Form S-1 (File No. 333-67350) on July 17, 2006.

(2) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Registrant’s Current Report on Form 8-K on June 22, 2007.

(3) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Post-Effective Amendment No. 2 to the Registrant’s Registration Statement on Form S-1 on January 28, 2008.

(4) Incorporated by reference to the exhibit shown in the preceding parentheses filed with the Registrant’s Current Report on Form 8-K on May 15, 2008.

\* Filed herewith.



SECTION 302 CERTIFICATION

I, Alton L. Boynton, certify that:

- (1) I have reviewed this quarterly report on Form 10-Q of Northwest Biotherapeutics, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
- (5) I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 14, 2009

By: /s/ Alton L. Boynton  
Alton L. Boynton  
President and Chief Executive Officer  
(Principal Executive, Financial and Accounting Officer)

---

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Northwest Biotherapeutics, Inc. (the “Company”) on Form 10-Q for the period ended June 30, 2009, as filed with the Securities and Exchange Commission (the “Report”), I, Alton L. Boynton, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2009

/s/ Alton L. Boynton  
\_\_\_\_\_  
Alton L. Boynton  
President and Chief Executive Officer  
(Principal Executive, Financial and Accounting Officer)

\_\_\_\_\_