



NORTHWEST BIOTHERAPEUTICS INC

FORM 10-Q

(Quarterly Report)

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

FORM 10-Q

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

For the quarterly period ended June 30, 2014

OR

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

For the transition period from _____ to _____

Commission File Number: 001-35737

NORTHWEST BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

94-3306718

(State or Other Jurisdiction of Incorporation or Organization)

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

4800 Montgomery Lane, Suite 800, Bethesda, MD 20814

(Address of principal executive offices) (Zip Code)

(240) 497-9024

(Registrant's telephone number)

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

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

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

(do not check if a smaller reporting company)

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

As of August 13, 2014, the total number of shares of common stock, par value \$0.001 per share, outstanding was 59,504,996.

NORTHWEST BIOTHERAPEUTICS, INC.

FORM 10-Q

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Part I – Financial Information

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share amount)

	June 30, 2014	December 31, 2013
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,853	\$ 18,499
Prepaid expenses and other current assets	177	147
Cash in custody account	3,414	-
Total current assets	12,444	18,646
Property and equipment, net	77	83
Other non-current assets	55	55
Total assets	<u>\$ 12,576</u>	<u>\$ 18,784</u>
LIABILITIES, REDEEMABLE COMMON STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable (includes related party of \$2,768 and \$3,619 as of June 30, 2014 and December 31, 2013, respectively)	\$ 9,543	\$ 8,937
Accrued expenses (includes related party of \$7 and \$5 as of June 30, 2014 and December 31, 2013, respectively)	655	842
Convertible notes, net (includes related party of \$50 and \$50 as of June 30, 2014 and December 31, 2013, respectively)	238	288
Notes Payable - in dispute	934	934
Derivative liability associated with warrants	31,078	8,688
Total current liabilities	42,448	19,689
Redeemable common stock (\$0.001 par value); 0 and 1,444,788 shares issued and outstanding as of June 30, 2014 and December 31, 2013, respectively	-	8,913
Stockholders' deficit:		
Preferred stock (\$0.001 par value); 40,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2014 and December 31, 2013, respectively	-	-
Common stock (\$0.001 par value); 450,000,000 shares authorized; 58,785,299 and 45,666,315 shares issued and outstanding as of June 30, 2014 and December 31, 2013, respectively	59	46
Additional paid-in capital	427,177	375,213
Stock subscription receivable	(125)	-
Accumulated deficit	(456,793)	(384,887)
Cumulative translation adjustment	(190)	(190)
Total stockholders' deficit	(29,872)	(9,818)
Total liabilities, redeemable common stock and stockholders' deficit	<u>\$ 12,576</u>	<u>\$ 18,784</u>

See accompanying notes to the unaudited condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Revenues:				
Research grants and other	\$ -	\$ 272	\$ -	\$ 409
Total revenues	-	272	-	409
Operating costs and expenses:				
Research and development	21,549	8,383	41,535	19,991
General and administration	3,875	3,290	7,570	5,760
Depreciation and amortization	3	3	6	6
Total operating costs and expenses	25,427	11,676	49,111	25,757
Loss from operations	(25,427)	(11,404)	(49,111)	(25,348)
Other income (expense):				
Inducement expense	(5,089)	-	(10,340)	-
Change in fair value of derivatives	4,684	-	(12,300)	-
Interest expense	(33)	(190)	(155)	(640)
Net loss	<u>\$ (25,865)</u>	<u>\$ (11,594)</u>	<u>\$ (71,906)</u>	<u>\$ (25,988)</u>
Net loss per share applicable to common stockholders - basic and diluted	\$ (0.45)	\$ (0.40)	\$ (1.31)	\$ (0.93)
Weighted average shares used in computing basic and diluted loss per share	57,442	29,105	54,923	28,078

See accompanying notes to the unaudited condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Common Stock		Additional Paid-	Subscription	Accumulated	Cumulative	Total Stockholders'
	Shares	Amount	in Capital	Receivable	Deficit	Translation	Equity (Deficit)
Balance December 31, 2013	45,666	\$ 46	\$ 375,213	\$ -	\$ (384,887)	\$ (190)	\$ (9,818)
Issuance of common stock for cash in a private placement	32	-	224	-	-	-	224
Conversion of accounts payable to common stock and warrants - Cognate	1,482	2	5,925	-	-	-	5,927
Inducement expenses associated with Conversion of accounts payable to common stock and warrants - Cognate	-	-	2,800	-	-	-	2,800
Conversion of note payable and accrued interest to common stock	70	-	217	-	-	-	217
Proceeds from warrants exercises	722	1	2,691	-	-	-	2,692
Cashless warrants exercises	41	-	-	-	-	-	-
Redemption of redeemable securities	1,445	1	8,912	-	-	-	8,913
Adjustment for issuance of common stock in 2012	20	-	-	-	-	-	-
Offering costs	-	-	(1)	-	-	-	(1)
Issuance of common stock in exchange for services - non-employees	239	-	1,567	-	-	-	1,567
Stock based compensation subject to service conditions - Cognate	5,101	5	2,455	-	-	-	2,460
Net loss	-	-	-	-	(46,041)	-	(46,041)
Balance as of March 31, 2014	54,818	55	400,003	-	(430,928)	(190)	(31,060)
Issuance of common stock for cash and over-allotment rights	2,273	2	14,998	-	-	-	15,000
Offering costs	-	-	(1,104)	-	-	-	(1,104)
Proceeds from the issuance of common stock and warrants in a private placement	259	-	1,835	-	-	-	1,835
Proceeds from the issuance of common stock and warrants - Cognate	563	1	2,249	-	-	-	2,250
Inducement expenses associated with issuance common stock and warrants for cash - Cognate	-	-	1,525	-	-	-	1,525
Subscription receivable for issuance of common stock	16	-	125	(125)	-	-	-
Proceeds from warrants exercises	92	-	395	-	-	-	395
Cashless warrants exercise	13	-	-	-	-	-	-
Conversion of accounts payable to common stock and warrants - Cognate	727	1	2,908	-	-	-	2,909
Inducement expenses associated with issuance of common stock on conversion of accounts payable - Cognate	-	-	1,426	-	-	-	1,426
Issuance of common stock for services - non-employees	25	-	155	-	-	-	155
Stock based compensation subject to service conditions - Cognate	-	-	2,662	-	-	-	2,662
Net loss	-	-	-	-	(25,865)	-	(25,865)
Balance as of June 30, 2014	58,785	\$ 59	\$ 427,177	\$ (125)	\$ (456,793)	\$ (190)	\$ (29,872)

See accompanying notes to the unaudited condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Six months ended June 30,	
	2014	2013
Cash Flows from Operating Activities:		
Net Loss	\$ (71,906)	\$ (25,988)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	6	6
Amortization of debt discount and accretion on redeemable securities	-	482
Change in fair value of derivatives	12,300	-
Accrued interest converted to common stock	76	-
Accreted interest on convertible promissory note	-	61
Stock-based compensation costs	-	1,219
Non-employee stock based compensation - Cognate	10,623	-
Stock and warrants issued for services	1,722	1,528
Inducement expense	10,340	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(30)	(251)
Accounts payable and accrued expenses	1,385	1,005
Related party accounts payable and accrued expenses	7,986	6,638
Deposits and other non-current assets	-	17
Net cash used in operating activities	<u>(27,498)</u>	<u>(15,283)</u>
Cash Flows from Investing Activities:		
Cash deposited in custody account	(3,414)	-
Net cash used in investing activities	<u>(3,414)</u>	<u>-</u>
Cash Flows from Financing Activities:		
Proceeds from issuance of notes payable	-	400
Repayment of convertible promissory note	(25)	-
Payments on note payable	-	(688)
Proceeds from exercise of warrants	3,087	-
Proceeds from the issuance of common stock and warrants - Cognate	2,250	-
Proceeds from issuance common stock and warrants	2,059	10,210
Gross proceeds from issuance common stock and overallotment rights	15,000	-
Offering costs	(1,105)	-
Net cash provided by financing activities	<u>21,266</u>	<u>9,922</u>
Net decrease in cash and cash equivalents	(9,646)	(5,361)
Cash and cash equivalents at beginning of period	18,499	7,346
Cash and cash equivalents at end of period	<u><u>\$ 8,853</u></u>	<u><u>\$ 1,985</u></u>

See accompanying notes to the unaudited condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Six months ended June 30,	
	2014	2013
Supplemental schedule of non-cash financing activities:		
Issuance of common stock in connection with conversion of notes payable and accrued expenses	\$ 140	\$ 1,850
Issuance of common stock and warrants in connection with conversion of accounts payable -		
Cognate	\$ 8,835	\$ -
Reclass of redeemable security to equity	\$ 8,913	\$ -

See accompanying notes to the unaudited condensed consolidated financial statements

NORTHWEST BIOTHERAPEUTICS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Description of Business and Recent Developments

Northwest Biotherapeutics, Inc. and its wholly owned subsidiaries NW Bio Europe S.A.R.L and NW Bio GmbH (collectively, the "Company", "we", "us" and "our") were organized to discover and develop innovative immunotherapies for cancer.

The Company's platform technology, DCVax, is currently being tested for the treatment of certain types of cancers through clinical trials in the United States and Europe that are in various phases.

Recent Developments

On January 17, 2014, the Company entered into the following agreements (collectively, the "Cognate Agreements" or the "Agreements") with Cognate BioServices, Inc. ("Cognate") for manufacturing and related services for our DCVax® products:

- a DCVax®-L Manufacturing and Services Agreement;
- a DCVax®-Direct Manufacturing and Services Agreement;
- an Ancillary Services Agreement; and
- a Manufacturing Expansion Services Agreement.

Together, these Agreements provide for substantial expansion of manufacturing capacity for the Company's programs, in multiple regions, as well as development of the necessary systems and logistics, and other near-term and long-term preparations, for large scale scale-up of the Company's programs. These Agreements include most favored nation treatment with respect to the terms provided to any other investors or creditors (including with respect to any warrants), including share issuances upon the exercise of previously issued derivative securities.

The Company also entered into a Lock-Up Agreement with Cognate on January 17, 2014, under which Cognate agreed to have all of the shares that are issued as part of the milestone and initiation payments and the invoice conversions under the Cognate Agreements (collectively, the "Lock-Up Shares") locked up for up to 36 months, in return for 15% warrant coverage for each 6-month period of lock-up, on the same terms as the warrants in the Cognate Agreements. During the lock-up, the Lock-Up Shares may not be sold or traded on the market. These lock-up terms are subject to the same most favored nation treatment as provided in the Cognate Agreements as described above.

2. Liquidity and Financial Condition

During the six months ended June 30, 2014, the Company used approximately \$25.2 million of cash in its operating activities including one-time expenditures relating to the clinical trials and to certain initial costs for new manufacturing capacity in Europe (net of \$2.3 million in cash received from Cognate in return for common stock and warrants). The Company incurred an aggregate combined cash and non-cash loss of \$71.9 million for the six months ended June 30, 2014, including \$44.4 million of net cash and aggregate non-cash charges associated with stock based compensation, a mark to market charge for the change in the fair value of its derivative liability, and inducement expenses related to the exchange of Cognate BioServices, Inc. ("Cognate") accounts payable for common stock and warrants.

The Company had current assets of \$12.4 million as of June 30, 2014, and current assets less accounts payable and accrued expenses and notes payable of approximately \$1.1 million at June 30, 2014. The accounts payable and notes payable include an aggregate of \$2.8 million of trade liabilities and convertible notes owed by the Company to related parties.

On April 9, 2014, the Company entered into a Securities Purchase Agreement with a single institutional investor for the sale of 2,272,727 shares of common stock at a purchase price of \$6.60 per share, for a total purchase price of \$15.0 million. Additionally, from the date of the closing until one year after the closing date, the investor has a non-transferable Over-allotment Right to purchase up to 2,272,727 additional shares of common stock at a price per share of \$7.50, for an additional subscription amount of up to \$17.05 million. See Note 11.

Because of recurring operating losses, net operating cash flow deficits, and an accumulated deficit there is substantial doubt about the Company's ability to continue as a going concern. 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 might become necessary should the Company be able to continue as a going concern.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated interim financial statements include the accounts of the Company and its subsidiaries. All material intercompany balances and transactions have been eliminated.

The accompanying unaudited condensed financial statements as of June 30, 2014 and for the three and six months then ended have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements. The condensed consolidated balance sheet as of June 30, 2014, condensed consolidated statements of operations for the three and six months ended June 30, 2014 and 2013, condensed consolidated statement of stockholders' equity (deficit) for the six months ended June 30, 2014, and the condensed consolidated statements of cash flows for the six months ended June 30, 2014 and 2013 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three and six months ended June 30, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014 or for any future interim period. The condensed balance sheet at December 31, 2013 has been derived from audited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2013, and notes thereto included in the Company's annual report on Form 10-K, which was filed with the SEC on April 1, 2014.

Recently Issued Accounting Standards

In June 2014, the FASB issued Accounting Standard Update No. 2014-10, Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. The amendments in this update remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. A public entity is required to apply the amendments for annual reporting periods beginning after December 15, 2014, and interim periods therein. An entity should apply the amendments retrospectively for all comparative periods presented. Early adoption is permitted. The Company adopted the guidance during the second quarter of 2014. Adoption of this standard did not have a material impact on the Company's financial position, results of operations, or cash flows.

The Financial Accounting Standards Board ("FASB") has issued Accounting Standards Update ("ASU") No. 2014-12, Compensation – Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period. This ASU requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's condensed consolidated financial position and results of operations.

Use of Estimates

In preparing financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include valuing equity securities in share-based payment arrangements, estimating the fair value of equity instruments recorded as derivative liabilities, and estimating the useful lives of depreciable assets and whether impairment charges may apply.

Research and Development Costs

Research and development costs are charged to operations as incurred and consist primarily of clinical trial costs for the Company's Phase III and Phase I/II clinical trials, related party manufacturing costs, consulting costs, contract research and development costs, and compensation costs. For the three and six months ended June 30, 2014, the Company recognized aggregate cash and non-cash research and developments costs of \$21.5 million and \$41.5 million, respectively. For the three and six months ended June 30, 2013, the Company recognized cash and non-cash research and developments costs of \$8.4 million and \$20.0 million, respectively.

For the six months ended June 30, 2014 and June 30, 2013, the Company recorded \$28.5 million and \$10.7 million, respectively, of cash and non-cash expenses related to services performed by Cognate (including manufacturing for both the Phase III and Phase I/II clinical trials, ongoing product and process development, and expansion of several company programs).

Comprehensive Loss

The Company's comprehensive loss is equal to its net loss for all periods presented.

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2013 Annual Report.

4. Fair Value Measurements

The Company is required under U.S. GAAP to measure certain of its assets and liabilities at fair value based upon a fair value hierarchy that requires the Company to maximize use of observable inputs (Level 1 and 2 inputs) and minimize use of unobservable inputs (Level 3 inputs). The Company is further required to classify each asset or liability measured at fair value into Level 1, 2, or 3 based on the significance of inputs used to measure fair value of the asset or liability in its entirety.

a. Derivative Liability

The following table classifies the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy as of June 30, 2014 and December 31, 2013 (in thousands):

Fair value measured at June 30, 2014				
	Fair value at June 30, 2014	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 31,078	\$ -	\$ -	\$ 31,078

Fair value measured at December 31, 2013				
	Fair value at December 31, 2013	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	\$ 8,688	\$ -	\$ -	\$ 8,688

There were no transfers between Level 1, 2 or 3 during the three and six month periods ended June 30, 2014.

The following table presents changes in Level 3 liabilities measured at fair value for the three and six month periods ended June 30, 2014. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs.

Balance - December 31, 2013	\$ 8,688
3,174,835 warrants issued during 1st quarter	7,952
Change in fair value of warrant liability	16,984
Balance - March 31, 2014	33,624
644,896 warrants issued during 2nd quarter	2,138
Change in fair value of warrant liability	(4,684)
Balance - June 30, 2014	<u>\$ 31,078</u>

The Company's warrant liabilities are measured at fair value using the Monte Carlo simulation valuation methodology. A summary of quantitative information about significant unobservable inputs (Level 3 inputs) used in measuring the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy for the three months ended June 30, 2014 is as follows (*dollars and shares in thousands*):

Warrants issuance date	January 6, 2014	January 17, 2014	January 31, 2014	February 3, 2014	February 28, 2014	March 31, 2014	Total
Number of warrants issued	139	2,434	143	119	195	145	3,175
Fair value of warrants at issuance date	\$ 308	\$ 5,501	\$ 383	\$ 327	\$ 844	\$ 589	\$ 7,952

Warrants issuance date	April 30, 2014	May 30, 2014	June 30, 2014	Total
Number of warrants issued	171	193	281	645
Fair value of warrants at issuance date	\$ 527	\$ 621	\$ 990	\$ 2,138

Date of valuation	January 6, 2014	January 17, 2014	January 31, 2014	February 3, 2014	February 28, 2014	March 31, 2014
Dividend yield (per share)	0%	0%	0%	0%	0%	0%
Strike price	\$ 4.00	\$ 4.00	\$ 4.00	\$ 4.00	\$ 4.00	\$2.40-\$6.00
Volatility (annual)	92.13%	93.12%	96.72%	91.79%	105.03%	74.43%-88.03%
Risk-free rate	1.73%	1.66%	1.55%	1.49%	1.49%	1.73%
Contractual term (years)	5.0	5.0	5.00	5.00	5.00	4.33-4.85

Date of valuation	April 30, 2014	May 30, 2014	June 30, 2014
Dividend yield (per share)	0%	0%	0%
Strike price	\$ 4.00	\$ 4.00	\$ 4.00
Volatility (annual)	84.18%	83.48%	79.79%-82.90%
Risk-free rate	1.74%	1.52%	1.62%-1.64%
Contractual term (years)	5.0	5.0	5.00

The development and determination of the unobservable inputs for Level 3 fair value measurements and fair value calculations are the responsibility of the Company's Management.

5. Cash in Custody Account

During the six months ended June 30, 2014, the Company continued its efforts to obtain large new manufacturing capacity for its DCVax products in Europe. This capacity will be developed and managed by Cognate BioServices pursuant to the Manufacturing Expansion Services Agreement entered into by the Company and Cognate in January, 2014. Under that Agreement, the Company is responsible for the costs of developing and maintaining manufacturing facilities or capacity that is dedicated exclusively to production of NWBT's DCVax products.

The Company found a suitable site and facility in Europe. Negotiations with the Seller for purchase of the property and facility continued for months. At the Seller's direction, the purchase terms and transaction documents were expected to be finalized by June 30, 2014. On June 25, 2014, in preparation for the anticipated completion of the transaction, and due to the uncertain timing of international wires, the Company wired to the law firm handling the transaction \$3.4 million for the payment at closing. The law firm held the \$3.4 million in its client account. On June 30, 2014, in anticipation of a closing occurring that evening, the law firm sent \$2.6 million to the Seller's law firm to hold in trust, pending the closing of the purchase transaction. However, the transaction terms and documents were not finalized by June 30, 2014, and the Seller was not prepared to proceed with the transaction at that time. The funds continued to be kept in the two law firms' trust accounts (\$2.6 million in the Seller's law firm and \$0.8 million in the Purchaser's law firm), and the Company was free to decide not to proceed and take the funds back. As of August 14, 2014, deal terms to the Company have not been finalized.

6. Stock-based Compensation

Stock Based Compensation to Non-employees

Stock-based compensation awards granted to non-employees are recognized over the related service period. The Company believes that the fair value of the stock-based awards is more reliably measurable than the fair value of the services received. The fair value of these awards are calculated at each reporting date. On January 17, 2014, in connection with the four Cognate Agreements, the Company issued one-time initiation payments of 5,101,366 shares of common stock. The common stock will vest over thirty six months from the closing date. Stock-based compensation expense related to Cognate was \$2.7 million and \$5.1 million for the three and six months ended June 30, 2014. Approximately \$2.8 million in compensation costs per calendar quarter may be recognized over the next 2.80 years based on the fair market value of stock of \$6.71.

7. Notes Payable

During the six months ended June 30, 2014, the Company converted notes and relevant accrued interest of \$0.1 million into approximately 0.07 million shares of common stock. During the six months ended June 30, 2013, \$0.9 million of notes were converted into 0.4 million shares of common stock.

Notes payable consist of the following at June 30, 2014 and December 31, 2013:

	June 30, 2014	December 31, 2013
Notes payable - current		
12% unsecured originally due July 2011 - in dispute (1)	934	934
	<u>934</u>	<u>934</u>
Convertible notes payable, net - current		
6% unsecured (2)	135	160
8% unsecured note due 2014 (3)	53	53
	<u>188</u>	<u>213</u>
Convertible Notes payable related party, net - current		
6% due on demand (4)	50	75
	<u>50</u>	<u>75</u>
Total notes payable, net	<u>\$ 1,172</u>	<u>\$ 1,222</u>

(1) This \$0.934 million note, which was originally due in July 2011 is currently under dispute with the creditor as to the validity of the note payable balance, which the Company believes has already been paid in full and is not outstanding.

(2) This \$0.135 million note as of June 30, 2014 consists of two separate 6% notes in the amounts of \$0.110 million and \$0.025 million. In regards to the \$0.110 million note, the Company has made ongoing attempts to locate the creditor to repay or convert this note, but has been unable to locate the creditor to date. In regards to the \$0.025 million note, the holder has elected to convert these notes into equity, the Company has delivered the applicable conversion documents to the holder, and the Company is waiting for the holder to execute and return the documents.

(3) This \$0.530 million note was due May 25, 2014, and is currently past due.

(4) This \$0.050 million demand note as of June 30, 2014 is held by an officer of the Company. The holder has made no demand for payment, but reserves the right to make a demand at any time.

8. Net Loss per Share Applicable to Common Stockholders

Options, warrants, and convertible debt outstanding were all considered anti-dilutive for three and the six month periods ended June 30, 2014, and 2013, due to net losses. The following securities were not included in the diluted net loss per share calculation because their effect was anti-dilutive as of the periods presented (in thousands):

	For the six months ended June 30,	
	2014	2013
Common stock options	1,551	1,574
Over-allotment rights	2,273	-
Common stock warrants - equity treatment	14,200	12,214
Common stock warrants - liability treatment	9,108	-
Convertible notes	81	2,709
Excluded potentially dilutive securities	<u>27,213</u>	<u>16,497</u>

9. Related Party Transactions

Cognate BioServices

Under the January 17, 2014 DCVax®-L Manufacturing Services Agreement and the DCVax-Direct Agreement, a modified set of provisions applies going forward to any shut down or suspension. Such shut down provisions have been included in all of the agreements with Cognate since 2005. Under the modified provisions, if the Company shuts down or suspends its DCVax-L program or DCVax-Direct program with Cognate in breach of the Agreement, the Company will be liable for certain fees in addition to any other remedies. The fees are based on the stage at which the shut down or suspension occurs:

- Prior to the last dose of the last patient enrolled in the Phase III trial for DCVax®-L or after the last dose of the last patient enrolled in the Phase III clinical trial for DCVax®-L but before any submission for product approval in any jurisdiction or after the submission of any application for market authorization but prior to receiving a marketing authorization approval: in any of these cases, the fee shall be \$3 million.
- At any time after receiving the equivalent of a marketing authorization for DCVax®-L in any jurisdiction, the fee shall be \$5 million.

For the three months ended June 30, 2014, the Company made net disbursements to Cognate of approximately \$4.0 million, including charges relating to manufacturing for both the Phase III and Phase I/II clinical trials, ongoing product and process development, and expansion of several Company programs under these service agreements.

As of June 30, 2014 and December 31, 2013, the Company owed Cognate (including third party sub-contract amounts) approximately \$2.7 million and \$3.6 million, respectively.

Cognate Accounts Payable Conversions and inducement charge -Six months ended June 30, 2014

Under the July 2013 Conversion and Lock-up Agreement, \$8.8 million in accounts payable due to Cognate was converted into common stock and warrants. 2.2 million shares of common stock were issued based on an above-market \$4.00 per share conversion price while the closing market price was \$3.55. 50% warrant coverage of the common stock issued, resulting in 1.1 million warrants issued with an initial exercise price of \$4.00. The shares and warrants are subject to most favored nation treatment with respect to the terms (including in regards to warrants) provided to any other investors or creditors, including share issuances upon the exercise of previously issued derivative securities.

The fair value of the shares was based upon the closing stock price of the stock on the date of conversion and in aggregate was approximately \$13.1 million (\$5.95 per share) without factoring in a discount in value for the 36-month lock-up. The fair value of the warrants was based on the Monte Carlo simulation model, the inputs of which are disclosed in Note 4 and was approximately \$3.6 million. The Company recorded a \$7.8 million of inducement expense in connection with these transactions.

The conversion shares are subject to a lock-up period of 36 months from the date of their issuance. Under the lock-up, the shares cannot be sold or traded on the market. The fair value of the shares does not include a liquidity discount related to the 36 month lock-up period as such liquidity discount.

The Company classified the warrants as liabilities measured at fair value and re-measured the instruments at fair value each reporting period.

Cognate common stock purchase and inducement charge –Six months ended June 30, 2014

On June 30, 2014, the Company issued Cognate 562,500 shares of common stock and 281,250 warrants, in return for a payment of \$2.3 million received from Cognate. The shares and warrants are subject to most favored nation treatment with respect to the terms (including in regards to warrants) provided to any other investors or creditors, including share issuances upon the exercise of previously issued derivative securities.

The fair value of the shares was based upon the closing stock price of the stock on the date of conversion and in aggregate was approximately \$3.8 million (\$6.71 per share) without factoring in a discount in value for the 36-month lock-up. The fair value of the warrants was based on the Monte Carlo simulation model, the inputs of which are disclosed in Note 4 and was approximately \$1.0 million at inception. The Company recorded a \$2.5 million of inducement expense in connection with these transactions. The fair value of the shares does not include a liquidity discount related to the 36 month lock-up period.

10. Redeemable Common Stock

During the first quarter of 2014, the redemption provision on all 1.4 million redeemable shares outstanding as of December 31, 2013 lapsed and \$8.9 million was transferred from redeemable common stock to stockholders' equity (deficit).

11. Stockholders' Deficit

Common Stock Issuances

First Quarter 2014

During the quarter ended March 31, 2014, the Company issued in aggregate 238,496 shares of common stock in exchange for consulting services for which performance was complete. The fair value of the common stock recognized was \$1.6 million.

During the quarter ended March 31, 2014, the Company issued 5,101,366 shares of common stock to Cognate as stock based compensation. The fair value of the common stock recognized was \$2.5 million.

During the quarter ended March 31, 2014, the Company issued in aggregate 32,000 shares of common stock for cash. The fair value of the common stock recognized was \$0.2 million.

During the quarter ended March 31, 2014, the Company converted accounts payable due to Cognate of approximately \$5.9 million into 1,481,644 shares. The Company recorded \$2.8 million of inducement expense associated with the issuance of the common shares. In addition, the Company issued warrants that were valued at \$2.5 million at the date of issuance related to the conversion of accounts payable. Total inducement charge was \$5.3 million.

During the quarter ended March 31, 2014, the Company converted notes and relevant accrued interest of \$0.2 million into approximately 0.07 million shares of common stock.

During the quarter ended March 31, 2014, the Company issued an aggregate of 721,827 shares of common stock from the exercise of warrants previously issued. The Company received proceeds of approximately \$2.7 million from the exercise of these warrants.

During the quarter ended March 31, 2014, 1,444,788 redeemable shares with a carrying value of \$8.9 million were no longer redeemable and were reclassified to stockholders' equity.

Second Quarter 2014

On April 9, 2014, the Company entered into a Securities Purchase Agreement with a single institutional investor for the sale of 2,272,727 shares of common stock at a purchase price of \$6.60 per share, for a total purchase price of \$15.0 million. Additionally, from the date of the closing until one year after the closing date, the investor has a non-transferable Over-allotment Right to purchase up to 2,272,727 additional shares of common stock at a price per share of \$7.50, for an additional subscription amount of up to \$17.05 million.

On June 30, 2014, the Company issued Cognate 562,500 shares of common stock and 281,250 warrants for proceeds of \$2.3 million. The shares and warrants are subject to most favored nation treatment with respect to the terms (including in regards to warrants) provided to any other investors or creditors, including share issuances upon the exercise of previously issued derivative securities.

During the quarter ended June 30, 2014, the Company issued 200,000 shares of common stock to an individual investor at \$7.00 per share. The total proceeds of \$1.4 million were received by the Company during the first quarter in 2014, and were recorded as shares payable on the balance sheet as of March 31, 2014. The \$1.4 million shares payable were re-classified to stockholders' deficit during the second quarter in 2014.

During the quarter ended June 30, 2014, the Company issued 58,614 shares of common stock for cash to an individual investor for proceeds of \$435,540.

During the quarter ended June 30, 2014, the Company issued 16,200 shares of common stock for cash to an individual investor, but the proceeds were not received until July 2014. The Company recorded \$125,550 as a subscription receivable and to offset an addition-paid-in-capital on the balance sheet as of June 30, 2014.

During the quarter ended June 30, 2014, the Company issued an aggregate of 92,100 shares of common stock from the exercise of warrants previously issued. The Company received proceeds of \$394,925 from the exercise of these warrants.

During the quarter ended June 30, 2014, the Company issued an aggregate of 12,533 shares of common stock from the cashless exercise of warrants previously issued.

During the quarter ended June 30, 2014, the Company issued in aggregate 24,924 shares of common stock in exchange for consulting services. The fair value of the common stock recognized was \$155,607.

During the quarter ended June 30, 2014, the Company converted accounts payable due to Cognate of approximately \$2.9 million into 727,291 shares of common stock and 363,646 warrants. The Company recorded \$1.4 million of inducement expense associated with the issuance of the common shares. In addition, as noted in Note 4 the Company issued warrants that were valued at \$1.1 million at the date of issuance related to the conversion of accounts payable. Total inducement charge was \$2.5 million.

Stock Purchase Warrants

The following is a summary of warrant activity for the six months ended June 30, 2014:

	Number of Warrants	Weighted Average Exercise Price
Outstanding as of December 31, 2013	20,116	\$ 5.23
Warrants issued in connection with conversion of Cognate accounts payable*	741	4.00
Warrants issued in exchange for services	2,434	4.00
Warrants issued in connection with common stock issued	150	5.00
Warrants exercised on a cashless basis	(73)	-
Warrants exercised for cash	(722)	3.66
Expired in first quarter of 2014	(6)	9.54
Outstanding as of March 31, 2014	22,640	5.12
Warrants issued in connection with conversion of Cognate accounts payable*	364	4.00
Warrants issued to Cognate in connection with common stock issued for cash*	281	4.00
Warrants exercised for cash	(90)	4.25
Over-allotment rights issued in connection with registered direct offering	2,273	7.50
Warrants issued to placement agent in connection with registered direct offering	113	8.25
Outstanding as of June 30, 2014 **	25,581	\$ 5.32

*The warrants contain "down round protection" and the Company classifies these warrant instruments as liabilities measured at fair value and remeasures these instruments at fair value each reporting period.

** Approximately 6,176,000 warrants issued to Cognate, during the six year period from 2008 through 2014, with a weighted average exercise price and remaining contractual term of \$2.80 and 4.5 years, respectively. The weighted average exercise price gives effect to adjustments related to the most favored nation clause that occurred during the period.

12. Subsequent Events

On August 14, 2014, the Company announced the pricing of \$17.5 million aggregate principal amount of its unsecured convertible notes (the "Notes") in a private placement. The Notes are initially convertible at \$7.30 per share, a 10% premium above the closing market price of \$6.64 per share on August 13, 2014. The Company plans to use the offering proceeds to fund new manufacturing capacity in Europe and for general corporate purposes. The Notes will bear interest at a rate of 5.00% per year, and mature in three years unless earlier converted. The Notes will be subject to certain adjustments as provided in the Indenture.

The investors in the Notes will have the right, exercisable for three months, to purchase up to an additional 30% of the aggregate principal amount of the Notes on the same terms and conditions.

The sale of the Notes to the initial purchasers is expected to settle on August 19, 2014, subject to customary closing conditions, and is expected to result in approximately \$16.15 million net proceeds to NW Bio, after deducting fees and estimated offering expenses payable by NW Bio. Neither the Notes nor the shares of the Company's common stock issuable upon conversion of the Notes, if any, have been registered under the Securities Act of 1933, as amended (the "Act") or the securities laws of any other jurisdiction, and may not be offered or sold in the United States absent registration or an applicable exemption from such registration requirements.

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" in our Form 10-K for the year ended December 31, 2013. These factors, among others, could cause results to differ materially from those presently anticipated by us. You should not place undue reliance on these forward-looking statements.

Overview

We are a biotechnology company focused on developing immunotherapy products to treat cancers more effectively than current treatments, without toxicities of the kind associated with chemotherapies, and, through a proprietary batch manufacturing process, on a cost-effective basis, initially in both the United States and Europe.

We have developed a platform technology, DCVax, which uses activated dendritic cells to mobilize a patient's own immune system to attack their cancer. The DCVax technology is expected to be applicable to all solid tumor cancers, and is embodied in several distinct product lines. One of the product lines (DCVax-L) is designed to cover all solid tumor cancers in which the tumors can be surgically removed. Another product line (DCVax-Direct) is designed for all solid tumor cancers which are considered inoperable and cannot be surgically removed. We believe the broad applicability of DCVax to many cancers provides multiple opportunities for commercialization and partnering.

Our DCVax platform technology involves dendritic cells, the master cells of the immune system, and is designed to reinvigorate and educate the immune system to attack cancers. The dendritic cells are able to mobilize the overall immune system, including T cells, B cells and antibodies, natural killer cells and many others. Such mobilization of the overall immune system provides a broader attack on the cancer than mobilizing just a particular component, such as T cells alone, or a particular antibody alone. Likewise, our DCVax technology is designed to attack the full set of biomarkers, or antigens, on a patient's cancer, rather than just a particular selected target or several targets. Clinical experience indicates that when just one or a few biomarkers on a cancer are targeted by a drug or other treatment, sooner or later the cancer usually develops a way around that drug, and the drug stops working. We believe that mobilizing all agents of the immune system, and targeting all biomarkers on the patient's cancer, contributes to the effectiveness of DCVax.

Critical Accounting Policies and Estimates

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

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

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2013. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

Results of Operations

Operating costs:

Operating costs and expenses consist primarily of research and development expenses, including clinical trial expenses which increase when we are actively participating in clinical trials and are especially high when we are in a large ongoing international phase III trial (as we now are) and when we also have an additional clinical trial program under way in parallel (as we have with our 60-patient Phase I/II trial with DCVax-Direct for all types of inoperable solid tumors), and general and administrative expenses.

Our operating costs include ongoing development work relating to the DCVax-Direct product and its manufacturing, such as the design, engineering, sourcing, production, testing, modification and validation of the manufacturing automationsystems, disposable sets to be used with the manufacturing automationsystems, and manufacturing processes, product ingredients, product release assays, and other matters, as well as development of standard operating procedures (SOPs), batch production records, and other necessary materials.

Our operating costs also include the costs of preparations for the launch of new or expanded clinical trial programs including the Phase III trial in the UK and Germany (with DCVax-L for brain cancer) and the Phase I/II trial (with DCVax-Direct for all inoperable solid tumor cancers). The preparation costs include upfront payments to the clinical trial sites and the CROs managing the trials and other service providers, and expenses related to institutional approvals, training of medical and other site personnel, trial supplies and other. Additional substantial costs relate to the expansion of manufacturing facilities and capacity, in both the US and Europe.

Research and development:

Discovery and preclinical research and development expenses include costs for substantial external scientific personnel, technical and regulatory advisers, and others, 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 pre-revenue company, we do not allocate research and development costs on a project basis. We adopted this policy, in part, due to the unreasonable cost burden associated with accounting at such a level of detail and our limited number of financial and personnel resources.

General and administrative:

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

Three Months Ended June 30, 2014 and 2013

We recognized a net loss of \$16.9 million in cash outlays and \$9.0 million in non-cash accounting charges (including increase in stock-based compensation, inducement expense and the issuance of warrants), for a combined (cash and non-cash) total net loss of \$25.9 million for the three months ended June 30, 2014 compared to a net loss of \$11.6 million for the three months ended June 30, 2013. This increase was primarily attributable to an increase in Research and Development Expense associated with expanding our existing Phase III clinical trial with DCVax-L, expanding and accelerating Phase I/II clinical trial with DCVax-Direct, expanding our German subsidiary operations, and initial arrangements for expanding our manufacturing capacity in Europe.

Research and Development Expense

Research and development expense was a combined (cash and non-cash) total of \$21.5 million for the three months ended June 30, 2014 compared to \$8.4 million for the three months ended June 30, 2013. The increase was primarily attributable to costs associated with launching, manufacturing for, and conducting (including CRO costs) the Phase III DCVax-L trial in Europe and the Phase I/II DCVax-Direct, which were just beginning as of this period last year, as well as expansion of the Company's German subsidiary and its operations, and expansion of the ongoing Phase III trial in the US.

As of June 30, 2014, we had over 51 clinical trial sites in operation in the US in our Phase III trial with DCVax-L, as well as German sites, compared to 50 clinical trial sites in the US only at June 30, 2013.

General and Administrative Expense

General and administrative expense included \$3.3 million of cash expenses, and \$0.6 of non-cash charges (i.e. amortization of previously issued stock based compensation and restricted stock and warrants issued for services), for a combined cash and non-cash total of \$3.9 million for the three months ended June 30, 2014 compared to \$3.3 million for the three months ended June 30, 2013. The increase in general and administrative expenses from the prior period is a result of increase in consulting expenses of \$0.6 million and increase in legal expenses of \$0.6 million due to the expansion of our platform, offset by a \$0.6 million decrease in stock based compensation expense.

Change in fair value of derivatives

During the three months ended June 30, 2014 and June 30, 2013 we recognized a non-cash gain on derivative liabilities of \$4.7 million and \$0 million, respectively, due primarily to the change in value of the warrants issued to Cognate in connection with the extinguishment of accounts payable.

Inducement expense

During the three months ended June 30, 2014 and June 30, 2013 we recognized an inducement expense of \$5.1 million and \$0 million, respectively. This inducement expense during the three months ended June 30, 2014 was related to the conversion of accounts payable to common stock and warrants to Cognate in connection with the extinguishment of accounts payable.

Interest (Expense)

Interest expense (including non-cash elements such as amortization of debt discount) decreased to \$0.03 million for the three months ended June 30, 2014 from \$0.2 million for the three months ended June 30, 2013. The decrease in interest expense is primarily related to the retirement of \$1.8 million in notes payable during 2013 and 2014.

Six Months Ended June 30, 2014 and 2013

During the six months ended June 30, 2014, we recognized a net loss of \$25.2 million in cash outlays (net of \$2.3 million in cash received from Cognate in return for common stock and warrants) and \$44.4 million in cash and non-cash accounting charges (including increase in stock-based compensation, inducement expense and the issuance of warrants), for a combined (cash and non-cash) total net loss of \$71.9 million compared to a net loss of \$26.0 million for the three months ended June 30, 2013. This increase was primarily attributable to an increase in Research and Development Expense associated with expanding our existing Phase III clinical trial with DCVax-L, expanding and accelerating Phase I/II clinical trial with DCVax-Direct, expanding our German subsidiary operations, and initial arrangements for expanding our manufacturing capacity in Europe.

Research and Development Expense

Research and development expense was a combined (cash and non-cash) total of \$41.5 million for the six months ended June 30, 2014 compared to \$20.0 million for the six months ended June 30, 2013. The increase was primarily attributable to costs associated with launching, manufacturing for, and conducting (including CRO costs) the Phase III DCVax-L trial in Europe and the Phase I/II DCVax-Direct, which were not under way as of this period last year, as well as establishment and expansion of the Company's German subsidiary and its operations, and expansion of the ongoing Phase III trial in the US.

As of June 30, 2014, we had over 51 clinical trial sites in operation in the US and UK in our Phase III trial with DCVax-L, compared to 50 clinical trial sites in the US only at June 30, 2013.

General and Administrative Expense

General and administrative expense was \$7.6 million for the six months ended June 30, 2014 compared to \$5.8 million for the six months ended June 30, 2013. The increase in general and administrative expenses from the prior period is a result of increase in consulting expenses of \$2.2 million and increase in legal expenses of \$1.1 million due to the expansion of our platform, offset by a \$1.1 million decrease in stock based compensation expense and \$0.3 million decrease in professional expenses and insurance expenses.

Change in fair value of derivatives

During the six months ended June 30, 2014 and June 30, 2013 we recognized a non-cash loss on derivative liabilities of \$12.3 million and \$0 million, respectively, due primarily to the change in value of the warrants issued to Cognate in connection with the extinguishment of accounts payable.

Inducement expense

During the six months ended June 30, 2014 and June 30, 2013 we recognized an inducement expense of \$10.3 million and \$0 million, respectively. This inducement expense during the six months ended June 30, 2014 was related to the conversion of accounts payable to common stock and warrants to Cognate in connection with the extinguishment of accounts payable.

Interest (Expense)

Interest expense (including non-cash elements such as amortization of debt discount) decreased to \$0.2 million for the six months ended June 30, 2014 from \$0.6 million for the six months ended June 30, 2013. The decrease in interest expense is primarily related to the retirement of \$1.8 million in notes payable during 2013 and 2014.

Liquidity and Capital Resources

We have experienced recurring losses from operations. During the six months ended June 30, 2014, net cash outflows from operations was \$25.2 million, including one-time expenditures related to the clinical trials and to certain initial costs for new manufacturing capacity in Europe (net of \$2.3 million in cash received from Cognate in return for common stock and warrants).

At June 30, 2014, current assets totaled \$12.4 million, compared to \$18.6 million at December 31, 2013. Current assets less accounts payable and accrued expenses and notes payable were \$1.1 million at June 30, 2014, compared to a deficit of \$1.0 million at December 31, 2013 (excluding redeemable common stock amounting to \$8.9 million). The working capital deficit decrease as of June 30, 2014 as compared to December 31, 2013 is primarily related to the conversion of \$8.8 million of accounts payable to Cognate to common stock and warrants during the six months ended June 30, 2014, and a \$3.4 million increase in cash in custody account, which was offset by decrease of \$9.6 million in cash and cash equivalents.

On a going forward basis, commencing with August 2013, and continuing throughout the lock-up period, we and Cognate agreed to establish an arrangement for regular ongoing payment of at least half of all invoices in common stock of our company, and the remainder in cash, at \$4.00 per share (the closing market price was \$3.55 at that time), subject to a most favored nation treatment with respect to terms provided to other investors or creditors (including with respect to any warrants), including share issuances upon exercise of previously issued derivative securities. The arrangement will continue for 18 months from the execution of the Cognate agreements or until terminated by mutual agreement. The contracts implementing these agreements are the Cognate Agreements that were executed in January 2014.

Since 2004, Toucan Capital Fund II, L.P. ("Toucan Capital"), Toucan Partners LLC ("Toucan Partners"), entities controlled by Ms. Linda Powers, our CEO and the managing director of Toucan Capital and managing member of Toucan Partners, and Ms. Linda Powers (collectively "Toucan") have provided substantial funding to us. From 2004 to date, Toucan has provided ongoing financings to us through the purchase of common stock, preferred stock (which was all converted to common stock), loans and debt securities. As of June 30, 2014, Toucan (other than Cognate) held approximately 7% of common stock outstanding.

Operating Activities

During the six months ended June 30, 2014, we used \$25.2 million in cash for operating activities, including one-time expenditures related to the clinical trials and to certain initial costs for new manufacturing capacity in Europe (net of \$2.3 million in cash received from Cognate in return for common stock and warrants) compared with \$15.3 million in cash that we used for operating activities during the six months ended June 30, 2013. The increase in cash used in operating activities was primarily attributable to an increase in Research and Development Expense associated with expanding our existing Phase III clinical trial with DCVax-L, expanding and accelerating Phase I/II clinical trial with DCVax-Direct, expanding our German subsidiary operations, and initial arrangements for expanding our manufacturing capacity in Europe.

As of June 30, 2014, we had an aggregate of over 51 clinical trial sites in operation in the US, UK and Germany in our Phase III trial with DCVax-L, compared to 41 clinical trial sites at June 30, 2013, in the US only.

Financing Activities

During the six months ended June 30, 2014, our financing activities primarily consisted of proceeds from an investor of \$1.4 million, \$3.1 million from the exercise of warrants and \$16.8 million, net, for the issuance of common stock with over-allotment rights and or warrants; partially offset by the payment of \$0.03 million of convertible promissory notes.

In order to continue with our current activities under our DCVax®-L and DCVax-Direct program, we will have to obtain substantial amounts of further funding, as described in the Risk Factors section in our annual report on Form 10-K for the year ended December 31, 2013. Our on-going funding requirements will depend on many factors, including the results of the reimbursement negotiations in Germany, the implementation of our Hospital Exemption approval in Germany, and the extent to which we realize and draw upon various sources of non-dilutive funding. One such source of non-dilutive funding is a \$5.5 million German grant awarded on May 1, 2012, by the German government through its Saxony Development Bank. The grant provides funding on a matching basis for up to 50% of the costs incurred by us for the DCVax-L clinical trial and manufacturing in Germany. We drew our first tranche of funds from this grant during the three months ended June 30, 2014.

Other factors affecting our ongoing funding requirements include the number of staff we employ, the number of sites and pace of patient enrollment in our Phase III brain cancer trial with DCVax-L and our Phase I/II clinical trial with DCVax-Direct, the costs of further development work relating to DCVax-Direct, the costs of expansion of manufacturing capacity for both DCVax-L and DCVax-Direct, the cost of establishing clinical studies and compassionate use/named patient programs in other countries, and unanticipated developments. The extent of resources available to us will determine the pace at which we can move forward with both our DCVax-L program and our DCVax-Direct program.

As we are dependent on our ability to obtain financing and ultimately to generate sufficient cash flow to meet our obligations on a timely basis, as well as successfully obtain financing on favorable terms to fund our long term plans, our financial statements indicate there is substantial doubt about our ability to continue as a going concern. We can give no assurance that our plans and efforts to achieve the above steps will be successful.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive, financial and accounting officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our principal executive, financial and accounting officer concluded that as of the end of the period covered by this report, in light of certain material weaknesses in our internal control over financial reporting described in our annual report on Form 10-K for the year ended December 31, 2013, our disclosure controls and procedures were not effective to ensure the segregation of duties and ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our chief executive officer, financial and accounting officer, to allow timely decisions regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods prescribed by the SEC.

Based on management's evaluation as of December 31, 2013, our management identified the material weaknesses set forth below in our internal control over financial reporting:

- (i) The Company's process for internally reporting material information in a systematic manner to allow for timely filing of material information is ineffective, due to its inherent limitations from being a small company and insufficient personnel for segregation of duties, and there exist material weaknesses in internal control over financial reporting that contribute to the weaknesses in our disclosure controls and procedures. These weaknesses include:
- insufficient segregation of duties and oversight of work performed in our finance and accounting function due to limited personnel; and
 - lack of controls in place to ensure that all material transactions and developments impacting the financial statements are reflected.
 - complications applying complex accounting principles.

Our Company's management concluded that in light of the material weaknesses described above, our Company did not maintain effective internal control over financial reporting as of June 30, 2014 based on the criteria set forth in Internal Control— 1992 Integrated Framework issued by the COSO.

Changes in Internal Control over Financial Reporting

There has been no change in our internal controls over financial reporting that occurred during the fiscal quarter ended June 30, 2014, that has materially affected, or is reasonably expected to materially affect, our internal controls over financial reporting.

Part II - Other Information

Item 1A. Risk Factors.

There have been no material changes to the discussion of risk factors included in our most recent Annual Report on Form 10-K, except as noted below.

Our management and our independent auditors have identified internal control deficiencies, which our management and our independent auditor believe constitute material weaknesses.

During the quarter ended June 30, 2014, as we had in connection with the preparation of our financial statements for the year ended December 31, 2013, and prior years, our management and our independent auditor identified certain internal control deficiencies that, in the aggregate, represent material weaknesses, including:

- insufficient segregation of duties and oversight of work performed in our finance and accounting function due to limited personnel; and
- lack of controls in place to ensure that all material transactions and developments impacting the financial statements are reflected.

We have begun taking appropriate and reasonable steps, and will continue and complete such steps in due course, to make the necessary improvements to address these deficiencies, but the timing of such steps is uncertain and the availability of funding and resources for such steps are also uncertain. Our ability to retain or attract qualified individuals to serve on our Board and to take on key management roles within our company is also uncertain. Our failure to successfully complete the remedies of the existing weaknesses could lead to heightened risk for financial reporting mistakes and irregularities, and/or lead to a loss of public confidence in our internal controls that could have a negative effect on the market price of our common stock.

A number of plaintiffs' law firms are purporting to conduct investigations relating to us; while these investigations have not resulted in litigation to date, we cannot assure you that litigation will not be initiated against us.

Certain plaintiffs' law firms have recently issued press releases announcing so-called "investigations" with a view towards possibly initiating securities litigation against us. These "investigations" generally purport to relate to positive disclosures made by us with respect to our ongoing DCVax-Direct clinical trial and to certain other allegations published by third parties in online media. To date, no litigations have been commenced against us; however, we cannot assure you that no such litigation will be filed in the future. We believe that the allegations these law firms are purporting to "investigate" are without merit, and we would defend vigorously against any such litigation, if initiated. Nonetheless, any such litigation, even though meritless, could be time consuming and expensive to defend, could divert our management's attention and resources, and could otherwise adversely affect us.

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

On June 30, 2014, we issued to Cognate 562,500 shares of common stock and 281,250 warrants for proceeds of \$2.3 million. The shares and warrants are subject to most favored nation treatment with respect to the terms (including in regards to warrants) provided to any other investors or creditors, including share issuances upon the exercise of previously issued derivative securities.

On May 15, 2014, we issued 200,000 shares of common stock to an individual investor at \$7.00 per share. The total proceeds received were \$1.4 million.

On April 8, 2014, we issued 58,614 shares of common stock for cash to an individual investor for proceeds of \$435,540.

During the quarter ended June 23, 2014, we issued 16,200 shares of common stock for cash to an individual investor for proceeds of \$125,550.

The securities sold in these transactions were exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(a) (2) thereof.

Item 5. Other Information

none

Item 6. Exhibits

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

SIGNATURES

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

NORTHWEST BIOTHERAPEUTICS, INC

Dated: August 14, 2014

By: /s/ Linda M. Powers

Name: Linda M. Powers

Title: President and Chief Executive Officer

Principal Executive Officer

Principal Financial and Accounting Officer