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NORTHWEST BIOTHERAPEUTICS INC

FORM 10-Q

(Quarterly Report)

Filed 11/10/16 for the Period Ending 09/30/16

Address	4800 MONTGOMERY LANE, BETHESDA, MD, 20814
Telephone	(727) 384-2323
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

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 x 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 x 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 x	Non-accelerated filer ¨ (do not check if a smaller reporting company)	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 x

As of November 8, 2016, the total number of shares of common stock, par value $0.001 per share, outstanding was 123,688,715.

NORTHWEST BIOTHERAPEUTICS, INC.

FORM 10-Q

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION
NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 802	$ 21,813
Restricted cash - interest payments held in escrow	685	886
Prepaid expenses and other current assets	785	1,402
Total current assets	2,272	24,101
Non-current assets:		
Property, plant and equipment, net	46,550	46,157
Restricted cash - interest payments held in escrow, net of current portion	-	349
Other assets	120	190
Total non-current assets	46,670	46,696
Total assets	$ 48,942	$ 70,797
COMMITMENTS AND CONTINGENCIES		
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 13,339	$ 11,721
Accounts payable to related party	11,845	5,455
Accrued expenses (includes related party of $14 and $11 as of September 30, 2016 and December 31, 2015, respectively)	1,295	1,309
Convertible notes (net of deferred financing cost of $246 and $0 as of September 30, 2016 and December 31, 2015, respectively; includes related party note of $50 as of September 30, 2016 and December 31, 2015)	10,939	185
Note payable - in dispute	-	934
Mortgage loan (net of deferred financing cost of $237 and $468 as of September 30, 2016 and December 31, 2015, respectively)	10,148	11,144
Environmental remediation liability	6,200	6,200
Derivative liability	198	27,982
Total current liabilities	53,964	64,930
Non-current liabilities:		
Convertible note (net of deferred financing cost of $0 and $457 as of September 30, 2016 and December 31, 2015, respectively)	-	10,543
Total non-current liabilities	-	10,543
Total liabilities	53,964	75,473
Commitments and Contingencies		
Stockholders' equity (deficit):		
Preferred stock ($0.001 par value); 40,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	-	-
Common stock ($0.001 par value); 450,000,000 shares authorized; 120,776,695 and 95,858,087 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	121	96
Additional paid-in capital	678,624	630,613
Accumulated deficit	(684,770)	(635,262)
Accumulated other comprehensive gain (loss)	1,003	(123)
Total stockholders' equity (deficit)	(5,022)	(4,676)
Total liabilities and stockholders' equity (deficit)	$ 48,942	$ 70,797

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Research grant and other	$ 159	$ 291	$ 552	$ 876
Total revenues	159	291	552	876
Operating costs and expenses:				
Research and development	21,094	9,138	43,247	56,562
General and administrative	4,581	4,366	15,323	19,212
Total operating costs and expenses	25,675	13,504	58,570	75,774
Loss from operations	(25,516)	(13,213)	(58,018)	(74,898)
Other income (expense):				
Inducement loss	(1,457)	-	(1,457)	-
Change in fair value of derivative liability	(217)	36,490	17,238	(12,362)
Loss from extinguishment of debt	(433)	-	(433)	-
Interest expense	(691)	(1,046)	(2,138)	(3,475)
Foreign currency transaction loss	(913)	384	(4,700)	72
Net income (loss)	(29,227)	22,615	(49,508)	(90,663)
Deemed dividend related to warrant modification	(3,007)	-	(5,647)	-
Net income (loss) applicable to common stockholders	$ (32,234)	$ 22,615	$ (55,154)	$ (90,663)
Net earnings (loss) per share applicable to common stockholders				
Basic	$ (0.28)	$ 0.29	$ (0.52)	$ (1.22)
Diluted	$ (0.28)	$ 0.25	$ (0.52)	$ (1.22)
Weighted average shares used in computing basic earnings (loss) per share	114,836	78,062	105,501	74,394
Weighted average shares used in computing diluted earnings (loss) per share	114,836	89,821	105,501	74,394

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

NORTHWEST BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Unaudited)
(in thousands)

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Net income (loss)	$ (29,227)	$ 22,615	$ (49,508)	$ (90,663)
Other comprehensive income (loss)				
Foreign currency translation adjustment	626	(461)	1,126	143
Total comprehensive income (loss)	$ (28,601)	$ 22,154	$ (48,382)	$ (90,520)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	Common Stock		Additional Paid-in	Accumulated	Cumulative Translation	Total Stockholders'
	Shares	Par value	Capital	Deficit	Adjustment	Equity (Deficit)
Balance January 1, 2016	**95,858**	**$ 96**	**$ 630,613**	**$ (635,262)**	**$ (123)**	**$ (4,676)**
Issuance of common stock and warrants for cash in a registered direct offering	13,282	13	13,687	-	-	13,700
Offering cost related to registered direct offering	-	-	(1,077)	-	-	(1,077)
Issuance of common stock and warrants for cash in private offering	2,572	3	923	-	-	926
Warrants exercised for cash	15,358	15	8,051	-	-	8,066
Offering costs related to warrants exercise	-	-	(795)	-	-	(795)
Modification on warrant exercise price	-	-	5,647	-	-	5,647
Deemed dividend related to warrant exercise price modification	-	-	(5,647)	-	-	(5,647)
Issuance of common stock for accounts payable conversion	78	0	28	-	-	28
Issuance of common stock and warrants for debt and accrued interest conversion	2,222	3	1,430	-	-	1,433
Common stock issued as compensation	190	-	98	-	-	98
Return of common stock and warrants from Cognate	(8,052)	(8)	8	-	-	-
Extinguishment of shares payable related to Cognate	-	-	22,539	-	-	22,539
Extinguishment of derivative liabilities related to Cognate	-	-	10,131	-	-	10,131
Shares payment due to Cognate BioServices	(732)	(1)	(8,884)	-	-	(8,885)
Reclassification of warrant liabilities related to warrants exercised for cash	-	-	1,872	-	-	1,872
Net loss	-	-	-	(49,508)	-	(49,508)
Cumulative translation adjustment	-	-	-	-	1,126	1,126
Balance at September 30, 2016	**120,776**	**$ 121**	**$ 678,624**	**$ (684,770)**	**$ 1,003**	**$ (5,022)**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	For the nine months ended September 30,	
	2016	**2015**
Cash Flows from Operating Activities:		
Net Loss	$ (49,508)	$ (90,663)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	135	44
Amortization of deferred financing cost	639	1,013
Change in fair value of derivatives	(17,238)	12,362
Inducement loss	1,457	-
Loss from extinguishment of debt	433	-
Stock issued to (returned by) Cognate BioServices	13,654	9,400
Common stock issued as compensation	98	3,389
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	617	(563)
Accounts payable and accrued expenses	1,697	7,083
Related party accounts payable and accrued expenses	6,391	1,496
Other non-current assets	70	(42)
Net cash used in operating activities	(41,555)	(56,481)
Cash Flows from Investing Activities:		
Purchase of property, plant and equipment	(4,770)	(4,010)
Funding of escrow - convertible notes	550	-
Net cash used in investing activities	(4,220)	(4,010)
Cash Flows from Financing Activities:		
Proceeds from mortgage loan	-	4,997
Deferred offering cost related to mortgage loan	-	(138)
Proceeds transferred from escrow account	-	287
Proceeds from issuance of common stock and warrants in a registered direct offering	13,700	-
Offering cost related to registered direct offering	(1,077)	-
Proceeds from issuance of common stock and warrants in private offering	926	40,000
Warrants exercised for cash	8,066	7,431
Offering costs related to warrants exercise	(795)	-
Net cash provided by financing activities	20,820	52,577
Effect of exchange rate changes on cash and cash equivalents	3,944	(84)
Net decrease in cash and cash equivalents	(21,011)	(7,998)
Cash and cash equivalents at beginning of period	21,813	13,390
Cash and cash equivalents at end of period	$ 802	$ 5,392
Supplemental disclosure of cash flow information		
Interest payments on mortgage loan	$ (1,497)	$ (1,025)
Interest payments on senior convertible notes	$ (550)	$ (1,103)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	For the nine months ended September 30,	
	2016	**2015**
Supplemental schedule of non-cash investing and financing activities:		
Deemed dividend related to modification of warrant	$ 5,647	$ -
Return of common stock and warrants from Cognate	$ 8	$ -
Extinguishment of shares payable related to Cognate	$ 22,539	$ -
Extinguishment of derivative liabilities related to Cognate	$ 10,131	$ -
Issuance of common stock for accounts payable conversion	$ 28	$ -
Issuance of common stock for debt conversion	$ 934	$ 6,500
Issuance of common stock for conversion of accrued interest	$ 66	$ 387
Accrued renewal fee incurred from mortgage loan	$ 211	$ -
Accrued exit fee incurred from mortgage loan	$ -	$ 51
Reclassification of warrant liabilities related to warrants exercised for cash	$ 825	$ 264
Reclassification of warrant liabilities related to cashless warrants exercise	$ -	$ 521
Redeemable security settlement	$ -	$ 299

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. Organization and Description of Business and Recent Developments

Northwest Biotherapeutics, Inc. and its subsidiaries NW Bio Gmbh and Aracaris Capital, Ltd. (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.

2. Liquidity and Financial Condition

For the three and nine months ended September 30, 2016, the Company recognized net losses of $29.2 million and $49.5 million, respectively.

During the three and nine months ended September 30, 2016, the Company used approximately $9.8 million and $41.6 million of cash in its operating activities respectively.

These cash outflows included substantial amounts of accrued costs relating to prior periods of higher activity and expenditures in the Company's Phase III clinical trial which have subsequently been reduced, and included substantial amounts of legal costs which the Company anticipates may be subject to reimbursement under the Company's insurance, with further legal expenses going forward being covered by insurance directly. The Company had current assets of $2.3 million, accounts payable of $13.3 million and accounts payable to related party of $11.8 million, convertible notes, net of $10.9 million and mortgage loans, net of $10.1 million.

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 not 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. Certain immaterial reclassifications have been made to prior period amounts to conform to the current period presentation.

The accompanying unaudited condensed consolidated financial statements of the Company 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 September 30, 2016, condensed consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015, condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2016 and 2015, condensed consolidated statement of stockholders' equity (deficit) for the nine months ended September 30, 2016, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2016 and 2015 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 nine months ended September 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016 or for any future interim period. The condensed consolidated balance sheet at December 31, 2015 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 unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2015, and notes thereto included in the Company's annual report on Form 10-K, which was filed with the SEC on March 16, 2016, as amended on April 29, 2016.

Use of Estimates

In preparing condensed consolidated 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, valuing environmental liabilities, 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.

Warrant Liability

The Company accounts for certain common stock warrants outstanding as a liability at fair value and adjusts the instruments to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's statements of operations. The fair value of the warrants issued by the Company in connection with the conversion transaction has been estimated using a Monte Carlo simulation.

Environmental Remediation Liabilities

The Company records environmental remediation liabilities for properties acquired. The environmental remediation liabilities are initially recorded at fair value. The liability is reduced for actual costs incurred in connection with the clean-up activities for each property. Upon completion of the clean-up, the environmental remediation liability is adjusted to equal the fair value of the remaining operation, maintenance and monitoring activities to be performed for the property. The amount of the additional liability resulting from the completion of the clean-up, if any, would be included in other income (expense). As of September 30, 2016, the Company estimated that the total environmental remediation costs associated with the purchase of the UK Facility will be approximately $6.2 million. This is a projected potential future cost. No such environmental costs have been incurred to date and none are currently pending. Contamination clean-up costs that improve the property from its original acquisition state will be capitalized as part of the property’s overall development costs. The Company engaged a third party specialist to conduct certain surveys of the condition of the property which included, among other things, a preliminary analysis of potential environmental remediation exposures. The Company determined, based on information contained in the specialist’s report, that it would be required to estimate the fair value of an unconditional obligation to remediate specific ground contamination at an estimated fair value of approximately $6.2 million. The Company computed the fair value of this obligation using a probability weighted approach that measures the likelihood of the following two potential outcomes: (i) a higher probability requirement of erecting a protective barrier around the affected area at an estimated cost of approximately $4.5 million, and (ii) a lower probability requirement of having to excavate the affected area at an estimated cost of approximately $32.0 million. The Company’s estimate is preliminary and therefore subject to change as further studies are conducted, and as additional facts come to the Company’s attention. Environmental remediation efforts are complex, technical and subject to various uncertainties. Accordingly, it is at least reasonably possible that any changes in the Company’s estimate could materially differ from the management’s preliminary assessment discussed herein.

Comprehensive Loss

The Company reports comprehensive loss and its components in its condensed consolidated financial statements. Comprehensive loss consists of net loss and foreign currency translation adjustments, affecting stockholders’ equity (deficit) that, under U.S, GAAP, are excluded from net loss.

Research and Development Costs

Research and development costs are charged to operations as incurred and consist primarily of clinical trial costs, related party manufacturing costs, consulting costs, contract research and development costs, clinical site costs and compensation costs.

Significant Accounting Policies

There have been no material changes in the Company’s significant accounting policies to those previously disclosed in the 2015 Annual Report.

Recent Issued Accounting Pronouncements

Statement of Cash Flows

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows* (Topic 230). This amendment provides guidance on the presentation and classification of specific cash flow items to improve consistency within the statement of cash flows. ASU 2016-15 is effective for fiscal years, and interim periods within those fiscal years beginning after December 15, 2017, with early adoption permitted. The Company is evaluating the effect that ASU 2016-15 will have on its financial statements and related disclosures.

Compensation-Stock Compensation

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting*. Under ASU No. 2016-09, companies will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital (“APIC”). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement and the APIC pools will be eliminated. In addition, ASU No. 2016-09 eliminates the requirement that excess tax benefits be realized before companies can recognize them. ASU No. 2016-09 also requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Furthermore, ASU No. 2016-09 will increase the amount an employer can withhold to cover income taxes on awards and still qualify for the exception to liability classification for shares used to satisfy the employer’s statutory income tax withholding obligation. An employer with a statutory income tax withholding obligation will now be allowed to withhold shares with a fair value up to the amount of taxes owed using the maximum statutory tax rate in the employee’s applicable jurisdiction(s). ASU No. 2016-09 requires a company to classify the cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation as a financing activity on the statement of cash flows. Under current U.S. GAAP, it was not specified how these cash flows should be classified. In addition, companies will now have to elect whether to account for forfeitures on share-based payments by (1) recognizing forfeitures of awards as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The amendments of this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted but all of the guidance must be adopted in the same period. The Company is currently assessing the impact that ASU No. 2016-09 will have on its consolidated financial statements.

Revenue from Contracts with Customer

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customer*. The new guidance is an update to ASC 606 and provides clarity on: identifying performance obligations and licensing implementation. For public companies, ASU No. 2016-10 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016. The Company is currently evaluating the impact that ASU No. 2016-10 will have on its consolidated financial statements.

Recognition and Measurement of Financial Assets and Financial Liabilities

In January 2016, FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements; and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 will be effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact that ASU 2016-01 will have on its consolidated financial statements and related disclosures.

Leases

In February 2016, FASB issued ASU No. 2016-02, *Leases (Topic 842)* which supersedes FASB ASC Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard will be effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the impact that ASU 2016-02 will have on its consolidated financial statements and related disclosures.

4. Fair Value Measurements

Extinguishment of Derivative Liabilities related to Cognate

On May 2, 2016, the Company submitted a remediation plan (the "Remediation Plan") related to certain stock issued to Cognate to regain compliance with Nasdaq's Rule 5635. The Remediation Plan was accepted by Nasdaq on August 30, 2016.

Pursuant to the Remediation Plan, the Company canceled the most favored nation provisions related to warrants issued to Cognate under 2013 Manufacturing Services agreement ("2013 Agreement") and 2014 Manufacturing Services Agreements ("2014 Agreements") through a binding agreement with Cognate. In addition, Cognate returned and the Company extinguished 6,880,574 warrants issued under the 2014 Agreements; the Company issued replacement warrants of 4,305,772 at a higher exercise price. The aggregate fair value of the warrants extinguished as of August 30, 2016 using Monte Carlo simulation was approximately $10.1 million, and was recorded through additional paid in capital.

A summary of weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring Cognate warrant extinguishment as of August 30, 2016 is as follows:

Date of valuation	**August 30, 2016**
Strike price	$ 0.35
Volatility (annual)	81%
Risk-free rate	1%
Contractual term (years)	2.8
Dividend yield (per share)	0%

Extinguishment of Warrant Liabilities Related to Cash Exercise

During the quarter ended September 30, 2016 approximately 2,555,000 warrants classified as derivative liabilities were exercised for cash (see footnote 9). A summary of weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring warrant exercises (originally recorded as liabilities) during the quarter ended September 30, 2016 is as follows:

	2016 Warrants Exercises
Strike price	$ 0.35
Volatility (annual)	83%
Risk-free rate	1%
Contractual term (years)	2.2
Dividend yield (per share)	0%

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.

The following table classifies the Company's liabilities measured at fair value on a recurring basis into the fair value hierarchy as of September 30, 2016 and December 31, 2015 (in thousands):

	Fair value measured at September 30, 2016			
	Fair value at September 30, 2016	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Derivative liability	$ 198	$ -	$ -	$ 198

	Fair value measured at December 31, 2015			
	Fair value at December 31, 2015	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Derivative liability	$ 27,982	$ -	$ -	$ 27,982

There were no transfers between Level 1, 2 or 3 during the nine month period ended September 30, 2016.

The following table presents changes in Level 3 liabilities measured at fair value for the nine-month period ended September 30, 2016. 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 (in thousands).

	Warrant Liability
Balance - January 1, 2016	$ 27,982
Extinguishment of derivative liabilities related to Cognate	(10,131)
Extinguishment of warrant liabilities related to warrants exercised for cash	(415)
Change in fair value	(17,238)
Balance – September 30, 2016	$ 198

The Company's warrant liabilities are measured at fair value using the Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) 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 nine months ended September 30, 2016 is as follows:

Date of valuation	**September 30, 2016**	**December 31, 2015**
Strike price	$ 3.98	$ 3.49
Volatility (annual)	89%	87%
Risk-free rate	1%	1%
Contractual term (years)	2.2	3.1
Dividend yield (per share)	0%	0%

5. Property, Plant and Equipment

Property and equipment consist of the following at September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Leasehold improvements	$ 69	$ 69
Office furniture and equipment	25	25
Computer equipment and software	626	598
Construction in progress (property in the United Kingdom)*	46,181	45,681
	46,901	46,373
Less: accumulated depreciation	(351)	(216)
	$ 46,550	$ 46,157

* Construction in progress includes both the land acquisition costs and the building costs.

Depreciation expense was approximately $55,000 and $29,000 for the three months ended September 30, 2016 and 2015. Depreciation expense was approximately $135,000 and $44,000 for the nine months ended September 30, 2016 and 2015.

6. Notes Payable

The following table summarizes outstanding debt as of September 30, 2016 and December 31, 2015 (amount in thousands):

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Accumulated Debt Discount	Carrying Value
6% unsecured (1)	9/19/2011	6%	$ 3.09	$ 135	$ -	$ 135
8% unsecured note to related party	On Demand	8%	N/A	50	-	50
2014 Senior convertible notes (2)	8/15/2017	5%	$ 6.60	11,000	(246)	10,754
Mortgage loan (3)	11/16/2016 & 8/13/2017	12%	N/A	10,385	(237)	10,148
Ending balance as of September 30, 2016				**$ 21,570**	**$ (483)**	**$ 21,087**

	Maturity Date	Stated Interest Rate	Conversion Price	Face Value	Accumulated Debt Discount	Carrying Value
15% unsecured - in dispute	7/31/2011	15%	N/A	$ 934	$ -	$ 934
6% unsecured	9/19/2011	6%	$ -	135	-	135
8% unsecured note to related party	On Demand	8%	N/A	50	-	50
2014 Senior convertible notes	8/15/2017	5%	$ -	11,000	(457)	10,543
Mortgage loan	11/16/2016 & 8/13/2017	12%	N/A	11,612	(468)	11,144
Ending balance as of December 31, 2015				**$ 23,731**	**$ (925)**	**$ 22,806**

(1) This $135,000 note as of September 30, 2016 consists of two separate 6% notes in the amounts of $110,000 and $25,000. In regard to the $110,000 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 regard to the $25,000 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.

(2) The Company has $0.7 million remaining in escrowed interest payments, which is sufficient to fund, when due, the total aggregate amount of the two scheduled semi-annual interest payments during the remaining term of the notes, excluding additional interest, if any.

(3) On August 17, 2016, the lender issued an automatic one year extension of the second mortgage loan maturity date to August 17, 2017 with a renewal fee of approximately $0.2 million, which is not due until the end of the extension period and will be recorded as deferred financing cost.

The following table summarizes total interest expenses related to senior convertible notes, other notes and mortgage loan for the three and nine months ended September 30, 2016 and 2015, respectively (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
Interest expenses related to senior convertible notes:				
Contractual interest	$ 139	$ 151	$ 413	$ 502
Accelerated interest due to the conversion of convertible senior notes into common stock	-	200	-	763
Amortization of debt issuance costs	71	80	211	292
Accelerated amortization of debt issuance cost due to the conversion of convertible senior notes into common stock	-	68	-	302
Total interest expenses related to senior convertible notes	**210**	**499**	**624**	**1,859**
Interest expenses related to other notes:				
15% unsecured originally due July 2011 - in dispute	35	35	105	105
6% unsecured	2	3	6	69
8% unsecured note due 2014 (related party) - on demand	1	1	3	3
Total interest expenses related to other notes	**38**	**39**	**114**	**177**
Interest expenses related to mortgage loan:				
Contractual interest	305	360	970	994
Amortization of debt issuance costs	136	147	428	437
Total interest expenses on the mortgage loan	**441**	**507**	**1,398**	**1,431**
Other interest expenses	2	1	2	8
Total interest expenses	**$ 691**	**$ 1,046**	**$ 2,138**	**$ 3,475**

7. Net Earnings (Loss) per Share Applicable to Common Stockholders

Basic and diluted earnings (loss) per common share are computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share includes the determinants of basic net income per share and, in addition, gives effect to the potential dilution that would occur if securities or other contracts to issue common stock were exercised, vested or converted into common stock, unless they are anti-dilutive. Diluted weighted average common shares include common stock potentially issuable under our convertible notes, vested and unvested stock options and unvested RSUs,

except where the effect of including them is anti-dilutive.

The following table summarizes the overall and per-share earnings (loss) calculation for the three and nine months ended September 30, 2016 and 2015, respectively (in thousands, except per share amount):

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
Net earnings (loss) applicable to common stockholders - basic	$ (32,234)	$ 22,615	$ (55,154)	$ (90,663)
Interest on convertible senior notes	-	79	-	-
Net earnings (loss) - diluted	$ (32,234)	$ 22,694	$ (55,154)	$ (90,663)
Weighted average shares outstanding - basic	114,836	78,062	105,501	74,394
Common stock warrants	-	12,373	-	-
Convertible notes	-	1,811	-	-
Less: unvested issued restricted stock	-	(2,425)	-	-
Weighted average shares outstanding - diluted	114,836	89,821	105,501	74,394
Per share data:				
Basic	$ (0.28)	$ 0.29	$ (0.52)	$ (1.22)
Diluted	$ (0.28)	$ 0.25	$ (0.52)	$ (1.22)

For the periods where the Company reported losses, all common stock equivalents are excluded from the computation of diluted earnings per share, since the result would be anti-dilutive. (in thousands):

	For the nine months ended September 30,	
	2016	2015
Common stock options	1,551	1,551
Common stock warrants - equity treatment	38,990	12,929
Common stock warrants - liability treatment	1,316	12,434
Convertible notes and accrued interest	1,744	1,811
Potentially dilutive securities	43,601	28,725

8. Related Party Transactions

Cognate BioServices, Inc.

Remediation Plan

As previously reported, on April 26, 2016, the Nasdaq Staff notified the Company that it had reviewed certain stock issuances by the Company to Cognate during 2014 and 2015, and that the Staff had determined that those issuances should be aggregated for purposes of applying Nasdaq rules. Under Nasdaq rules, for purposes of measuring against the limit of 20% of total shares outstanding, all of the stock issuances made by the Company to Cognate during 2014 and 2015 were aggregated, and they were measured against only the shares outstanding in January 2014.

As a result the Company proposed a remediation plan (the "Remediation Plan") that Cognate would surrender certain shares and warrants it had received in connection with the Contracts, Cognate would accept an increase in the exercise price of certain warrants received in connection with the Contracts, and the most favored nation anti-dilution provisions would be deleted from the Contracts.

The Remediation Plan was accepted by the Nasdaq staff on August 30, 2016. Pursuant to the Remediation Plan:

(a) Cognate returned and the Company canceled 8,052,092 restricted shares previously issued to Cognate under the most favored nation anti-dilution provisions of the Contracts, and the most favored nation provisions were deleted from the Contracts on September 7, 2016;

(b) Cognate returned and the Company canceled warrants for 6,880,574 shares issued under the 2014 Agreements and the Company issued to Cognate new warrants for 4,305,772 shares at exercise price of $4.27 with 5 years term; and

(c) Cognate returned and the Company canceled 731,980 of the total of 5,101,330 restricted shares initially issued under the 2014 Agreements.

The remaining portions of the multi-year lock-up and vesting periods relating to shares and warrants held by Cognate were also cancelled.

The Nasdaq settlement does not affect other obligations of the Company to Cognate, including for existing unpaid invoices, as the Company has previously reported.

Cognate Expenses and Accounts Payable

At September 30, 2016 and December 31, 2015, the Company owed Cognate $11.8 million and $5.5 million, respectively, for unpaid invoices for manufacturing, product distribution, product and process development, and related services.

The following table shows a summary of research and development cost from Cognate relating to the DCVax-L and DCVax-Direct programs, product and process development work and preparations for upcoming Phase II trials for the three and nine months ended September 30, 2016 and 2015, respectively (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
Cognate research and development cost - services	$ 6,794	$ 10,137	$ 21,135	$ 29,992
Stock issued to and returned by Cognate	11,376	(6,385)	13,653	9,400
Total	$ 18,170	$ 3,752	$ 34,788	$ 39,392

Share Based Payments

As of August 30, 2016, the research and development expense associated with the remaining 731,980 shares of unvested stock payable to Cognate was approximately $221,000. Pursuant to the Remediation Plan mentioned above, the Company cancelled the remaining unvested 731,980 shares without a replacement of shares. The Company also cancelled 8,052,092 vested shares, which was recorded as reduction of shares outstanding.

The Company recorded $8.9 million of income and $9.4 million of expense for the nine-month periods ended September 30, 2016 and 2015, respectively, for stock based payment expense to Cognate through August 30, 2016 (the date of vesting). The fair value calculation of these shares was determined using the market price for tradable shares.

Shares payable to related party – elimination of most favored nation provision

Shares and warrants previously issued to Cognate in partial payment of invoices for manufacturing services were under a 3-year lock-up, which had been in place since January 2014. The lock-up prevented Cognate from selling the shares received. During the lock-up, if the Company entered into a transaction with other investors or creditors on more favorable terms than Cognate received, the Company had an ongoing obligation, under the Manufacturing Services Agreements, to conform the terms of Cognate's shares and warrants to the same terms as the other investors or creditors, under a most favored nation provision.

During the nine months period ended September 30, 2016, the Company entered into several financings with unrelated institutional investors that triggered the most favored nation provision (but which were not implemented, due to being cancelled and eliminated under the Remediation Agreement). The first reset occurred in February 2016, had an effective price of $1.70 and would have resulted in an obligation by the Company to issue 6.0 million shares to Cognate. The second reset occurred in May 2016, had an effective price of $0.96 and would have resulted in an obligation to issue an additional 12.0 million shares. The third reset occurred in July 2016, had an effective price of $0.60 and would have resulted in an obligation to issue an additional 16.6 million shares. The final reset occurred in August 2016, had an effective price of $0.35 and would have resulted in an obligation to issue an additional 31.6 million shares.

None of these most favored nation shares were issued to Cognate. Under the Remediation Agreement, Cognate agreed to eliminate the most favored nation provisions, and to forego all these shares that had already been triggered. As a result of the elimination of the most favored nation, the Company reclassified $22.5 million shares payable which resulted in an increase additional paid in capital.

9. Stockholders' Equity (Deficit)

Common Stock Issuances

First Quarter of 2016

On February 29, 2016, the Company entered into a Securities Purchase Agreement (the "Agreement") with certain institutional investors (the "Purchasers"), for a registered direct offering (the "Offering") of 5,882,353 shares (the "Shares") of the Company's Common Stock at the purchase price of $1.70 per share, and Series A Warrants (the "Series A Warrants") to purchase an additional 2,941,177 shares of Common Stock at an exercise price of $2.25 per share. The Series A Warrants will become exercisable on the six month anniversary of issuance and expire five years thereafter.

In addition, the Company granted the Purchasers a sixty (60) day overallotment option in the form of Series B Warrants to purchase an additional 5,882,353 shares of Common Stock at an exercise price of $3.00 per share (the "Series B Warrants"). The Series B Warrants were exercisable immediately and were to expire within sixty (60) days. However, on May 2, 2016, the Company and the investors agreed to extend this warrant exercise period by twenty-one (21) days, from May 2 to May 23, 2016. The Company and the Purchasers consummated the purchase and sale of the Securities on March 3, 2016 (the "Closing") and the Company raised gross proceeds of $10 million and net proceeds of approximately $9.2 million, after deducting placement agent fees, attorneys' fees and other expenses. Subsequent to the reporting period, the Series B Warrants were extended an additional twenty-one (21) days to May 23, 2016.

Each Purchaser also received Series C Warrants (the "Series C Warrants") to purchase up to 2,941,177 shares of Common Stock. The Series C Warrants vest and become exercisable only if, and to the extent that, the Series B Warrants held by such Purchaser are exercised. The Series C warrants will be issuable and exercisable for one-half share of Common Stock per each Series B Warrant exercised. The Series C Warrants have an exercise price of $4.00 per share, shall be exercisable on the six-month anniversary of issuance and will expire five years thereafter.

In connection with the Offering and the concurrent private placement, the Company agreed to pay the Placement Agent a cash placement fee equal to 7% of the aggregate purchase price for the common stock sold in the registered offering. The Placement Agent also received Common Stock purchase warrants (the "Compensation Warrants") to purchase up to 294,118 shares of Common Stock, or 5% of the aggregate number of shares of common Stock sold in the registered offering, at an exercise price of $2.125, or 125% of the public offering price per share in the registered offering, which are exercisable six months following issuance and terminate on February 29, 2021.

Second Quarter of 2016

On May 15, 2016, the Company entered into an agreement with a holder (the "Holder") of the Company's existing Series A, B and C Warrants, pursuant to which the Holder agreed to exercise all of the Holder's Series B Warrants to purchase 4,411,764 shares of Common Stock. In consideration, the Company agreed to reduce the exercise price of the Series B Warrants to $0.96 per share, the Company's closing price on the prior trading day, for gross proceeds of approximately $4,235,000, and agreed to issue new Series D Common Stock Purchase Warrants (the "Series D Warrants") to purchase up to 2,205,882 shares of Common Stock at an exercise price of $1.00 per share (subject to customary adjustments such as for stock splits and dividends), with an exercise period of five years, commencing six months after issuance.

The Holder's exercise of the Series B Warrants to purchase 4,411,764 shares of Common Stock triggered the existing outstanding Series C Warrants to become vested and exercisable for up to 2,205,882 shares of Common Stock. The Company agreed to reset the exercise price of the Series A and Series C Warrants to $1.00 per share.

In connection with the offering and the concurrent private placement, the Company agreed to pay the Placement Agent a cash placement fee equal to 7% of the aggregate purchase price for the common stock sold. The Placement Agent also received Common Stock purchase warrants (the "Compensation Warrants") to purchase up to 220,588 shares of Common Stock, or 5% of the aggregate number of shares of common Stock sold, at an exercise price of $1.20, or 125% of the public offering price per share, which are exercisable six months following issuance and terminate on May 15, 2021.

The modification of the warrant exercise price increased the value of the warrants by approximately $2.6 million. This cost was recorded as a deemed dividend in additional paid-in capital due to the absence of retained earnings. This cost is included in modification of warrants and increased the net loss available to common shareholders on the condensed, consolidated statements of operations.

Third Quarter of 2016

During the quarter ended September 30, 2016, the Company issued 7,400,000 shares of common stock at $0.50 per share, and warrants to purchase an additional 3,700,000 shares of Common Stock at an exercise price of $0.60 per share with five years term through a registered direct offering. The Company received net proceeds of approximately $3.4 million, after deducting aggregate placement agent fees and attorneys' fees of approximately $321,000.

During the quarter ended September 30, 2016, the Company entered into multiple agreements with certain holders (the "Holders") of the Company's existing warrants, pursuant to which the Holders agreed to exercise all of the Holders' warrants to purchase 10,945,694 shares of common stock. In consideration, the Company agreed to reduce the exercise price of the warrants to $0.35 per share, for net proceeds of approximately $3.4 million, after deducting aggregate placement agent fees, attorneys' fees and bank clearing fees of approximately $454,000, and agreed to issue new common stock purchase warrants to purchase up to 10,945,694 shares of common stock at a weighted average exercise price of $0.44 per share, with an exercise period of 5 years, commencing 6 months after issuance. In connection with the registered direct offering, the Company granted 263,122 warrants at an exercise price of $0.44 to the placement agents. The placement agent warrants are exercisable 6 months following issuance and terminate on February 22, 2022.

The modification of the warrant exercise price increased the value of the warrants by approximately $3.0 million. This cost was recorded as a deemed dividend in additional paid-in capital due to the absence of retained earnings. This cost is included in modification of warrants and increased the net loss available to common shareholders on the condensed, consolidated statements of operations.

During the quarter ended September 30, 2016, the Company issued a total of 2,572,216 shares of Common stock at $0.36 per share to several angel investors for aggregate proceeds of $0.9 million. The Company also issued 1,286,111 warrants at an exercise price of $0.42 per share, with an exercise period of 5 years.

On September 16, 2016, the Company converted a note in dispute and relevant accrued interest of $1.0 million into 2,222,222 shares of common stock. The fair value of the common shares on the issuance date was approximately $1.0 million. In addition, the Company issued 1,111,111 warrants at an exercise price of $0.45 with an exercise period of 5 years, commencing 6 months after issuance. The fair value of the warrants was approximately $0.4 million using a Black-Scholes model at the date of issuance related to the conversion of note and accrued interest. The total loss on extinguishment of debt recorded on the statement of operations was approximately $0.4 million related to this conversion.

Stock Purchase Warrants

The following is a summary of warrant activity for the nine months ended September 30, 2016 (in thousands, except per share data):

	Number of Warrants	Weighted Average Exercise Price
Outstanding as of December 31, 2015	**27,267,441**	**$ 4.40**
Warrants granted in a registered direct offering	12,058,825	3.04
Warrants granted to Cognate*	3,405,671	1.70
Warrants expired and cancelled	(16,791)	11.86
Outstanding as of March 31, 2016	**42,715,146**	**$ 3.53**
Warrants granted in a registered direct offering	2,426,440	1.02
Warrants granted to Cognate*	5,329,961	0.96
Warrants exercised for cash	(4,411,764)	0.96
Warrants expired and cancelled	(1,614,837)	8.82
Outstanding as of June 30, 2016	**44,444,946**	**$ 2.67**
Warrants granted to investors	18,428,640	0.64
Warrants granted to Cognate	4,305,772	4.27
Cognate warrants returned/cancelled	(15,806,512)	0.35
Warrants exercised for cash	(10,945,739)	0.35
Warrants expired and cancelled	(120,979)	11.30
Outstanding as of September 30, 2016	**40,306,128**	**$ 2.83**

* Warrants contained down round protection (most favored nation provisions).

10. Contingencies

Derivative and Class Action Litigation

In 2014, as previously reported, the Company received demand letters from three purported individual shareholders seeking to inspect our corporate books and records pursuant to Section 220 of the Delaware General Corporation Law. The demand letters were all substantially similar, and claimed that their purpose is to investigate possible mismanagement and breaches of fiduciary duty by the Company's directors and officers. They requested a range of documents. On November 13, 2014, one of the purported shareholders filed a complaint in the Delaware Court of Chancery seeking to enforce her books and records demand. The Company reached negotiated agreements and provided limited records, under confidentiality agreements. On July 16, 2015, the parties filed, and the court entered, a stipulation dismissing the case.

On June 19, 2015, two of the purported shareholders filed a complaint purportedly suing on behalf of a class of similarly situated shareholders and derivatively on behalf of the Company in the Delaware Court of Chancery. The lawsuit names Cognate BioServices, Inc., Toucan Partners, Toucan Capital Fund III, our CEO Linda Powers and the Company's Board of Directors as defendants, and names the Company as a "nominal defendant" with respect to the derivative claims. The complaint generally objects to certain transactions between the Company and Cognate and the Toucan entities, in which Cognate and the Toucan entities provided services and financing to the Company, or agreed to conversion of debts owed to them by the Company into equity. The complaint seeks unspecified monetary relief for the Company and the plaintiffs, and various forms of equitable relief, including disgorgement of allegedly improper benefits, rescission of the challenged transactions, and an order forbidding similar transactions in the future. On September 1, 2015, the Company and other named defendants filed motions to dismiss. In response, the plaintiffs filed an amended complaint on November 6, 2015. The Company and the other named defendants filed motions to dismiss plaintiffs' amended complaint on January 19, 2016. The plaintiffs filed an answering brief in opposition to the motion to dismiss on April 4, 2016. The Company and the other defendants filed reply briefs on May 18, 2016. The Company intends to continue to vigorously defend the case.

On November 19, 2015, a third purported shareholder who had sought corporate books and records filed a complaint in the U.S. District Court for the District of Maryland, claiming to sue derivatively on behalf of the Company. The complaint names the Company's Board of Directors, Toucan Capital Fund III, L.P., Toucan General II, LLC, Toucan Partners, LLC, and Cognate as defendants, and names the Company as a nominal defendant. The complaint claims that the plaintiff made a demand on the Company's Board of Directors to commence an action against the Company's directors and its CEO and that the plaintiff commenced the derivative action after not receiving a response to the demand letter within an allegedly "sufficient time." The complaint further claims that the Company purportedly overcompensated Cognate and Toucan for certain services and loans in payments of stock, and that the Company's CEO, Ms. Powers, benefited from these transactions with Cognate and Toucan, which she allegedly owns or controls. The complaint asserts that the alleged overpayments unjustly enriched Ms. Powers, Toucan, and Cognate. The Complaint also claims that the Company's directors breached their fiduciary duties of loyalty and good faith to the Company by authorizing the payments to Cognate. Finally, the complaint claims that Ms. Powers, Cognate, and Toucan aided and abetted the directors' breaches of fiduciary duties by causing the board to enter into the agreements with Cognate. The plaintiff seeks an award of unspecified damages to the Company and seeks equitable remedies, including disgorgement by Ms. Powers, Toucan, and Cognate of the allegedly improper benefits received as a result of the disputed transactions. The plaintiff also seeks costs and disbursements associated with bringing suit, including attorneys' fees and expert fees. On February 2, 2016, plaintiff and defendants filed a joint motion to stay the proceedings pending an investigation by a special committee of the Company's Board of Directors into the allegations asserted in the demand letter and underlying the lawsuit. The court entered the stay on March 18, 2016. The Company intends to vigorously defend the case.

Class Action Securities Litigation

On August 26, 2015, a purported shareholder of the Company filed a putative class action complaint in the U.S. District Court for the District of Maryland. The lawsuit names the Company and Ms. Powers as defendants. On December 14, 2015, the court appointed two lead plaintiffs. The Lead Plaintiffs filed an amended complaint on February 12, 2016, purportedly on behalf of all of those who purchased common stock in NW Bio between January 13, 2014 and August 21, 2015. The amended complaint generally claims that the defendants violated Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934 by making misleading statements and/or omissions on a variety of subjects, including the status and results of the Company's DCVax trials. The amended complaint seeks unspecified damages, attorneys' fees, and costs. The Company and Ms. Powers filed a motion to dismiss plaintiffs' amended complaint on April 12, 2016. The plaintiffs filed an opposition to the motion to dismiss on June 13, 2016. The Company and Ms. Powers filed a reply in support of their motion to dismiss on July 28, 2016. The Company intends to vigorously defend the case.

Shareholder Books and Record Demand

On December 7, 2015, the Company received a letter on behalf of shareholders demanding to inspect certain corporate books and records pursuant to Section 220 of the Delaware General Corporation Law. The demand letter claimed that its purpose was to investigate: (1) allegedly improper transactions, misconduct, and mismanagement by directors and an officer of the Company; (2) the possible breach of fiduciary duty by certain directors and officers of the Company; and (3) the independence and disinterestedness of the Company's board, to determine whether a pre-suit demand would be necessary before commencing any derivative action on behalf of the Company. The Company has appointed a special committee of its Board of Directors consisting of independent and disinterested directors to investigate the allegations set forth in the demand letter, as well as the allegations asserted in the litigation summarized above.

11. Subsequent Events

Debt Financing

As the Company previously reported, in late October and thereafter the Company engaged in discussions with institutional investors interested in providing financing. Under Nasdaq rules, the number of shares which the Company may issue is limited in certain types of transactions (and not similarly limited in other types of transactions). The number of shares which the investors were interested to purchase may exceed the maximum number of shares issuable by the Company in the type of transaction contemplated. While this issue is being addressed, the Company has entered into a debt financing.

On November 4, 2016, the Company entered into Promissory Note Agreements (the "Notes") for $2.5 million principal amount. The Notes are not convertible; they have one-year maturity and 10% annual interest, with the interest payable at maturity. No equity or derivative equity securities were issued in connection with this transaction.

Nasdaq Issue

In connection with the discussions with interested investors, the Company contacted Nasdaq to make the necessary filings for Listing of Additional Shares and to pursue a determination of the maximum number of shares the Company may issue to investors. On November 1, 2016, the Company submitted to Nasdaq information about the Company's prior financing transactions during the

preceding six-month period. On November 7, 2016, the Company received a letter from Nasdaq indicating that certain of the Company's financing transactions did not comply with Nasdaq rules. The Nasdaq Staff had determined to aggregate a series of transactions that were completed with various unrelated parties between May 15, 2016 and October 13, 2016 for purposes of assessing whether the 20% threshold for shareholder approval had been triggered for issuances priced below the applicable market price. These transactions included repricing of existing common stock purchase warrants and issuances of new common shares and common stock purchase warrants.

The Company and its representatives are in discussions with the Nasdaq Staff regarding available avenues for remediation, and the Company intends to submit its plan of remediation to Nasdaq on or before the November 18, 2016 deadline established by Nasdaq. If Nasdaq does not accept the plan of remediation, Nasdaq may issue a notice of delisting. The Company would then have the right to request a hearing before an independent Nasdaq Listing Qualifications Panel (the "Panel"). A request for a hearing would stay any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel. The Panel would have the discretion to grant the Company an extension period of up to 180 calendar days from the date of the delisting letter within which the Company would be required to demonstrate compliance with all applicable listing requirements.

Sale of Common Stock and Issuance of Warrants in a Private Placement

In October 2016, the Company issued 740,909 shares of Common stock at $0.44 per share to several angel investors for aggregate proceeds of $326,000. The Company also issued 370,456 warrants at an exercise price of $0.52 per share, with an exercise period of five years.

Issuance of Common Shares in Satisfaction of Outstanding Obligations

On October 13, 2016, the Company converted accrued interest of $0.5 million into 1,111,111 shares of common stock. In conjunction with the conversion, the Company issued 555,556 warrants at an exercise price of $0.45 with an exercise period of 5 years, commencing 6 months after issuance.

Assignment Agreement with Related Party

As previously reported, on October 13, 2016 the Company entered into a Letter Agreement (the "Agreement") with Cognate and related agreements in connection with an institutional financing of Cognate and to enable the Company to continue obtaining services from Cognate for the Company's ongoing Phase III DCVax®-L trial and upcoming Phase II DCVax®-Direct trials. As an initial implementation step pursuant to the Agreement, on October 13, 2016 the Company entered into an Assignment and Assumption Agreement (the "Assignment Agreement") pursuant to which the Company agreed to assume certain Cognate debt obligations in connection with preparations for initiation of Phase II clinical trials and further services in ongoing trials. The Company's prior report noted that the third party lender and the Company were negotiating to finalize the arrangements related to this Assumption and that the Company planned to report the results in a future periodic filing. Based on discussions to date, the Company anticipates that, over a period of up to a year, the obligations could total an amount up to approximately $5 million. The Company will report on the results of further negotiations and finalization in a future periodic filing. To discharge an initial obligation of $480,000, the Company issued to the lender 1 million shares of common stock at $0.48 per share.

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, 2015 and in Part II Item 1A of this report. These factors, among others, could cause results to differ materially from those presently anticipated by us. You should not place undue reliance on these forward-looking statements.

Overview

We are a 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 the United States, Canada 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 the overall immune system, and targeting the full set of biomarkers on the patient's cancer, contributes to the effectiveness of DCVax.

Our lead product, DCVax-L, is in an ongoing Phase III trial for newly diagnosed Glioblastome multiforme (GBM), with over 60 trial sites as of December 31, 2015. GBM is the most aggressive and lethal form of brain cancer, and is an "orphan disease." The trial is on partial clinical hold for screening of new patients for further enrollment; however, over 300 of the planned 348 patients are enrolled in the trial, and the patients already in the trial have continued to be treated in accordance with the trial protocol, without interruption. The Company is in ongoing dialog with regulators in regard to the partial hold.

Our second product, DCVax-Direct, is being studied in a 60-patient Phase I/II trial for inoperable solid tumors. The 40-patient Phase I stage of the trial has been completed except for ongoing follow-up on long-term survivor patients. The Company is working on preparations for Phase II trials of DCVax-Direct.

We have undertaken lower levels of fundraising as our research and development costs have been substantially lower during the current posture of our DCVax-L and DCVax-Direct programs. We plan to increase our fundraising activities as the upcoming Phase II trials become ready for enrollment and execution.

Critical Accounting Policies and Estimates

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

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

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2015. 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, 2015.

Results of Operations

For the nine months ended September 30, 2016, we recognized a net loss of $49.5 million (cash and non-cash combined) versus a net loss of $90.7 million (cash and non-cash combined) for the nine months ended September 30, 2015.

During the three and nine months ended September 30, 2016, the Company used approximately $9.8 million and $41.6 million of cash in its operating activities respectively.

These cash outflows included substantial amounts of accrued costs relating to prior periods of higher activity and expenditures in the Company's Phase III clinical trial which have subsequently been reduced, and included substantial amounts of legal costs which the Company anticipates may be subject to reimbursement under the Company's insurance, with further legal expenses going forward being covered by insurance directly.

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 well as undertaking product and process development, and preparing for multiple Phase II trials.

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 well as undertaking product and process development, and preparing for multiple Phase II trials.

Our operating costs include ongoing development work relating to our DCVax products and their manufacturing, such as the development, testing and optimization of different product preparations and methods, the design, engineering, sourcing, production, testing, modification and validation of manufacturing automation systems, disposable sets to be used with the manufacturing automation systems, 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.

In our DCVax-L program, our operating costs also include the costs of continuing our ongoing Phase III trial in the US, UK, Germany and Canada (with DCVax-L for brain cancer), and early access programs in Europe.

In our DCVax-Direct program, our operating costs include preparations for multiple Phase II trials. The preparation costs include product and process development, upfront payments to the clinical trial sites and the CROs managing the trials and other service providers, and legal, regulatory and expert expenses related to regulatory approvals, institutional approvals and clinical trial agreements with each site, database development, 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.

We have undertaken lower levels of fundraising as our research and development costs have been substantially lower during the current posture of our DCVax-L and DCVax-Direct programs. We plan to increase our fundraising activities as the upcoming Phase II trials become ready for enrollment and execution.

Research and development:

Discovery and preclinical research and development expenses include costs for external technical and regulatory advisers, scientific or medical personnel and others, costs of laboratory supplies and equipment used in 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 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 both cash and non-cash measures. The cash expenses also include large amounts of legal fees and related expenses, large amounts of external expert consultants (including statisticians, regulatory advisers in multiple countries and others), and substantial intellectual property costs, in addition to Company operating costs, salary and benefit expenses, cost of facilities, insurance and travel, property and equipment. The non-cash expenses include stock-based compensation and depreciation.

Three Months Ended September 30, 2016 and 2015

For the three months ended September 30, 2016, we recognized a net loss of approximately $29.2 million (cash and non-cash combined) (including $11.4 million of non-cash liability for most favored nation share issuance obligations, which was recorded as research and development expense and which was subsequently cancelled and eliminated in the Remediation Agreement with Cognate) versus net income of $22.6 million (cash and non-cash combined) for the three months ended September 30, 2015. For the three-month period ended September 30, 2016, the Company recorded loss of approximately $0.2 million related to the change in fair value of derivative liability. For the period ended September 30, 2015, the Company recorded additional income of approximately $36.5 million expense related to the change in fair value of derivative liabilities.

Research and Development Expense

Research and development expense was approximately $21.1 million (comprised of approximately $6.8 million of cash expenses for clinical programs, including substantial accrued expenses from prior periods, and $11.4 of non-cash liability for most favored nation share issuance obligations, which obligations were subsequently cancelled and eliminated in the Remediation Agreement with Cognate) for the three months ended September 30, 2016 versus $9.1 million for the three months ended September 30, 2015.

For the three months ended September 30, 2016 and 2015, we made cash payments of approximately $2.4 million, and $7.1 million, respectively, to Cognate. At September 30, 2016 and 2015, we owed Cognate $11.8 million and $7.2 million, respectively, for unpaid invoices for DCVax-L and DCVax-Direct programs, product and process development work and preparations for upcoming Phase II trials.

For the three months ended September 30, 2016 and 2015, we incurred non-cash equity based benefit and expense (restricted common stock and warrants) for the applicable pro rata portion of the ongoing vesting (in equal monthly installments over 3 years) of the one-time initiation payments of shares and warrants under the four agreements the Company entered into with Cognate in January 2014. The Company recorded $0.7 million of income and $6.4 million income for the three months ended September 30, 2016 and 2015. The income for the three months ended September 30, 2016 and 2015 was due to the drop in share price compared with the prior period. The fair value calculation of these shares was determined using the market price for tradable shares. The multi-year lock-up and vesting were cancelled pursuant to the Remediation Agreement entered on August 30, 2016.

General and Administrative Expense

General and administrative expense was approximately $4.6 million (cash and non-cash expenses combined) for the three months ended September 30, 2016 versus $4.4 million for the three months ended September 30, 2015. Aggregate costs are consistent with last year; however, this includes a large increase in legal costs and substantial reductions in other costs The Company anticipates substantial portions of the large legal costs will be subject to reimbursement under the Company’s insurance, with further legal expenses going forward being covered by insurance directly.

Inducement Loss

During the three months ended September 30, 2016, we recorded inducement loss of $1.5 million related to the extinguishment and modification on warrant liabilities.

Change in fair value of derivatives

During the three months ended September 30, 2016 and 2015 we recognized a non-cash loss of approximately $0.2 million and gain of approximately $36.5 million, respectively, on the fair value of derivative liability. The significant reduction relates to the change in the fair value of the derivative liability which was due to all Cognate derivative liabilities that were extinguished pursuant to the Remediation Plan.

Loss on Extinguishment of Debt

During the three months ended September 30 2016, we recorded loss on extinguishment of debt of approximately $0.4 million related to the conversion of $1.0 million debt and accrued interest to common stock and warrants. The fair value of the common stock and warrants were approximately $1.4 million, and the excess amount was recorded as inducement cost.

Interest Expense

The Company’s reduction in outstanding debt resulted in a reduction of interest expense. Interest expense (including non-cash elements such as amortization of debt discount and debt issuance cost) was approximately $0.7 million and $1.0 million for the three months ended September 30, 2016 and 2015, respectively.

Foreign currency transaction loss

During the three months ended September 30, 2016 and 2015, we recognized foreign currency transaction loss of approximately $0.9 million and gain of approximately $0.4 million, respectively. The increased loss is due to the strengthening of the U.S. dollar relative to the British pound sterling.

Nine Months Ended September 30, 2016 and 2015

For the nine months ended September 30, 2016 we recognized a net loss of $49.5 million (cash and non-cash combined) (including $13.7 million of non-cash liability for most favored nation share issuance obligations, which was recorded as research and development expense and which was subsequently cancelled and eliminated in the Remediation Agreement with Cognate) versus a net loss of $90.7 million (cash and non-cash combined) for the nine months ended September 30, 2015. For the period ended September 30, 2016 and 2015, the Company recorded additional income of $17.2 million and additional expense of $12.4 million, respectively, related to the change in fair value of its derivative liability.

Research and Development Expense

Research and development expense was $43.2 million (including $13.7 million of non-cash liability for most favored nation share issuance obligations, which was recorded as research and development expense and which was subsequently cancelled and eliminated in the Remediation Agreement with Cognate) for the nine months ended September 30, 2016 versus $56.6 million for the nine months ended September 30, 2015. The decrease was primarily due to decreased non-cash manufacturing and services costs as described below.

During the nine months ended September 30, 2016 and 2015, we made cash payments of approximately $12.4 million, and $28.4 million, respectively, to Cognate. At September 30, 2016 and 2015, we owed Cognate $11.8 million and $7.2 million, respectively, for unpaid invoices for DCVax-L and DCVax-Direct programs, product and process development work and preparations for upcoming Phase II trials.

For the nine months ended September 30, 2016 and 2015, we incurred non-cash equity based benefit and expense (restricted common stock and warrants) for the applicable pro rata portion of the ongoing vesting (in equal monthly installments over 3 years) of the one-time initiation payments of shares and warrants under the four agreements the Company entered into with Cognate in January 2014. The Company recorded $8.9 million of income for the nine months ended September 30, 2016 versus $9.4 million expense for the nine months ended September 30, 2015.

General and Administrative Expense

General and administrative expense was $15.3 million (cash and non-cash combined) for the nine months ended September 30, 2016 versus $19.2 million (cash and non-cash combined) for the nine months ended September 30, 2015. The overall decrease in general and administrative expenses resulted from substantial reductions in the use of external consultants and other costs, offsetting large increases in legal costs during the period.

Inducement Loss

During the nine months ended September 30, 2016, we recorded inducement loss of $1.5 million related to the extinguishment and modification on warrant liabilities.

Change in fair value of derivatives

During the nine months ended September 30, 2016 and 2015, we recognized a non-cash gain of $17.2 million and a non-cash loss of $12.4 million, respectively, on the fair value of derivative liability. The change in the fair value of the derivative liability during the nine months ended September 30, 2016 was due to a decrease in our stock price compared to December 31, 2015.

Loss on Extinguishment of Debt

During the nine months ended September 30 2016, we recorded loss on extinguishment of debt of $0.4 million related to the conversion of $1.0 million debt and accrued interest to common stock and warrants. The fair value of the common stock and warrants were approximately $1.4 million, and the excess amount was recorded as inducement cost.

Interest Expense

The Company’s reduction in outstanding debt resulted in a reduction of interest expense. Interest expense (including non-cash elements such as amortization of debt discount and debt issuance cost) was $2.1 million and $3.5 million for the nine months ended September 30, 2016 and 2015, respectively.

Liquidity and Capital Resources

We have experienced recurring losses from operations. During the nine months ended September 30, 2016 and 2015, net cash outflows from operations were $41.6 million and $56.5 million, respectively. These cash outflows included substantial amounts of accrued costs relating to prior periods of higher activity and expenditures in the Company’s Phase III clinical trial which have subsequently been reduced, and included substantial amounts of legal costs which the Company anticipates may be subject to reimbursement under the Company’s insurance, with further legal expenses going forward being covered by insurance directly.

At September 30, 2016, the Company had current assets of $2.3 million, accounts payable of $13.3 million and accounts payable to related party of $11.8 million, convertible notes, net of $10.9 million and mortgage loans, net of $10.1 million.

Operating Activities

During the nine months ended September 30, 2016 and 2015, net cash outflows from operations were $41.6 million and $56.5 million, respectively.

Investing Activities

During the nine months ended September 30, 2016 and 2015, we used $4.8 million and $4.0 million to capitalize costs related to the UK facility and UK facility purchase, respectively.

Financing Activities

During the nine months ended September 30, 2016 and 2015, our financing activities provided net proceeds after expenses of $20.8 million and $52.6 million, respectively. The $20.8 million in the nine months ended September 2016 consisted of $12.6 million from registered direct offerings, $0.9 million from private offering, and $7.3 million from warrants exercised for cash. The $52.6 million in the nine months ended September 2015 consisted of $40.0 million proceeds from issuance of common stock, $7.4 million proceeds from the exercise of warrants, and $5 million in net mortgage loan proceeds.

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

Other factors affecting our ongoing funding requirements include the number of staff we employ, the number of sites and number of patients still undergoing treatment in our Phase III brain cancer trial, the costs of further product and process development work relating to our DCVax products, the costs of preparations for multiple Phase II trials, the costs of expansion of manufacturing, the cost of pursuing our Hospital Exemption program and potential reimbursements in Germany, and unanticipated developments. The extent of resources available to us will determine which programs can move forward and at what pace.

Nasdaq Listing

The Company's common stock is listed on The Nasdaq Capital Market ("Nasdaq") under the symbol "NWBO." One of the requirements for continued listing on Nasdaq is maintenance of a minimum closing bid price of $1.00 per share. On June 24, 2016, the Company received a letter (the "Notice") from the Listing Qualifications Staff of The NASDAQ Stock Market LLC ("Nasdaq") notifying the Company that, based upon the closing bid price of the Company's common stock, $0.001 par value per share (the "Common Stock") for the 30 consecutive business days preceding receipt of such letter, the Common Stock no longer met the requirement to maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been granted a period of 180 days, or until December 21, 2016, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for at least 10 consecutive business days during this 180-day period.

The Company intends to monitor the closing bid price of its common stock on an ongoing basis, and consider a range of available options to regain compliance with the share price listing standard. The Company could remedy the deficiency, either now or at a later date, through a reverse stock split. However, the Company currently plans to regain compliance by focusing on progress in its operational programs.

In the event the Company does not regain compliance by December 21, 2016, the Company may be eligible for a second 180-day grace period if it meets the initial listing standards (with the exception of the bid price and market value of publicly held shares requirements) for The Nasdaq Capital Market, and provides written notice to Nasdaq of its intention to cure the deficiency during the second 180-day grace period, by effecting a reverse stock split, if necessary, and satisfying any other applicable requirements. If the Company does not regain compliance within the allotted compliance period(s), Nasdaq will provide notice that the Company's common stock will be subject to delisting. At that time, the Company would be entitled to a hearing before a Nasdaq Listing Qualifications Panel (the "Panel"). The hearing request would automatically stay any suspension or delisting action until the issuance of the hearing decision and the expiration of any additional extension period granted by the Panel.

On April 26, 2016, the Company received a letter (the "Letter") from the Nasdaq Staff indicating that the Staff had reviewed certain stock issuances by the Company to Cognate BioServices, Inc. ("Cognate"), and had determined that those issuances did not comply with Nasdaq Listing Rules 5635(c) and (d). On May 2, 2016, the Company submitted a remediation plan related to certain stock issued to Cognate to regain compliance with Nasdaq's Rule 5635. The Remediation Plan was accepted by Nasdaq on August 30, 2016.

On November 7, 2016, the Company received a letter from Nasdaq indicating that certain of the Company's financing transactions did not comply with Nasdaq rules. The Nasdaq Staff had determined to aggregate a series of transactions that were completed with various unrelated parties between May 15, 2016 and October 13, 2016 for purposes of assessing whether the 20% threshold for shareholder approval had been triggered for issuances priced below the applicable market price. These transactions included repricing of existing common stock purchase warrants and issuances of new common shares and common stock purchase warrants.

The Company and its representatives are in discussions with the Nasdaq Staff regarding available avenues for remediation, and the Company intends to submit its plan of remediation to Nasdaq on or before the November 18, 2016 deadline established by Nasdaq.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in its market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. Our exposure to market risk is directly related to derivatives, debt and equity linked instruments related to our financing activities.

Our assets and liabilities are overwhelmingly denominated in U.S. dollars. We do not use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. We use an interest rate sensitivity simulation to assess our interest rate risk exposure. For purposes of presenting the possible earnings effect of a hypothetical, adverse change in interest rates over the 12-month period from our reporting date, we assume that all interest rate sensitive financial instruments will be impacted by a hypothetical, immediate 100 basis point increase in interest rates as of the beginning of the period. The sensitivity is based upon the hypothetical assumption that all relevant types of interest rates that affect our results would increase instantaneously, simultaneously and to the same degree. We do not believe that our cash and equivalents have significant risk of default or illiquidity.

The sensitivity analyses of the interest rate sensitive financial instruments are hypothetical and should be used with caution. Changes in fair value based on a 1% or 2% variation in an estimate generally cannot be extrapolated because the relationship of the change in the estimate to the change in fair value may not be linear. Also, the effect of a variation in a particular estimate on the fair value of financial instruments is calculated independent of changes in any other estimate; in practice, changes in one factor may result in changes in another factor, which might magnify or counteract the sensitivities. In addition, the sensitivity analyses do not consider any action that we may take to mitigate the impact of any adverse changes in the key estimates.

Based on our analysis, as of September 30, 2016, the effect of a 100+/- basis point change in interest rates on the value of our financial instruments and the resultant effect on our net loss are considered immaterial.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Company's finance and accounting functions are performed by an external firm on a contract services basis. This firm specializes in providing finance and accounting functions for biotech companies, and the founders and senior managers are highly experienced former partners of national accounting firms. The number and seniority of personnel in the external firm performing the finance and accounting functions for the Company were increased during 2015. In addition, during the quarter ended December 31, 2015, the Company retained a full-time controller. Further, during the quarter ended June 30, 2016, the Company engaged a second external firm: one that specializes in Sarbanes-Oxley matters and helping public companies improve their disclosure controls and procedures. Together with these two external firms and our controller, 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 the evaluation of our disclosure controls and procedures, our principal executive, financial and accounting officer concluded that during the period covered by this report, our Company's processes for internally reporting material information in a systematic manner to allow for timely filing of material information were significantly improved compared with prior periods, but were not effective, due to inherent limitations from being a small company, and there remain some material weaknesses as described below. We have been working together with the two external firms and our controller to further mitigate the remaining weaknesses, as also described below.

Changes in Internal Control over Financial Reporting

As of the date of this filing, the Company has completed remediation or made substantial progress towards remediation of the material weaknesses identified in the Company's annual report on Form 10-K, filed in March 2016.

During the quarter ended June 30, 2016, we conducted a comprehensive entity-wide risk assessment to evaluate and ultimately report on risks to financial reporting throughout the organization. Following this assessment, we undertook an action plan to strengthen internal controls and procedures.

During the quarter ended June 30, 2016, we completed remediation of two material weaknesses identified in the Company's 10-K for 2015 related to (1) insufficient segregation of duties, oversight of work performed and lack of compensating controls in the Company's finance and accounting functions due to limited personnel and (2) the lack of an effective anti-fraud program designed to detect and prevent fraud relating to (i) an effective whistle-blower program or other comparable mechanism and (ii) an ongoing program to manage identified fraud risks.

During the quarter ended September 30, 2016, we thoroughly revised and upgraded our documentation of internal controls over financial reporting and continued testing key controls for operating effectiveness.

During the quarter ended September 30, 2016, we completed remediation of two additional material weaknesses identified in the Company's 10-K for 2015 related to (1) documentation to support occurrences of review and approval procedures and (2) maintenance of an adequate risk oversight function to evaluate and report on risks to financial reporting throughout the organization, including completion of a comprehensive risk assessment to identify all potential risk areas and evaluate the adequacy of controls to mitigate identified risk.

We have made substantial progress on remediation of the three remaining material weaknesses identified in the Company's 10-K for 2015:

- We have further segregated duties within our finance and accounting functions, to ensure that incompatible duties are segregated.
- We have implemented a new process to more fully document the Company's identification of related parties and related party transactions, to ensure that all material transactions and developments impacting the financial statements are reflected and properly recorded.
- We have implemented a new process to more fully document the Company's accounting operations throughout the organization, including the review, supervision and monitoring taking place.
- We have expanded the personnel resources allocated to our Company's work, and the activities performed for our Company, by the two external firms.
- We have recruited additional personnel, and we are in the process of recruiting further personnel, to enable still further segregation of duties and increased oversight.

We plan to continue taking steps to improve our internal control system and to address the remaining deficiencies, but the timing of such steps is uncertain and our ability to retain or attract qualified individuals to undertake these functions is also uncertain. Other than the changes described above, there has been no change in our internal controls over financial reporting that occurred during the fiscal quarter ended September 30, 2016, that has materially affected, or is reasonably expected to materially affect, our internal controls over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

Derivative and Class Action Litigation

In 2014, as previously reported, the Company received demand letters from three purported individual shareholders seeking to inspect our corporate books and records pursuant to Section 220 of the Delaware General Corporation Law. The demand letters were all substantially similar, and claimed that their purpose is to investigate possible mismanagement and breaches of fiduciary duty by the Company's directors and officers. They requested a range of documents. On November 13, 2014, one of the purported shareholders filed a complaint in the Delaware Court of Chancery seeking to enforce her books and records demand. The Company reached negotiated agreements and provided limited records, under confidentiality agreements. On July 16, 2015, the parties filed, and the court entered, a stipulation dismissing the case.

On June 19, 2015, two of the purported shareholders filed a complaint purportedly suing on behalf of a class of similarly situated shareholders and derivatively on behalf of the Company in the Delaware Court of Chancery. The lawsuit names Cognate BioServices, Inc., Toucan Partners, Toucan Capital Fund III, our CEO Linda Powers and the Company's Board of Directors as defendants, and names the Company as a "nominal defendant" with respect to the derivative claims. The complaint generally objects to certain transactions between the Company and Cognate and the Toucan entities, in which Cognate and the Toucan entities provided services and financing to the Company, or agreed to conversion of debts owed to them by the Company into equity. The complaint seeks unspecified monetary relief for the Company and the plaintiffs, and various forms of equitable relief, including disgorgement of allegedly improper benefits, rescission of the challenged transactions, and an order forbidding similar transactions in the future. On September 1, 2015, the Company and other named defendants filed motions to dismiss. In response, the plaintiffs filed an amended complaint on November 6, 2015. The Company and the other named defendants filed motions to dismiss plaintiffs' amended complaint on January 19, 2016. The plaintiffs filed an answering brief in opposition to the motion to dismiss on April 4, 2016. The Company and the other defendants filed reply briefs on May 18, 2016. The Company intends to continue to vigorously defend the case

On November 19, 2015, a third purported shareholder who had sought corporate books and records filed a complaint in the U.S. District Court for the District of Maryland, claiming to sue derivatively on behalf of the Company. The complaint names the Company's Board of Directors, Toucan Capital Fund III, L.P., Toucan General II, LLC, Toucan Partners, LLC, and Cognate as defendants, and names the Company as a nominal defendant. The complaint claims that the plaintiff made a demand on the Company's Board of Directors to commence an action against the Company's directors and its CEO and that the plaintiff commenced the derivative action after not receiving a response to the demand letter within an allegedly "sufficient time." The complaint further claims that the Company purportedly overcompensated Cognate and Toucan for certain services and loans in payments of stock, and that the Company's CEO, Ms. Powers, benefited from these transactions with Cognate and Toucan, which she allegedly owns or controls. The complaint asserts that the alleged overpayments unjustly enriched Ms. Powers, Toucan, and Cognate. The Complaint also claims that the Company's directors breached their fiduciary duties of loyalty and good faith to the Company by authorizing the payments to Cognate. Finally, the complaint claims that Ms. Powers, Cognate, and Toucan aided and abetted the directors' breaches of fiduciary duties by causing the board to enter into the agreements with Cognate. The plaintiff seeks an award of unspecified damages to the Company and seeks equitable remedies, including disgorgement by Ms. Powers, Toucan, and Cognate of the allegedly improper benefits received as a result of the disputed transactions. The plaintiff also seeks costs and disbursements associated with bringing suit, including attorneys' fees and expert fees. On February 2, 2016, plaintiff and defendants filed a joint motion to stay the proceedings pending an investigation by a special committee of the Company's Board of Directors into the allegations asserted in the demand letter and underlying the lawsuit. The court entered the stay on March 18, 2016. The Company intends to vigorously defend the case.

Class Action Securities Litigation

On August 26, 2015, a purported shareholder of the Company filed a putative class action complaint in the U.S. District Court for the District of Maryland. The lawsuit names the Company and Ms. Powers as defendants. On December 14, 2015, the court appointed two lead plaintiffs. The Lead Plaintiffs filed an amended complaint on February 12, 2016, purportedly on behalf of all of those who purchased common stock in NW Bio between January 13, 2014 and August 21, 2015. The amended complaint generally claims that the defendants violated Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934 by making misleading statements and/or omissions on a variety of subjects, including the status and results of the Company’s DCVax trials. The amended complaint seeks unspecified damages, attorneys’ fees, and costs. The Company and Ms. Powers filed a motion to dismiss plaintiffs’ amended complaint on April 12, 2016. The plaintiffs filed an opposition to the motion to dismiss on June 13, 2016. The Company and Ms. Powers filed a reply in support of their motion to dismiss on July 28, 2016. The Company intends to vigorously defend the case.

Shareholder Books and Record Demand

On December 7, 2015, the Company received a letter on behalf of shareholders demanding to inspect certain corporate books and records pursuant to Section 220 of the Delaware General Corporation Law. The demand letter claimed that its purpose was to investigate: (1) allegedly improper transactions, misconduct, and mismanagement by directors and an officer of the Company; (2) the possible breach of fiduciary duty by certain directors and officers of the Company; and (3) the independence and disinterestedness of the Company’s board, to determine whether a pre-suit demand would be necessary before commencing any derivative action on behalf of the Company. The Company has appointed a special committee of its Board of Directors consisting of independent and disinterested directors to investigate the allegations set forth in the demand letter, as well as the allegations asserted in the litigation summarized above.

Item 1A. Risk Factors

Other than the following additional risk factor, the risk factors described in our most recent Annual Report on Form 10-K and other filings continue to apply as described therein:

If we fail to comply with Nasdaq listing rules, or remedy non-compliance, we could be subject to adverse action by Nasdaq

As the Company has reported, on June 24, 2016 the Company received a letter from the Nasdaq Staff notifying the Company that, based upon the closing bid price of the Company’s common stock, $0.001 par value per share (the “Common Stock”) for the 30 consecutive business days preceding receipt of such letter, the Common Stock had no longer met the requirement to maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). On November 7, 2016 the Company also received a letter from the Nasdaq Staff notifying the Company that certain of the Company’s financing transactions did not comply with Nasdaq rules. The Nasdaq Staff had determined to aggregate a series of transactions that were completed with various unrelated parties between May 15, 2016 and October 13, 2016 for purposes of assessing whether the 20% threshold for shareholder approval had been triggered for issuances priced below the applicable market price. These transactions included repricing of existing common stock purchase warrants and issuances of new common shares and common stock purchase warrants. If we fail to comply with Nasdaq’s continued listing standards, we could be delisted and our common stock would then trade, if at all, only on the over-the-counter market, such as the OTCQB or OTCQX markets or the Pink Current information tier. In addition, delisting of our common stock could depress our stock price or limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Further, delisting of our common stock would likely result in our common stock becoming a “penny stock” under the Securities Exchange Act.

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

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not applicable.

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.**
101.INS	XBRL Instance Document.
101.SCH	XBRL Schema Document.
101.CAL	XBRL Calculation Linkbase Document.
101.DEF	XBRL Definition Linkbase Document.
101.LAB	XBRL Label Linkbase Document.
101.PRE	XBRL Presentation Linkbase Document.

* Filed herewith
** Furnished 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: November 10, 2016

By: /s/ Linda F. Powers
Name: Linda F. Powers

Title: President and Chief Executive Officer
Principal Executive Officer
Principal Financial and Accounting Officer