# NORTHWEST BIOTHERAPEUTICS INC

# FORM 10-Q

(Quarterly Report)

Filed 11/19/14 for the Period Ending 09/30/14

Address 4800 MONTGOMERY LANE, BETHESDA, MD, 20814 Telephone (727) 384-2323 CIK 0001072379 Symbol NWBO

SIC Code 2834 - Pharmaceutical Preparations

Fiscal Year 12/31

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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, 2014

#### OR

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

For the transition period from to

#### Commission File Number: 001-35737

#### NORTHWEST BIOTHERAPEUTICS. INC.

(Exact name of registrant as specified in its charter)

Delaware

94-3306718

(State or Other Jurisdiction of Incorporation or Organization)

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

4800 Montgomery Lane, Suite 800, Bethesda, MD 20814

(Address of principal executive offices) (Zip Code)

#### (240) 497-9024

(Registrant's telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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.

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

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

As of November 18, 2014, the total number of shares of common stock, par value \$0.001 per share, outstanding was 62,218,685.

# NORTHWEST BIOTHERAPEUTICS, INC.

# FORM 10-Q

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Part I – Financial Information

# NORTHWEST BIOTHERAPEUTICS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share amount)

		September 30, 2014 (Unaudited)		30, 2014 2		ecember 31, 2013
ASSETS						
Current assets:						
Cash and cash equivalents	\$	1,403	\$	18,499		
Prepaid expenses and other current assets		167		147		
Total current assets		1,570		18,646		
Non-current assets:						
Property and equipment, net		23,914		83		
Deferred financing cost, net		1,230		-		
Interest in Escrow		2,625		-		
Other non-current assets		55		55		
Total non-current assets		27,824		138		
Total assets	\$	29,394	\$	18,784		
LIABILITIES, REDEEMABLE COMMON STOCK AND STOCKHOLDERS' DEFICIT						
Current liabilities:						
Accounts payable (includes related party of \$2,343 and \$3,619 as of September 30, 2014 and						
December 31, 2013, respectively)	\$	11,504	\$	8,937		
Accrued expenses (includes related party of \$8 and \$5 as of September 30, 2014 and Decembe	-	700		0.40		
31, 2013, respectively)		790		842		
Convertible notes, net (includes related party of \$50 and \$50 as of September 30, 2014 and December 31, 2013, respectively)		238		288		
Notes payable - in dispute		230 934		934		
Derivative liability associated with warrants		28,048		8,688		
Interest make-whole derivative		1,783		0,000		
				10.000		
Total current liabilities		43,297		19,689		
Non-current liabilities:						
Convertible notes, net		15,717		-		
Environmental remediation liabilities		1,600		-		
Total non-current liabilities		17,317		-		
<b>*</b> - 10 100		CO C1 4		10.000		
Total liabilities		60,614		19,689		
Redeemable common stock (\$0.001 par value); 0 and 1,444,788 shares issued and outstanding as						
of September 30, 2014 and December 31, 2013, respectively		-		8,913		
Stockholders' deficit:						
Preferred stock (\$0.001 par value); 40,000,000 shares authorized; 0 shares issued and						
outstanding as of September 30, 2014 and December 31, 2013, respectively		-		-		
Common stock (\$0.001 par value); 450,000,000 shares authorized; 62,218,685 and 45,666,315						
shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively		62		46		
Additional paid-in capital		446,744		375,213		
Accumulated deficit		(477,836)		(384,887)		
Cumulative translation adjustment		(11,000)		(22.,007)		
		(190)		(190)		
Total stockholders' deficit		(31,220)		(9,818)		
Total liabilities, redeemable common stock and stockholders' deficit	\$	29,394	\$	18,784		

See accompanying notes to the unaudited condensed consolidated financial statements

# NORTHWEST BIOTHERAPEUTICS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except per share data)

	Three months ended September 30,					Nine months ended September 30,				
		2014		2013		2014		2013		
Revenues:										
Research grants and other	\$	582	\$	400	\$	582	\$	809		
Total revenues		582		400		582		809		
Operating costs and expenses:										
Research and development		22,707		12,794		64,242		32,785		
General and administration		4,137		3,059		11,707		8,819		
Depreciation and amortization		346		3		352		9		
Total operating costs and expenses		27,190		15,856		76,301		41,613		
Loss from operations		(26,608)		(15,456)		(75,719)		(40,804)		
Other income (expense):										
Inducement expense		(8,166)		(7,451)		(18,506)		(7,451)		
Change in fair value of derivatives		14,002		63		1,702		63		
Interest expense		(271)		(66)		(426)		(706)		
Net loss	\$	(21,043)	\$	(22,910)	\$	(92,949)	\$	(48,898)		
Net loss per share applicable to common stockholders - basic										
and diluted	\$	(0.35)	\$	(0.65)	\$	(1.64)	\$	(1.60)		
Weighted average shares used in computing basic and diluted										
loss per share		60,604		35,275		56,838		30,605		

See accompanying notes to the unaudited condensed consolidated financial statements

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

	Commo	on Ste	ock	А	dditional			Cumulative	Total Stockholders'
	Shares		Amount		Paid-in Capital	Subscription Receivable	Accumulated Deficit	Translation Adjustment	Equity (Deficit)
Balance December 31, 2013	45,666	\$	46	\$	375,213	\$-	\$ (384,887)	\$ (190)	\$ (9,818)
Issuance of common stock for cash in a private					-				
placement	32		-		224	-	-	-	224
Conversion of accounts payable to common stock and									
warrants - Cognate	1,482		2		5,925	-	-	-	5,927
Inducement expenses associated with Conversion of accounts payable to common stock and warrants -					2 000				2 000
Cognate	-		-		2,800	-	-	-	2,800
Conversion of note payable and accrued interest to common stock	70				217				217
Proceeds from warrants exercises	70		1		2,691	-	-	-	2,692
Cashless warrants exercises	41		-		2,031				2,052
Redemption of redeemable securities	1.445		1		8.912				8,913
Adjustment for issuance of common stock in 2012	20		-		0,512				-
Offering costs	-				(1)		-		(1)
Issuance of common stock in exchange for services -					(1)				(1)
non-employees	239				1,567				1,567
Stock based compensation - Cognate	5,101		5		2,455				2,460
Net loss	5,101		-		2,435	-	(46,041)	-	(46,041)
Balance as of March 31, 2014	54,818		55		400,003		(430,928)	(190)	(31,060)
Issuance of common stock for cash and overallotment	54,010		33		400,005		(450,520)	(150)	(31,000)
rights	2.273		2		14.998				15.000
Offering costs	-		-		(1,104)		-	-	(1,104)
Proceeds from the issuance of common stock and					(1,104)				(1,104)
warrants in a private placement	259				1,835				1,835
Proceeds from the issuance of common stock and	255				1,000				1,000
warrants - Cognate	563		1		2.249	-	-	-	2.250
Inducement expenses associated with issuance					_,				_,
common stock and warrants for cash - Cognate	-		-		1,525	-	-	-	1.525
Subscription receivable for issuance of common stock	16				125	(125)		-	-,
Proceeds from warrants exercises	92		-		395	-	-	-	395
Cashless warrants exercise	13		-		-	-	-	-	-
Conversion of accounts payable to common stock and									
warrants - Cognate	727		1		2,908	-	-	-	2,909
Inducement expenses associated with issuance of common stock on conversion of accounts payable -									
Cognate	-		-		1,426	-	-	-	1,426
Issuance of common stock for services - non-									
employees	25		-		155	-	-	-	155
Stock based compensation - Cognate	-		-		2,662	-	-	-	2,662
Net loss	-	_	-	_	-	-	(25,865)	-	(25,865)
Balance as of June 30, 2014	58,785		59		427,177	(125)	(456,793)	(190)	(29,872)
Issuance of common stock and warrants for cash	883		1		4,499	-	-	-	4,500
Proceeds from warrants exercises	497		-		1,730	-	-	-	1,730
Conversion of accounts payable to common stock and									
warrants - Cognate	1,986		2		7,943	-	-	-	7,945
Inducement expenses associated with issuance of									
common stock on conversion of accounts payable -									
Cognate	-		-		4,427	-	-	-	4,427
Subscription receivable for issuance of common stock	-		-		-	125	-	-	125
Issuance of common stock for services - non-									
employees	15		-		95	-	-	-	95
Adjustment for issuance of common stock in 2012	52		-		2	-	-	-	2
Stock based compensation - Cognate	-		-		871	-	-	-	871
Net loss			-		-	-	(21,043)		(21,043)
Balance as of September 30, 2014	62,218	\$	62	\$	446,744	<u>\$</u>	<u>\$ (477,836</u> )	<u>\$ (190)</u>	<u>\$ (31,220</u> )

See accompanying notes to the unaudited condensed consolidated financial statements

# NORTHWEST BIOTHERAPEUTICS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited) (in thousands)

	Nine month Septemb	
	2014	2013
Cash Flows from Operating Activities:		+ (40.000)
Net Loss	\$ (92,949) \$	\$ (48,898)
Reconciliation of net loss to net cash used in operating activities:	252	0
Depreciation and amortization	352	9
Amortization of debt discount and accretion on redeemable securities	71	497
Amortization of deferred financing cost	50	-
Change in fair value of derivatives	(1,702)	(63)
Accrued interest converted to common stock	76	-
Accreted interest on convertible promissory note	-	61
Stock-based compensation costs	-	1,350
Non-employee stock based compensation - Cognate	18,656	-
Stock and warrants issued for services	1,819	1,625
Inducement expense	18,506	7,319
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(20)	(26)
Accounts payable and accrued expenses	3,654	1,119
Related party accounts payable and accrued expenses	15,507	13,791
Deposits and other non-current assets	-	17
Net cash used in operating activities	(35,980)	(23,199)
Cash Flows from Investing Activities:		
Purchase of property and equipment, net	(22,332)	(54)
Funding of escrow - convertible notes	(2,625)	-
Cash in custody account		(4,500)
Net cash used in investing activities	(24,957)	(4,554)
Cash Flows from Financing Activities:		( ) ;
Payments on note payable	_	(688)
Proceeds from issuance of notes payable to related parties	-	1,005
Repayment of note payable to related parties	-	(605)
Proceeds from issuance of convertible notes, net of deferred financing cost	16,220	(005)
Repayment of convertible promissory notes	(25)	(209)
Repayment on redeemable securities	(23)	(240)
Proceeds from exercise of warrants	4,817	(240)
Proceeds from the issuance of common stock and warrants - Cognate	2,250	_
Proceeds from issuance common stock and warrants	6,684	24,001
Gross proceeds from issuance common stock and overallotment rights	15,000	24,001
Offering costs	(1,105)	
Net cash provided by financing activities		-
Net cash provided by infancing activities	43,841	23,264
Net decrease in cash and cash equivalents	(17,096)	(4,489)
Cash and cash equivalents at beginning of period	10 400	7 246
	18,499	7,346
Cash and cash equivalents at end of period	<u>\$ 1,403</u>	\$ 2,857

See accompanying notes to the unaudited condensed consolidated financial statements

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

IN	thousands)	

	Nine months ended September 30,			
		2014		2013
Supplemental schedule of non-cash financing activities:				
Issuance of common stock in connection with conversion of notes payable and accrued expenses	\$	165	\$	2,335
Issuance of common stock and warrants in connection with conversion of accounts payable -				
Cognate	\$	16,780	\$	10,302
Reclass of redeemable security to equity	\$	8,913	\$	1,307
Deferred offering cost related to issuance of convertible notes	\$	1,280	\$	-
Initial value of interest make-whole derivative issued in connection with the convertible debt	\$	1,854	\$	-
Environmental remediation liabilities	\$	1,600	\$	-
Fixed assets payable	\$	251	\$	-

See accompanying notes to the unaudited condensed consolidated financial statements

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

# 1. Organization and Description of Business and Recent Developments

Northwest Biotherapeutics, Inc. and its subsidiaries NW Bio Europe S.A.R.L, 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 that are in various phases.

# Recent Developments

On August 19, 2014, the Company completed a private offering of \$17.5 million aggregate principal amount of 5% Senior Secured Convertible Promissory Notes (the "Senior Notes") with an initial conversion price of \$7.30 per share, for total net proceeds to the Company of approximately \$16.2 million after deducting placement agent fees and other expenses. The Company capitalized these placement agent fees as deferred financing cost. The primary purpose of the financing was for expansion of manufacturing capacity for the Company's products in Europe.

On August 19, 2014, the Company completed the acquisition of a facility and property in the U.K ("UK Facility"). The purchase price was £13 million (approximately \$20.8 million, excluding professional fees of \$1.5 million associated with the purchase of the U.K Facility). The facility is an existing building of approximately 65,000 square feet. The Company plans to re-purpose the facility and have it built out as part of the expansion of manufacturing capacity for its products in Europe, potentially doubling the building's square footage. Such re-purposing requires approval of the applicable Planning Commission. If re-purposing is approved, then the specific design and engineering of the proposed build out will also have to be approved. In addition to the facility, the acquisition included about 25 acres of potentially developable land (as well as non-developable land). Any future development for business use will require removal of certain existing structures, permission from the Planning Commission for the intended purpose, and then permission from the Planning Commission for the specific designs and engineering.

On October 6, 2014, the Company entered into a Stock Purchase, Amendment and Issuance Agreement (the "Agreement") with an existing single institutional investor for the sale of 2,272,727 shares of common stock at a purchase price of \$5.05 per share, for a total purchase price of about \$11.5 million. In the Agreement, the Company terminated the investor's existing contractual overallotment purchase right to purchase up to \$17,045,452.50 worth of shares of common stock for \$7.50 per share at any time prior to April 14, 2015, and agreed to issue the purchaser a warrant to purchase up to \$14,085,250.00 worth of shares at an exercise price of \$5.15 per share (2,735,000 warrants) exercisable commencing six months after issuance and with an exercise period of 30 months. The offering closed on October 9, 2014.

On November 17, 2014, the Company entered into a private offering of \$25 million of unregistered shares of common stock of the Company, at a price of \$5.79 per share (the closing price of the stock on November 14, 2014, the trading day prior to the sale of shares). The shares were purchased by C.F. Woodford Equity Income Fund of the U.K. The Company plans to use the proceeds to expand and accelerate its clinical trial programs, including expansion of the Phase III trial of DCVax-L for GBM brain cancer, undertaking at least two simultaneous Phase II trials of DCVax-Direct in two different cancers, as well as building its Hospital Exemption program and other early access programs. The Company agreed to file a registration statement within two weeks after the closing, and to use best efforts to complete the registration within sixty days thereafter. There are no warrants, overallotment rights, pre-emptive rights or other securities or rights entitling the investor to purchase or obtain additional shares.

Also on November 17, 2014, the Company completed a \$10 million mortgage secured solely by the UK facility and property. The Company plans to use the proceeds in connection with its expansion of manufacturing capacity in Europe. The mortgage has a term of 2 years, interest only payments until maturity, and an interest rate of 12%.

# 2. Liquidity and Financial Condition

During the nine months ended September 30, 2014, the Company used approximately \$36.0 million of cash in its operating activities including one-time expenditures relating to the clinical trials and to certain initial costs for new manufacturing capacity in Europe. The Company incurred an aggregate combined cash and non-cash loss of \$92.9 million for the nine months ended September 30, 2014, including \$37.8 million of non-cash charges associated with stock based compensation, a mark to market charge for the change in the fair value of its derivative liability, and inducement expenses related to the exchange of Cognate accounts payable for common stock and warrants.

The Company had current assets of \$1.6 million as of September 30, 2014, and current assets less accounts payable and accrued expenses and notes payable of approximately negative \$11.9 million at September 30, 2014. The accounts payable and notes payable include an aggregate of \$2.4 million of trade liabilities and convertible notes owed by the Company to related parties.

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

On August 13, 2014, the Company entered into a purchase agreement with Oppenheimer & Co. Inc, with respect to the Company's issuance and sale of \$17.5 million aggregate principal amount of the Senior Notes due on August 15, 2017 (the "Notes"). The offering of the Notes was completed on August 19, 2014. See Note 7.

Because of recurring operating losses, net operating cash flow deficits, and an accumulated deficit there is substantial doubt about the Company's ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might become necessary should the Company be able to continue as a going concern.

# 3. Summary of Significant Accounting Policies

# **Basis of Presentation**

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

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

#### **Recently Issued Accounting Standards**

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

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



The FASB has issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* The guidance, which is effective for annual reporting periods ending after December 15, 2016, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and when going-concern disclosures would be required under U.S. GAAP. The Company has elected to early adopt the provisions of ASU 2014-15 in connection with the issuance of these unaudited condensed consolidated financial statements. Management's evaluation regarding the events and conditions that raise substantial doubt regarding the Company's ability to continue as a going concern have been disclosed in Note 2.

#### **Use of Estimates**

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

#### **Embedded Derivatives**

The Company has issued financial instruments such as debt in which a derivative instrument is "embedded." Upon issuing the financial instrument, the Company assesses whether the economic characteristics of the embedded derivative are clearly and closely related to the economic characteristics of the remaining component of the financial instrument (i.e., the host contract) and whether a separate, non-embedded instrument with the same terms as the embedded instrument would meet the definition of a derivative instrument. When it is determined that (1) the embedded derivative possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract and (2) a separate, stand-alone instrument with the same terms would qualify as a derivative instrument, the embedded derivative is separated from the host contract and carried at fair value, with changes in fair value recorded in the consolidated statements of operations. The convertible notes contain an interest make-whole payment provision pursuant to which holders who convert their notes prior to maturity will receive, all interest due through the term of the note. Under ASC 815-10-15-74(a), the interest make-whole payment is considered an embedded derivative and is separated from the host contract, the convertible notes are carried at fair value. As of September 30, 2014, the carrying amount of embedded derivatives associated with the convertible notes was approximately \$1.8 million.

#### **Property and Equipment**

Property and equipment are stated at cost. Depreciation and amortization are provided for using straight-line methods, in amounts sufficient to charge the cost of depreciable assets to operations over their estimated service lives. Repairs and maintenance costs are charged to operations as incurred.

#### **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 reduction in the liability resulting from the completion of the clean-up is included in other income. As of August 20, 2014 and September 30, 2014, we estimate that the total environmental remediation costs associated with the purchase of the UK Facility will be approximately \$1.6 million. Contamination clean-up costs that improve the property from its original acquisition state are 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 of approximately \$1.6 million. The Company computed its preliminary estimate of 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 \$1.0 million, and (ii) a lower probability requirement of having to excavate the affected area at an estimated cost of approximately \$20 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 discussed herein.

#### Impairment of Long-lived assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In performing a review for impairment, the Company compares the carrying value of the assets with their estimated future undiscounted cash flows from the use of the asset and eventual disposition. If the estimated undiscounted future cash flows are less than carrying value, an impairment loss is charged to operations based on the difference between the carrying amount and the fair value of the asset.

# **Deferred Financing Costs, net**

The Company capitalizes costs related to the issuance of debt which are included on the accompanying consolidated balance sheets. Deferred financing costs are amortized using a method that approximates the interest method over the life of the related loan and are included as a component of interest expense on the accompanying consolidated statements of operations. The Company recorded

\$1.2 million of deferred financing costs related to convertible notes issued in August 2014 as of September 30, 2014, netted by accumulated amortization expense of \$0.05 million for the three months ended September 30, 2014.

#### **Non-Employee Stock Based Compensation**

The Company accounts for stock based compensation awards issued to non-employees for services, as prescribed by ASC 505, at either the fair value of the services or the instruments issued in exchange for such services (based on the same methodology described for employee stock based compensation), whichever is more readily determinable. Subsequent to the measurement date, the Company recognizes and classifies any future changes in the fair value in accordance with the relevant accounting literature on financial instruments ASC 815-40.

#### **Research and Development Costs**

Research and development costs are charged to operations as incurred and consist primarily of clinical trial costs for the Company's Phase III and Phase I/II clinical trials, related party manufacturing costs, consulting costs, contract research and development costs, and compensation costs.

For overall clinical trial costs for the three months ended September 30, 2014, the Company recognized cash research and development costs of \$14.7 million and combined aggregate cash and non-cash research and development costs of \$22.7 million. For the nine months ended September 30, 2014, the Company recognized cash research and development costs of \$45.4 million, and combined aggregate cash and non-cash research and development costs of \$45.4 million, and combined aggregate cash and non-cash research and development costs of \$45.4 million, and combined aggregate cash and non-cash research and development costs of \$45.4 million.

For overall clinical trial costs for the three months ended September 30, 2013, the Company recognized cash research and development costs of \$12.75 million and combined aggregate cash and non-cash research and development costs of \$12.8 million. For the nine months ended September 30, 2013, the Company recognized cash research and development costs of \$32.6 million, and combined aggregate cash and non-cash research and development costs of \$32.6 million, and combined aggregate cash and non-cash research and development costs of \$32.8 million.

For the three months ended September 30, 2014, the Company made cash payments of approximately \$1.4 million to Cognate and owed Cognate \$2.3 million for services performed by Cognate (including manufacturing for both the Phase III and Phase I/II clinical trials, ongoing product and process development, expansion of several company programs and services related to expansion of manufacturing capacity). For the three months ended September 30, 2014, the Company recorded combined cash and non-cash expenses related to services performed by Cognate of \$16.9 million.

For the nine months ended September 30, 2014, the Company made cash payments of approximately \$12.8 million to Cognate and owed Cognate \$2.3 million for the services performed by Cognate.

For the three months and nine months ended September 30, 2013, the Company made cash payments of approximately \$1.4 million and \$7.4 million, respectively for the services performed by Cognate. For the three months and nine months ended September 30, 2013, the Company recorded combined cash and non-cash expenses of \$8.6 and \$19.2 million, respectively, related to the services performed by Cognate.

#### **Comprehensive Loss**

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

# 4. Fair Value Measurements

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In determining fair value, the Company uses various methods including market, income and cost approaches. Based on these approaches, the Company often utilizes certain assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated, or generally unobservable inputs. The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs. Based on the observability of the inputs used in the valuation techniques the Company is required to provide the following information according to the fair value hierarchy. The fair value hierarchy ranks the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1 — Quoted prices for identical assets and liabilities traded in active exchange markets, such as the New York Stock Exchange.

Level 2 — Observable inputs other than Level 1 including quoted prices for similar assets or liabilities, quoted prices in less active markets, or other observable inputs that can be corroborated by observable market data. Level 2 also includes derivative contracts whose value is determined using a pricing model with observable market inputs or can be derived principally from or corroborated by observable market data.

Level 3 — Unobservable inputs supported by little or no market activity for financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation; also includes observable inputs for nonbinding single dealer quotes not corroborated by observable market data.

The Company has various processes and controls in place to ensure that fair value is reasonably estimated. A model validation policy governs the use and control of valuation models used to estimate fair value. The Company performs due diligence procedures over third-party pricing service providers in order to support their use in the valuation process. Where market information is not available to support internal valuations, independent reviews of the valuations are performed and any material exposures are escalated through a management review process.

While the Company believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

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, 2014 and December 31, 2013 (in thousands):

	Fair value measured at September 30, 2014									
	Quoted prices in									
		active Significant other								
		value at ember 30,		markets	observable	inputs		inputs		
		2014		(Level 1)	(Level 2	2)		(Level 3)		
Warrant liability	\$	28,048	\$	-	\$	-	\$	28,048		
Interest make-whole derivative		1,783		-		-		1,783		
Total	\$	29,831	\$	-	\$	-	\$	29,831		

	F	air value measure	ed at December 31, 201	.3
		Quoted prices in		
		active	Significant other	Significant unobservable
	Fair value at December 31,	markets	observable inputs	inputs
	2013	(Level 1)	(Level 2)	(Level 3)
Warrant liability	\$ 8,688	\$	- \$ -	\$ 8,688

There were no transfers between Level 1, 2 or 3 during the nine month period ended September 30, 2014.

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

	Derivative Liability				
	Interest Warrant				
	Make-Whole		Liability		Total
Balance – December 31, 2013	\$	- \$	8,688	\$	8,688
Additions during the period		-	7,952		7,952
Total unrealized losses include in net loss		-	16,984		16,984
Balance – March 31, 2014		-	33,624		33,624
Additions during the period		-	2,138		2,138
Total unrealized gains include in net loss		-	(4,684)		(4,684)
Balance – June 30, 2014		-	31,078		31,078
Additions during the period	1,85	4	10,901		12,755
Total unrealized gains include in net loss	(7	1)	(13,931)		(14,002)
Balance – September 30, 2014	\$ 1,78	3 \$	28,048	\$	29,831

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

# <u>Warrant Liability</u>

Risk-free rate

Contractual term (years)

Marranta issuence data		2014	January 2	17, _	anuary 31,		oruary 3,	E a bassa		4 Mauria 7	1 2014		Tabal
Warrants issuance date	January 6		2014		2014		2014	Februa	ry 28, 2014		31, 2014		Total
Number of warrants issued	1	139	2	2,434	143		119		195	5	145		3,175
Fair value of warrants at	<i>*</i>	200	÷ -	F01 +	202	÷	227	÷	0.4		F 0 0		7 05 2
issuance date	\$	308	\$ 5	5,501 \$	383	\$	327	\$	844	4 \$	589	\$	7,952
Warrants issuance date				۵n	ril 30, 2014	May	30, 2014	lune	30, 2014	Tot	al		
Number of warrants issued	1			<u></u>	171	may	193	June	281		645		
Fair value of warrants at is	-			\$	527	\$	621	\$	990	\$	2,138		
Tail value of warrants at is	suance uate			Ą	527	Ą	021	P	990	æ	2,130		
Warrants issuance date					July 1, 2014	July 1	17, 2014	August 2	1, 2014 5	September :	1, 2014		Total
Number of warrants issued	l			_	473		2,325		329	•	320		3,447
Fair value of warrants at is	suance date			\$	5 1,671	\$	7,162	\$	1,071 \$	5	997	\$	10,901
Date of valuation	January 6,	2014	January 1	7, 2014	January 31,	2014	February	y 3, 2014	Februa	ary 28, 20	14 Ma	rch 3	31, 2014
Dividend yield (per			-										
share)		0%		0%	)	0%	6	(	0%		0%		0%
Strike price	\$	4.00	\$	4.00	\$	4.00	\$	4.00	D \$	4.	00	\$2.4	0 - \$6.00
Volatility (annual)		92.13%		93.12%	)	96.72%	6	91.79	9%	105.	03% 7	4.439	%-88.03%
Risk-free rate		1.73%		1.66%	)	1.55%	6	1.49	9%	1.	49%		1.73%
Contractual term (years)		5.0		5.0		5.00		5.00	0	5.	00	4	4.33-4.85
Date of valuation					A	oril 30,	2014	May 30,	2014	June 30,	2014		
Dividend yield (per share)							0%		0%		0%	5	
Strike price					\$		4.00 \$		4.00	\$	4.00		
Volatility (annual)							84.18%		83.48%	79.79%-	82.90%		
Risk-free rate							1.74%		1.52%	1.62%	5-1.64%		
Contractual term (years)							5.0		5.0		5.00		
							August 1	•					
Date of valuation			July 1	, 2014	July 17, 20		2014		eptember		Septem	ber	30, 2014
Dividend yield (per share)				0%		0%		0%		0%			0%
Strike price			\$	3.35		3.35 \$		3.35 \$		4.00	\$		4.00
Volatility (annual)				79.97%	78	3.25%	74	4.45%		85.73%			70.89%

13

1.71%

5.0

1.67%

5.00

1.63%

5.00

1.78%

5.00

1.62%

5.0

#### Make-whole interest

	August 19,	
Date of valuation	2014	September 30, 2014
Contractual discount rate	2%	2%
Volatility (annual)	69.67%	69.70%
Risk-free rate	0.89%	1.07%
Contractual term (years)	3	2.9
Make-whole interest issuance date	August 19, 2014	
Fair value of make-whole interest at issuance date	\$1,854	

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

# 5. Stock-based Compensation

#### Stock Based Compensation to Non-employees

Stock-based compensation awards granted to non-employees are recognized over the related service period. The Company believes that the fair values of the stock-based awards is more reliably measurable than the fair value of the services received. The fair value of these awards are calculated at each reporting date. On January 17, 2014, in connection with the four Cognate Agreements, the Company issued one-time initiation payments of 5,101,366 shares of common stock. The common stock is vesting over thirty six months from the closing date. Stock-based compensation expense related to Cognate was \$0.9 million and \$6.0 million for the three and nine months ended September 30, 2014. Approximately \$2.0 million in compensation costs per calendar quarter may be recognized over the next 2.30 years based on the fair market value of stock of \$5.03.

The Company also entered into a Lock-Up Agreement with Cognate on January 17, 2014, under which Cognate agreed to have all of the shares that are issued as part of the Cognate Agreements ("Lock-Up Shares") locked up for up to 36 months, in return for 15% warrant coverage for each 6-month period of lock-up, on the same terms as the warrants in the Cognate Agreements. The parties had previously agreed on such lock-ups in July, 2013. During the lock-ups, the Lock-Up Shares may not be sold or traded on the market. These lock-up terms are subject to the same most favored nation treatment as provided in the Cognate Agreements as described in Note 1. On July 17, 2014, the Company issued 2,325,467 warrants. The warrants had a term of 5.0 years and an initial exercise price of \$4.00. Using a Monte Carlo simulation model, the Company valued the warrants at \$3.08 and \$2.38 per share on July 17, 2014 and September 30, 2014, respectively. The fair value of the warrants granted is based on the Monte Carlo simulation model using the following assumptions:

Date of valuation	July	17, 2014	Septer	mber 30, 2014
Dividend yield (per share)		0%		0%
Strike price	\$	3.35	\$	4.00
Volatility (annual)		78.25%		70.89%
Risk-free rate		1.71%		1.78%
Contractual term (years)		5.00		5.00

The Company has evaluated the terms of the warrants with reference to the guidance provided in ASC 815-40-15. The Company has concluded that these warrants are not indexed to the Company's own stock due to the most favored nation provision. Therefore, these warrants have been classified as a derivative liability as of July 17, 2014 and September 30, 2014.

### 6. Property and Equipment

Property and equipment consist of the following at September 30, 2014 and December 31, 2013 (in thousands):

	September 3 2014	),	December 31, 2013
Leasehold improvements	\$	69 \$	69
Office furniture and equipment		25	25
Computer equipment and software	1	37	137
Property	24,2	83	-
	24,4	14	231
Less: accumulated depreciation	(5	00)	(148)
	\$ 23,9	14 \$	83

Depreciation expense was approximately \$0.4 million for the nine months ended September 30, 2014. The Company also capitalized a \$1.6 million environmental liability addition to the UK Facility land in August 2014. The building is currently under construction and the Company will incur various development costs in the future.

#### 7. Notes Payable

#### **2014 Convertible Senior Notes**

#### Overview

On August 19, 2014, the Company completed a private offering of \$17.5 million aggregate principal amount of Senior Notes with an initial conversion price of \$7.30 per share, for total net proceeds to the Company of approximately \$16.2 million after deducting placement agent fees and other expenses. The Company capitalized these placement agent fees as deferred financing cost.

The Senior Notes are due on August 15, 2017, and are not convertible during the first three months, unless the current stock price is greater than 150% of the conversion price. Thereafter, the Senior Notes are convertible at any time. Pursuant to a one-time potential price reset provision, the conversion price may be reset as described below. The initial investors have a 3-month right to purchase an additional 30% on the same terms and conditions as the initial purchase. The Company deposited approximately \$2.6 million from the total proceeds in an escrow account. The escrow account will contain an amount of highly liquid securities sufficient to fund, when due, the total aggregate amount of the six scheduled semi-annual interest payments on the notes, excluding additional interest.

#### Conversion Price and Interest Make Whole

Pursuant to a one-time potential price reset provision, on February 15, 2015, the initial conversion price of \$7.30 shall be reset ("Reset") to the lower of (a) the initial conversion price or (b) 110% of the common stock price on the 10 trading days ending on February 15, 2015, but such adjustment will not be more than a 20% decrease from \$7.30. Additionally, the conversion price will be adjusted if the Company issues to all or substantially all of its stockholders any equity or convertible debt at a purchase price that is less than the current exercise price or in certain fundamental transactions, with certain exceptions. The conversion price will also adjust on any subsequent issuance of shares of common stock or common stock equivalents based on a formula intended to maintain the fully diluted percentage ownership on an "if converted" basis. The Company determined that the Reset is an input to the fair value of a "fixed-for-fixed" conversion option. As a result this conversion option is indexed to the Company's own stock.

The convertible notes contain an interest make-whole payment provision pursuant to which holders who convert their notes prior to maturity will receive, all interest due through the term of the note. Under ASC 815-10-15-74(a), the interest make-whole payment is considered an embedded derivative and is separated from the host contract, the convertible notes are carried at fair value. As of September 30, 2014, the carrying amount of embedded derivatives associated with the convertible notes was approximately \$1.8 million.

#### Summary of Key Terms

lssuer:	Northwest Biotherapeutics, Inc. (the "Company")
Ticker / Exchange for Common Stock:	NWBO Nasdaq Common Market (the "NASDAQ")
Pricing Date:	August 13, 2014
Trade Date:	August 14, 2014
Closing Date:	August 19, 2014
Notes:	5% Senior Convertible Notes due 2017
Aggregate Principal Amount Offered:	\$17.5 million
Issue Price:	100%, plus accrued interest, if any, from the Closing Date
Maturity:	August 15, 2017
Interest Rate:	5% per annum

Interest Payment:	February 15 and August 15, commencing February 15, 2015
Conversion Premium:	10% above the last reported sale price of our common stock on August 13, 2014
Conversion Price:	Approximately \$7.30 per share
Initial Conversion Ratio:	136.9113 shares of common stock per \$1,000 principal amount of notes
Conversion Price Reset:	The conversion price shall be reset to the lower of (a) the initial conversion price or (b) 110% of the common stock price on the 10 trading days ending on February 15, 2015. However, in no event shall the reset conversion price be lower than 80% of the initial conversion price, subject to customary adjustments.
Convertibility:	The Notes are not convertible during the first three months, unless the current stock price is greater than 150% of the conversion price. Thereafter, the Notes are convertible at anytime
Addition Purchase Right:	The initial investor shall have a 3 month right to purchase an additional 30% at the same terms and conditions as the initial purchase.
Make Whole Provision:	In addition, holders of the Notes who convert their Notes after February 15, 2015 will receive an additional payment. The additional payment shall equal the unpaid interest payments on the bonds through August 15, 2017. We will satisfy our obligation to pay any additional payment in shares of our common stock, without a cash payment in lieu of any fractional shares. We may elect to pay such payment in cash.
	Notwithstanding the foregoing, the number of shares we may deliver in connection with a conversion of notes, including those delivered in connection with the additional payment described above, will not exceed 150.6024 shares per \$1,000 principal amount of notes, subject to adjustment at the same time and in the same manner as the conversion rates as set forth under "Description of the Notes - Conversion Rate Adjustments."
	If we pay such addition payment, the number of shares of common stock a holder will receive will be that number of shares equal to the amount of the additional payment to be paid to such holder, divided by the current conversion price
	Notwithstanding the forgoing, if in connection with any conversion the conversion rate is adjusted as described under "Adjustment to Conversion Rate Upon Conversion Upon a Make- Whole Fundamental Change" in the Offering Memorandum, then such holder will not receive the additional payment with respect to such note.
Record Dates:	February 1 and August 1

#### Debt Discount

As of September 30, 2014, the debt discount associated with the convertible debt was approximately \$1.8 million. This debt discount was a result of the make-whole interest derivative, and will be amortized over the term of convertible note. There was no beneficial conversion feature associated with this transaction.

#### **Other Notes Payable**

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

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

	September 30, 2014	December 31, 2013
Notes payable - current		
12% unsecured orginally due July 2011 - in dispute (1)	934	934
	934	934
Convertible notes payable, net - current		
6% unsecured (2)	135	160
8% unsecured note due 2014 (3)	53	53
	188	213
Convertible Notes payable related party, net - current		
6% due on demand (4)	50	75
	50	75
Convertible notes payable, net of debt discount of \$1,783 as of So 2014 - non-current	eptember 30,	
5% secured due 2017	15,717	-
	15,717	-
Total notes payable, net	¢ 16.990	¢ 1.000
iotal notes payable, net	\$ 16,889	\$ 1,222

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

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

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

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

#### 8. Net Loss per Share Applicable to Common Stockholders

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

		For the nine months ended September 30,	
	2014	2013	
Common stock options	1,551	1,551	
Over-allotment rights	2,273	-	
Common stock warrants - equity treatment	14,134	15,321	
Common stock warrants - liability treatment	12,555	2,233	
Convertible notes	2,479	127	
Excluded potentially dilutive securities	32,992	19,232	

#### 9. Related Party Transactions

#### Cognate BioServices

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

other remedies. The fees are based on the stage at which the shut down or suspension occurs:

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

For the three and nine months ended September 30, 2014, the Company made net disbursements to Cognate of approximately \$1.4 million and \$12.7 million, respectively, including charges relating to manufacturing for both the Phase III and Phase I/II clinical trials, ongoing product and process development, and expansion of several Company programs under these service agreements.

As of September 30, 2014 and December 31, 2013, the Company owed Cognate (including third party sub-contract amounts) approximately \$2.3 million and \$3.6 million, included in accounts payable related party, respectively.

#### Cognate Accounts Payable Conversions and inducement charge -Nine months ended September 30, 2014

Under the July 2013 Conversion and Lock-up Agreement, for the nine months ended September 30, 2014, \$16.8 million in accounts payable due to Cognate was converted into common stock and warrants. 4.2 million shares of common stock were issued based on an above-market \$4.00 per share conversion price while the closing market price was \$3.55 on July 31, 2013. 50% warrant coverage of the common stock issued, resulting in 2.2 million warrants issued with an initial exercise price of \$4.00. The shares and warrants are subject to most favored nation treatment with respect to the terms (including in regards to warrants) provided to any other investors or creditors, including share issuances upon the exercise of previously issued derivative securities.

The fair value of the shares was based upon the closing stock price of the stock on the date of conversion and in aggregate was approximately \$25.5 million (\$6.07 per share) without factoring in a discount in value for the 36-month lock-up at inception. The fair value of the warrants was based on the Monte Carlo simulation model, the inputs of which are disclosed in Note 4 and was approximately \$7.3 million. The Company recorded an \$16.0 million of inducement expense in connection with these transactions.

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

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

#### Cognate common stock purchase and inducement charge -Nine months ended September 30, 2014

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

#### **10. Redeemable Common Stock**

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

# 11. Stockholders' Deficit

#### **Common Stock Issuances**

### <u>First Quarter 2014</u>

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

During the quarter ended March 31, 2014, the Company issued 5,101,366 shares of common stock to Cognate as stock based compensation vesting over 36 months. The fair value of the common stock recognized was \$2.5 million during the three months ended March 31, 2014.

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

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

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

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

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

#### Second Quarter 2014

On April 9, 2014, the Company entered into a Securities Purchase Agreement with a single institutional investor for the sale of 2,272,727 shares of common stock at a purchase price of \$6.60 per share, for a total purchase price of \$15.0 million. Additionally, from the date of the closing until one year after the closing date, the investor had a non-transferable over-allotment right to purchase up to 2,272,727 additional shares of common stock at a price per share of \$7.50, for an additional subscription amount of up to \$17.05 million. This over-allotment right was cancelled on October 9, 2014. See Note 12 for further explanation.

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

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

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

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

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

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

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

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

#### Third Quarter 2014

During the quarter ended September 30, 2014, the Company entered into a Securities Purchase Agreement with an individual investor for the sale of 435,202 shares of restricted common stock at purchase price of \$5.17 per share and 448,207 shares of restricted common stock at a purchase price of \$5.02 per share, for aggregate proceeds of \$4.5 million. Additionally, the Company also agreed to reset the expiration date of the investor's 1,398,625 warrants to September 15, 2018. The modification of the warrants in connection with this transaction was accounted for as a component of equity. During the quarter ended September 30, 2014, the Company issued an aggregate of 497,133 shares of common stock from the exercise of warrants previously issued. The Company received proceeds of \$1.7 million from the exercise of these warrants.

During the quarter ended September 30, 2014, the Company converted accounts payable due to Cognate of approximately \$7.9 million into 1,986,205 shares of common stock and 1.1 million warrants. The Company recorded \$4.5 million of inducement expense associated with the issuance of the common shares. In addition, as noted in Note 4, the warrants were valued at \$3.8 million at the date of issuance, resulting in a total inducement charge for the quarter of \$8.3 million.

During the quarter ended September 30, 2014, the Company issued an aggregate of 14,519 shares of common stock in exchange for consulting services. The fair value of the common stock recognized was \$94,999.

On August 12, 2014, the Company issued 3,013 common shares at a purchase price of \$5.60 per share and 1,507 warrants to an individual investor. The proceeds of \$15,000 were received by the Company in August 2012. Therefore the Company made a reclassification between additional paid-in-capital and common stock par value during the quarter ended September 30, 2014, and the excess amount of \$1,873 were recorded as interest expense.

On September 19, 2014, the Company issued 49,107 shares of common stock at purchase price of \$5.60 per share and 14,732 warrants to an individual investor. The proceeds of \$275,000 were received by the Company in August 2012. Therefore the Company made a reclassification between additional paid-in-capital and common stock par value during the quarter ended September 30, 2014.

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# Stock Purchase Warrants

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

		Weighted
	Number of	Average
	Warrants	Exercise Price
Outstanding as of December 31, 2013	20,116	\$ 5.23
Warrants issued in connection with conversion of Cognate accounts payable*	741	4.00
Warrants issued in exchange for services*	2,434	4.00
Warrants issued in connection with common stock issued	150	5.00
Warrants exercised on a cashless basis	(73)	-
Warrants exercised for cash	(722)	3.66
Expired in first quarter of 2014	(6)	9.54
Outstanding as of March 31, 2014	22,640	5.12
Warrants issued in connection with conversion of Cognate accounts payable*	364	4.00
Warrants issued to Cognate in connection with common stock issued for cash*	281	4.00
Warrants exercised for cash	(90)	4.25
Over-allotment rights issued in connection with registered direct offering	2,273	7.50
Warrants issued to placement agent in connection with registered direct offering	113	8.25
Outstanding as of June 30, 2014	25,581	5.32
Warrants issued in connection with conversion of Cognate accounts payable*	1,121	4.00
Warrants issued to Cognate for services*	2,326	4.00
Warrants issued for services	17	6.33
Warrants exercised for cash	(497)	3.48
Expired in third quarter of 2014	(1)	7.63
Adjustment related to prior issued warrants	415	6.44
Outstanding as of September 30, 2014 **	28,962	\$ 4.90

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

\*\* Approximately 9,622,907 warrants issued to Cognate, during the six year period from 2008 through 2014, with a weighted average exercise price and remaining contractual term of \$3.00 and 3.8 years, respectively. The weighted average exercise price gives effect to adjustments related to the most favored nation clause that occurred during the period.



#### **12. Subsequent Events**

On October 6, 2014, the Company entered into a Stock Purchase, Amendment and Issuance Agreement (the "Agreement") with an existing single institutional investor for the sale of 2,272,727 shares of common stock at a purchase price of \$5.05 per share, for a total purchase price of about \$11.5 million. In the Agreement, the Company terminated the investor's existing contractual overallotment purchase right to purchase up to \$17,045,452.50 worth of shares of common stock for \$7.50 per share at any time prior to April 14, 2015, and agreed to issue the purchaser a warrant to purchase up to \$14,085,250.00 worth of shares at an exercise price of \$5.15 per share (2,735,000 warrants) exercisable commencing six months after issuance and with an exercise period of 30 months. The offering closed on October 9, 2014.

On November 12, 2014, the Board approved the issuance of 10,577,176 restricted stock units ("RSUs") to employees and Board members of the Company, pursuant to the equity compensation plan approved by shareholders in December 2013. These are the first such equity awards to employees in 3.7 years, since June, 2011, and are also the first such awards to Board members. These RSUs will vest on various dates over a period of 5 years, and will also be subject to both service and performance conditions.

On November 12, 2014, the Board approved the issuance of 8,052,092 shares of common stock to Cognate for services and most favored nation provisions in accordance with the Cognate agreements.

On November 12, 2014, the Board approved the issuance of 3,812,555 warrants to Cognate for services and most favored nation provisions in accordance with the Cognate agreements. The warrants will have a term of 5.0 years and an initial exercise price of \$4.00, and will be subject to a most favored nation provision.

On November 17, 2014, the Company entered into a private offering of \$25 million of unregistered shares of common stock of the Company, at a price of \$5.79 per share (the closing price of the stock on November 14, 2014, the trading day prior to the sale of shares). The shares were purchased by C.F. Woodford Equity Income Fund of the UK. The Company plans to use the proceeds to expand and accelerate its clinical trial programs, including expansion of the Phase III trial of DCVax-L for GBM brain cancer, undertaking at least two simultaneous Phase II trials of DCVax-Direct in two different cancers, as well as building its Hospital Exemption program and other early access programs. The Company agreed to file a registration statement within two weeks after the closing, and to use best efforts to complete the registration within sixty days thereafter. There are no warrants, overallotment rights, pre-emptive rights or other securities or rights entitling the investor to purchase or obtain additional shares.

Also on November 17, 2014, the Company completed a \$10 million mortgage secured solely by the UK facility and property. The Company plans to use the proceeds in connection with its expansion of manufacturing capacity in Europe. The mortgage has a term of 2 years, interest only payments until maturity, and an interest rate of 12%.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes to those statements included with this report. In addition to historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected. The words "believe," "expect," "intend," "anticipate," and similar expressions are used to identify forward-looking statements, but some forward-looking statements are expressed differently. Many factors could affect our actual results, including those factors described under "Risk Factors" in our Form 10-K for the year ended December 31, 2013 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 both the United States and Europe.

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

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

#### **Critical Accounting Policies and Estimates**

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

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

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

#### **Results of Operations**

#### **Operating costs:**

Operating costs and expenses consist primarily of research and development expenses, including clinical trial expenses which increase when we are actively participating in clinical trials and are especially high when we are in a large ongoing international phase III trial (as we now are). Such costs have increased and will continue to increaseas we bring on an additional clinical trial programs which under way in parallel (as we have with our 60-patient Phase I/II trial with DCVax-Direct for all types of inoperable solid tumors), and general and administrative expenses. Such expenses also increase in later stage trials (such as our ongoing Phase III trial) as we begin to prepare for commercialization, which involves process optimization, validation and scale-up. The associated administrative expenses increase as such operating activities grow.

Our operating costs include ongoing development work relating to the DCVax-Direct product and its manufacturing, such as the design, engineering, sourcing, production, testing, modification and validation of the manufacturing 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.

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

#### Research and development:

Discovery and preclinical research and development expenses include costs for substantial external scientific personnel, technical and regulatory advisers, and others, costs of laboratory supplies used in our internal research and development projects, travel, regulatory compliance, and expenditures for preclinical and clinical trial operation and management when we are actively engaged in clinical trials.

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

#### General and administrative:

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

#### Three Months Ended September 30, 2014 and 2013

We recognized a net loss of \$18.2 million in cash outlays and \$2.8 million in non-cash accounting charges (including increase in stockbased compensation, inducement expense and the issuance of warrants), for a combined (cash and non-cash) total net loss of \$21.0 million for the three months ended September 30, 2014 compared to a net loss of \$22.9 million for the three months ended September 30, 2013. This decrease was primarily attributable to unrealized gain from revaluation of our outstanding derivative liabilities as of September 30, 2014 due to the decrease of stock price on the revaluation date compared with the issuance date.

#### Research and Development Expense

Research and development expense was a combined (cash and non-cash) total of \$22.7 million for the three months ended September 30, 2014 compared to \$12.8 million for the three months ended September 30, 2013. The increase was primarily attributable to costs associated with launching, manufacturing for, and conducting (including CRO costs) the Phase III DCVax-L trial in Europe and the Phase I/II DCVax-Direct, which were just beginning as of this period last year, as well as expansion of the our German subsidiary and its operations, expansion of the ongoing Phase III trial in the U.S. and expansion of the manufacturing capacity for our products in Europe.

As of September 30, 2014, we had over 60 clinical trial sites in operation in the U.S and Europe in our Phase III trial with DCVax-L, compared to about 50 clinical trial sites in the U.S and 1 European site at September 30, 2013.

#### General and Administrative Expense

General and administrative expense included \$1.0 million of cash expenses, and \$3.1 of non-cash charges (i.e. amortization of previously issued stock based compensation and restricted stock and warrants issued for services), for a combined cash and non-cash total of \$4.1 million for the three months ended September 30, 2014 compared to \$3.1 million for the three months ended September 30, 2013. The increase in general and administrative expenses from the prior period is a result of increased in legal expenses of \$1.0.

#### Change in fair value of derivatives

During the three months ended September 30, 2014 and September 30, 2013 we recognized a non-cash gain on derivative liabilities of \$14.0 million and \$0.06 million, respectively, due primarily to the change in value of the warrants issued to Cognate in connection with the extinguishment of accounts payable.

#### Inducement expense

During the three months ended September 30, 2014 and September 30, 2013 we recognized an inducement expense of \$8.2 million and \$7.5 million, respectively. The increase in the inducement expense for the three months ended September 30, 2014 was related to an increase of the conversion of accounts payable to common stock and warrants to Cognate in connection with the extinguishment of accounts payable, and the fair value of the common stock and warrants were higher than the conversion price.

#### Interest (Expense)

Interest expense (including non-cash elements such as amortization of debt discount) increased to \$0.3 million for the three months ended September 30, 2014 from \$0.07 million for the three months ended September 30, 2013. The increase in interest expense is primarily related to the issuance of senior convertible notes with an aggregate principal amount of \$17.5 million at 5% annual interest rate.

#### Nine Months Ended September 30, 2014 and 2013

During the nine months ended September 30, 2014, we recognized a net loss of \$55.1 million in cash outlays (net of \$2.3 million in cash received from Cognate in return for common stock and warrants) and \$37.8 million in cash and non-cash accounting charges (including increase in stock-based compensation, inducement expense and the issuance of warrants), for a combined (cash and non-cash) total net loss of \$92.9 million compared to a net loss of \$48.9 million for the nine months ended September 30, 2013. This increase was primarily attributable to an increase in research and development expense associated with expanding our existing Phase III clinical trial with DCvax-L, expanding and accelerating Phase I/II clinical trial with DCVax-Direct, expanding our German subsidiary and UK operations, initial arrangements for expanding our manufacturing capacity in Europe, and an increased inducement expense related to issuance of derivative liabilities.

#### Research and Development Expense

Research and development expense was a combined (cash and non-cash) total of \$64.2 million for the nine months ended September 30, 2014 compared to \$32.8 million for the nine months ended September 30, 2013. The increase was primarily attributable to costs associated with launching, manufacturing for, and conducting (including CRO costs) the Phase III DCVax-L trial in Europe and the Phase I/II DCVax-Direct, which were essentially not under way as of this period last year, as well as establishment and expansion of our German and UK subsidiaries and operations, and expansion of the ongoing Phase III trial in the U.S.



As of September 30, 2014, we had over 60 clinical trial sites in operation in the U.S., UK and Germany in our Phase III trial with DCVax-L, compared to 50 clinical trial sites in the U.S and one UK center at September 30, 2013.

## General and Administrative Expense

General and administrative expense was \$11.7 million for the nine months ended September 30, 2014 compared to \$8.8 million for the nine months ended September 30, 2013. The increase in general and administrative expenses from the prior period is mainly a result of an increase in consulting expenses of \$2.5 million and an increase in legal expenses of \$2.1 million due to the expansion of our platform, offset by a \$1.2 million decrease in stock based compensation expense and \$0.3 million decrease in professional expenses and insurance expenses.

#### Change in fair value of derivatives

During the nine months ended September 30, 2014 and September 30, 2013 we recognized a non-cash loss and gain on derivative liabilities of \$1.7 million and \$0.06 million, respectively, due primarily to the change in value of the warrants issued to Cognate in connection with the extinguishment of accounts payable.

#### Inducement expense

During the nine months ended September 30, 2014 and September 30, 2013 we recognized an inducement expense of \$18.5 million and \$7.4 million, respectively. This increase in inducement expense during the nine months ended September 30, 2014 was related to the conversion of more accounts payable to common stock and warrants to Cognate in connection with the extinguishment of accounts payable, and the fair value of the common stock and warrants were higher than the conversion price.

#### Interest (Expense)

Interest expense (including non-cash elements such as amortization of debt discount) decreased to \$0.4 million for the nine months ended September 30, 2014 from \$0.7 million for the nine months ended September 30, 2013. The decrease in interest expense is primarily related to the retirement of \$1.8 million in notes payable during 2013 and 2014.

#### Liquidity and Capital Resources

We have experienced recurring losses from operations. During the nine months ended September 30, 2014, net cash outflows from operations was \$36.0 million, including one-time expenditures related to the clinical trials and to certain initial costs for new manufacturing capacity in Europe.

At September 30, 2014, current assets totaled \$1.6 million, compared to \$18.6 million at December 31, 2013. Current assets less current liabilities produces working capital deficit in the amount of \$39.9 million at September 30, 2014, compared to a deficit of \$1.0 million at December 31, 2013 (excluding redeemable common stock amounting to \$8.9 million). The working capital deficit increase as of September 30, 2014 as compared to December 31, 2013 is primarily related to non-cash charges relating to the conversion of \$16.8 million of accounts payable to Cognate to common stock and warrants during the nine months ended September 30, 2014, and a decrease of \$17.1 million in cash and cash equivalents.

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

Since 2004, Toucan Capital Fund II, L.P. ("Toucan Capital"), Toucan Partners LLC ("Toucan Partners"), entities controlled by Ms. Linda Powers, our CEO and the managing director of Toucan Capital and managing member of Toucan Partners, and Ms. Linda Powers (collectively "Toucan") have provided substantial funding to us. From 2004 to date, Toucan has provided ongoing financings to us through the purchase of common stock, preferred stock (which was all converted to common stock), loans and debt securities. As of September 30, 2014, Toucan (other than Cognate) held approximately 5% of common stock outstanding.

On August 19, 2014, we completed the acquisition of a facility and property in the U.K ("UK Facility"). The purchase price was £13 million (\$20.8 million, excluding professional fees of \$1.5 million associated with the purchase of the U.K Facility). The facility is an existing building of approximately 65,000 square feet. We plan to re-purpose the facility and have it built out as part of the expansion of manufacturing capacity, potentially doubling the building's square footage. Such re-purposing requires approval of the applicable Planning Commission. If re-purposing is approved, then the specific design and engineering of the proposed build out will also have to be approved. In addition to the facility, the acquisition included about 25 acres of potentially developable land (as well as non-developable land). Any future development for business use will require removal of certain existing structures, permission from the Planning Commission for the intended purpose, and then permission from the Planning Commission for the specific designs and engineering.

We 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. We determined, based on information contained in the specialists report, that it would be required to estimate the fair value of an unconditional obligation to remediate specific ground contamination at an estimated fair of approximately \$1.6 million. We computed our preliminary estimate of the fair value of this obligation using a probability approach that measures likelihood of the following two potential outcomes: (i) a higher probability (>95%) requirement of erecting a protective barrier around the affected area at an estimated cost of approximately \$20 million.

Our estimate is preliminary and therefore subject to change as further studies are conducted, and as additional facts come to our attention. Environmental remediation obligations are complex and technical. Accordingly, It is at least reasonably possible that any changes in our estimates could materially differ from management's preliminary estimates.

# **Operating Activities**

During the nine months ended September 30, 2014, we used \$36 million in cash for operating activities, including one-time expenditures related to the clinical trials and to certain initial costs for new manufacturing capacity in Europe compared with \$23.2 million in cash that we used for operating activities during the nine months ended September 30, 2013. The increase in cash used in operating activities was primarily attributable to an increase in research and development expense associated with expanding our existing Phase III clinical trial with DCVax-L, expanding and accelerating Phase I/II clinical trial with DCVax-Direct, expanding our German subsidiary operations, and initial arrangements for expanding our manufacturing capacity in Europe. The DCVax-Direct Phase I trial was not under way yet during most of the nine months ended September 30, 2013, whereas virtually all of the enrollment in the trial and all of the manufacturing for the trial took place during the nine months ended September 30, 2014.

As of September 30, 2014, we had an aggregate of over 60 clinical trial sites in operation in the U.S, UK and Germany in our Phase III trial with DCVax-L, compared to 50 clinical trial sites at September 30, 2013, with all but one site in the U.S only.

# Investing Activities

During the nine months ended September 30, 2014, we used \$22.3 million in cash for investing activities compared with \$4.6 million during the nine months ended September 30, 2013. The increase in cash used in investing activities was primarily related to the purchase of a UK facility and for a purchase price of £13 million (a total of \$22.3 million, including all related capitalized costs).

# **Financing Activities**

During the nine months ended September 30, 2014, our financing activities primarily consisted of net proceeds after expenses of \$23.9 million from issuance of common stock and/or warrants, net proceeds of \$16.2 million from issuance of convertible notes (offset by related interest payment transferred to escrow account for \$2.6 million), and net proceeds of \$4.8 million from the exercise of warrants; partially offset by the payment of \$0.03 million of convertible promissory notes.

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

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

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

# Item 4. Controls and Procedures

# **Evaluation of Disclosure Controls and Procedures**

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

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



Our company's process for internally reporting material information in a systematic manner to allow for timely filing of material information is ineffective, due to inherent limitations from being a small company and insufficient personnel for segregation of duties, and there exist material weaknesses in internal control over financial reporting that contribute to the weaknesses in our disclosure controls and procedures. These weaknesses include:

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

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

#### **Changes in Internal Control over Financial Reporting**

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

#### Part II - Other Information

#### Item 1A. Risk Factors.

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

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

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

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

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



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

On August 27, 2014 and September 16, 2014, we sold to an individual investor 435,202 shares of common stock at \$5.17 per share and 448,207 shares of common stock at \$5.02 per share, respectively. The total proceeds received were \$4.5 million.

During the quarter ended September 30, 2014, we converted accounts payable owed to Cognate in the amount of approximately \$7.9 million into 1,986,205 shares of common stock and warrants to purchase 1,121,404 shares of common stock. The shares and warrants are subject to most favored nation treatment with respect to the terms (including in regards to warrants) provided to any other investors or creditors, including share issuances upon the exercise of previously issued derivative securities. The shares are also subject to a 36-month lock-up as described above.

During the quarter ended September 30, 2014, we issued 14,519 shares of common stock in exchange for consulting services valued at \$94,999.

On November 17, 2014, we sold \$25 million of unregistered shares of common stock of the Company (4,317,789 shares), at a price of \$5.79 per share (the closing price of the stock on November 14, 2014, the trading day prior to the sale of shares).

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

#### Item 5. Other Information

On November 17, 2014, the Company entered into a private offering of \$25 million of unregistered shares of common stock of the Company, at a price of \$5.79 per share (the closing price of the stock on November 14, 2014, the trading day prior to the sale of shares). The shares were purchased by C.F. Woodford Equity Income Fund of the UK. In connection with the offering, the Company agreed to file a registration statement within two weeks after the closing and to use best efforts to complete the registration within sixty days thereafter.

Also on November 17, the Company completed a \$10 million mortgage secured solely by the Company's UK facility and property. The Company plans to use the proceeds in connection with its expansion of manufacturing capacity in Europe. The mortgage has a term of 2 years and accrues interest at the rate of 12%.

On November 12, 2014, the Board approved the issuance of 10,577,176 restricted stock units ("RSUs") to employees and board members of the Company, pursuant to the equity compensation plan approved by shareholders in December 2013. These are the first such equity awards to employees in 3.7 years, since June, 2011, and are also the first such awards to Board members. These RSUs will vest on various dates over a period of 5 years, and will also be subject to both service and performance conditions.

On November 12, 2014, the Board approved the issuance of 8,052,092 shares of common stock to Cognate for services and most favored nation provisions in accordance with the Cognate agreements.

On November 12, 2014, the Board approved the issuance of 3,812,555 warrants to Cognate for services and most favored nation provisions in accordance with the Cognate agreements. The warrants will have a term of 5.0 years and an initial exercise price of \$4.00, and will be subject to a most favored nation provision.

On October 6, 2014, the Company entered into a Stock Purchase, Amendment and Issuance Agreement (the "Agreement") with an existing single institutional investor for the sale of 2,272,727 shares of common stock at a purchase price of \$5.05 per share, for a total purchase price of approximately \$11.5 million. In the Agreement, the investor's existing contractual over-allotment purchase right to purchase up to \$17,045,452.50 worth of shares of our common stock for \$7.50 per share at any time prior to April 14, 2015 was terminated. The Company also issued the purchaser a warrant to purchase up to \$14,085,250.00 of shares at an exercise price of \$5.15 per share, or up to \$14,085,250 in aggregate, exercisable commencing six months after issuance and with an exercise period of 30 months.

On August 27, 2014 and September 16, 2014, the Company sold an aggregate of 435,202 shares of restricted common stock at \$5.17 per share and 448,207 shares of restricted common stock at \$5.02 per share, respectively for total proceeds of \$4.5 million.

On August 19, 2014, the Company completed the acquisition of a facility and property in the UK ("UK Facility"). The purchase price of the property was £13 million (approximately \$20.8 million, excluding professional fees of \$1.5 million). The facility is an existing building of approximately 65,000 square feet The Company plans to re-purpose the facility and have it built out as part of the expansion of manufacturing capacity for its products in Europe, potentially doubling the building's square footage. Such re-purposing requires approval of the applicable Planning Commission. If re-purposing is approved, then the specific design and engineering of the proposed build out will also have to be approved. In addition to the facility, the acquisition included about 25 acres of potentially developable land (as well as non-developable land). Any future development for business use will require removal of certain existing structures, permission from the Planning Commission for the intended purpose, and then permission from the Planning Commission for the intended purpose.

Also on August 19, 2014, the Company completed a private offering of \$17.5 million aggregate principal amount of 5% Senior Secured Convertible Promissory Notes (the "Senior Notes") with an initial conversion price of \$7.30 per share, for total net proceeds to the Company of approximately \$16.2 million after deducting placement agent fees and other expenses.

#### **Item 6. Exhibits**

10.1 Contract for the Sale and Purchase of Land and Buildings at Sawston, England, dated July 3, 2014, by and among Spicers Limited, Aracaris Capital Limited and Cognate Bioservices, Inc.

- 10.2 Stock Purchase Agreement, dated November 17, by and among the Company and C.F. Woodford Equity Income Fund.
- 31.1 Certification of President (Principal Executive Officer and Principal Financial and Accounting Officer), Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of President, Chief Executive Officer and Principal Financial and Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

#### SIGNATURES

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

### NORTHWEST BIOTHERAPEUTICS, INC

Dated: November 19, 2014

By: /s/ Linda F. Powers

Name: Linda F. Powers Title: President and Chief Executive Officer Principal Executive Officer Principal Financial and Accounting Officer