# NORTHWEST BIOTHERAPEUTICS INC

# FORM 10-Q

(Quarterly Report)

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

FORM 10-Q

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

For the quarterly period ended March 31, 2015

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

(State or Other Jurisdiction of Incorporation or Organization)

94-3306718 B.S. Employer Identification No.

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

4800 Montgomery Lane, Suite 800, Bethesda, MD 20814

(Address of principal executive offices) (Zip Code)

(240) 497-9024

(Registrant's telephone number)

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

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

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

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

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

As of May 6, 2015, the total number of shares of common stock, par value \$0.001 per share, outstanding was 76,889,028.

# 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 and per share amounts)

	м	arch 31, 2015	De	cember 31, 2014
	(U)	naudited)		
ASSETS	-	-		
Current assets:				
Cash and cash equivalents	\$	3,170	\$	13,390
Restricted cash - interest payments held in escrow		879		865
Prepaid expenses and other current assets		666		387
Total current assets		4,715		14,642
	-	<u> </u>		· · · ·
Non-current assets:				
Property, plant and equipment, net		41,386		39,999
Deferred financing cost, net		1,939		1,985
Restricted cash - interest payments held in escrow, net of current portion		1,318		1,760
Other assets		55		55
Total non-current assets		44,698		43,799
		44,090		45,755
Total assets	\$	49,413	\$	58,441
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:	*	0 744	*	0.000
Accounts payable	\$	9,744	\$	9,826
Accounts payable from related party		5,831		5,729
Accrued expenses (includes related party of \$9 and \$8 as of March 31, 2015 and December 31, 2014, respectively)		940		1,211
Convertible notes, net (includes related party note of \$50 and \$50 as of March 31, 2015 and				
December 31, 2014, respectively)		238		238
Note payable - in dispute		934		934
Environmental remediation liability		6,200		6,200
Derivative liability		67,081		44,742
Total current liabilities		90,968		68,880
		50,500		00,000
Non-current liabilities:				
Convertible note		17,500		17,500
Mortgage loan		11,496		6,990
Other accrued expenses		148		98
Total non-current liabilities		29,144		24,588
				,
Total liabilities		120,112		93,468
Stockholders' equity (deficit):				
Preferred stock (\$0.001 par value); 40,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2015 and December 31, 2014, respectively		-		-
Common stock (\$0.001 par value); 450,000,000 shares authorized; 70,310,724 and 68,957,469 shares issued and outstanding as of March 31, 2015 and December 31, 2014,				
respectively		70		69
		496,443		
Additional paid-in capital				485,615
Accumulated deficit		(566,954)		(520,521
Cumulative translation adjustment		(258)		(190
Total stockholders' equity (deficit)		(70,699)		(35,027
Total liabilities and stockholders' equity (deficit)	\$	49,413	\$	58,441

See accompanying notes to the unaudited condensed consolidated financial statements

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

(in thousands, except per share and per share amounts)

	Fo	r the three r Marcl		ıs ended
		2015		2014
Revenues:				
Research grant and other	\$	194	\$	-
Total revenues		194		-
Operating costs and expenses:				
Research and development		19,703		19,986
General and administrative		3,319		3,693
Depreciation and amortization		3		3
Total operating costs and expenses		23,025		23,682
Loss from operations		(22,831)		(23,682)
Other income (expense):				
Inducement expense		-		(5,251)
Change in fair value of derivative liability		(23,158)		(16,984)
Interest expense		(793)		(122)
Gain (loss) on foreign currency exchange		349		(2)
Net loss	\$	(46,433)	\$	(46,041)
Net loss per share applicable to common stockholders - basic and diluted	\$	(0.67)	\$	(0.88)
Weighted average shares used in computing basic and diluted loss per share	<u>.</u>	69,406	<u>.</u>	52,377

See accompanying notes to the unaudited condensed consolidated financial statements

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

(in thousands, except per share and per share amounts)

	I	or the three mon March 31	
		2015	2014
Net loss	\$	(46,433) \$	(46,041)
Other comprehensive loss			
Foreign currency translation adjustment		(68)	-
Total comprehensive loss	\$	(46,501) \$	(46,041)

See accompanying notes to the unaudited condensed consolidated financial statements

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

(in thousands)

	Comm	on Stock	Additional Paid-in	Ac	cumulated	Cumulative Translation	Total Stockholders'
	Shares	Par value	Capital		Deficit	Adjustment	Equity (Deficit)
Balance as of December 31, 2014	68,957	\$ 69	\$ 485,615	\$	(520,521)	\$ (190)	\$ (35,027)
Proceeds from warrants exercises	888	1	3,650		-	-	3,651
Redeemable securities settlement	80	-	299		-	-	299
Cashless warrants exercise	385	-	520		-	-	520
Stock compensation expense - Cognate							
BioServices	-	-	6,359		-	-	6,359
Net loss	-	-	-		(46,433)	-	(46,433)
Cumulative translation adjustment	-	-	-		-	(68)	(68)
Balance as of March 31, 2015	70,310	\$ 70	\$ 496,443	\$	(566,954)	\$ (258)	\$ (70,699)

See accompanying notes to the unaudited condensed consolidated financial statements

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

(in thousands)

	Fo	or the three moi March 3	
		2015	2014
Cash Flows from Operating Activities:			
Net Loss	\$	(46,433) \$	(46,041)
Reconciliation of net loss to net cash used in operating activities:			
Depreciation and amortization		3	3
Amortization of deferred financing cost		234	-
Change in fair value of derivatives		23,158	16,984
Gain on foreign currency exchange		(349)	-
Accrued interest converted to common stock		-	76
Stock and warrants issued to Cognate BioServices as compensation under Cognate			
Agreements		6,359	7,961
Stock and warrants issued for services		-	1,567
Inducement expense		-	5,251
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets		(279)	-
Accounts payable and accrued expenses		(378)	277
Related party accounts payable and accrued expenses		103	3,363
Net cash used in operating activities		(17,582)	(10,559)
Cash Flows from Investing Activities:			· · ·
Purchase of property and equipment		(1,133)	-
Net cash used in investing activities		(1,133)	-
Cash Flows from Financing Activities:		( ,,	
Proceeds from mortgage loan		4,997	-
Deferred offering cost related to mortgage loan		(138)	-
Proceeds from investor deposit		-	1,400
Repayment of convertible promissory notes		-	(25)
Proceeds from exercise of warrants		3,651	2,692
Proceeds from issuance common stock and warrants, net of offering cost		-	224
Offering costs		-	(1)
Net cash provided by financing activities		8,510	4,290
Effect of exchange changes on cash		(15)	1,230
Net decrease in cash and cash equivalents		(10,220)	(6,269)
		(/	(=,=00)
Cash and cash equivalents at beginning of period		13,390	18,499
Cash and cash equivalents at end of period	\$	3,170 \$	12,230

See accompanying notes to the unaudited condensed consolidated financial statements

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

(Unaudited)

(in	thousands)	

Issuance of common stock and warrants in connection with conversion of accounts payable - Cognate BioServices \$ - \$ 5,9		For the three months ended March 31,			
Issuance of common stock in connection with conversion of notes payable and accrued\$-\$1expenses\$-\$\$1Issuance of common stock and warrants in connection with conversion of accounts payable\$5Cognate BioServices\$-\$\$Reclass of redeemable security to equity\$-\$\$Accrued Exit Fee incurred from mortgage loan\$50\$Cashless warrant exercise on warrant liability\$520\$			2015		2014
expenses\$\$1Issuance of common stock and warrants in connection with conversion of accounts payable - Cognate BioServices\$\$\$Reclass of redeemable security to equity\$\$\$\$Accrued Exit Fee incurred from mortgage loan\$\$\$\$Cashless warrant exercise on warrant liability\$\$\$\$	Supplemental schedule of non-cash investing and financing activities:				
Issuance of common stock and warrants in connection with conversion of accounts payable - Cognate BioServices\$-\$ <t< td=""><td>Issuance of common stock in connection with conversion of notes payable and accrued</td><td></td><td></td><td></td><td></td></t<>	Issuance of common stock in connection with conversion of notes payable and accrued				
Cognate BioServices\$-\$5,9Reclass of redeemable security to equity\$-\$8,9Accrued Exit Fee incurred from mortgage loan\$50\$Cashless warrant exercise on warrant liability\$520\$	expenses	\$	-	\$	140
Reclass of redeemable security to equity\$-\$8,9Accrued Exit Fee incurred from mortgage loan\$50\$Cashless warrant exercise on warrant liability\$520\$	Issuance of common stock and warrants in connection with conversion of accounts payable -				
Accrued Exit Fee incurred from mortgage loan\$50\$Cashless warrant exercise on warrant liability\$520\$	Cognate BioServices	\$	-	\$	5,926
Cashless warrant exercise on warrant liability \$ 520 \$	Reclass of redeemable security to equity	\$	-	\$	8,913
	Accrued Exit Fee incurred from mortgage loan	\$	50	\$	-
Increase in accounts payable related to UK property \$ 257 \$	Cashless warrant exercise on warrant liability	\$	520	\$	-
	Increase in accounts payable related to UK property	\$	257	\$	-
Interest payment on convertible note from escrow \$ 428 \$	Interest payment on convertible note from escrow	\$	428	\$	-
Redeemable security settlement\$299\$	Redeemable security settlement	\$	299	\$	-
Supplemental disclosure of cash flow information:	Supplemental disclosure of cash flow information:				
Cash paid for interest \$ 735 \$	Cash paid for interest	\$	735	\$	-

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 February 13, 2015, the Company entered into a mortgage loan agreement ("the Mortgage") with Lancashire Mortgage Corporation Limited in UK for approximately \$5.0 million. The Mortgage has an 18 month term with a 12% annual interest rate.

On April 2, 2015, the Company entered into a stock purchase agreement (the "Agreement") with Woodford Investment Management LLP as agent for the CF Woodford Equity Income Fund and other clients (collectively, "Woodford"). Pursuant to the Agreement, the Company sold 5,405,405 shares of the Company's unregistered common stock, par value \$0.001 per share (the "Shares"), at a purchase price of \$7.40 per Share for an aggregate purchase price of \$40,000,000. The sale of the Shares took place in two separate closings as follows: (i) 1,554,054 shares for a purchase price of \$11,500,000 which closed on April 8, 2015; and (ii) an additional 3,851,351 shares for a purchase price of \$28,500,000 which closed on May 1, 2015. There are no warrants, pre-emptive rights or other rights or preferences.

On April 13, 2015, an unrelated institutional investor elected to exchange all \$2.5 million of its existing 5.00% Convertible Senior Notes due in August 2017 (the "Notes") for common stock of the Company on the terms set forth in the Notes. The convertible debt was entered into in August 2014. Pursuant to the exchange, the investor received 378,535 shares of the Company's common stock. The shares are being issued pursuant to the exemption from the registration requirements afforded by Section 3(a)(9) of the Securities Act of 1933, as amended.

# 2. Liquidity and Financial Condition

During the three months ended March 31, 2015, the Company used approximately \$17.6 million of cash for its operations and for certain one-time payments. The Company incurred an aggregate combined cash and non-cash loss of \$46.4 million for the three months ended March 31, 2015, including \$29.4 million of non-cash charges associated with a mark to market charge for the change in the fair value of its derivative liability and other non-cash charges.

The Company had cash and cash equivalents of \$3.2 million as of March 31, 2015, and a deficit in current assets less accounts payable and accrued expenses, non-cash derivative liabilities and estimated potential environmental liabilities and notes payable of approximately \$86.3 million at March 31, 2015. The non-cash derivative liabilities comprised \$67.1 million of the \$86.1 million total. The Company owes an aggregate of \$5.8 million of trade liabilities and convertible notes to related parties.

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 March 31, 2015 and for the three 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 March 31, 2015, condensed consolidated statements of operations for the three months ended March 31, 2015 and 2014, condensed consolidated statements of comprehensive loss for the three months ended March 31, 2015 and 2014 condensed consolidated statement of stockholders' equity (deficit) for the three months ended March 31, 2015, and the condensed consolidated statements of cash flows for the three months ended March 31, 2015 and 2014 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for the year ending December 31, 2015 or for any future interim period. The condensed balance sheet at December 31, 2014 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, 2014, and notes thereto included in the Company's annual report on Form 10-K, which was filed with the SEC on March 17, 2015.



#### **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.

#### **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 March 31, 2015, we estimate that the total environmental remediation costs associated with the purchase of the UK Facility will be approximately \$6.2 million and. 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 \$6.2 million. The Company computed the fair value of this obligation using a probability weighted approach that measures the likelihood of the following two potential outcomes: (i) a higher probability requirement of erecting a protective barrier around the affected area at an estimated cost of approximately \$4.5 million, and (ii) a lower probability requirement of having to excavate the affected area at an estimated cost of approximately \$32.0 million. The Company's estimate is preliminary and therefore subject to change as further studies are conducted, and as additional facts come to the Company's attention. Environmental remediation efforts are complex, technical and subject to various uncertainties. Accordingly, it is at least reasonably possible that any changes in the Company's estimate could materially differ from the management's preliminary discussed herein.

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

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

For the three months ended March 31, 2015 and 2014, the Company recognized research and development costs (cash and non-cash combined) of \$19.7 million and \$20.0 million, respectively. Included in research and development expense was \$2.4 million and \$1.4 million, and \$0.7 million and \$0.9 million, respectively, related to clinical site expenses such as CRO fees and site fees.

For the three months ended March 31, 2015 and 2014, the Company made cash payments of approximately \$8.2 million, and \$5.3 million, for the two periods, respectively, to Cognate BioServices, Inc. ("Cognate"). At March 31, 2015 and 2014, the Company owed Cognate \$5.8 million and \$1.0 million, respectively, for unpaid invoices 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 March 31, 2015 and 2014, the Company incurred non-cash equity based compensation (restricted common stock and warrants) related to Cognate BioServices of \$6.4 million and \$8.0 million, respectively. This equity compensation primarily involved one-time initiation payments of shares and warrants relating to the four new agreements the Company entered into with Cognate in January, 2014. The shares are vesting over a period of three years from the date of the agreements. The fair value calculation of these shares was determined using the market price for tradable shares; however the shares issued to Cognate were unregistered restricted shares. The equity compensation also included lock-up warrants (for the lock-up of Cognate shares) and most favored nation shares and warrants.

#### **Foreign Currency Transactions**

The mortgage loan, which is denominated in a foreign currency (British Pounds), is converted into the Company's functional currency (the United States dollar) at the exchange rate on the balance sheet date.

#### **Foreign Currency Translation**

Assets and liabilities related to the Company's German operations are calculated using Euros and are translated at end-of-period exchange rates, while the related expenses are translated at average exchange rates prevailing during the period. Translation adjustments are recorded as a separate component of consolidated stockholders' equity (deficit).

#### **Comprehensive Loss**

During the three months ended March 31, 2015, the Company's comprehensive loss (cash and non-cash combined) is \$46.5 million.

#### **Significant Accounting Policies**

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2014 Annual Report.

#### **Recent Accounting Pronouncements**

In April 2015, the FASB issued ASU 2015-03, S *implifying the Presentation of Debt Issuance Costs*, which require debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. ASU 2015-03 is effective for the interim and annual periods ending after December 15, 2015. The Company does not expect any material impact from adoption of this guidance on the Company's condensed consolidated financial statements.

#### 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 March 31, 2015 and December 31, 2014 (in thousands):

			Fair value measure	d at Marcl	h 31, 2015			
	 <sup>-</sup> value at h 31, 2015	Quo	ted prices in active markets (Level 1)	5	nificant other ervable inputs (Level 2)		unobser	ificant /able inputs /vel 3)
Warrant liability	\$ 67,081	\$		- \$		-	\$	67,081
		Fa	ir value measured	at Decemb	er 31, 2014			
	 value at ber 31, 2014	Quo	ted prices in active markets (Level 1)		nificant other ervable inputs (Level 2)		unobser	ificant /able inputs /vel 3)
Warrant liability	\$ 44,742	\$	(	- \$	(	-	\$	44,742

There were no transfers between Level 1, 2 or 3 during the three month period ended March 31, 2015.

The following table presents changes in Level 3 liabilities measured at fair value for the three month period ended March 31, 2015. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-

dated volatilities) inputs (in thousands).

	Warrant
	Liability
Balance – December 31, 2014	\$ 44,742
Change in fair value	23,158
Cashless warrants exercise	(520)
Redeemable security settlement	(299)
Balance – March 31, 2015	\$ 67,081

The Company's warrant liabilities are measured at fair value using the Monte Carlo simulation valuation methodology. A summary of quantitative information about significant unobservable inputs (Level 3 inputs) used in measuring the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy for the three months ended March 31, 2015 is as follows:

Date of valuation	Ма	arch 4, 2015*	March 31, 2015
Dividend yield (per share)		0%	0%
Strike price	\$	3.35	\$2.40-\$5.97
Volatility (annual)		70%	75%
Risk-free rate		0.30%	0.9%-1.4%
Contractual term (years)		1.5	3.3-4.4

\* Inputs for cashless exercise derivative warrants

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- Non-Employees

Stock-based payment expense related to Cognate services was \$6.4 million and \$2.5 million for the three months ended March 31, 2015 and March 31, 2014, respectively. Approximately \$3.1 million in compensation costs per calendar quarter may be recognized over the next 1.6 years based on the fair market value of stock of \$7.37.



#### 6. Property and Equipment

Property and equipment consist of the following at March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015	De	ecember 31, 2014
Leasehold improvements	\$ 69	\$	69
Office furniture and equipment	25		25
Computer equipment and software	137		137
Construction in progress (property in the United Kingdom)	41,318		39,928
	 41,549		40,159
Less: accumulated depreciation	 (163)		(160)
	\$ 41,386	\$	39,999

Depreciation expense was approximately \$3,000 for the three months ended March 31, 2015.

## 7. Notes Payable

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

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 offering costs. The Company capitalized these placement agent fees and other offering costs as deferred financing cost. Interest expense amounted to \$0.3 million which included \$0.2 million related to the 5% coupon and \$0.12 million related to the deferred offering costs for the three months ended March 31, 2015.

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 was reset from \$7.30 per share to \$6.60 per share, as described below. The initial investors had a 3-month right to purchase an additional 30% on the same terms and conditions as the initial purchase, but did not exercise it. The Company deposited approximately \$2.6 million from the total proceeds in an escrow account. This funding is sufficient to fund, when due, the total aggregate amount of the six scheduled semi-annual interest payments during the term of the notes, excluding additional interest, if any.

#### Conversion Price

Pursuant to a one-time potential price reset provision, on February 15, 2015, the initial conversion price of \$7.30 was 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. The adjustment resulted in reduction of the conversion price from \$7.30 to \$6.60 per share (151.4142 shares per \$1,000). The fair value of the common stock was \$6.07 on the rest date.

## Mortgage Loan

On November 17, 2014, the Company entered into a mortgage loan agreement ("the First Mortgage") with Lancashire Mortgage Corporation Limited in UK for approximately \$10 million (£6.25 million). The First Mortgage has a 2 year term with a 12% annual interest rate. The Company initially received the first tranche of approximately \$7 million (£4.5 million), and this amount was netted by approximately \$0.3 million of a related financing charge, which was capitalized as deferred financing cost that is being amortized over the term of the First Mortgage. Interest expense amounted to \$0.2 million for the three months ended March 31, 2015, which included \$0.2 million related to the 12% coupon and \$0.05 million related to the amortization of deferred offering financing costs on the mortgage loan.

On February 13, 2015, the Company entered into a second mortgage loan agreement ("the Second Mortgage") with Lancashire Mortgage Corporation Limited in UK to expand the facility to \$12 million (£7.75 million). The Second Mortgage has a 1.5 year term with a 12% annual interest rate. The Company received gross proceeds of approximately \$5 million (£3.25 million), and this amount was netted by approximately \$0.1 million of a related financing charge, which was capitalized as deferred financing cost that is being amortized over the term of the Second Mortgage. Interest expense amounted to \$0.09 million for the three months ended March 31, 2015, which included \$0.07 million related to the 12% coupon and \$0.02 million related to the amortization of deferred offering financing costs on the mortgage loan.

#### **Other Notes Payable**

Notes payable consist of the following at March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015		December 31, 2014	
Notes payable - current				
12% unsecured originally due July 2011 - in dispute (1)	\$ 934	\$	934	
	 934		934	
Convertible notes payable, net - current				
6% unsecured (2)	135		135	
8% unsecured note due 2014 (3)	53		53	
	 188		188	
Note payable				
6% due on demand (4)	50		50	
	 50		50	
Total notes payable, net	\$ 1,172	\$	1,172	

(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 March 31, 2015 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 \$0.053 million note was due May 25, 2014, and is currently past due.

(4) This \$0.050 million demand note as of March 31, 2015 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. Potentially Dilutive Securities

Options, warrants, and convertible debt outstanding were all considered anti-dilutive for the three month periods ended March 31, 2015, and 2014, 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 three months ended March 31,		
	2015	2014		
Common stock options	1,551	1,551		
Common stock warrants - equity treatment	15,830	14,177		
Common stock warrants - liability treatment	12,500	8,463		
Convertible notes	2,797	81		
Potentially dilutive securities	32,678	24,272		

#### 9. Related Party Transactions

#### Cognate BioServices, Inc.

Under the January 17, 2014 DCVax®-L Manufacturing Services Agreement and the DCVax-Direct Agreement, if the Company, in breach of the Agreements, 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 months ended March 31, 2015, the Company made net disbursements to Cognate of approximately \$8.2 million, including charges relating to manufacturing for both the Phase III and Phase I/II clinical trials, ongoing product and process development, and expansion of several Company programs under these service agreements.

As of March 31, 2015 and December 31, 2014, the Company owed Cognate (including third party sub-contract amounts) approximately \$5.8 million and \$1.0 million, included in accounts payable related party, respectively.

#### **10. Stockholders' Equity (Deficit)**

#### Common Stock Issuances

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During the quarter ended March 31, 2015, the Company issued an aggregate of 888,187 shares of common stock from the exercise of warrants receiving approximately \$3.7 million of proceeds.

During the quarter ended March 31, 2015, the Company issued 80,068 shares of common stock to an individual investor as settlement of redemption of redeemable securities. The fair value of the settlement was \$0.3 million and was recorded to offset derivative liabilities.

During the quarter ended March 31, 2015, the Company issued an aggregate of 385,000 shares of common stock to an individual investor from the cashless exercise of warrants previously issued. The warrants were classified as warrant liability. The fair value of the warrants on the date of exercise was \$0.5 million.

#### Stock Purchase Warrants

The following is a summary of warrant activity for the three months ended March 31, 2015 (in thousands):

	Number of Warrants	Weighted Average Exercise Price
Outstanding as of December 31, 2014	29,385	\$ 4.72
Warrants exercised for cash	(888)	4.11
Warrants exercised on a cashless basis*	(117)	3.35
Warrant adjustment due to Cognate price reset	62	3.35
Expired in first quarter of 2015	(128)	9.42
Adjustment related to prior issued warrants	16	5.73
Outstanding as of March 31, 2015 **	28,330	\$ 4.72

\*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 14,323,003 warrants issued to Cognate, during the eight year period from 2008 through 2015, with a weighted average exercise price and remaining contractual term of \$3.3 and 4.4 years, respectively. The weighted average exercise price gives effect to adjustments related to the most favored nation clause that occurred during the period.

#### **11. Subsequent Events**

Management of the Company performed an evaluation of all subsequent events that occurred as of the date these financial statements were issued to determine if they must be reported. Management has determined that the following subsequent events are required to be disclosed:

On April 2, 2015, the Company entered into a stock purchase agreement (the "Agreement") with Woodford Investment Management LLP as agent for the CF Woodford Equity Income Fund and other clients (collectively, "Woodford"). Pursuant to the Agreement, the Company has agreed to sell, and Woodford has agreed to purchase, 5,405,405 shares of the Company's unregistered common stock, par value \$0.001 per share (the "Shares"), at a purchase price of \$7.40 per Share for an aggregate purchase price of \$40,000,000. The sale of the Shares took place in two separate closings as follows: (i) 1,554,054 shares for a purchase price of \$11,500,000 which closed on April 8, 2015; and (ii) an additional 3,851,351 shares for a purchase price of \$28,500,000 which closed on May 1, 2015. There are no warrants, pre-emptive rights or other rights or preferences.

Subsequent to March 31, 2015 \$3.0 million of the 2014 Convertible Senior Notes were converted into common stock of the Company on the terms set forth in the agreement. Pursuant to the exchange, on the terms set forth in the Notes, the investors received approximately 454,000 shares of the Company's common stock. The shares are being issued pursuant to the exemption from the registration requirements afforded by Section 3(a)(9) of the Securities Act of 1933, as amended.



#### 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, 2014 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 the overall immune system, and targeting the full set of 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 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, 2014. 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, 2014.



#### **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 increase as we bring on an additional clinical trial programs which are 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 a pre-revenue company, we do not allocate research and development costs on a project basis. We adopted this policy, in part, due to the unreasonable cost burden associated with accounting at such a level of detail and our limited number of financial and personnel resources.

## General and administrative:

General and administrative expenses include 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 March 31, 2015 and 2014

We recognized a (combined cash and non-cash) net loss of \$46.4 million for the three months ended March 31, 2015 which was comparable to the net loss of \$46.0 million for the three months ended March 31, 2014.

#### Research and Development Expense

Research and development expense was \$19.7 million for the three months ended March 31, 2015 which was comparable to the \$20.0 million for the three months ended March 31, 2014.

For the three months ended March 31, 2015 and 2014, we made cash payments for the two periods, respectively, of approximately \$8.2 million, and \$5.5 million to Cognate. At March 31, 2015 and 2014, we owed Cognate \$5.8 million and \$1.0 million, respectively, for unpaid invoices 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 March 31, 2015 and 2014, we incurred non-cash equity based payment (restricted common stock and warrants) expense related to Cognate services of \$6.4 million and \$8.0 million, respectively. This equity payment primarily involved one-time initiation payments of shares and warrants relating to the four new agreements we entered into with Cognate in January, 2014. The shares are vesting over a period of three years from the date of the agreements. The fair value calculation of these shares was determined using the market price for tradable shares; however the shares issued to Cognate were unregistered restricted shares. The equity compensation also included lock-up warrants (for the lock-up of Cognate shares) and most favored nation warrants.

#### General and Administrative Expense

General and administrative expense was \$3.3 million for the three months ended March 31, 2015 which was comparable to the \$3.7 million for the three months ended March 31, 2014.

#### Change in fair value of derivatives

During the three months ended March 31, 2015 and 2014 we recognized a non-cash loss on derivative liabilities of \$23.2 million and \$17.0 million, respectively, due primarily to the change in value of the warrants, due to an increase in our stock price, issued to Cognate in connection with the extinguishment of accounts payable.

#### Inducement expense

During the three months ended March 31, 2015 there was no inducement expense versus inducement expense of \$5.3 million for the three months ended March 31, 2014. The inducement expense for the three months ended March 31, 2014 was related to 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 \$0.8 million for the three months ended March 31, 2015 from \$0.1 million for the three months ended March 31, 2014. The increase in interest expense is primarily related to the issuance of senior convertible notes and mortgage loans.

#### Liquidity and Capital Resources

We have experienced recurring losses from operations. During the three months ended March 31, 2015, net cash outflows for operations and for one-time expenses was \$17.6 million.

At March 31, 2015, current assets totaled \$4.7 million, compared to \$14.6 million at December 31, 2014. Current assets less current liabilities produces working capital deficit in the amount of \$86.3 million at March 31, 2015, compared to a deficit of \$54.2 million at December 31, 2014, as described above.

#### **Operating Activities**

During the three months ended March 31, 2015, we used \$17.6 million in cash for operating activities and certain one-time payments.

## Investing Activities

During the three months ended March 31, 2015, we used \$1.1 million in cash. There were no investing activities during the three months ended March 31, 2014.

#### Financing Activities

During the three months ended March 31, 2015, our financing activities provided net proceeds after expenses of \$8.5 million, consisting of \$4.9 million in net mortgage loan proceeds and net proceeds of \$3.7 million from the exercise of warrants.

Our financial statements indicate there is substantial doubt about our ability to continue as a going concern as we are dependent on our ability to obtain short term 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. We can give no assurance that our plans and efforts to achieve the above steps will be successful.

In order to continue with our current activities under our DCVax®-L program, we will have to obtain substantial amounts of further funding, as described in the Risk Factors. Our on-going funding requirements will depend on many factors, including the extent to which we realize and draw upon various sources of non-dilutive funding. One such source of non-dilutive funding that we drew upon in 2014 is a \$5.5 million German grant awarded on May 1, 2012, by the German government through its Saxony Development Bank. The grant provided funding on a matching basis for up to 50% of costs incurred by us for the DCVax-L clinical trial and manufacturing in Germany.



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 and our Phase I/II clinical trial with DCVax-Direct, the possible launch of additional Phase II trials with DCVax-Direct, the costs of further development work relating to DCVax-Direct, the costs of expansion of manufacturing of both DCVax-L and DCVax-Direct, the cost of developing our Hospital Exemption program in Germany, 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.

#### **Off-Balance Sheet Arrangements**

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

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

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

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

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

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

Based on our analysis, as of March 31, 2015, the effect of a 100+/- basis point change in interest rates on the value of our financial instruments and the resultant effect on our net loss are considered immaterial.

## Item 4. Controls and Procedures

#### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management (including our principal executive, financial and accounting officer), and the external firm that performs the finance and accounting functions for our Company, 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.

Since 2012, our Company's finance and accounting functions have been performed by an external firm on a contract services basis. This firm specializes in providing financing and accounting functions for biotech companies, and the founders and senior managers are highly experienced former partners of national accounting firms.



Based on the evaluation of our controls and procedures, our principal executive, financial and accounting officer concluded that during the period covered by this report, our Company's processes for internally reporting material information in a systematic manner to allow for timely filing of material information were ineffective, due to inherent limitations from being a small company and insufficient personnel for segregation of duties, and there existed material weaknesses in our oversight over the financial reporting that contribute to the weaknesses in our disclosure controls and procedures.

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

We have been taking steps to remediate the weaknesses identified above, which continue to exist as of the end of the period covered by this report. Specifically, we have expanded the personnel resources and activities performed by the external firm. We plan to continue taking steps to improve our internal control system and to address these deficiencies (including by potentially bringing some of the functions in-house), but the timing of such steps is uncertain and our ability to retain or attract qualified individuals to undertake these functions is also uncertain. Aside from these changes, there has been no change in our internal controls over financial reporting that occurred during the fiscal quarter ended March 31, 2015, that has materially affected, or is reasonable expected to materially affect, our internal controls over financial reporting.

# Part II - Other Information

# Item 1. Legal Proceedings

#### Section 16 Demand Letters

We have received demand letters from two purported individual shareholders seeking disgorgement of possible "short swing" profits within the meaning of Section 16(b) of the Exchange Act from Cognate Bioservices, Inc. and affiliated persons by reasons of certain sales of our common stock. However, prior to either of these demand letters, we had already filed a Form 8-K on December 19, 2014 in which we already disclosed the potential Section 16(b) short swing profits (which had been found in the course of a joint review by Cognate and us), and we disclosed that the disgorgement of those profits (\$448,681) had already been agreed by Cognate and us, and resolved. We believe that this review and the payment from Cognate fully resolve the matters raised by the demand letters.

#### 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.

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

During the quarter ended March 31, 2015, the Company issued an aggregate of 888,187 shares of common stock from the exercise of warrants previously issued for proceeds of approximately \$3.7 million.

During the quarter ended March 31, 2015, the Company issued 80,068 shares of common stock to an individual investor as settlement of redemption of redeemable securities.

During the quarter ended March 31, 2015, the Company issued an aggregate of 385,000 shares of common stock to an individual investor from the cashless exercise of warrants previously issued.

On April 2, 2015, the Company entered into a stock purchase agreement (the "Agreement") with Woodford Investment Management LLP as agent for the CF Woodford Equity Income Fund and other clients (collectively, "Woodford"). Pursuant to the Agreement, the Company has agreed to sell, and Woodford has agreed to purchase, 5,405,405 shares of the Company's unregistered common stock, par value \$0.001 per share (the "Shares"), at a purchase price of \$7.40 per Share for an aggregate purchase price of \$40,000,000. The sale of the Shares took place in two separate closings as follows: (i) 1,554,054 shares for a purchase price of \$11,500,000 which closed on April 8, 2015; and (ii) an additional 3,851,351 shares for a purchase price of \$28,500,000 which closed on April 30, 2015. There are no warrants, pre-emptive rights or other rights or preferences.



On April 13, 2015, an unrelated institutional investor elected to exchange all \$2.5 million of its existing 5.00% Convertible Senior Notes due in August 2017 (the "Notes") for common stock of the Company on the terms set forth in the Notes. The convertible debt was entered into in August 2014. Pursuant to the exchange, on the terms set forth in the Notes, the investor received 378,535 shares of the Company's common stock. The shares are being issued pursuant to the exemption from the registration requirements afforded by Section 3(a)(9) of the Securities Act of 1933, as amended.

Except as noted above, all of the 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 4. Mine Safety Disclosures

None

#### Item 5. Other Information

None

# Item 6. Exhibits

- 31.1 Certification of President (Principal Executive Officer and Principal Financial and Accounting Officer), Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Certification of President, Chief Executive Officer and Principal Financial and Accounting Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*\*
- 101 The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014, (ii) the Condensed Consolidated Statements of Operations for the three-month periods ended March 31, 2015 and 2014, (iii) the Condensed Consolidated Statements of Comprehensive Loss for the three-month periods ended March 31, 2015 and 2014, (iv) the Condensed Consolidated Statement Of Stockholders' Equity (Deficit), (v) the Condensed Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2015 and 2014, and (vi) the Notes to Condensed Consolidated Financial Statements.\*

\* Filed herewith

\*\* Furnished herewith

# SIGNATURES

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

Dated: May 11, 2015

# NORTHWEST BIOTHERAPEUTICS, INC

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