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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 June 30, 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	**94-3306718**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4800 Montgomery Lane, Suite 800, Bethesda, MD 20814
(Address of principal executive offices) (Zip Code)

(240) 497-9024
(Registrant's telephone number)

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

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

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

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

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

As of August 7, 2015, the total number of shares of common stock, par value $0.001 per share, outstanding was 78,169,566.

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)

	June 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,202	$ 13,390
Restricted cash - interest payments held in escrow	1,021	865
Prepaid expenses and other current assets	978	387
Total current assets	21,201	14,642
Non-current assets:		
Property, plant and equipment, net	41,999	39,999
Restricted cash - interest payments held in escrow, net of current portion	739	1,760
Other assets	309	55
Total non-current assets	43,047	41,814
Total assets	$ 64,248	$ 56,456
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 11,072	$ 9,826
Accounts payable to related party	4,198	5,729
Accrued expenses (includes related party of $10 and $8 as of June 30, 2015 and December 31, 2014, respectively)	1,188	1,211
Convertible notes, net (includes related party note of $50 and $50 as of June 30, 2015 and December 31, 2014, respectively)	238	238
Note payable - in dispute	934	934
Environmental remediation liability	6,200	6,200
Derivative liability	92,716	44,742
Total current liabilities	116,546	68,880
Non-current liabilities:		
Convertible note (net of deferred financing cost of $677 and $1,123 as of June 30, 2015 and December 31, 2014, respectively)	12,323	16,377
Mortgage loan (net of deferred financing cost of $780 and $862 as of June 30, 2015 and December 31, 2014, respectively)	11,401	6,128
Other accrued expenses	149	98
Total non-current liabilities	23,873	22,603
Total liabilities	140,419	91,483
Stockholders' deficit:		
Preferred stock ($0.001 par value); 40,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	-	-
Common stock ($0.001 par value); 450,000,000 shares authorized; 77,727,823 and 68,957,469 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	78	69
Additional paid-in capital	557,136	485,615
Accumulated deficit	(633,799)	(520,521)
Cumulative translation adjustment	414	(190)
Total stockholders' deficit	(76,171)	(35,027)
Total liabilities and stockholders' deficit	$ 64,248	$ 56,456

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2015	2014	2015	2014
Revenues:				
Research grant and other	$ 391	$ -	$ 585	$ -
Total revenues	391	-	585	-
Operating costs and expenses:				
Research and development	29,434	21,549	49,137	41,535
General and administrative	9,811	3,878	13,133	7,576
Total operating costs and expenses	39,245	25,427	62,270	49,111
Loss from operations	(38,854)	(25,427)	(61,685)	(49,111)
Other income (expense):				
Inducement expense	-	(5,089)	-	(10,340)
Change in fair value of derivative liability	(25,694)	4,684	(48,852)	(12,300)
Interest expense	(1,636)	(33)	(2,429)	(155)
Foreign currency transaction loss	(661)	-	(312)	-
Net loss	$ (66,845)	$ (25,865)	$ (113,278)	$ (71,906)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.88)	$ (0.45)	$ (1.56)	$ (1.31)
Weighted average shares used in computing basic and diluted loss per share	75,619	57,442	72,530	54,923

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2015	**2014**	**2015**	**2014**
Net loss	$ (66,845)	$ (25,865)	$ (113,278)	$ (71,906)
Other comprehensive loss				
Foreign currency translation adjustment	672	-	604	-
Total comprehensive loss	$ (66,173)	$ (25,865)	$ (112,674)	$ (71,906)

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

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

	Common Stock		**Additional Paid-in**	**Accumulated**	**Cumulative Translation Adjustment**	**Total Stockholders'**
	Shares	**Par value**	**Capital**	**Deficit**	**Adjustment**	**Deficit**
Balance as of January 1, 2015	**68,957**	**$ 69**	**$ 485,615**	**$ (520,521)**	**$ (190)**	**$ (35,027)**
Proceeds from issuance of common stock	5,405	5	39,995	-	-	40,000
Redeemable securities settlement	80	-	299	-	-	299
Issuance of common stock for debt conversion	682	1	4,499	-	-	4,500
Issuance of common stock for conversion of accrued interest	20	-	187	-	-	187
Proceeds from warrants exercises	1,612	2	6,790	-	-	6,792
Reclassification of warrant liabilities related to warrants exercised for cash	-	-	58	-	-	58
Cashless warrants exercise	569	1	520	-	-	521
Issuance of common stock as compensation	403	-	3,389	-	-	3,389
Stock compensation expense - Cognate BioServices	-	-	15,784	-	-	15,784
Net loss	-	-	-	(113,278)	-	(113,278)
Cumulative translation adjustment	-	-	-	-	604	604
Balance as of June 30, 2015	**77,728**	**$ 78**	**$ 557,136**	**$ (633,799)**	**$ 414**	**$ (76,171)**

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

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

	For the six months ended June 30,			
		2015		**2014**
Cash Flows from Operating Activities:				
Net Loss	$	(113,278)	$	(71,906)
Reconciliation of net loss to net cash used in operating activities:				
Depreciation and amortization		15		6
Amortization of deferred financing cost		717		-
Change in fair value of derivatives		48,852		12,300
Accrued interest converted to common stock		-		76
Stock and warrants issued to Cognate BioServices as compensation under Cognate Agreements		15,784		10,623
Stock and warrants issued for services		3,389		1,722
Inducement expense		-		10,340
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		(591)		(30)
Accounts payable and accrued expenses		2,211		1,385
Related party accounts payable and accrued expenses		(1,529)		7,986
Deposits and other non-current assets		(254)		-
Net cash used in operating activities		(44,684)		(27,498)
Cash Flows from Investing Activities:				
Purchase of property and equipment/cost of construction in progress		(2,015)		-
Cash deposited in custody account		-		(3,414)
Net cash used in investing activities		(2,015)		(3,414)
Cash Flows from Financing Activities:				
Proceeds from mortgage loan		4,997		-
Deferred offering cost related to mortgage loan		(138)		-
Proceeds transferred from escrow account		62		-
Repayment of convertible promissory notes		-		(25)
Proceeds from exercise of warrants		6,792		3,087
Proceeds from the issuance of common stock and warrants - Cognate		-		2,250
Proceeds from issuance common stock and warrants		-		2,059
Proceeds from issuance common stock		40,000		-
Gross proceeds from issuance common stock and overallotment rights		-		15,000
Offering costs		-		(1,105)
Net cash provided by financing activities		51,713		21,266
Effect of exchange rate changes on cash and cash equivalents		798		-
Net increase (decrease) in cash and cash equivalents		5,812		(9,646)
Cash and cash equivalents at beginning of period		13,390		18,499
Cash and cash equivalents at end of period	$	19,202	$	8,853
Supplemental disclosure of cash flow information				
Interest payments on mortgage loan	$	(673)	$	-

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

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

	For the six months ended June 30,			
	2015		2014	
Supplemental schedule of non-cash investing and financing activities:				
Issuance of common stock in connection with conversion of notes payable and accrued expenses	$	-	$	140
Issuance of common stock and warrants in connection with conversion of accounts payable - Cognate BioServices	$	-	$	8,835
Reclass of redeemable security to equity	$	-	$	8,913
Deferred offering cost related to mortgage loan	$	51	$	-
Reclassification of warrant liabilities related to cashless warrants exercise	$	521	$	-
Reclassification of warrant liabilities related to warrants exercised for cash	$	58	$	-
Interest payment on convertible note from escrow	$	803	$	-
Issuance of common stock for debt conversion	$	4,500	$	-
Issuance of common stock for conversion of accrued interest	$	187	$	-
Redeemable security settlement	$	299	$	-

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

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

During the quarter ended June 30, 2015, the Company expanded its patient recruitment in the Phase III trial of DCVax-L for Glioblastoma multiforme (GBM) brain cancer. The Company conducted further product development activities and intellectual property filings. The Company undertook legal, regulatory, scientific and operational preparatory work for multiple Phase II trials which the Company anticipates launching during the second half of the year. The Company expanded and accelerated the engineering, systems design and development, infrastructure arrangements, land use and zoning, legal and contractual, regulatory analyses and other work related to development of new manufacturing capacity in Europe.

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.

In April and June of 2015, an unrelated institutional investor elected to exchange $4.50 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 701,033 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 six months ended June 30, 2015, the Company used approximately $44.7 million of cash for its operations and for certain one-time payments (e.g., development work and related patent costs, engineering, legal, regulatory, and other development costs related to the U.K. facility). The Company incurred a net loss of $113.3 million for the six months ended June 30, 2015, including $68.8 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 $19.2 million and a working capital deficiency (cash and non-cash liabilities combined) of approximately $95.3 million at June 30, 2015 (with $92.7 million of the $95.3 million deficit comprised of non-cash derivative liabilities). The Company owes an aggregate of $4.2 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 consolidated financial statements of the Company have been prepared in accordance with the accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission (“SEC”) and on the same basis as the Company prepares its annual audited consolidated financial statements. The condensed consolidated balance sheet as of June 30, 2015, condensed consolidated statements of operations for the three months and six months ended June 30, 2015 and 2014, condensed consolidated statements of comprehensive loss for the three months and six months ended June 30, 2015 and 2014, condensed consolidated statement of stockholders’ equity (deficit) for the six months ended June 30, 2015, and the condensed consolidated statements of cash flows for the six months ended June 30, 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 and six months ended June 30, 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 unaudited condensed consolidated 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.

Reclassifications

The Company reclassified debt issuance costs from other long-term assets to long-term debt, net on the condensed consolidated balance sheets for all periods presented pursuant to early adoption of Accounting Standards Update ("ASU") No. 2015-03 - *Simplifying the Presentation of Debt Issuance Costs*.

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 amount of the liability resulting from the completion of the clean-up, if any, would be included in other income(expense). As of June 30, 2015, we estimate that the total environmental remediation costs associated with the purchase of the UK Facility will be approximately $6.2 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 value of approximately $6.2 million. The Company computed the fair value of this obligation using a probability weighted approach that measures the likelihood of the following two potential outcomes: (i) a higher probability requirement of erecting a protective barrier around the affected area at an estimated cost of approximately $4.5 million, and (ii) a lower probability requirement of having to excavate the affected area at an estimated cost of approximately $32.0 million. The Company’s estimate is preliminary and therefore subject to change as further studies are conducted, and as additional facts come to the Company’s attention. Environmental remediation efforts are complex, technical and subject to various uncertainties. Accordingly, it is at least reasonably possible that any changes in the Company’s estimate could materially differ from the management’s preliminary 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 six months ended June 30, 2015 and 2014, the Company recognized research and development costs (cash and non-cash combined) of $49.1 million and $41.5 million, respectively. Clinical trial site fees and contract research organization (“CRO”) costs are included in research and development expenses. CRO cost amounted to $6.6 million and $3.3 million for the six months ended June 30, 2015 and 2014, respectively. Clinical trial site fees amounted to $1.5 million and $2 million for the six months ended June 30, 2015 and 2014, respectively.

For the six months ended June 30, 2015 and 2014, the Company made cash payments of approximately $21.3 million (with invoices generally being paid all in cash) and $12.4 million (with invoices generally being paid half in cash and half in stock), respectively, to Cognate BioServices, Inc. ("Cognate"). At June 30, 2015 and 2014, the Company owed Cognate $4.2 million and $2.7 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 six months ended June 30, 2015 and 2014, the Company incurred non-cash equity based compensation (restricted common stock and warrants) for the ongoing vesting (in equal monthly installments over 3 years) of the one-time initiation payments of shares and warrants under the four agreements the Company entered into with Cognate in January 2014. The vesting amounts during the six months ended June 30, 2015 and 2014 were $15.8 million (comprising 0.9 million shares per six months) and $10.6 million (comprising 0.9 million shares per six months), respectively. The value of the monthly vesting amounts was higher in the six months ended June 2015 than the period ended June 2014 because the price per share of the Company's stock has risen to $9.93 as of June 30, 2015 . 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 ongoing installments also included lock-up warrants (for a 3-year lock-up of Cognate shares) and most favored nation shares and warrants.

Foreign Currency Translation and Transactions

The Company maintains operations in Germany, the United Kingdom and Canada. Assets and liabilities are translated into U.S. dollars using end of period exchange rates and revenues and expense are translated into U.S. dollars using weighted average rates. Foreign currency translation adjustments are reported as a separate component of Accumulated Other Comprehensive Loss within Shareholders' Equity.

During the six months ended June 30, 2015, the Company recorded $0.6 million of foreign currency translation gain primarily due to the strengthening of the U.S. dollar relative to the euro and British pound sterling.

Foreign currency transaction losses are recognized in the Consolidated Statements of Operations as incurred.

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 Financial Accounting Standards Board ("FASB") issued ASU No. 2015-03*, Simplifying the Presentation of Debt Issuance Costs* (ASU 2015-03), which requires 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, but early adoption is permitted. As of June 30, 2015, the Company adopted ASU 2015-03 and such adoption resulted in debt issuance costs for all periods presented to be reclassified to long-term debt, net.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers: Topic* 606 (ASU 2014-09), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues, when promised goods or services are transferred to customers, in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective the first quarter of 2018 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. The Company is currently evaluating the impact of ASU 2014-09 on its 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 June 30, 2015 and December 31, 2014 (in thousands):

	Fair value measured at June 30, 2015			
	Fair value at June 30, 2015	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 92,716	$ -	$ -	$ 92,716

	Fair value measured at December 31, 2014			
	Fair value at December 31, 2014	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Warrant liability	$ 44,742	$ -	$ -	$ 44,742

There were no transfers between Level 1, 2 or 3 during the six month period ended June 30, 2015.

The following table presents changes in Level 3 liabilities measured at fair value for the six month period ended June 30, 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 – January 1, 2015	$ 44,742
Change in fair value	48,852
Cashless warrants exercise	(521)
Warrants exercised for cash	(58)
Redeemable security settlement	(299)
Balance – June 30, 2015	$ 92,716

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 six months ended June 30, 2015 is as follows:

Date of valuation	June 8, 2015*	June 9, 2015*	June 12, 2015*	June 23, 2015*	June 30, 2015
Strike price	$ 5.97	$ 5.97	$ 5.97	$ 5.97	$2.40-$5.97
Volatility (annual)	66.4%	66.4%	66.4%	66.4%	66.4%-65.9%
Risk-free rate	1.2%	1.3%	1.3%	1.2%	1.0%-1.4%
Contractual term (years)	3.5	3.5	3.5	3.4	3.0-4.2
Dividend yield (per share)	0%	0%	0%	0%	0%

* Inputs for derivative warrants exercise for cash that were marked to fair value through the time of exercise.

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 (restricted common stock and warrants) to Cognate for the ongoing vesting over 3 years of one-time initiation payments under the four agreements that were entered into in January 2014 for Cognate services was $15.8 million (comprising 0.9 million shares per six months) and $10.6 million (comprising 0.9 million shares per six months) for the six months ended June 30, 2015 and 2014, respectively. Approximately $4.4 million in compensation costs per calendar quarter may be recognized over the next 1.5 years based on the fair market value of stock of $9.93 as of June 30, 2015.

6. Property and Equipment

Property and equipment consist of the following at June 30, 2015 and December 31, 2014 (in thousands):

	June 30, 2015	December 31, 2014
Leasehold improvements	$ 69	$ 69
Office furniture and equipment	25	25
Computer equipment and software	191	137
Construction in progress (property in the United Kingdom)	41,889	39,928
	42,174	40,159
Less: accumulated depreciation	(175)	(160)
	$ 41,999	$ 39,999

Depreciation expense was approximately $15,000 and $6,000 for the six months ended June 30, 2015 and 2104, respectively.

7. Notes Payable

2014 Convertible Senior Notes

The 2014 Convertible Senior Notes are due on August 15, 2017 and have a conversion price of $6.60.

The Company has remaining $1.8 million in escrowed interest payments, which 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.

During the six months ended June 30, 2015, $4.5 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 701,033 shares of the Company's common stock, which includes accelerated interest. The Company also accelerated the remaining portion of deferred offering cost upon the conversion of the Senior Notes and recorded as additional interest expense.

The following table shows the details of interest expenses related to 2014 Convertible Senior Notes for the three and six months ended June 30, 2015 (in thousands):

	Three months ended June 30, 2015	Six months ended June 30, 2015
Contractual interest	$ 135	$ 351
Accelerated interest associated with the converted portion of convertible senior notes into common stock	563	563
Amortization of debt issuance costs	107	212
Accelerated amortization of debt issuance cost due to the converted portion of convertible senior notes into common stock	234	234
Total interest expense on the convertible senior notes	$ 1,039	$ 1,360

Mortgage Loan

On February 13, 2015, the Company entered into a mortgage loan agreement (the "Mortgage") with Lancashire Mortgage Corporation Limited in the UK to expand the facility to $12 million (£7.75 million). The 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 Mortgage.

Interest expense related to the February 13, 2015 and November 17, 2014 mortgage loans amounted to $0.6 million and $0.9 million for the three and six months ended June 30, 2015, respectively, which included $0.3 million and $0.6 million related to the 12% coupon and $0.1 million and $0.3 million related to the amortization of deferred offering financing costs on the mortgage loan.

Other Notes Payable

Notes payable consist of the following at June 30, 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 June 30, 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 June 30, 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 and six month periods ended June 30, 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 for the periods presented (in thousands):

	For the six months ended June 30,	
	2015	2014
Common stock options	1,551	1,551
Over-allotment rights	-	2,273
Common stock warrants - equity treatment	13,166	14,200
Common stock warrants - liability treatment	12,491	9,108
Convertible notes	2,135	81
Potentially dilutive securities	29,343	27,213

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 six months ended June 30, 2015, the Company made net disbursements to Cognate of approximately $21.3 million (with invoices generally paid all in cash rather than half in cash and half in stock), 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. With the substantial expansion of recruitment in the Phase III DCVax-L trial during this period, patient volume has exceeded the maximum amount contracted for, and as a result the disbursements have included excess production costs. In addition, the disbursements have included preparatory work for multiple different Phase II clinical trials, which the Company anticipates launching during the second half of this year, as well as development work connected with new intellectual property and certain regulatory requirements. The disbursements have also included substantial one-time services related to manufacturing expansion in Europe.

As of June 30, 2015 and December 31, 2014, the Company owed Cognate (including third party sub-contract amounts) approximately $4.2 million and $5.7 million, respectively. These amounts are included in accounts payable related party.

The Company issued 318,116 common shares to Cognate's designee in partial satisfaction of the 8.1 million shares that were approved by the Company's Board in November 2014 to satisfy certain anti-dilution obligations to Cognate under the most favored nation provisions in the Company's agreements with Cognate that had not yet been issued. The Company recorded a $2.7 million charge to stock based compensation based upon the fair value of the common shares on the date of issuance.

Of note, in accordance with ASC 718, *Stock Based Compensation*, certain key terms related to 8.1 million shares have not been finalized (e.g., vesting conditions), therefore the Company has not recorded this transaction in its condensed consolidated financial statements as of June 30, 2015.

10. Stockholders' Equity (Deficit)

Common Stock Issuances

First Quarter 2015

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.

Second Quarter 2015

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 agreed to sell, and Woodford 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 million. The sale of the Shares took place in two separate closings as follows: (i) 1,554,054 shares for a purchase price of $11.5 million which closed on April 8, 2015; and (ii) an additional 3,851,351 shares for a purchase price of $28.5 million which closed on May 1, 2015. There are no warrants, pre-emptive rights or other rights or preferences.

During the quarter ended June 30, 2015, the Company converted $4.5 million of the 2014 Convertible Senior Notes into common stock on the terms set forth in the agreement. Pursuant to the exchange, on the terms set forth in the Notes, the investors received 701,033 shares of the Company's common stock.

During the quarter ended June 30, 2015, the Company issued an aggregate of 723,422 shares of common stock from the exercise of warrants for total proceeds of $3.1 million. Of which 9,200 shares of common stock was related to extinguishment of warrant liabilities. The fair value of the warrant liabilities was $0.06 million on the date of exercise, which was recorded as a component of additional paid-in-capital.

During the quarter ended June 30, 2015, the Company issued an aggregate of 183,895 shares of common stock to multiple investors from the cashless exercise of warrants previously issued.

During the quarter ended June 30, 2015, the Company issued an aggregate of 85,228 shares of common stock to an individual investor as stock based compensation. The fair value of the stock on the issuance date was $0.7 million.

During the quarter ended June 30, 2015, the Company issued an aggregate of 318,116 shares of common stock to Cognate's designee in partial satisfaction of the 8.1 million shares that were approved by the Company's Board last November to satisfy certain anti-dilution obligations to Cognate under the most favored nation provisions in the Company's agreements with Cognate, and were reported by the Company last November, but had not yet been issued.

Stock Purchase Warrants

The following is a summary of warrant activity for the six months ended June 30, 2015 (in thousands):

	Number of Warrants	Weighted Average Exercise Price
Outstanding as of December 31, 2014	**29,385**	**$ 4.72**
Warrants exercised for cash	(1,611)	4.18
Warrants exercised on a cashless basis*	(302)	3.94
Warrant adjustment due to Cognate price reset	62	3.35
Warrants expired and cancellation	(2,134)	4.63
Adjustment related to prior issued warrants	257	4.31
Outstanding as of June 30, 2015 **	**25,657**	**$ 4.76**

**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 8-year period from 2008 through 2015, with a weighted average exercise price and remaining contractual term of $3.3 and 4.2 years, respectively. The weighted average exercise price gives effect to adjustments related to the most favored nation clause in these warrants.*

11. Subsequent Events

The Company reviewed its activities and concluded that no subsequent events have occurred that would require recognition in our condensed consolidated financial statements or in the notes to our condensed consolidated financial statements.

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 the United States, Canada and Europe.

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

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

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), as well as preparing for multiple parallel Phase II trials. Such costs have increased and will continue to increase as we expand and accelerate these programs, and bring on additional clinical trial programs and additional intellectual property development, and general and administrative expenses. Such expenses will also increase as we undertake preparations for eventual commercialization, which involves extensive work for process optimization, validation and scale-up. The associated administrative expenses also increase as such operating activities grow.

Research and development expense was $29.4 million for the three months ended June 30, 2015 versus $21.5 million for the three months ended June 30, 2014.

Our operating costs include ongoing development work relating to the DCVax-Direct product and its manufacturing, such as the development, testing and optimization of different product preparations and methods, 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 expansion of our clinical trial programs including the Phase III trial in the US, UK, Germany and Canada (with DCVax-L for brain cancer), early access programs in Europe, and multiple Phase II trials (with DCVax-Direct for inoperable solid tumor cancers). The preparation costs include process development, upfront payments to the clinical trial sites and the CROs managing the trials and other service providers, and legal, regulatory and expert expenses related to regulatory approvals, institutional approvals and clinical trial agreements with each site, database development, training of medical and other site personnel, trial supplies and other. Additional substantial costs relate to the expansion of manufacturing facilities and capacity, in both the US and Europe.

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 both cash and non-cash measures. The non-cash expenses include stock-based compensation and depreciation. The cash expenses include administrative personnel related salary and benefit expenses, cost of facilities, insurance, travel, legal support, property and equipment and amortization of stock options and warrants.

Three Months Ended June 30, 2015 and 2014

For the three months ended June 30, 2015 and 2014, we recognized a net loss of $66.8 million and $25.9 million, respectively. For the three months ended June 30, 2014, the net loss was $25.7 million. The increase in net loss is mainly due to a non-cash change in fair value of derivative liability of $25.7 million recorded during the 2nd quarter of 2015.

Research and Development Expense

Research and development expense was $29.4 million for the three months ended June 30, 2015 versus $21.5 million for the three months ended June 30, 2014. The increase was primarily attributable to costs associated with manufacturing for, conducting (including CRO and site costs) and expanding the Phase III DCVax-L trial in Europe and the preparations for multiple Phase II trials, which we are expanding as compared to this period last year, as well as establishment and expansion of our German and UK subsidiaries and operations.

For the three months ended June 30, 2015 and 2014, we made cash payments for the two periods, respectively, of approximately $13.1 million (with the invoices generally being paid all in cash), and $7.1 million (with the invoices generally being paid half in cash and half in stock) to Cognate. At June 30, 2015 and 2014, we owed Cognate $4.2 million and $2.7 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 June 30, 2015 and 2014, we incurred non-cash equity based expense (restricted common stock and warrants) for the ongoing vesting (in equal monthly installments over 3 years) of the one-time initiation payments of shares and warrants under the four agreements the Company entered into with Cognate in January 2014. The vesting amounts during the three months ended June 30, 2015 and 2014 were $9.4 million (comprising 0.9 million shares per six months) and $2.7 million (comprising 0.9 million shares per six months) , respectively. The value of the monthly vesting amounts was higher in the three months ended June 2015 than the period ended June 2014 because the price per share of the Company’s stock has risen. 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 ongoing installments also included lock-up warrants (for a 3-year lock-up of Cognate shares) and most favored nation warrants.

General and Administrative Expense

General and administrative expense was $9.8 million (cash and non-cash expenses combined) for the three months ended June 30, 2015 versus $3.9 million for the three months ended June 30, 2014. The increase in general and administrative expenses can be mainly attributed to non-cash stock based payment to Cognate’s designee in partial satisfaction of the 8.1 million shares that were approved by the Company’s Board last November to satisfy certain anti-dilution obligations to Cognate, and were reported by the Company last November, but had not yet been issued.

Of note, in accordance with ASC 718, *Stock Based Compensation*, certain key terms related to 8.1 million shares have not been finalized (e.g., vesting conditions), therefore the Company has not recorded this transaction in its condensed consolidated financial statements as of June 30, 2015.

Change in fair value of derivatives

During the three months ended June 30, 2015 and 2014 we recognized a non-cash loss and gain on derivative liabilities of $25.7 million and $4.7 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 June 30, 2015 there was no inducement expense versus inducement expense of $5.1 million for the three months ended June 30, 2014. The inducement expense for the three months ended June 30, 2014 was related to the conversion of accounts payable to common stock and warrants to Cognate in connection with the extinguishment of accounts payable, 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 and debt issuance cost) increased to $1.6 million for the three months ended June 30, 2015 from $0.03 million for the three months ended June 30, 2014. The increase in interest expense is primarily related to the issuance of senior convertible notes and mortgage loans during the 2nd half of 2014 and 1st quarter of 2015.

Six Months Ended June 30, 2015 and 2014

We recognized a (combined cash and non-cash) net loss of $113.3 million for the six months ended June 30, 2015 which was comparable to the net loss of $71.9 million for the six months ended June 30, 2014.

Research and Development Expense

Research and development expense was $49.1 million for the six months ended June 30, 2015 versus $41.5 million for the six months ended June 30, 2014.

For the six months ended June 30, 2015 and 2014, we made cash payments for the two periods, respectively, of approximately $21.3 million (with invoices generally being paid in all cash), and $12.4 million (with invoices generally being paid half in cash and half in stock) to Cognate. With the substantial expansion of recruitment in the Phase III DCVax-L trial, patient volume exceeded the maximum amount contracted for, and as a result, the payments have included excess production costs. In addition, the payments have included preparatory work for multiple different Phase II clinical trials, which the Company anticipates launching during the second half of this year, as well as development work connected with new intellectual property and certain regulatory requirements. The payments have also included substantial one-time services related to manufacturing expansion in Europe.

As of June 30, 2015 and 2014, we owed Cognate $4.2 million and $2.7 million, respectively, for unpaid invoices for services performed by Cognate.

For the six months ended June 30, 2015 and 2014, we incurred non-cash equity based payment (restricted common stock and warrants) expense for the ongoing vesting (in equal monthly installments over 3 years) of the one-time initiation payments of shares and warrants under the four agreements the Company entered into with Cognate in January 2014. The vesting amounts during the six months ended June 30, 2015 and 2014 were $15.8 million (comprising 0.9 million shares per six months) and $10.6 million (comprising 0.9 million shares per six months), respectively. The value of the monthly vesting amounts was higher in the three months ended June 2015 than the period ended June 2014 because the price per share of the Company's stock has risen. 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 ongoing installments also included lock-up warrants (for a 3-year lock-up of Cognate shares) and most favored nation warrants.

General and Administrative Expense

General and administrative expense was $13.1 million (cash and non-cash expenses combined) for the six months ended June 30, 2015 versus $7.6 million for the six months ended June 30, 2014. The increase in general and administrative expenses were mainly from an increase of approximately $2.3 million in legal fees, and non-cash stock based compensation issued to Cognate's designee in partial satisfaction of the 8.1 million shares that were approved by the Company's Board last November to satisfy certain anti-dilution obligations to Cognate, and were reported by the Company last November, but had not yet been issued.

Of note, in accordance with ASC 718, *Stock Based Compensation*, certain key terms related to 8.1 million shares have not been finalized (e.g., vesting conditions), therefore the Company has not recorded this transaction in its condensed consolidated financial statements as of June 30, 2015.

Change in fair value of derivatives

During the six months ended June 30, 2015 and 2014 we recognized a non-cash loss on derivative liabilities of $48.9 million and $12.3 million, respectively, due primarily to the change in value of the warrants, due to an increase in our stock price, previously issued to Cognate in connection with the extinguishment of accounts payable.

Inducement expense

During the six months ended June 30, 2015 there was no inducement expense versus inducement expense of $10.3 million for the six months ended June 30, 2014. The inducement expense for the six months ended June 30, 2014 was related to the conversion of accounts payable to common stock and warrants to Cognate in connection with the extinguishment of accounts payable, and the fair value of the common stock and warrants of marketable, tradable shares of the Company's common stock were higher than the conversion price for the unregistered, restricted stock issued to Cognate.

Interest Expense

Interest expense (including non-cash elements such as amortization of debt discount and debt issuance cost) increased to $2.4 million for the six months ended June 30, 2015 from $0.2 million for the six months ended June 30, 2014. The increase in interest expense is primarily related to the issuance of senior convertible notes and mortgage loans during the 2^{nd} half of 2014 and 1st quarter of 2015.

Liquidity and Capital Resources

We have experienced recurring losses from operations. During the six months ended June 30, 2015, net cash outflows for operations and for one-time expenses was $44.7 million.

At June 30, 2015, current assets totaled $21.2 million, compared to $14.6 million at December 31, 2014. Current assets less current liabilities produces working capital deficit (cash and non-cash liabilities combined) in the amount of $95.3 million at June 30, 2015 (with $92.7 million of the $95.3 million deficit comprised of non-cash derivative liabilities), compared to a deficit of $54.2 million at December 31, 2014, as described above.

Operating Activities

During the six months ended June 30, 2015, we used $44.7 million in cash for operating activities and certain one-time expenses.

Investing Activities

During the six months ended June 30, 2015, we used $2.0 million in cash related to capitalized costs related to the UK facility. There were no investing activities during the six months ended June 30, 2014.

Financing Activities

During the six months ended June 30, 2015, our financing activities provided net proceeds after expenses of $51.7 million, consisting of $5 million in net mortgage loan proceeds, proceeds of $6.8 million from the exercise of warrants, and proceeds of $40.0 million from issuance of common stock.

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

Other factors affecting our ongoing funding requirements include the number of staff we employ, the number of sites and pace of patient enrollment in our Phase III brain cancer trial and our Phase II clinical 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 financial instruments due to fluctuations in its market price. Market risk is inherent in all financial instruments. Market risk may be exacerbated in times of trading illiquidity when market participants refrain from transacting in normal quantities and/or at normal bid-offer spreads. Our exposure to market risk is directly related to derivatives, debt and equity linked instruments related to our financing activities.

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

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

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

Based on our analysis, as of June 30, 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 the external firm that performs the finance and accounting functions for our Company, together with 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.

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. We have been working together with the external firm who performs the Company's finance and accounting functions to address the weaknesses.

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, 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 June 30, 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

In 2014, as previously reported, the Company received demand letters from three purported individual shareholders seeking to inspect our corporate books and records pursuant to Section 220 of the Delaware General Corporation Law. The demand letters were all substantially similar, and claimed that their purpose is to investigate possible mismanagement and breaches of fiduciary duty by the Company's directors and officers. They requested a range of documents. The Company reached negotiated agreements and provided limited records, under confidentiality agreements.

On June 19, 2015, two of the purported shareholders filed a complaint purportedly suing on behalf of a class of similarly situated shareholders and derivatively on behalf of the Company. The lawsuit names Cognate BioServices, Inc. Toucan Partners, Toucan Capital Fund III, Linda Powers and the Company's Board of Directors as defendants, and names NW Bio as a "nominal defendant" with respect to the derivative claims. The complaint generally claims that the Company overpaid the Cognate and Toucan defendants with respect to financings provided by those parties or conversions of debts owed to those parties. The complaint seeks various forms of relief. The Company strongly disputes the allegations of the complaint and intends to vigorously defend the case.

As previously reported, the Company previously received demand letters from two purported individual shareholders alleging "short swing" profits under Section 16(b) of the Exchange Act arising from Cognate awarding to some of its own employees some of the NW Bio shares that Cognate owned, and arising from a convertible debt financing transaction in which the unrelated investor chose to convert the debt into shares of NW Bio stock owned by Cognate rather than being repaid in cash. However, prior to either of these demand letters, NW Bio had already filed a Form 8-K on December 19, 2014, in which it already disclosed this same information (which had been found in the course of a joint review by Cognate and NW Bio), already agreed with Cognate on the disgorgement of those deemed profits ($448,681) by Cognate and resolved the matter. The Company believes that the payment by Cognate fully resolved the matters, and so informed the purported shareholders who sent the demand letters.

In April, 2015, one of those purported individual shareholders filed a complaint against the Company and Cognate. The same plaintiff had previously filed such a complaint and then withdrew it to amend it. The complaint seeks to force disgorgement of a larger amount, which the plaintiff alleges is unknown but is estimated to be approximately $1.4 million, reduced by the payment already made. The Company and Cognate dispute the plaintiff's claim for further disgorgement, have filed an Answer denying such liability, and are defending against these claims.

Item 1A. Risk Factors

The risk factors described in our most recent Annual Report on Form 10-K and other filings continue to apply as described therein.

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

During the quarter ended June 30, 2015, the Company converted $4.5 million of the 2014 Convertible Senior Notes and accrued interest into common stock on the terms set forth in the agreement. Pursuant to the exchange, on the terms set forth in the Notes, the investors received 701,033 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.

During the quarter ended June 30, 2015, the Company issued an aggregate of 723,422 shares of common stock from the exercise of warrants for total proceeds of $3.1 million. Of which 9,200 shares of common stock was related to extinguishment of warrant liabilities. The fair value of the warrant liabilities was $0.06 million on the date of exercise, which was recorded as a component of additional paid-in-capital.

During the quarter ended June 30, 2015, the Company issued an aggregate of 183,895 shares of common stock to multiple investors from the cashless exercise of warrants previously issued.

During the quarter ended June 30, 2015, the Company issued an aggregate of 85,228 shares of common stock to an individual investor as stock compensation. The fair value of the stock on the issuance date was $0.7 million.

During the quarter ended June 30, 2015, the Company issued an aggregate of 318,116 shares of common stock to Cognate's designee in partial satisfaction of the 8.1 million shares that were approved by the Company's Board last November to satisfy certain anti-dilution obligations to Cognate under the most favored nation provisions in the Company's agreements with Cognate, and were reported by the Company last November, but had not yet been 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 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 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 3. Defaults Upon Senior Securities

Not Applicable.

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 June 30, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of June 30, 2015 and December 31, 2014, (ii) the Condensed Consolidated Statements of Operations for the three-month and six-month periods ended June 30, 2015 and 2014, (iii) the Condensed Consolidated Statements of Comprehensive Loss for the three-month and six-month periods ended June 30, 2015 and 2014, (iv) the Condensed Consolidated Statement of Stockholders' Equity (Deficit), (v) the Condensed Consolidated Statements of Cash Flows for the six-month periods ended June 30, 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.

NORTHWEST BIOTHERAPEUTICS, INC

Dated: August 10, 2015	By: /s/ Linda F. Powers
	Name: Linda F. Powers
	Title: President and Chief Executive Officer
	Principal Executive Officer
	Principal Financial and Accounting Officer