

NANOIRICIDES, INC.  
Form 10-Q  
May 15, 2015

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT 1934.**

**For the quarterly period ended March 31, 2015**

*Commission File Number: 333-148471*

**NANOIRICIDES, INC.**

*(Exact name of Company as specified in its charter)*

<u>NEVADA</u>	<u>76-0674577</u>
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

**1 Controls Drive**

**Shelton, Connecticut 06484**

(Address of principal executive offices and zip code)

(203) 937-6137

*(Company's telephone number, including area code)*

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

Indicate by check mark whether the Company 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 Company was required to submit and post such files). Yes  No

Indicate by check mark whether the Company is a larger accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the Company is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of shares outstanding of the Company's Common Stock as of May 15, 2015 was approximately:  
57,150,000

NanoViricides, Inc.

FORM 10-Q

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NanoViricides, Inc.

## Balance Sheets

	March 31, 2015 (Unaudited)	June 30, 2014 As Restated
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$33,919,404	\$36,696,892
Prepaid expenses	308,604	108,089
Prepaid expenses - related parties	66,100	-
Other current assets	-	150,000
<b>Total Current Assets</b>	<b>34,294,108</b>	<b>36,954,981</b>
<b>PROPERTY AND EQUIPMENT</b>		
Property and equipment	12,300,894	6,736,742
Accumulated depreciation	(1,393,982 )	(1,239,986 )
<b>Property and equipment, net</b>	<b>10,906,912</b>	<b>5,496,756</b>
<b>TRADEMARK AND PATENTS</b>		
Trademark and patents	458,954	458,954
Accumulated amortization	(57,149 )	(50,696 )
<b>Trademark and patents, net</b>	<b>401,805</b>	<b>408,258</b>
<b>SECURITY DEPOSIT</b>	<b>-</b>	<b>1,000,000</b>
<b>Total Assets</b>	<b>\$45,602,825</b>	<b>\$43,859,995</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$23,375	\$376,446
Accounts payable – related parties	-	49,455
Accrued expenses	125,054	91,838
Deferred interest payable	375,000	-
<b>Total Current Liabilities</b>	<b>523,429</b>	<b>517,739</b>
<b>LONG TERM LIABILITIES:</b>		
Deposit for debenture	-	5,000,000

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Debentures payable - Series B, net of discount	4,525,729	4,037,568
Debentures payable - Series C, net of discount	2,340,568	-
Derivative liability -Series B debentures	930,940	5,699,703
Derivative liability - Series C debentures	809,305	-
Derivative liability - warrants	4,611,472	5,235,682
Total Long Term Liabilities	13,218,014	19,972,953
Total Liabilities	13,741,443	20,490,692
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, \$0.001 par value, 4,000,000 shares designated, 3,406,085 and 3,193,079 shares issued and outstanding, respectively	3,407	3,194
Series B Convertible Preferred stock, \$0.001 par value, 2,857,143 shares designated, none issued and outstanding	-	-
Series C Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, none issued and outstanding	-	-
Common stock, \$0.001 par value; 85,714,285 shares authorized; 57,150,415 and 54,620,993 shares issued and outstanding, respectively	57,150	54,621
Additional paid-in capital	84,982,686	75,212,888
Accumulated deficit	(53,181,861)	(51,901,400)
Total Stockholders' Equity	31,861,382	23,369,303
Total Liabilities and Stockholders' Equity	\$45,602,825	\$43,859,995

*See accompanying notes to the financial statements*

NanoViricides, Inc.

## Statements of Operations

**(Unaudited)**

	For the Three Months Ended March 31, 2015	For the Three Months Ended March 31, 2014  As Restated	For the Nine Months Ended March 31, 2015	For the Nine Months Ended March 31, 2014  As Restated
<b>OPERATING EXPENSES</b>				
Research and development	\$ 546,464	\$ 625,737	\$ 2,274,310	\$ 2,930,436
General and administrative	576,173	607,628	2,352,115	1,943,123
Total operating expenses	1,122,637	1,233,365	4,626,425	4,873,559
<b>LOSS FROM OPERATIONS</b>	(1,122,637 )	(1,233,365 )	(4,626,425 )	(4,873,559 )
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	35,009	54,789	156,035	78,850
Interest expense	(1,920,268 )	(2,725,716 )	(2,412,712 )	(2,972,216 )
Discount on convertible debentures	(297,276 )	(143,051 )	(860,454 )	(419,305 )
Change in fair value of derivatives	3,054,154	5,371,197	6,463,095	1,585,067
Other income (expense), net	871,619	2,557,219	3,345,964	(1,727,604 )
<b>(LOSS) INCOME BEFORE INCOME TAX PROVISION</b>	(251,018 )	1,323,854	(1,280,461 )	(6,601,163 )
<b>INCOME TAX PROVISION</b>	-	-	-	-
<b>NET (LOSS) INCOME</b>	\$(251,018 )	\$ 1,323,854	\$(1,280,461 )	(6,601,163 )
<b>NET (LOSS) INCOME PER COMMON SHARE</b>				
- Basic	\$(0.00 )	\$ 0.02	\$(0.02 )	(0.13 )
- Diluted	\$(0.02 )	\$(0.02 )	\$(0.07 )	(0.13 )
Weighted average common shares outstanding				
- Basic	56,941,122	53,318,736	56,356,105	50,307,984
- Diluted	59,607,788	55,033,023	59,022,772	50,307,984

*See accompanying notes to the financial statements*



NanoViricides, Inc.

## Statement of Changes in Stockholders' Equity

For the period from June 30, 2014 through March 31, 2015

**(Unaudited)**

	Series A Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2014	3,193,079	\$ 3,194	54,620,993	\$54,621	\$ 75,212,888	\$ (51,901,400)	\$23,369,303
Series A Preferred Shares issued with Debenture - Series C	187,000	187	-	-	1,152,110		1,152,297
Series A Preferred Shares issued for employee stock compensation	23,148	23	-	-	181,340		181,363
Shares issued for consulting and legal services			20,880	21	82,339		82,360
Warrants issued to Scientific Advisory Board			-	-	52,130		52,130
Common Shares issued in connection with exercise of warrants			1,926,656	1,927	6,741,370		6,743,297
Common shares issued for debenture interest			571,433	571	1,502,298		1,502,869
Series A Preferred Shares issued for consulting and legal services rendered	2,858	3			24,471		24,474
Shares issued for Directors fees			10,453	10	33,740		33,750



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Net loss - (1,280,461 ) (1,280,461 )

Balance, March 31, 2015 3,406,085 \$ 3,407 57,150,415 \$ 57,150 \$ 84,982,686 \$ (53,181,861) \$ 31,861,382

NanoViricides, Inc.

## Statements of Cash Flows

**(Unaudited)**

	For the Nine Months Ended March 31, 2015	For the Nine Months Ended March 31, 2014 <b>As Restated</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(1,280,461 )	\$(6,601,163 )
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	205,837	70,524
Common shares issued for services	116,110	96,751
Common shares issued for interest	1,502,869	2,605,716
Warrants granted to Scientific Advisory Board	52,130	167,954
Depreciation	153,996	151,902
Amortization	6,453	6,581
Change in fair value of derivative liability	(6,463,095 )	(1,585,067 )
Amortization of debt discount convertible debentures	860,454	419,305
Changes in operating assets and liabilities:		
Prepaid expenses	(200,515 )	(740,515 )
Other current assets	150,000	-
Deferred interest payable	375,000	-
Accounts payable	(353,071 )	(8,256 )
Prepaid expenses/accounts payable - related parties	(115,555 )	35,469
Accrued expenses	33,215	2,736
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(4,956,633 )</b>	<b>(5,378,063 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Collateral advance for affiliate	1,000,000	(1,000,000 )
Purchase of property and equipment	(5,564,152 )	(3,618,201 )
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(4,564,152 )</b>	<b>(4,618,201 )</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock and warrants in connection with private placements of common stock, net of issuance costs	-	28,602,740

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Proceeds from exercise of warrants	6,743,297	735,626
NET CASH PROVIDED BY FINANCING ACTIVITIES	6,743,297	29,338,366
NET CHANGE IN CASH and CASH EQUIVALENTS	(2,777,488 )	19,342,102
Cash and Cash Equivalents at beginning of period	36,696,892	13,923,245
Cash and Cash Equivalents at end of period	\$33,919,404	\$33,265,347
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	\$-	\$-
Income tax paid	\$-	\$-
NON CASH FINANCING AND INVESTING ACTIVITIES:		
Series A Preferred stock issued as discount on debentures	\$1,152,297	\$-
Issuance of Series C Debenture for deposit received	5,000,000	-
Bifurccation of embedded derivative	1,879,428	-
Stock warrants granted to brokers	-	248,758

*See accompanying notes to the financial statements*

**NANOIRICIDES, INC.**

**March 31, 2015 AND 2014**

**NOTES TO THE FINANCIAL STATEMENTS**

**(Unaudited)**

**Note 1 - Organization and Nature of Business**

NanoViricides, Inc. (the "Company") was incorporated under the laws of the State of Colorado on July 25, 2000 as Edot-com.com, Inc. which was organized for the purpose of conducting internet retail sales. On April 1, 2005, Edot-com.com, Inc. was incorporated under the laws of the State of Nevada for the purpose of re-domiciling as a Nevada corporation. On May 12, 2005, the corporations were merged and Edot-com.com, Inc., the Nevada corporation, became the surviving entity.

On June 1, 2005, Edot-com.com, Inc. ("ECMM") acquired Nanoviricide, Inc., a privately owned Florida corporation ("NVI"), pursuant to an Agreement and Plan of Share Exchange (the "Exchange"). Nanoviricide, Inc. was incorporated under the laws of the State of Florida on May 12, 2005.

Pursuant to the terms of the Exchange, ECMM acquired NVI in exchange for an aggregate of 80,000,000 newly issued shares of ECMM common stock resulting in an aggregate of 100,000,000 shares of ECMM common stock issued and outstanding. NVI then became a wholly-owned subsidiary of ECMM. The ECMM shares were issued to the NVI shareholders on a pro rata basis, on the basis of 4,000 shares of the Company's common stock for each share of NVI common stock held by such NVI shareholder at the time of the Exchange.

As a result of the Exchange transaction, the former NVI stockholders held approximately 80% of the voting capital stock of the Company immediately after the Exchange. For financial accounting purposes, this acquisition was a reverse acquisition of ECMM by NVI, under the purchase method of accounting, and was treated as a recapitalization with NVI as the acquirer. Accordingly, the financial statements have been prepared to give retroactive effect to May 12, 2005 (date of inception), of the reverse acquisition completed on June 1, 2005, and represent the operations of NVI.

On June 28, 2005, NVI was merged into its parent ECMM and the separate corporate existence of NVI ceased. Effective on the same date, Edot-com.com, Inc. changed its name to NanoViricides, Inc. and its stock symbol to "NNVC", respectively.

NanoViricides, Inc. (the “Company”), is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. We are a company with several drugs in various stages of early development. Our drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. (“TheraCour”), an entity owned and controlled by a significant stockholder, to which we have the necessary exclusive, worldwide licenses in perpetuity. The first agreement we executed with TheraCour Pharma on September 1, 2005, gave us an exclusive, worldwide license for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus.

On February 15, 2010, the Company executed an Additional License Agreement with TheraCour. Pursuant to the Additional License Agreement, the Company was granted exclusive, worldwide licenses, in perpetuity, for technologies, developed by TheraCour, for the development of drug candidates for the treatment of Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes. As consideration for obtaining these exclusive licenses, we agreed to pay a onetime licensing fee equal to 2,000,000 shares (adjusted for the 3.5 to 1 reverse split) of the Company’s Series A Convertible Preferred Stock (the “Series A Preferred Stock”). The Series A Preferred Stock is convertible, only upon sale or merger of the Company, or the sale of or license of substantially all of the Company’s intellectual property, into shares of the Company’s common stock at the rate of 3.5 shares of common stock for each share of Series A Preferred Stock. The Series A Preferred Stock has a preferred voting preference at the rate of nine votes per share. The Preferred Series A do not contain any rights to dividends, have no liquidation preference, and are not to be amended without the holder’s approval. The 2,000,000 shares were valued at the par value of \$2,000.

**Note 2- Restatement of Previously Issued Financial Statements**

In connection with the preparation of our unaudited financial statements for the quarter ended December 31, 2014, we determined that in preparing our audited financial statements for the year ended June 30, 2014, we inadvertently overlooked the anti-dilution provisions in certain warrants issued in connection with the Company's private placements of securities. Specifically, the warrants issued contained certain anti-dilution ratchet provisions that provided for an adjustment to the exercise price of the warrants if the Company issued any stock equivalent securities at a lower price in the future while the warrants were still outstanding. Adjustments to settlement amounts by future equity offerings or contractual terms of other equity linked financial instruments issued in a subsequent period are not inputs to the fair value of a fixed-for-fixed option on equity shares. Accordingly, the warrants are not considered indexed to its own stock and thus must be accounted for as derivative liabilities which require initial measurement at fair value and adjustment to fair value in subsequent periods. The Company determined that the error caused a material understatement of its derivative liability at June 30, 2014. As a result of this error, we filed the Form 10-K/A to restate our audited financial statements for the year ended June 30, 2014, on February 23, 2015 and the Form 10-Q/A to restate the unaudited financial statements for the three month periods ended September 30, 2014 and 2013. Form 10-Q for the three and six month periods ended December 31, 2014 and 2013 has also been restated for the three and six month periods ended December 31, 2013 to reflect the correction of the aforementioned error included in those periods.

The financial statements for the three and nine month periods ended March 31, 2014, include restatements to reflect the aforementioned omission of the derivative liabilities arising from the anti-dilution provisions in the aforesaid warrants issued in conjunction with the Company's private placement of securities included in those periods. For the three and nine months ended March 31, 2014 the net adjustment to net income/loss recognized by the Company is \$1,618,264 and \$1,658,409 respectively. The net adjustment resulting from the recognition of the warrant derivative liability is an increase of \$4,082,131 to derivative liability and a corresponding reduction in additional paid in capital of \$4,082,131.

The impact of the above adjustment to the line items in our unaudited financial statements as of March 31, 2014 and for the three and nine months ended March 31, 2014 are summarized in the tables below:

## Balance Sheet Data

March 31, 2014 (Unaudited) <b>As Originally Reported</b>	Net Adjustments	March 31, 2014 (Unaudited) <b>As Restated</b>
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LONG TERM LIABILITIES:

Debentures payable - Series B	\$3,887,378	\$ -	\$3,887,378
Derivative liability -Series B	3,824,986	-	3,824,986
Derivative liability -warrants	-	4,082,131	4,082,131
Total Long Term Liabilities	7,712,364	4,082,131	11,794,495

Total Liabilities	8,920,548	4,082,131	13,002,679
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STOCKHOLDERS' EQUITY:

Additional paid-in capital	78,531,194	(5,740,540 )	72,790,654
Accumulated deficit	(46,559,356)	1,658,409	(44,900,947)

Total Stockholders' Equity	\$32,029,392	\$(4,082,131 )	\$27,947,261
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## Statements of Operations

**(Unaudited)**

	For the Three Months Ended March 31, 2014 As Originally Reported	Net Adjustments	For the Three Months Ended March 31,2014 As Restated	For the Nine Months Ended March 31, 2014 As Originally Reported	Net Adjustments	For the Nine Months Ended March 31,2014 As Restated
<b>OPERATING EXPENSES</b>						
Research and development	\$625,737	\$ -	\$625,737	\$2,930,436	\$ -	\$2,930,436
Refund credit research and development costs	-	-	-	-	-	-
General and administrative	607,628	-	607,628	1,943,123	-	1,943,123
Total operating expenses	1,233,365	-	1,233,365	4,873,559	-	4,873,559
<b>LOSS FROM OPERATIONS</b>	(1,233,365 )	-	(1,233,365 )	(4,873,559 )	-	(4,873,559 )
<b>OTHER INCOME (EXPENSE):</b>						
Interest income	54,789	-	54,789	78,850	-	78,850
Interest expense	(2,725,716 )	-	(2,725,716 )	(2,972,216 )	-	(2,972,216 )
Discount on convertible debentures	(143,051 )	-	(143,051 )	(419,305 )	-	(419,305 )
Change in fair market value of derivatives	3,752,933	1,618,264	5,371,197	(73,342 )	1,658,409	1,585,067
Other income (expense), net	938,955	1,618,264	2,557,219	(3,386,013 )	1,658,409	(1,727,604 )
<b>(LOSS ) INCOME BEFORE INCOME TAX PROVISION</b>	(294,410 )	1,618,264	1,323,854	(8,259,572 )	1,658,409	(6,601,163 )
<b>INCOME TAX PROVISION</b>	-	-	-	-	-	-
<b>NET (LOSS) INCOME</b>	\$(294,410 )	\$ 1,618,264	\$ 1,323,854	\$(8,259,572 )	\$ 1,658,409	\$(6,601,163 )
<b>NET (LOSS) INCOME PER COMMON SHARE</b>						
- Basic	\$(0.01 )		\$0.02	\$(0.16 )		(0.13 )



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- Diluted	\$ (0.01 )	\$ (0.02 )	\$ (0.16 )	\$ (0.13 )
Weighted average common shares outstanding				
- Basic	53,318,736	53,318,736	50,307,984	50,307,984
- Diluted	53,318,736	55,033,023	50,307,984	50,307,984

### **Note 3 - Summary of Significant Accounting Policies**

#### *Basis of Presentation – Interim Financial Information*

The accompanying unaudited interim financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission for Interim Reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim financial statements furnished reflect all adjustments (consisting of normal recurring accruals) which are, in the opinion of management, considered necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. The accompanying financial statements and the information included under the heading “Management’s Discussion and Analysis or Plan of Operation” should be read in conjunction with our Company’s audited financial statements and related notes included in our Company’s form 10-K/A for the fiscal year ended June 30, 2014 filed with the SEC on February 23, 2015.

#### *Reclassifications*

Certain accounts in the June 30, 2014 financial statements have been reclassified to conform to the current period presentation.

For a summary of significant accounting policies, see the Company’s Annual Report on Form 10-K/A for the fiscal year ended June 30, 2014 filed on February 23, 2015.

#### *Net Income (Loss) per Common Share*

Net income (loss) per common share is computed pursuant to section 260-10-45 of the FASB Accounting Standards Codification. Basic net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock and potentially outstanding shares of common stock during the period to reflect the potential dilution that could occur from common shares issuable through stock options, warrants, convertible preferred stock, and convertible debentures.

The following table shows the number of potentially outstanding dilutive common shares excluded from the diluted net income (loss) per common share calculation as they were anti-dilutive:

	Potentially Outstanding Dilutive Common Shares	
	For the Nine Months Ended March 31, 2015	For the Nine Months Ended March 31, 2014
Stock options	535,715	535,715
<b>Warrants</b>	5,959,527	8,870,065
Total potentially outstanding dilutive common shares	6,495,242	9,405,780

In addition, the Company has issued Convertible Debentures, to investors. A portion of the interest required to be paid on the debentures had been paid in shares of the Company's \$0.001 par value common stock ("Interest Shares") according to the terms of the Debenture. No additional Interest Shares are required to be issued under the terms of the debenture. The Company will need to issue 571,428 warrants on January 15, 2016 relating to the additional interest to be paid on the Series B debentures. Coupon interest payable quarterly related to the Series B Debentures is payable in cash or shares of Common Stock at the average of the open and close value on the date such interest payment is due at the option of the Holder. The Holders have elected to receive coupon interest in cash.

At March 31, 2015, the estimated number of potentially dilutive shares of the Company's common stock into which the Series B debentures can be converted based upon the conversion price of \$3.50 is 1,714,286. At March 31, 2015 the number of potential dilutive shares of the Company's common stock into which the Series C debentures can be converted based upon the conversion provisions contained in the debenture is 952,381.

The Company has also issued 3,406,085 of \$0.001 par value Preferred A shares to investors and others as of March 31, 2015. Only in the event of a "change of control" of the Company, each Series A preferred share is convertible to 3.5 shares of its new common stock. A "Change of Control" is defined as an event in which the Company's shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition. In the absence of a Change of Control event, the Series A stock is not convertible into Common Stock, and does not carry any dividend rights or any other financial effects. At March 31, 2015, the estimated number of potentially dilutive shares of the Company's common stock into which these Series A Preferred shares can be converted into is 11,921,298, and is not included in diluted earnings per share since the shares are contingently convertible only upon a Change of Control.

Pursuant to the Redemption provisions of the Series C Debentures, the Company, at its sole option, shall have the right, but not the obligation, to repurchase the Debenture at any time prior to the Maturity Date (the "Redemption"). If the Company intends to repurchase the Debenture, and if the closing bid price of the Common Stock is greater than \$5.25 on the Redemption Date, unless the Holder, on or prior to the Redemption Date, elects to receive the "Redemption Payment", as that term is defined herein, the Company shall pay to the Holder: (i) 952,381 shares of Common Stock in consideration of the exchange of the principal amount of the Debenture; and (ii) any and all accrued coupon interest. If on or prior to the Redemption Date, the Holder elects to receive the Redemption Payment, or the closing bid price of the Common Stock is less than \$5.25, the Company shall issue to the Holder: (i) the principal amount of the Debenture; (ii) any accrued coupon interest; (iii) additional interest of 7% per annum for the period from the date of issuance of the Debenture to the Redemption Date; and (iv) warrants to purchase 619,048 shares of Common Stock which shall expire in three years from the date of issuance at an exercise price of \$6.05 per share of Common Stock (the "Redemption Warrants", and collectively with (i) – (iii), the "Redemption Payment"). The Company shall use its best efforts to register the shares underlying the Redemption Warrants under a "shelf" registration statement, provided same is available to the Company, in accordance with the provisions of the Securities Act.

The following represents a reconciliation of the numerators and denominators of the basic and diluted per share calculations for income from continuing operations:

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	For the three months ended		For the nine months ended	
	March 31, 2015	March 31, 2014	March 31, 2015	March 31, 2014
Calculation of basic loss per share of common stock:				
Net (loss) income attributable to common stockholders	\$ (251,018 )	\$ 1,323,854	\$ (1,280,462 )	\$ (6,601,163 )
Denominator for basic weighted average shares of common stock	56,941,122	53,318,736	56,356,105	50,307,984
Basic (loss) income per share of common stock	\$ (0.00 )	\$ 0.02	\$ (0.02 )	\$ (0.13 )
Calculation of diluted loss per share of common stock:				
Net (loss) income attributable to common stockholders	\$ (251,018 )	\$ 1,323,854	\$ (1,280,462 )	\$ (6,601,163 )
Add: Income impact of assumed conversion of Debentures	(696,103 )	(2,502,430 )	(2,740,562 )	-
Net (loss) income attributable to common stockholders plus assumed conversions	\$ (947,121 )	\$ (1,178,576 )	\$ (4,021,024 )	\$ (6,601,163 )
Denominator for basic weighted average shares of common stock	56,941,122	53,318,737	56,356,105	50,307,984
Incremental shares from assumed conversions of Debentures payable	2,666,667	1,714,286	2,666,667	-
Denominator for diluted weighted average shares of common stock	59,607,788	55,033,023	59,022,772	50,307,984
Diluted (loss) income per share of common stock	\$ (0.02 )	\$ (0.02 )	\$ (0.07 )	\$ (0.13 )

Series B Debentures were excluded from the loss per share calculation for the three and nine months ended March 31, 2014 because the impact is anti-dilutive.

Recently Issued Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-12, “Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period.” This ASU requires a reporting entity to treat a performance target that affects vesting and that could be achieved after the requisite service period as a performance condition, and apply existing guidance under the Stock Compensation Topic of the ASC as it relates to awards with performance conditions that affect vesting to account for such awards. The provisions of this ASU are effective for interim and annual periods beginning after December 31, 2015. The Company is currently evaluating the impact of this ASU.

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” (“ASU 2014-15”). ASU 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently evaluating the impact of the adoption of ASU 2014-14 on the Company’s financial statements and disclosures.

In April 2015, the FASB issued ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30), "Simplifying the Presentation of Debt Issuance Costs," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU requires retrospective adoption and will be effective for fiscal years beginning after December 15, 2015 and for interim periods within those fiscal years. We expect the adoption of this guidance will not have a material impact on our financial statements.

#### **Note 4 - Financial Condition**

The Company's financial statements for the interim period ended March 31, 2015 have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business. The Company has an accumulated deficit at March 31, 2015 of (\$53,181,861). In addition, the Company has not generated any revenues and no revenues are anticipated in the short-term. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of March 31, 2015 the Company had cash and cash equivalents of \$33,919,404. The Company has sufficient capital to continue its business, at least, through March 31, 2017, at the current rate of expenditure.

While the Company continues to incur significant operating losses with significant capital requirements, the Company has been able to finance its business through sale of its securities. The Company may require additional capital to finance planned and currently unplanned capital costs and additional staffing requirements during the next 24 months. The Company has in the past adjusted its priorities and goals in line with the cash on hand and capital availability. The Company believes it can adjust its priorities of drug development and its plan of operations as necessary, if it is unable to raise additional funds.

#### **Note 5 - Related Party Transactions**

##### Related Parties

Related parties with whom the Company had transactions are:

<b>Related Parties</b>	<b>Relationship</b>
Anil R. Diwan	Chairman, President, significant stockholder and director
Eugene Seymour	CEO, significant stockholder, director
TheraCour Pharma, Inc.	An entity owned and controlled by significant stockholder
Inno-Haven, LLC	An entity owned and controlled by significant stockholder
Milton Boniuk, MD	Director and significant stockholder

Property and Equipment

	<b>For the nine months ended March 31, 2015</b>
During the reporting period, the Company acquired 1 Controls Drive Shelton Ct from Inno-Haven, LLC	\$4,222,549
During the reporting period, Inno-Haven, LLC, acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, at cost, to the Company	\$-
During the reporting period, TheraCour Pharma, Inc. acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, at cost, to the Company	\$222,582



Prepaid Expense (Accounts Payable) Related Party

	As of March 31, 2015	As of June 30, 2014
Pursuant to an Exclusive License Agreement and an Additional License Agreement we entered into with TheraCour Pharma, Inc., (TheraCour), the Company was granted exclusive licenses in perpetuity for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies, and others. In consideration for obtaining these exclusive licenses, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed. (2) we will pay \$25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour, (3) we will pay \$2,000 per month or actual costs, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf. Prepaid Expense (Accounts payable) due TheraCour Pharma Inc. (including a two (2) month security advance):	\$66,100	\$(49,455)

Research and Development Costs Paid to Related Parties

	For the three months ended		For the nine months ended	
	March 31, 2015	March 31, 2014	March 31, 2015	March 31, 2014
Development fees and other costs charged by and paid to TheraCour Pharma, Inc. pursuant to exclusive License Agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at March 31, 2015 and 2014	\$398,407	\$391,628	\$1,688,547	\$1,315,753

Long Term Debenture Payable to a Director

	March 31, 2015	June 30, 2014
Series B Convertible Debentures - Milton Boniuk	\$4,000,000	\$4,000,000
Series C Convertible Debentures: - Milton Boniuk	5,000,000	-

Total Long Term Debentures Payable to a Director \$9,000,000 \$4,000,000

**Note 6 - Property and Equipment**

Property and equipment, stated at cost, less accumulated depreciation consisted of the following:

	March 31, 2015	June 30, 2014
Building GMP Facility	\$8,376,336	\$3,099,780
Office Equipment	30,048	30,048
Furniture and Fixtures	1,400	1,400
Lab Equipment	3,893,110	3,605,514
Total Property and Equipment	12,300,894	6,736,742
Less Accumulated Depreciation	(1,393,982 )	(1,239,986)
Property and Equipment, Net	\$10,906,912	\$5,496,756

Depreciation expense for the nine months ended March 31, 2015 and 2014 was \$153,996 and \$151,902, respectively.

On December 31, 2014, the Company entered into and consummated an Agreement for the Purchase and Sale of a cGMP-compliant pilot manufacturing and lab facility at 1 Controls Drive, Shelton, Connecticut. The purchase price of the facility was comprised solely of the repayment of the direct costs of the seller, Inno-Haven, LLC (“Inno-Haven”), an entity owned and controlled by a significant stockholder, incurred in acquiring and renovating the property and the facility plus Inno-Haven’s closing costs in connection with the sale. The purchase price consisted of the repayment of Inno-Haven’s acquisition and renovation expenses of \$4,222,549 and closing costs of \$81,230.

**Note 7 - Trademark and Patents**

Trademark and patents, stated at cost, less accumulated amortization consisted of the following:

March 31,	June 30, 2014
--------------	------------------

2015

Trademarks and Patents	\$458,954	\$458,954
Less Accumulated Amortization	(57,149 )	(50,696 )
Trademarks and Patents, Net	\$401,805	\$408,258

Amortization expense amounted to \$6,453 and \$6,581 for the nine months ended March 31, 2015, and 2014, respectively.

#### Note 8 – Convertible Debentures

On February 1, 2013, the Company raised gross proceeds of \$6,000,000 which includes \$4,000,000 from a family investment office and a charitable foundation controlled by Dr. Milton Boniuk, a member of the Company’s board of directors, through the issuance of our Series B Debentures. The investors purchased unsecured convertible debentures with a 4-year term. The debentures bear an interest rate of 8% p.a. payable quarterly in cash or the Holder at its option may elect to receive such coupon interest payment in shares of common stock and calculated on the issuance, average of the open and close value on the date such interest payment is due. Additional interest is payable in restricted common stock of 571,429 shares at issuance, January 15, 2014, and 2015, and additional interest of 571,429 warrants to be issued on January 15, 2016. The warrants are exercisable at \$3.50 per warrant and will be valid for 3 years after issuance. The investors can convert the principal and any accrued interest into common stock at a fixed price of \$3.50 per share. The Company can prepay the debentures, in which case the base interest rate shall increase by a 7% prepayment penalty. The Company agreed to use its best efforts to register the interest shares and the shares issuable from the interest warrants under a “shelf” registration statement provided same is available, in accordance with the provisions of the Securities Act.

The following table presents the balance of the Debenture payable – Series B, net of discount at March 31, 2015 and June 30, 2014. The debt discount is being accreted to interest expense over the term of the debenture:

	March 31, 2015	June 30, 2014
Proceeds	\$6,000,000	\$6,000,000
Debt discount for bifurcated derivative	(2,735,310)	(2,735,310)
	3,264,690	3,264,690
Amortization of debt discount	1,261,039	772,878
Debenture payable - Series B, net	\$4,525,729	\$4,037,568

The debenture contains embedded derivatives which are not clearly and closely related to the host instrument. The embedded derivatives are bifurcated from the host debt instrument and treated as a liability.

The single compound embedded derivative features valued include the:

1. Principal conversion feature at maturity based on fixed conversion price subject to standard adjustments.
2. Redemption additional interest and Redemption Warrants offering.
3. Additional Interest Shares and Interest Warrants.

For the three and nine months period ended March 31, 2015 the Company recognized amortization of this discount as an additional interest charge to “Discount on convertible debentures” in the amounts of \$166,543 and \$488,161 respectively.

The Company used a lattice model that values the compound embedded derivatives of the Series B Convertible Debenture based on a probability weighted discounted cash flow model at March 31, 2015.

The following assumptions were used for the valuation of the compound embedded derivative at March 31, 2015:

· The balance of the Series C Convertible Debenture as of issuance and March 31, 2015 is \$6,000,000;

· The underlying stock price was used as the fair value of the common stock; The stock price decreased to **\$2.25** at March 31, 2015 which decreased the warrant value with the \$3.50 exercise price (further out to in the money);

· The projected annual volatility was based on the Company historical volatility:

**1 year**

**12/31/2014 75%**

**3/31/2015 67%**

· An event of default would occur 0% of the time, increasing 1.00% per month to a maximum of **10%**;

· The Company would redeem the debentures projected initially at 0% of the time and increase monthly by 1.0% to a maximum of **5.0%** (from alternative financing being available for a Redemption event to occur);

· The Holder would automatically convert the interest if the Company was not in default and its shares value would equivalent to the cash value;

· The Holder would automatically convert the debenture at maturity if the registration was effective and the Company was not in default.

· The Weighted Cost of Capital discount rate (based on the Market Value of the transaction at issuance) adjusted for changes in the risk free rate is **21.86%**.

· Even through the shares are restricted the underlying assumption is that any restriction on resale will be removed either through registration or the passage of time at the time of issuance.

The fair value of the compound embedded derivatives of the Series B Convertible Debenture at March 31,2015 was \$930,940.

On July 2, 2014 (the "Closing Date"), the Company accepted a subscription in the amount of \$5,000,000 for a 10% Coupon Series C Convertible Debenture (the "Debenture") from Dr. Milton Boniuk, a member of the Company's Board of Directors (the "Holder"). The \$5,000,000 funding of the Debenture had been received by the Company prior to June 30, 2014, the year-end reporting period and the Company has reported the said Debenture in the financial statements at June 30, 2014 under long term liabilities. The Debenture is due on June 30, 2018 (the "Maturity Date") and is convertible, at the sole option of the Holder, into restricted shares of the Company's common stock, par value \$0.001 per share (the "Common Stock") at the conversion price of \$5.25 per share of Common Stock. The Debenture bears interest at the coupon rate of ten percent (10%) per annum, computed on an annual basis of a 365 day year, payable in quarterly installments on March 31, June 30, September 30 and December 31 of each calendar year until the Maturity Date. The Holder at its option may choose to receive such coupon interest payment in shares of Common Stock calculated on the average of the open and close value on the date such interest payment is due. To date, the Holder has elected to take such coupon interest in cash. The Company has the right, but not the obligation, to repay the Debenture prior to the Maturity Date (the "Redemption Payment"). If the closing bid price of the Common Stock is in excess of \$5.25 when the Company notifies the Holder it has elected to prepay the Debenture (the "Redemption Date"), the Company must redeem the Debenture by delivering to the Holder 952,381 shares of Common Stock and any unpaid coupon interest in lieu of a cash Redemption Payment. If the Holder elects to receive the Redemption Payment in cash, or if the closing bid price of the Common Stock is less than \$5.25, the Company shall pay to the Holder a Redemption Payment in cash equal to the principal amount of the Debenture, plus any accrued coupon interest, plus additional interest of 7% per annum for the period from the Closing Date to the Redemption Date and warrants to purchase 619,048 shares of Common Stock which shall expire in three years from the date of issuance at the exercise price of \$6.05 per share of Common Stock. The Company cannot conclude that it has sufficient authorized and unissued shares to settle the contract after considering all other commitments that may require the issuance of stock during the maximum period the derivative instrument could remain outstanding. This is due to the fact that the interest payments are payable in stock of the Company, at the option of the Holder, based on the current market price of the common stock on the date such payments are due. Therefore, the number of shares due as interest payments is essentially indeterminate and the Company cannot conclude that it has sufficient authorized and unissued shares to settle the conversion feature. Accordingly, the Company bifurcated the embedded features from the host contract and recorded them as a derivative liability at fair value. A debt discount was recognized for a derivative liability associated with embedded features bifurcated from the Series C Convertible Debenture.

On July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debentures, the Company issued 187,000 shares of its Series A Convertible Preferred stock (the "Series A") to Dr. Milton Boniuk, pursuant to the terms of the Debenture. Proceeds received in a financing transaction are allocated to the instruments issued prior to evaluating hybrid contracts for bifurcation of embedded derivatives. Since the Series A Convertible Preferred Stock is classified as equity, the proceeds allocated to the Preferred Stock are recorded at relative fair value. The fair value of the Series A was \$1,645,606 at issuance and the relative fair value was calculated as \$1,152,297. The remaining amount of the proceeds was allocated to the Debenture and a debt discount of \$1,152,297 was recorded to offset the amount of the proceeds allocated to the Series A. Then, the embedded derivative was bifurcated at its fair value of \$1,879,428 with the remaining balance allocated to the host instrument (Debenture). The total debt discount will be amortized over the term of the Debenture using the effective interest method. For the three and nine months period ended March 31, 2015 the Company recognized amortization of this discount as an additional interest charge to "Discount on convertible debentures" in the amounts of \$130,733 and \$372,293 respectively.

The following represents the balance of the Debenture payable – Series C, net of discount at March 31, 2015:

Proceeds	\$5,000,000
Debt discount	
Series A Preferred	(1,152,297)
Embedded derivative	(1,879,428)
	1,968,275
Amortization of debt discount for the nine months ended March 31, 2015	372,293
Balance at March 31, 2015	\$2,340,568



The Company used a lattice model that values the compound embedded derivatives of the Series C Convertible Debenture based on a probability weighted discounted cash flow model at March 31, 2015.

The following assumptions were used for the valuation of the compound embedded derivative at March 31, 2015:

- The balance of the Series C Convertible Debenture as of March 31, 2015 is \$5,000,000;

- The underlying stock price was used as the fair value of the common stock; The stock price decreased to **\$2.25** at March 31, 2015 which decreased the warrant value with the \$6.05 exercise price (further out to in the money);

- The projected annual volatility was based on the Company historical volatility:

**1 year**

**12/31/2014 75%**

**3/31/2015 67%**

- An event of default would occur 0% of the time, increasing 1.00% per month to a maximum of **10%**;

- The Company would redeem the debentures projected initially at 0% of the time and increase monthly by 1.0% to a maximum of **5.0%** (from alternative financing being available for a Redemption event to occur);

- The Holder would automatically convert the interest if the Company was not in default and its shares value was equivalent to the cash value;

- The Holder would automatically convert the debenture at maturity if the registration was effective and the Company was not in default.

- The weighted cost of capital discount rate (based on the market value of the transaction at issuance) adjusted for changes in the risk free rate is **21.86%**.

Even though the shares are restricted the underlying assumption is that any restriction on resale will be removed either through registration or the passage of time at the time of issuance.

The fair value of the compound embedded derivatives of the Series C Convertible Debenture at March 31, 2015 was \$809,305.

#### **Note 9 - Equity Transactions**

On July 17, 2014 the Company filed a registration statement on Form S-3 (the "Form S-3") registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009, ("Old Warrants") as described more fully in the Form S-3 (the "Registered Warrants"). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. Holders of the Old Warrants were required to submit Notice of Exercise by August 15, 2014, or their warrants would expire. The Company received Notices to Exercise Warrants and the exercise price to purchase an aggregate of 1,926,656 shares of the Company's common stock at the exercise price of \$3.50 per share for an aggregate purchase price of \$6,743,297.

On February 1, 2015 the Company's Board of Directors authorized the issuance of 571,433 shares of the Company's \$0.001 par value common stock as annual interest payable to holders of the Company's Series B Debentures. The Company recorded interest expense of \$1,502,869 for the three month period ended March 31, 2015 calculated using the fair market value of the Company's common stock on the date issued.

Unregistered Securities

As discussed in Note 8, on July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debentures, the Company issued 187,000 Shares of its Series A Convertible Preferred stock to Dr. Milton Boniuk, pursuant to the terms of the Debenture. The Company allocated the proceeds received between the Debenture and the Preferred Stock on a relative fair value basis. The amount allocated to the Preferred stock was \$1,152,297.

For the nine months ended March 31, 2015, the Scientific Advisory Board was granted fully vested warrants to purchase 51,444 shares of common stock at exercise prices between \$3.62- \$5.04 per share expiring in the fiscal year ending June 30, 2018. These warrants were valued at \$52,130 and recorded as consulting expense.

For the nine months ended March 31, 2015, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

Expected life (year)	4	
Expected volatility	37.44%	-45.84 %
Expected annual rate of quarterly dividends	0.00	%
Risk-free rate(s)	1.20 - 1.67	%

For the nine months ended March 31, 2015, the Company's Board of Directors authorized the issuance of 23,148 shares of its Series A Convertible Preferred stock for employee compensation. The Company recorded an expense of \$181,363.

For the nine months ended March 31, 2015, the Company's Board of Directors authorized the issuance of 2,858 shares of its Series A Convertible Preferred Stock which are fully vested for consulting services. The Company recorded an expense of \$24,474.

For the nine months ended March 31, 2015, the Company's Board of Directors authorized the issuance of 20,881 shares of its common stock which are fully vested with a restrictive legend for consulting services. The Company recorded an expense of \$82,360 which is the fair value at date of issuance.

For the nine months ended March 31, 2015, the Company's Board of Directors authorized the issuance of 10,453 shares of its common stock which are fully vested with a restrictive legend for Director services. The Company recorded an expense of \$33,750 which is the fair value at date of issuance.

There is currently no market for the shares of Series A Preferred Stock and they can only be converted into shares of common stock upon a Change of Control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Preferred A shares granted to various employees and others on the date of grant. The Preferred Series A shares fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; ii) the value of the voting rights since the holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a Change of Control. The valuations of the Series A Preferred Stock at March 31, 2015 used the following inputs:

- a. The common stock price was in the range \$2.72 to \$2.29;
- b. The calculated weighted average number of shares of common stock in the period;

c. A 5.36% premium over the common shares for the voting preferences;

d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 4.896% to 5.046% of the total;

e. The conversion value is based on an assumption for calculation purposes only of a Change of Control in 4 years from March 1, 2013 and a remaining restricted term of 2.08 to 1.92 years;

f. 32.61% to 31.42% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 78.63% to 69.38% volatility, 0.674% to 0.47% risk free rate) applied to the converted common.

### Note 10 – Stock Options and Warrants

The following table presents the activity of stock options issued for the nine months ended March 31, 2015 as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding at June 30, 2014	535,715	\$ 0.35	1.23	\$2,094,643
Granted	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding at March 31, 2015	535,715	\$ 0.35	0.48.	\$996,424

As of March 31, 2015 there was no unrecognized compensation cost.

Stock Warrants	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding and exercisable at June 30, 2014	8,894,355	\$ 5.01	2.78	\$ 2,278,458

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Granted	51,444	4.18	-	-
Exercised	1,926,656	3.50	-	-
Expired	1,059,616	-	-	-
Canceled	-	-	-	-
Outstanding and exercisable at March 31, 2015	5,959,527	\$ 5.15	3.34	\$ 19,004

Of the above warrants, 277,149 expire in fiscal year ending June 30, 2015; and 68,571 expire in fiscal year ending June 30, 2016; 68,571 expire in fiscal year ending June 30, 2017; 68,570 in fiscal year ending June 30, 2018; 5,476,666 in fiscal year ending June 30, 2019.

**Note 11 – Fair Value Measurement**

**Fair value measurements**

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value for applicable assets and liabilities, we consider the principal or most advantageous market in which we would transact and we consider assumptions market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. This guidance also establishes a fair value hierarchy to prioritize inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

At March 31, 2015 and June 30, 2014, the fair value of derivative liabilities is estimated using a lattice model that is based on the individual characteristics of our warrants, preferred and common stock, the derivative liability on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate and, in some cases, credit spread. The derivative liabilities are the only Level 3 fair value measures.

At March 31, 2015 and June 30, 2014, the estimated fair values of the liabilities measured on a recurring basis are as follows:

	Fair Value Measurements at March 31, 2015:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series B debentures	\$-	-	\$930,940
Derivative liability – Series C debentures	-	-	809,305

Derivative liability – warrants	-	-	4,611,472
Total derivatives	\$-	\$ -	\$6,351,717

Fair Value  
Measurements at  
June 30, 2014  
(Restated):

(Level 1) (Level 2) (Level 3)

Derivative liability – Series B debentures	\$-	\$ -	5,699,703
Derivative liability - warrants	-	-	5,235,682
Total derivatives	\$-	\$ -	\$10,935,385

The following tables present the activity for liabilities measured at estimated fair value using unobservable inputs for the nine months ended March 31, 2015:

	Fair Value Measurement Using Significant Unobservable Inputs		
	Derivative liability – Series B	Derivative liability – Series C	Derivative liability - warrant
Beginning balance at July 1, 2014	\$5,699,703	\$-	\$5,235,682
Additions during the year	-	1,879,428	-
Change in fair value	(4,768,763)	(1,070,123)	(624,210 )
Transfer in and/or out of Level 3	-	-	-
Ending balance at March 31, 2015	\$930,940	\$809,305	\$4,611,472



**Note 12 - Commitments and Contingencies**

Operating Lease

The Company maintains facilities located at 135 Wood Street, West Haven, Connecticut, that includes approximately 7,000 square feet of office and laboratory space at a base monthly rent of \$8,695. The term of lease expired on February 28, 2011 and is now on a month-by-month basis.

Total rent expense at 135 Wood Street, West Haven, Connecticut amounted to \$78,255 and \$78,255 for the nine months ended March 31, 2015 and 2014, respectively.

Legal Proceedings

There are no pending legal proceedings against the Company to the best of the Company's knowledge as of the date hereof and to the Company's knowledge, no action, suit or proceeding has been threatened against the Company.

## **PART I**

The following discussion should be read in conjunction with the information contained in the financial statements of the Company and the notes thereto appearing elsewhere herein and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in the Company's Annual Report on Form 10-K for the year ended June 30, 2014. Readers should carefully review the risk factors disclosed in this Form 10-K and other documents filed by the Company with the SEC.

As used in this report, the terms "Company", "we", "our", "us" and "NNVC" refer to NanoViricides, Inc., a Nevada corporation.

### **SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS**

The information in this report contains forward-looking statements. All statements other than statements of historical fact made in this report are forward looking. In particular, the statements herein regarding industry prospects and future results of operations or financial position are forward-looking statements. These forward-looking statements can be identified by the use of words such as "believes," "estimates," "could," "possibly," "probably," "anticipates," "projects," "expects," "may," "will," or "should," or other variations or similar words. No assurances can be given that the future results anticipated by the forward-looking statements will be achieved. Forward-looking statements reflect management's current expectations and are inherently uncertain. Our actual results may differ significantly from management's expectations.

Although these forward-looking statements reflect the good faith judgment of our management, such statements can only be based upon facts and factors currently known to us. Forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. As a result, our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors." For these statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. They give our expectations regarding the future but are not guarantees. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

### **Description of Business**

**Organization and Nature of Business**

NanoViricides, Inc. is a leading company in the application of novel nanomedicine technologies to the complex issues of viral diseases.

The nanoviricide® technology enables direct attacks at multiple points on a virus particle. It is believed that such attacks would lead to the virus particle becoming ineffective at infecting host cells. Antibodies in contrast attack a virus particle at only a maximum of two attachment points per antibody.

The Company develops its drugs, that we call a nanoviricide®, using unique platform technology. Our approach enables rapid development of new drugs against a number of different viruses. A nanoviricide is a “biomimetic” - it is designed to “look like” the cell surface to the virus. To accomplish this, we have developed a polymeric micelle structure composed of PEG and fatty acids, that is designed to create a surface like the cell membrane, with the fatty acids going inside of the micelle. On this surface, we chemically attach, at regular intervals, virus-binding ligands. The virus is believed to be attracted to the nanomicelle by these ligands, and thereby binds to the nanoviricide using the same glycoproteins that it uses for binding to a host cell. Upon such binding, a “lipid mixing” interaction between the lipid envelope of the virus and the nanomicelle is thought to take place, leading to the virus attempting to enter the nanomicelle. Many different kinds of viruses are likely to get destroyed in the process.

We engineer the ligands to “mimic” the same site on the cell surface protein to which the virus binds. These sites do not change no matter how much a given virus mutates. Thus we believe that if a virus so mutates that it is not attacked by our nanoviricide, then it also would not bind to the human host cell receptor effectively and therefore would be substantially reduced in its pathogenicity. Our success at developing broad-spectrum nanoviricides depends upon how successfully we can design decoys of the cell surface receptor as ligands, among other factors.

### NanoViricides Drug Pipeline

The Company currently has six drugs in development with very large commercial markets. These include (i) Injectable FluCide™ for hospitalized patients with severe influenza, (ii) Oral FluCide™ for out-patients, (iii) DengueCide™, a broad spectrum nanoviricide designed to attack all types of dengue viruses and expected to be effective in the Severe Dengue Disease syndromes including Dengue Hemorrhagic Fever (DHS) and Dengue Shock Syndrome (DSS), (iv) HIVCide™ for HIV/AIDS, (v) HerpeCide™ for cold sores and genital sores caused by HSV, and (vi) Broad-spectrum Anti-Viral Eye drops for adenoviral and herpesviral infections of the external eye. In addition, the Company has research programs to develop drugs against Ebola and Marburg viruses, including the Makona variant Ebola virus that is the cause of the recent epidemic in West Africa, Rabies virus, as well as the recent MERS Coronavirus (Middle-East Respiratory Syndrome). The Company also has a technology that we call “ADIF” or “Accurate-Drug-In-Field” technology with which an effective drug can be developed against a novel virus right in the field using stockpiled nanoviricides® precursors. The estimated market size for the current drug candidates is well in excess of \$40 billion worldwide.

We believe that the pace of development of our broad drug pipeline is now accelerating. The strong financing we have been able to raise concomitant with our up-listing to the NYSE-MKT exchange in late 2013, the new facility with the capability of large scale batch production, and of clinical cGMP-quality drug material production, and significant additional resources are strong enablers that we have been able to establish in the past few years. (“cGMP” means current good manufacturing practices.) These enablers are now helping us to move our pipeline further towards Investigational New Drug (“IND”) Application filing stage.

### The HerpeCide™ Program Update

In April 2015, subsequent to the reporting period, the Company reported that its anti-Herpes nanoviricides drug candidates demonstrated dramatic effectiveness in a lethal mouse model of dermal herpes infection. The reported studies were performed in Professor Ken Rosenthal’s laboratory at the NorthEast Ohio Medical University (“NEOMED”). Professor Rosenthal retired last year and continued as Professor Emeritus at NEOMED. Even after his retirement, he continued his research, and was personally involved in on-going studies of nanoviricides drug candidates in his laboratory. Professor Rosenthal has now joined Roseman University of Health Sciences, Las Vegas, Nevada, as a Professor of Biomedical Sciences. He will continue as a consultant to NanoViricides for our anti-herpes drug development program. He is a leading researcher in herpes virus anti-viral agents and vaccines.

The Company reported that topical dermal treatment with two of its anti-herpes nanoviricides formulations led to almost complete (>85%) survival of the lethally infected mice in this animal model. In contrast, animals treated with an acyclovir formulation exhibited significantly lower survival rates (<58%) even though it was employed at twice the human dosage concentration; and all untreated mice died of the disease.

The nanoviricides treatment also led to dramatic improvements in clinical symptoms associated with herpes simplex virus infection. The nanoviricides appeared to block the progression of the virus infection as observed by a reduction in the progression of the spreading of lesions. In addition, the nanoviricides prevented the development of scabbing of the herpes virus infected lesions in the animal model. Development of scabbing is a negative clinical indicator in this model - it indicates an increase in morbidity. For untreated and sham treated animals, the HSV infection progressed from initial redness at the site of infection to lesions that progressed on the skin along the nerve and internally to ultimately kill the mouse. Topical dermal treatment with the two nanoviricide formulations significantly delayed the onset of the clinical symptoms, prevented the progression of the lesions, and produced survival of almost all of the mice (>85%).

The observed delay in initiation of disease signs and the dramatic survival of the mice were estimated to indicate a reduction of 90% or more in the production of virus in the animals, possibly during the initial period of replication. These nanoviricides have also demonstrated significant reduction in virus production in cell culture studies.

The survival improvement correlated with a significant reduction in disease severity. The results indicate that these nanoviricides were significantly superior to acyclovir in this animal model study. These studies employed the HSV-1 H129c strain. This highly neurotropic strain is derived from a patient. It is known to be far more virulent than other HSV-1 strains that have been used in drug and vaccine development against herpes viruses.

The Company had previously reported that its earlier anti-HSV drug candidates had exhibited greater than 99.9% viral load reduction in cell culture studies employing the HSV-1 McCrae strain.

The nanoviricides® mechanism of action is believed to mimic a natural host cell receptor using which the virus binds and infects cells; binding of a nanoviricide nanomicelle to the virus is expected to render it non-infectious. A nanoviricide would thus stop the spread of the viral infection to new uninfected cells. This mechanism is different from that of currently available anti-Herpes drugs. The Company therefore believes that it is able to develop broad-spectrum anti-herpes nanoviricide drugs.

These results are very significant considering that topical acyclovir in the form of cream and ointment are approved for the treatment of cold sores.

The Company believes that it will be able to declare a broad-spectrum drug candidate against herpes viruses after certain additional testing. Further drug development is necessary towards the goal of drug approval.

The Company believes that the drug approval process for a topical herpes treatment could be relatively rapid, based on the strong effectiveness results. The Company intends to meet with its FDA advisory consulting group, namely, Biologics Consulting Group, Inc., to chart out the path towards approval. In addition, the Company intends to engage a Contract Research Organization (CRO) for further development of a topical anti-herpes drug into the regulatory approval pathway for US FDA as well as internationally.

We anticipate that the same broad-spectrum anti-herpes nanoviricide drug candidate could be a viable drug for multiple indications. These include: Herpes cold sores, caused by HSV-1; Genital Herpes lesions, caused by HSV-2; and Herpes Keratitis (a disease of the eye, caused primarily by HSV-1). In addition, CMV (cytomegalovirus), another herpesvirus, causes CMV-mononucleosis and can result in severe eye diseases. Further, Varicella Zoster Virus (VZV), the cause of shingles in adults and chickenpox in children, is also a herpes virus. Shingles results in post-herpetic neuralgia (PHN), that the Company believes can be minimized if shingles are treated so that nerve damage is minimized. Further, HHV-6 and HHV-7 cause roseola in children and infants, and infect almost all humans. Further, various herpes virus infections reaching the brain may be linked to some forms of neurologic deficit disorders such as multiple sclerosis, mesial temporal lobe epilepsy, status epilepticus (seizures), chronic fatigue syndrome, as well as Alzheimer's disease, according to recent studies. These herpes viruses continue to reside latently in ganglia or other

sites, and are reactivated periodically, causing diseases. Epstein-Barr Virus (EBV), another herpesvirus, is a major cause of infectious mononucleosis, and may lead to various lymphomas and B-cell malignancies including multiple myeloma later in life in a small percentage of cases. EBV becomes latent in B cells and it can genetically transform them, which then may lead to the various cancers that it can cause.

Almost all of these herpesviruses infect over 90% of humans, most in early childhood, and others in adolescence. Recently, valacyclovir has been shown to have some effectiveness during acute EBV mononucleosis infection, although it is recommended for use only in complicated cases. Existing therapies against HSV include acyclovir and drugs chemically related to it. These drugs must be taken orally or by injection and are not very effective as topical agents. Other drugs such as docosanol are largely ineffective. Currently, there is no cure for herpes infection.

Our broad-spectrum anti-herpes nanoviricide drug can significantly reduce viral load during reactivation phase, thereby limiting the frequency, duration, and severity of current and future recurrences. We believe that our drugs are likely to be far superior to current therapies, based on our results in cell culture and animal studies.

The market size for herpes simplex virus treatments is in excess of \$2 billion annually. The Company believes that a drug that is superior to existing therapies could result in significantly expanded market size, as has been demonstrated in the case of HIV, Hepatitis C and other diseases. An estimate of over \$40 billion for an effective anti-herpes drug may not be excessive, considering the near-complete penetration of the various herpesviruses in human population, and the repetitive and debilitating nature of illnesses that they can cause.

In just four cycles of further improvements undertaken since 2010, the Company has now reached its goal of substantially complete survival in the highly lethal animal model of dermal herpesvirus infection (HSV-1 H129c strain), wherein no current drugs have shown substantial survival effect. Our anti-Herpes program began in 2009, and soon thereafter, the Company demonstrated strong anti-herpes efficacy in cell cultures against two different HSV-1 strains at two different sites. Since then the Company has been optimizing the drug candidates to achieve strong effectiveness in a highly lethal animal model. Due to resource constraints, the Company has been able to perform these studies only sporadically. Since up-listing in late 2013 and raising significant amounts of financing, the Company has been able to make strong further progress against Herpes that has resulted in the recent achievements.

### Facility Update

The Company reports that the process of commissioning of its new facility in Shelton is on course. Our Bio-Analytics Group has already moved operations to the new facility. Large Scale Chemistry Group is completing the necessary modifications to the facility to enable large scale production processes. Various laboratory instruments are being installed by vendors under warranty programs for installation qualification and operational qualification.

We implemented a phased program for commissioning the new facility. This has enabled us to continue to progress in all of our existing programs, without interruptions, while the facility preparations were going on. Because of this phased approach, we were able to make and send novel candidates for testing against Ebolavirus in January, 2015. We were able to send the modified formulations of our anti-herpes drug candidates to the Rosenthal Lab at NEOMED in March, 2015. In addition, we have been able to continue advancing in developing the CMC program for FluCide™, our broad-spectrum drug candidate against all influenza viruses.

In addition, the Company has developed a flexible, multi-product, pilot manufacturing facility capable of manufacturing any of its drug candidates in c-GMP compliant manner. Construction of this facility was completed in July, 2014. It is now undergoing cleaning, validation and fit-out for specialized equipment. We have started working in this facility, albeit to a very limited extent. This facility will be able to provide the cGMP-compliant clinical drug substances for its future human clinical studies. “c-GMP”= current Good Manufacturing Practices, a set of guidelines developed by the US FDA that the manufacture of a drug must adhere to for human clinical trials and future sales. Internationally, there are similar guidelines promoted by local regulatory agencies, and ICH harmonization guidelines promoted by the WHO. A group of private financiers that includes our founder Dr. Anil Diwan acquired an 18,000 sqft building on 4 acres with possibilities for expansion, in Shelton, CT, via Inno-Haven, LLC, a company formed specifically for the purpose of acquiring the lab. This building was completely renovated to facilitate setting up a modern cGMP drug substance manufacturing facility with injectable drugs capability, as well as supporting analytical and chemistry laboratory facilities.

We assembled a marquee team of experts to help with the design, engineering, architecture, and construction of this facility. Mr. Andrew Hahn continues to provide overall stewardship for this project. He was formerly Senior Director



of Engineering, Pharmaceutical Facilities, Global Engineering, at the Bristol-Myers-Squibb Company Worldwide Medicines Group (BMS). He has almost 30 years of experience in architecture, design and project management in the creation of new and refurbished facilities at Bristol-Myers Squibb Company. Phil Mader and his firm, MPH Engineering, LLC (“MPH”), continue to help with the overall project management and design engineering of the laboratory and cGMP pilot production facility. Prior to founding MPH, from 2000 to 2007, Phil Mader served as the Senior Capital Project Manager at Bristol-Myers Squibb Company in Wallingford, CT (“BMS”). He was involved in the design, implementation, and commissioning of various biology and chemistry laboratory projects within budget and in a timely manner. Ms. Kathyann Cowles of ID3A, LLC, serves as the Principal Architect. Ms. Cowles, co-founder of ID3A, has over thirty years of experience as a licensed Architect and Senior Project Manager for diverse and complex design and construction projects in the academic, science, technology, corporate and research sectors. This team worked with the expert advice and guidance of the Company’s Scientific Advisor, Dr. Harmon Aronson. Dr. Aronson is a well-known cGMP consultant in the pharmaceutical industry, and was formerly Vice President of Quality Management at Biocraft Laboratories, a company that was acquired by Teva Pharmaceuticals.

We evaluated the lease versus purchase option regarding this facility. The Board of Directors authorized the purchase of this facility. The Board commissioned due diligence thereafter. The purchase was completed on December 31, 2014.

The Company purchased the facility solely by repaying for the costs borne by Inno-Haven, LLC, in acquiring and renovating the property. NanoViricides' Board of Directors had approved the purchase of the facility on these terms in July 2014.

Dr. Diwan recused himself from the NanoViricides' processes pertaining to the lease or purchase of the facility including commissioning and study of reports, as well as the Board of Directors meetings and discussions.

Dr. Diwan originally purchased the existing building and land at this location in August, 2011, using his savings, funds he had raised from a sale of his founders stock under a 10b-5 plan, and certain private loans from other private parties. Inno-Haven, LLC was formed as a special purpose limited liability company, with Dr. Diwan as its controlling member, to execute this project. The facility was intended to be a standalone contract manufacturing operation supporting multiple clients, including NanoViricides, Inc. Later, Inno-Haven obtained additional non-bank commercial loans to further modify the facility as per the stringent specifications of NanoViricides, Inc. At the time that Dr. Diwan engaged into this project, NanoViricides Inc. had limited finances available, and was unable to raise funding to engage into this critical project on its own. NanoViricides common stock was trading on the OTC bulletin board, with limited trading volume. The Company had already identified in 2006 that cGMP manufacturing capability was going to be critical for advancing its drug candidates towards human clinical trials and licensure. The Company diligently investigated contract manufacturing as well as leasing of existing cGMP facilities to satisfy its needs. However, as a result of the novelty of its technology, it became apparent that external parties did not have the necessary expertise. Dr. Diwan therefore took an extreme personal risk in order to advance the Company's goals, and engaged into this facility development project.

Subsequently, NanoViricides and Inno-Haven executed a Memorandum of Understanding (MoU) in January, 2013, in which NanoViricides agreed to lease the facility from Inno-Haven upon completion, with a right to purchase. The Company determined that it was in the best interests of the Company and its shareholders to purchase the facility rather than to lease it. Dr. Diwan recused himself from this entire process.

NanoViricides now intends to move its operations to the new facility in a phased manner in order to minimize any potential impact on our ongoing projects. The Company expects to manufacture its drug candidates for human clinical trials at the new facility. The Company further reports that all of its drug development programs are progressing satisfactorily.

NanoViricides believes that its cash in hand enables this purchase without impacting any of its drug development programs. Further, the Company believes that this purchase represents a net positive cash flow impact as compared to the leasing option, over the long term.

All of the infrastructure systems needed for production of the nanoviricides® drug candidates are now operational at the new facility, and have either been validated by outside experts, or are in the process of such validation.

The 18,000 sqft building at 1 Controls Drive, Shelton, CT, was completely renovated in order to build a modern, state-of-the-art c-GMP-compliant manufacturing facility for the production of clinical scale quantities of a wide variety of injectable nanomedicines drug substances and drug products, modern nanomedicines research and development facilities, as well as an on-site state-of-the-art nanomedicines analysis and characterization facility. The new facility comprises a small office space, R&D Chemistry Labs, R&D Biology Labs, R&D Analytical Lab and cGMP supporting Analytical Lab, cGMP-compliant raw materials handling and dispensing area, and c-GMP compliant Clean Room Suites for nanomedicines production and product packaging processes. All of the R&D labs employ class 100,000 or cleaner air systems. The clean room suites comprise class 10,000 air quality areas as well as class 1,000 and the ultra-clean class 100 air quality areas (the class specifies the number of particles per 1,000 liters of air). This allows production and handling of nanomedicines with minimal risk of entraining foreign particles. All of the R&D labs employ deionized water. For critical processes, WFI-quality water is also produced on site in quantities needed to support the production scale (WFI = water for injection, comprises a specification of water quality that specifies minimal endotoxins and maximum sterility).

Since February 2013, NanoViricides, Inc. has raised more than approximately \$48 million dollars. Therefore, the Company is now in a strong financial position and is capable of purchasing the facility outright without adversely impacting its R&D programs. The Company also determined that purchasing is the low cost option in the long term.

We will need to set up new equipment at this facility and ensure that its performance is adequate. Thereafter we will need to conduct several validation studies and also establish our new laboratories in the new facility. In addition, we will need to set up cGMP compliant systems for working in this new facility. We will need to establish the scaled up manufacturing processes of our drug candidates under cGMP guidelines in this facility. Only after that, the Company will be able to make cGMP-like material using the same processes as c-GMP material but prior to undergoing the FDA registration process. Such c-GMP-like product can be used for clinical batches for human clinical studies in several countries around the world. The Company is currently investigating all such options in order to expedite the timeline to entering human clinical trials. The Company intends to contract out clinical batch fulfillments to outside established contract manufacturers.

#### FluCide™ Program Update

We are continuing the CMC studies on FluCide production processes. These studies are necessary to enable further scale-up from the current multi-100g scale of production to kg-scale production of our nanoviricides drug candidates. CMC stands for “Chemistry, Manufacture, and Controls”, and relates to being able to make the drug substance and the drug product in a reproducible fashion, batch after batch. CMC programs for nanomedicines are relatively complex compared to those of small molecules. Most of the complexity relates to the synthesis of the polymer in a reproducible fashion. Additional complexities also may arise in further functionalization of the polymer and attachment of other entities to the polymer. The multifunctional design of our polymer system requires us to develop proper process control systems in order to achieve good reproducibility. We have focused on developing scalable, reproducible processes from the very onset. We are now enabling in-process control instrumentation in order to perform the processes in an observable and reproducible fashion.

Our FluCide Program is expected to move to the Shelton facility as soon as all of the equipment and instrumentation ordered for the scaled up syntheses arrives and is put into use.

As part of the advanced IND-enabling development of our Injectable FluCide drug candidate, we have continued to scale up our production processes for both the backbone polymer and the ligands. We are now progressing to a 1Kg scale of production. We are working on implementing in-process measurement and control instrumentation, in order to rapidly implement quality control of the processes. This includes implementing some novel instruments that we believe are valuable in the process control for our nanomedicine polymeric materials. We have been able to make up to 200g batches in our existing facility in West Haven. We believe that we will be able to make as much as a few kilograms in a single batch in the new cGMP-capable facility in Shelton, CT.

We need to make approximately 2.5Kg of our FluCide drug candidate for further Tox Package studies because of the excellent safety demonstrated by this drug candidate in safety and toxicology studies in both mouse and rat animal models.

Much of our R&D work, until undertaking the Ebola program on a “war footing”, was focused on the IND-enabling development of our anti-influenza drug candidate, Injectable FluCide. The objective of our CMC-related studies on FluCide is to develop pathways that will allow industrial manufacturing scale production of a well-defined drug substance, so that multiple batches will produce consistent product. Our studies also involve the development of methods of chemical and physical characterization of the materials at various stages in the entire production process. These studies also include performing the syntheses at different scales, and at least sufficiently characterizing the products at different stages to enable decision-making regarding different possible process variations. We are also continuing to develop additional tests that are needed for analyses of samples from animals that will be generated during the safety/toxicology studies, and later in the human clinical trials. Such tests are needed for estimating a drug’s distribution pattern in the body as well as the time profile of the distribution. Such tests are also needed to decipher the metabolic fate of the drug. Since a nanoviricide drug is not a simple small chemical or an antibody, development of these tests is relatively complex, and is taking a significant amount of time. The work on FluCide continues, albeit at a reduced pace, due to the urgency of the anti-Ebola drug development program.

The work on production of the polymeric micelle backbone material is common to FluCide and the current anti-Ebola drug candidates, thereby saving both time and money in these drug development processes.

We have been able to produce the Injectable FluCide drug candidate in a batch as large as 200g in our existing facilities at present. We began initial safety/toxicology studies with this batch of material in October, 2014. We have engaged BASi Toxicology Services of West Lafayette, IN, to perform the IND-enabling safety/toxicology study for our Injectable FluCide drug candidate.

In late January 2015, we reported that an optimized FluCide® drug candidate was found to possess a good safety profile in a GLP-like toxicology study in rats. (“GLP” means Good Laboratory Practice.) These results are extremely important since they indicate that FluCide continues to look very promising as one of the most advanced candidates in the Company’s drug development pipeline. The study was conducted at BASi (Bioanalytical Systems, Inc., NASDAQ: BASI) in Evansville, Indiana. The study was performed in a cGLP-like fashion, compliant with BASi Evansville standard operating procedures. BASi has over 40 years of experience providing contract research services and niche instrumentation to the life sciences, primarily drug research and development.

No direct adverse clinical effects were found upon administration of the FluCide candidate intravenously at doses of up to 300mg/kg/day for 14 days (a total of 4,200mg/kg) in rats. Organs were examined for gross histological observations. Microscopic histological tissue analysis was also performed. There were no adverse histological findings in gross organ level histological examination, nor were there any adverse findings in microscopic histological analysis. Equally importantly, there were no meaningful effects observed on animal weight gain, food consumption, hematology, or clinical chemistry at the end of the 14 day dosing period.

These results are in agreement with the previously reported results of a non-GLP toxicology study in mice. The current study results also support the Company’s positive findings in animal models of infection with different influenza A virus strains in which no safety or toxicology concerns were observed. The Company has previously reported that many of its FluCide candidates demonstrated extremely high anti-influenza activity in those models.

This study was developed in collaboration with BASi and conducted by BASi in a c-GLP-like fashion in order to understand the safety parameters of FluCide intravenous dosing.

The next phase of the toxicology package studies will involve larger animals, and will require much larger quantities of the drug candidate. The Company is in the process of commissioning operations at the new facility at 1 Controls Drive, Shelton, CT, in order to perform the scale up studies needed for making the large quantities of materials in a controlled manner. These upcoming studies will be performed in cGLP compliant manner to provide safety and toxicology data that are required for an IND submission to regulatory agencies.

Injectable FluCide is our most advanced candidate. This drug candidate has shown extremely high effectiveness in a lethal influenza infection mouse model against two different types of influenza A virus, namely H1N1 and H3N2. The Company believes that this drug should be effective against most if not all influenza A subtypes, and strains, including the novel H7N9 strain. The Company held a pre-IND Meeting with the US FDA for its clinical drug candidate NV-INF-1 (i.e. Injectable FluCide) in the FluCide program in March 2012. The Company obtained valuable advice and is developing this candidate towards an investigational drug application (“IND”) to the US FDA as well as for similar applications to other international regulatory agencies. The Company recently performed a short preliminary non-GLP study designed to guide the planned GLP Safety and Toxicology studies (“Tox Package”) that are required for an IND filing. Previously, on October 7, 2013, the Company announced that in this small animal non-GLP safety/toxicology study of NV-INF-1 drug candidate, even at maximum feasible dosage, the drug was well tolerated and that no adverse events were found at study completion. On March 2, 2013, the Company reported that detailed laboratory analyses of samples from this non-GLP safety and toxicology study showed no overall systemic effects and no direct effects on the primary organs. This includes liver and kidney tissues as well as liver and kidney function. This is important as the liver and kidneys are major organs involved in drug toxicity. In addition, FluCide showed no adverse effects on the lungs from the treated animals. This is very important because the respiratory system is a primary site of influenza virus infection and tissue damage. These strong safety findings were seen at all doses tested, even at the maximum feasible dose (“MFD”). MFD was much higher than the therapeutic dose range used to treat influenza virus infections in our animal model efficacy studies. FluCide was administered intravenously by tail-vein injections or by infusion in this study. This non-GLP safety/toxicology study was conducted at KARD Scientific in Massachusetts. Our recent safety and toxicology studies in rats have further corroborated the safety of FluCide.

These results support the Company’s positive findings in animals that were infected with different influenza A virus strains. In those studies, no safety or toxicology concerns were observed. The Company has previously reported that its FluCide candidate demonstrated extremely high anti-influenza activity in lethal infection animal models using multiple influenza A subtypes. The extremely high anti-influenza activity coupled with the strong safety data were the basis for the selection of this FluCide candidate for further drug development. As previously reported, the results of this study will provide both the basis and focus for the GLP safety and toxicology studies of FluCide that are required for the IND submission to the U.S. FDA. These GLP studies will be performed on both large and small animals at the BASi facility in Indiana. The Company has started certain initial safety/toxicology studies at BASi with the current product in hand. We need to perform further scale up and produce a much larger batch of the drug substance in order to perform the full suite of the safety/toxicology studies. The quantity required for these studies was estimated to be as much 2.5kg or more, because of the strong safety observed in preliminary studies. This scale-up will be performed at the Company’s new cGMP-capable manufacturing facilities in Shelton, CT.

The Company believes that these strong safety data bode well for our other drug programs as well. This is because a nanoviricide is built of two parts – (1) a virus specific ligand, that is chemically attached to (2) a “nanomicelle” or polymeric micelle based on our specific chemistries. It is reasonable to believe that the nanomicelle structures of our other drug candidates should also be safe. In addition, we believe that we have chosen antiviral ligands for our other drug candidates in a very conservative, safety-biased fashion.

The Company is currently performing process development and scale up studies on its FluCide drug candidate in its existing facilities. This activity is comprised of three parts: (a) Scale-up and characterization studies of the selected broad-spectrum anti-influenza ligand in FluCide; (b) Scale-up and characterization of the nanomicelle-forming polymer in FluCide; and (c) Scale-up and characterization of the FluCide resulting from chemical conjugation of the ligand with the nanomicelle. The scale-up studies were necessitated to be performed at this early stage of our drug development because of the extremely high safety of FluCide that resulted in a very large quantity requirement for the GLP Safety/Toxicology studies. The limitations of the current laboratory facilities impose that we produce these materials in multiple batches at present, resulting in extended production and characterization time periods. We were able to perform production of 200g batch in our current facilities. This quantity allowed us to initiate certain safety studies.



### The Annual Shareholders Meeting Update

On January 23, 2015, the Company conducted its Annual Meeting of Shareholders at the Hampton Inn, Stamford, CT. Mr. Stanley Glick was reappointed as a Director, Class 3, to serve an additional 2-year term. Proposal of an amendment to our Articles of Incorporation to increase the number of authorized shares of common stock to 150,000,000 shares and the preferred stock to 10,000,000 shares was approved. The Company has no immediate plans for seeking any additional funding. However, the Company had determined upon discussion with counsel and other stakeholders, that an expansion in the authorized capital was necessary in order to improve the Company's fiscal robustness and in order to avoid future potential risks in financing. With our recent financings and after accounting for purchase of the Shelton facility, as of March 31, 2015, the Company has current assets including security deposits and prepaid expenses of approximately \$34.3 million. The Company continues to be frugal in its expenditures, and has successfully held the rate of operational cash expenditures at approximately \$5.0 million this quarter. We believe we have sufficient funds in hand for more than two years of operations at the current rate of expenditure, and including the projected expenditures. In addition, the selection of EisnerAmper LLP as the Company's independent registered public accounting firm for the 2015 fiscal year was ratified and approved. EisnerAmper is our independent auditing firm as of this quarterly report.

In response to questions from shareholders, the Company said that it now has sufficient production capacity for initial market entry of our first Injectable FluCide drug candidate when approved, and that it also has sufficient capacity to fulfill all the manufacturing needs of responding to the current Ebola epidemic, should any of our new anti-Ebola drug candidates move to further field application. These initial revenue opportunities supportable entirely by our current production capacity at the Shelton plant could be in the range of \$100 million to \$500 million, according to some estimates. The Company also stated that it is engaging into looking at additional capacity expansion at the Shelton site, as well as looking into initial requirements analysis for a future full scale manufacturing plant. As with its prior efforts, the Company intends to perform a country-wide site search for location of its full scale manufacturing facility. The search will be based on various parameters including local, state and federal grants, financing, tax abatement, and other available concessions, as well as attractiveness of the location for talented professionals that we will need to hire at such a facility. At present, the Company has no plans for raising any financing that would be necessary for such a full-scale manufacturing plant. The Company believes that as it gets closer to initial revenues, it would be able to finance a full scale manufacturing facility using traditional non-dilutive or low-dilutive options. If the Company's Ebola drug candidate is successful, the Company believes that it would be able to attract manufacturing support from government grants and contracts.

### Ebola Program Update

An Ebola virus epidemic began in western Africa with an index case in March 2013. The epidemic was identified only in March/April 2014, as it began to spread into multiple countries. It has continued to expand rapidly geographically, and also to grow exponentially in spite of the serious efforts by the international community to contain it. As of February 3, 2015, the World Health Organization (WHO) and respective governments have reported a total of 22,560 suspected cases and 9,019 deaths, though the WHO believes that this substantially understates the magnitude of the

outbreak ("[Ebola data and statistics - Latest available situation summary, 6 February 2015](#)". World Health Organization. 6 February 2015. Retrieved 6 February 2015.). Sporadic cases have occurred elsewhere in the world, including the United States, which were due to persons infected with Ebola virus traveling to other countries. Secondary infections from such patients mainly to health care workers have also occurred. However, these local outbreaks outside of West Africa have been successfully controlled so far with strong case management protocols as well as public health measures, including quarantine.

The Company identified that anti-Ebola drug development provided an opportunity for us to validate our rapid drug development platform, as well as potentially to enter first-in-human studies quickly. Our strategy was based on the lethal nature of Ebola virus infection, and based on the complete lack of effective treatments despite billions of dollars that have been spent in development. We therefore re-engaged our anti-Ebola drug development program. Along the course, an anti-Ebola drug has also become a viable business proposition, due to several legislative efforts and other changes. For example, Ebola has been added to the list of diseases that enable a Priority Review Voucher (“PRV”) (see further details on PRV elsewhere in this report). In addition, substantial government and non-profit funding has become available for anti-Ebola drug development recently, in response to the current epidemic in West Africa.

In August 2014, we announced that we restarted our anti-Ebola drug development program. In September 2014, we announced that we had completed the design of anti-Ebola small chemical ligands that are designed to mimic the putative binding site on the Niemann-Pick C1 (NPC1) protein in host cells, to which Ebola virus glycoprotein binds prior to gaining access to the cellular machinery for making its own copies. In late October, 2014, we reported that the Company had executed a CRADA (Collaborative Research and Development Agreement for Material Transfer) with the United States Army Medical Research Institute of Infectious Diseases (“USAMRIID”), for the evaluation of our novel anti-Ebola nanomedicine drug by USAMRIID scientists in their BSL-4 facilities for activity against the deadly Ebola virus.

The Company has designed these novel anti-Ebola broad-spectrum drug candidates such that they are expected to continue to work in spite of mutations in the field.

Using NanoViricides’ rapid design platform, it took only 4 months from design to synthesis of the multiple drug candidates. These candidates are designed to attack the Ebola virus at the site on the virus that does not change in spite of mutations because the virus uses this site to bind to its cognate receptor in human cells, namely NPC1. Some of the candidates are designed to attack another conserved site on the Ebola virus that is thought to be involved in the fusion process of the virus required for it to successfully enter the cell.

The Company already has the capability of producing sufficient quantities of a successful anti-Ebola drug in its new cGMP-capable facility in Shelton, CT, for combating the current Ebola epidemic. This pilot scale manufacturing facility will be able to supply the successful nanoviricides drug candidate in quantities needed for the treatment of patients in West Africa infected with the Ebola virus. NanoViricides, Inc. is one of the very few companies that has the ability to produce its drug candidates at this full-response scale.

The Company had previously developed anti-Ebola drug candidates that demonstrated the validity and potential of the Company’s approach, based on cell culture and animal testing conducted at USAMRIID in 2008-2009. At that time, the cognate receptor of the Ebola virus was still unknown and the Company used certain heuristic approaches to design potential drug candidates for the purpose of validating our approach. The Company had to de-prioritize this development in order to focus on the development of its lead drug candidate, Injectable FluCide™, for treatment of

hospitalized patients with influenza. The current outbreak in Africa has unequivocally demonstrated the need for an effective, broad-spectrum, anti-Ebola therapeutic. NanoViricides engaged into the anti-Ebola drug development with the highest priority in order to respond to this challenge.

The site at which the Ebola virus binds to its cognate cellular receptor, namely NPC1, does not change, in spite of mutations. Thus the Company believes that its new drug candidates would continue to work in spite of field mutations in the virus. This is unlike vaccines, antibodies, siRNA, antisense, and several other therapeutic modes, which a virus can readily overcome due to mutations it acquires in the field. In late January 2015, the Company announced that it had sent several novel anti-Ebola drug candidates to a BSL-4 Hi-Security Biocontainment Laboratory in the USA for testing. The Company reported that, in addition to attacking the NPC1 site, some of the candidates were designed to attack another conserved site on the Ebola virus that is thought to be involved in the fusion process of the virus, which is essential for it to successfully enter the cell.

Currently there are neither any drugs nor vaccines against Ebola, although some vaccines and some drug candidates have advanced into clinical trials. Recently, Chimerix Inc. announced that it has stopped the field clinical trial of its anti-herpes drug candidate, namely brincidofovir, against Ebola after treating approximately ten patients. In addition, in a new publication in the journal *mBio* (Kugelman, *et al.* *mBio* 2015;6(1):e02227-14), scientists at USAMRIID, Harvard University, and Massachusetts Institute of Technology (MIT) studied genetic changes in the Ebola virus (EBOV) circulating in West Africa, and concluded that genomic drift of the EBOV over time may be sufficient to block the action of otherwise potential therapies that target EBOV genetic sequences. The types of potential drugs at risk include monoclonal antibodies and small-interfering RNA (siRNA) that are scheduled to be evaluated during the current outbreak. This casts doubt as to how effective, if at all, zMAPP (MAPP Bio, an antibody cocktail), TKM-Ebola drug candidate from TEKIRA (an siRNA cocktail), and the Sarepta drug candidate (a modified oligonucleotide cocktail), would be expected to be in the current outbreak. Hemispherx recently announced that its two drugs, Alferon®-N (a mixed natural interferon alpha injection), and Ampligen® (a double-stranded RNA), were found to be effective in cell cultures and that Ampligen protected 100% of ebola infected mice in a study conducted by USAMRIID scientists. However, both of these drugs act by exciting the human immune response, and therefore, their effectiveness in severely ill Ebola patients can only be assessed in the field. BioCryst stated that it is developing a broad-spectrum viral RNA Polymerase inhibitor against Ebola and other viruses. This drug, BCX-4430, is in Phase I human clinical trials. A related drug, Avigan® (favipravir, or T-705), (being developed now by FujiFilm), has shown promising results in Ebola infected patients in the field. Of 69 patients treated, only in a subset, i.e. those patients who had limited viral load, Avigan reduced mortality to 15% from the historical control value of 30% mortality in the same two hospital sites treating the patients, according to a recent news release ([http://www.nytimes.com/2015/02/05/science/ebola-drug-has-encouraging-early-results-and-questions-follow.html?\\_r=1](http://www.nytimes.com/2015/02/05/science/ebola-drug-has-encouraging-early-results-and-questions-follow.html?_r=1)). The effect of the superior case management protocols employed in connection with the treatment need to be removed from the analysis to evaluate the actual effect of the drug in such weak but promising signals. Nevertheless, the trial has been expanded and favipravir may be made more widely available to patients. In contrast, a clinical trial of one of the Ebola vaccine candidates was stopped in Phase I. Another ebola vaccine candidate is in clinical trial at present, but statisticians have raised doubts about these clinical trials in terms of producing statistically definitive results. Nevertheless, a vaccine would require vaccination of thousands of times the number of people actually affected by the disease, and given the EBOV mutation effects, vaccines of this cycle can no longer be expected to be effective to provide immunity against a future epidemic strain, similar to what is widely known in the case of influenza.

Thus development of a highly effective therapeutic against Ebola and related viruses such as Marburg remains an important and urgent unmet medical need. We believe that NanoViricides is well poised to re-enter this field and should be able to develop an effective drug rapidly, possibly in a timeline responsive to the current epidemic.

The current epidemic Ebola virus, a Zaire Ebola virus variant, has been shown to mutate in the field frequently. This raises significant doubts regarding the success of standard antiviral approaches including vaccines, antibodies, antisense technologies, and siRNA approaches. In spite of the mutations, however, the cognate receptor of the virus on the cells and how the virus binds to it does not change. Fortunately, this receptor has now been identified for Ebola virus, as the Niemann-Pick C1 protein (NPC1), a cholesterol transporter whose function is essential for health. An approach of blocking the cellular protein, NPC1 in analogy to the development of maraviroc to block CCR5 and thereby affect HIV/AIDS, is unlikely to be successful, because NPC1 function is essential to human health. In contrast, the nanoviricides approach of attacking the virus itself by presenting to the virus a biomimetic surface like a cell membrane studded with the same binding sites which the virus binds to, namely its site on NPC1, shows significant promise. Sufficient structural information has been elucidated recently about Ebola virus-NPC1 interaction

that it has become possible for us to develop novel drug candidates against Ebola that the virus is unlikely to escape. In addition, since the NPC1 interaction is essential for EBOV to cause disease, such a nanoviricide candidate is expected to have strong efficacy in the field, and would be expected to remain effective in spite of mutations in the virus.

In October 2014, the Company announced that it had signed a Cooperative Research and Development Agreement-Material Transfer Agreement (CRADA-MTA) with US Army Medical Research Institute for Infectious Diseases (USAMRIID). USAMRIID will be able to perform cell culture as well as animal testing of the Company's new anti-Ebola drug candidates under this Agreement. Should a successful candidate be identified, further development towards an Investigational New Drug (IND) Application and clinical studies as well as usage in the field in the current epidemic in West Africa is possible. The World Health Organization (WHO) has recently established guidelines for use of un-licensed novel anti-Ebola drug candidates in the field in an effort to help control the current epidemic. Additionally, design and conduct of clinical trials in an active theater of a raging lethal epidemic has also become relatively clear in recent months. Funding for manufacturing, supply of drugs, conduct of clinical trials, and other efforts, has become available from a number of governmental and charitable organizations. We are currently awaiting results of in vitro studies of our anti-Ebola drug candidates at USAMRIID.

The Company believes it has the ability to produce requisite large quantities of such a drug candidate in its new cGMP-capable manufacturing facility in Shelton, CT. We may be able to manufacture thousands of doses in a single batch. For a highly effective drug, it has been estimated that as few as 30 patients would provide statistically significant efficacy data on drug efficacy, because of the known high mortality rate in untreated patients.

Initial cell culture testing of our drug new candidates against Ebola virus that was completed recently at a BSL-4 facility in the USA indicated that a further improvement in the effectiveness of these drug candidates in cell cultures is needed in view of current guidelines for advancing into animal studies. From previous experience with many of our programs, we are aware that our nanoviricide drug candidates, which are based on a whole systems-biology-based approach, do not fare well in the cell culture assays that are optimized for testing of small molecules, even as they have demonstrated extremely high effectiveness and safety in animal models. It is also likely that the NPC1-binding site on Ebolavirus glycoprotein, which is thought to be buried, may have been substantially inaccessible to our drug candidates. We believe that we can substantially improve the effectiveness and thereby produce a highly effective, broad-spectrum, drug candidate against Ebola/Marburg in a few cycles of optimization. We believe USAMRIID will continue to be our collaborator for testing the new drug candidates for such optimization. We are looking for potential funding for this program from non-dilutive sources.

#### The DengueCide Program

The Company has previously announced that its anti-dengue drug candidate in the DengueCide™ program achieved an unprecedented 50% survival rate in a special mouse model that mimics the most severe dengue disease in humans. This study was performed by Professor Eva Harris at the University of California, Berkeley.

On August 12, 2013, the Company announced that this anti-dengue drug candidate has been awarded an orphan drug designation by the US FDA. On November 11, 2013, we announced that this anti-dengue drug candidate was also awarded an orphan drug designation by the European Medicines Agency (EMA). These orphan drug designations provide the Company with several financial and other benefits that have now enabled the Company to give a high priority to the development of this drug.

#### Miscellaneous Achievements and Highlights

The Company is now being recognized as a leader in nanomedicines, and particularly, in nanomedicines against viruses.

NanoViricides, Inc. was selected as one of twenty finalists in the “Technologies of Tomorrow” category for the “Buzz of BIO-2015” voting competition held by BIO, the Biotechnology Industry Organization. This is a significant distinction, although we did not win the most votes.

Our CEO, Eugene Seymour, MD, MPH, was invited to discuss the current Ebola outbreak “The Independents”, a show on the Fox Business News Channel (FBN) on September 16, 2014, at 9PM EDT. He discussed some of the difficulties that could be encountered in attempts to bring the Ebola epidemic under control. Dr. Seymour has extensive field experience in the area of infectious diseases. He has previously worked on HIV/AIDS in Africa, Eastern Europe and Asia. Dr. Seymour was interviewed on the same show on FBN again on October 7<sup>th</sup>, 2014, when he discussed the Company’s progress on a novel experimental Ebola drug. On August 12th, 2014, we rang “The Opening Bell” ® at the New York Stock Exchange.

We are very happy to report that NanoViricides won the prestigious “IAIR Award” in 2014 as the “Best North American Company for Leadership in the Nanomedicine Sector”. These awards are given by the IAIR Group. IAIR (International Alternative Investment Review) is a publication of EDITRICE LE FONTI® SRL, Milan, Italy. In addition, Anil R. Diwan, Ph.D., President, Chairman, and co-Founder of the Company was recognized as the “2014 Researcher of the Year” by BusinessNewHaven, a business journal, and the New Haven magazine, that serve the State of Connecticut. We are pleased with these recognitions and awards that attest to our leadership position in the nanomedicines sector.



In August 2012, we announced that we were successful in developing an anti-influenza drug candidate that was orally effective. We believe this may be the very first targeted nanomedicine that is available via the oral route. Oral availability of FluCide would open up a much larger market than the injectable version. The Company intends to continue to develop the injectable version for hospitalized patients first. For severe, hospitalized cases of influenza, we are developing a concentrated solution that is administered by “piggy-back” incorporation into the standard IV fluid supplement system that is commonly used in hospitalized patients. In addition, we now plan to develop an oral version for out-patients and later also for pediatric patient populations. This oral version will then replace the injectable drug that we were developing for out-patients.

In September 2012, we announced that the oral version of FluCide was also highly effective against a different strain of influenza A, namely H3N2, in addition to the influenza strain of H1N1 that we had been using for development, in the same lethal animal challenge model. This is an important indication that our drug candidates against influenza are indeed broad-spectrum, i.e. capable of combating most if not all influenza viruses. We will need to perform animal studies against a few additional strains of influenza viruses in order to substantiate that this drug is indeed a broad-spectrum drug candidate. Additional studies in cell cultures against different strains of influenza are also planned. All of these studies are necessary for filing an IND application.

Nanoviricide technology is built on the TheraCour® polymeric micelle platform technology. The design of these materials is like building blocks. We can select components to achieve desired effects. This tailor-made customizability has many implications. It allows us to (1) rapidly create a new drug against a different virus; (2) rapidly develop a drug with desired length of time for which its effect should persist; and (3) quickly develop new drugs with different routes of administration; among many other benefits.

We had always suspected that the polymeric nature of nanoviricides would enable a long drug effectiveness time frame, thus enabling infrequent dosing. We have indications now that this is very likely true, from both FluCide™ and HIVCide™ programs. We have observed sustained antiviral effects for a long time after last drug administration in various animal model studies.

Infrequent dosing would translate into ease of patient compliance. Patient compliance is a major issue for all antiviral drug therapies, and particularly for HIV/AIDS.

We have been able to develop drugs using many different routes of administration with very little development time and effort.

Initially we focused on developing only injectable formulations since these afford the maximum bioavailability of the drug inside the body. We have also developed eye drop solutions against EKC in a very short time frame.

A skin cream appears to be the right formulation for the treatment of oral and genital warts caused by HSV-1 and HSV-2. Last year we had already observed that our drug candidates, in the solution form, were effective in cell cultures against at least two different strains of HSV-1 in two different laboratories. We needed to make skin creams for conducting animal studies and selected different building blocks for our backbone polymer, and built new drugs against HSV this year. The skin cream drug candidates against HSV were developed within a matter of weeks. The formulation development itself took only a few days. In contrast, many drug development companies spend years in formulations development.

We have successfully developed what may be the first ever orally available targeted nanomedicine, in our Flucide program.

We demonstrated that we can rapidly develop different formulations because of the inherent strength of the nanoviricide platform technology. The technology also enables us to develop nasal sprays and bronchial aerosols. We plan to develop the appropriate formulations as necessary.

We have limited our expenditures on socially conscious projects such as “Neglected Tropical Diseases” (NTD’s), and “Bio-defense” projects to the extent that participatory funding from third parties is available. To this end, we attempt to obtain grants and contracts financing from government and non-government sources. We will continue to work on these programs as time and resources permit. In addition, we continue to develop novel technologies such as ADIF™ (“Accurate-Drug-In-Field™”) which may possibly represent one of the best scientific approaches against manmade and natural novel disease agents. Outbreaks of natural, novel viral diseases, such as Ebola, MERS-CoV, SARS-CoV, H7N9 Influenza, and others, will continue to occur. At present, there is no feasible therapeutic intervention for outbreaks of novel viruses, such as the new Ebola virus epidemic, and the MERS coronavirus outbreak reported recently.

In order to enhance our corporate governance and oversight, we added two marquee independent board members to our Board of Directors in May/June, 2013. Dr. Milton Boniuk is the Caroline F. Elles Chair Professor of Ophthalmology, in the Alkek Eye Center at the Baylor College of Medicine, Houston, TX, a practicing ophthalmic surgeon, an astute businessperson, a renowned humanitarian, and a strong investor in and supporter of the Company. Dr. Mukund S. Kulkarni, MBA, PhD, is currently the Chancellor of Penn State University, and continues to be Professor of Finance. Together with Mr. Stanley Glick, Practicing CPA and Chair of our Audit Committee, we now have a majority of independent board members.

We have continued to successfully raise financing. We had previously completed a \$6 million convertible debentures placement with our prior investors with long positions in February, 2013. In addition, we completed a registered direct offering of approximately \$10 million on September 9, 2013, after reverse-split of our common stock by a factor of 3.5 old common shares for 1 new common share. With the newly established stock price, subsequently, we met the eligibility criteria for both NASDAQ and NYSE MKT. On September, 25, 2013, the Company’s common stock began trading on the NYSE MKT exchange under the symbol NNVC. This uplisting was a major milestone for the Company and an important advance in the Company’s corporate lifecycle. Subsequent to the uplisting, we raised approximately \$20 million in January 2014, in a Registered Direct Offering. Later, in July, 2014, we sold convertible debentures worth \$5 million. In addition, in September 2014, we accepted exercises of our old warrants at \$3.50 per share, for a total of approximately \$6.74 million.

On July 2, 2014, the Company reported that its common stock, NNVC, was added as a member of the U.S. small-cap Russell 2000 Index after the equity markets closed on June 27, when Russell Investments reconstituted its comprehensive family of global indexes. Membership in the Russell 2000, which remains in place for one year, is based on membership in the broad-market Russell 3000 Index. The stock was also added systematically to the appropriate growth and value indexes.

With these recent financings and after accounting for purchase of the Shelton facility, as of March 31, 2014, the Company has cash and cash equivalents of approximately \$34.3 million. The Company continues to be frugal in its expenditures, and has successfully held the rate of operational cash expenditures at approximately \$5 million this quarter. We believe we have sufficient funds in hand for more than two years of operations at the current rate of expenditure, and including the projected expenditures.

We believe we have sufficient funds in hand to complete Phase I and Phase IIa human clinical studies for at least one of our drug candidates, and advance, at least, one additional drug candidate into human clinical studies. Our estimate is based on a number of assumptions and cost estimates. The Company itself does not have the expertise in taking a drug through human clinical trials and as such depends upon outside experts to generate such estimates as well as to help the Company formulate and conduct its drug development programs. As such. Thus, these estimates may be grossly in error and there may also be hidden costs that we are not aware of.

Our strategy is to minimize capital expenditure. We therefore rely on third party collaborations for the testing of our drug candidates. We continue to engage with our previous collaborators. We also seek to engage with additional collaborators, as necessitated for the progress of our programs.

In November 2013, we renewed our contract with the Professor Eva Harris lab at the University of California at Berkeley for evaluation and development of our Denguecide drug candidate. With cases in Florida, Texas and recently in New York, in addition to 25,000 suspected cases reported in Puerto Rico this past summer, dengue virus is clearly becoming an important pathogen of concern in the United States.

We have engaged Biologics Consulting Group, Inc., to help us with the US FDA regulatory submissions. We are also engaged with Australian Biologics Pty, Ltd to help us with clinical trials and regulatory approvals in Australia. We believe that cGMP-like manufactured product is acceptable for entering human clinical trials in Australia.

In addition, we signed a Master Services Agreement with Public Health England (PHE), UK. We have also signed a new CRADA-Materials Transfer Agreement with USAMRIID for the evaluation of our anti-Ebola nanoviricide drug candidates. We anticipate completing master services agreements, after performing our due diligence, with additional parties in furtherance of our anti-viral drug development programs.

We have continued to achieve significant milestones in our drug development activities. All of our drug development programs are presently at pre-clinical stage. We believe we are advancing these programs at a faster pace than industry peers. We continue to test several drug candidates under each program even though we may achieve extremely strong results with some of the candidates.

The Company reports summaries of its studies as the data becomes available to the Company, after analyzing and verifying the same, in its press releases.

In July-August 2011, we reported on the anti-HIV studies that were designed to discriminate the comparative effectiveness of different ligands. We reported that our lead anti-HIV candidate achieved anti-HIV efficacy equivalent to a HAART (highly active anti-retroviral therapy) triple drug cocktail in this recently completed animal study. Treatment with this lead anti-HIV nanoviricide reduced HIV levels and protected the human T cells (CD4+/CD8+) to the same extent as treatment with the HAART cocktail. The three drug HAART cocktail used for comparison in this study is one of the combination therapies recommended for initial therapy in humans. No evidence of drug toxicity was observed in the case of nanoviricide drug candidates. We later reported that this lead anti-HIV drug candidate achieved a long term anti-HIV effect with a much shorter dosing regimen and a markedly lower total drug dose than the HAART drug cocktail therapy in a recent animal study. The antiviral effect of the anti-HIV nanoviricide (“HIVCide™”) continued throughout the 48 days of study even though HIVCide dosing was discontinued after only 20 days. The clinical benefit of HIVCide was found to be sustained for at least four weeks after the last drug dose. Treatment with the lead anti-HIV nanoviricide both (1) reduced the HIV viral load and (2) also protected the human T cells (CD4+,CD8+), equally well as compared to treatment with the three-drug HAART cocktail, at 24-days as well as at 48-days, even though the HIVCide treatment was stopped at 20 days. The lead candidate is now undergoing further optimization.

In September 2013, we announced that we had further improved the HIVCide drug candidates, based on results of cell culture studies conducted by Southern Research Institute, Frederick, MD. A broad-spectrum anti-HIV-I activity was demonstrated in that HIV-1 Ba-L, a CCR5-using strain as well as HIV-1 IIIB, a CXCR4-using strain, were both inhibited equally well by two different nanoviricide drug candidates in the standard MAGI HIV Antiviral Assay

A long and sustained effect of HIVCide would lead to improved patient compliance, which is a sought after goal in HIV therapy. With this new study, we believe that we are close to a “Functional Cure” of HIV wherein the patient can take treatment until the viral load is undetectable and then stop treatment until an episode of virus reawakening occurs. Anti-HIV drug development is very expensive and therefore the Company continues to keep this program at a lower priority than our other drug development programs.

In September 2011, we announced that we have selected a clinical candidate, now designated NV-INF-1, for FDA submission in our highly successful FluCide™ anti-influenza therapeutics program. The Company is now developing certain additional information on NV-INF-1, with input from its FDA consultants, for the pre-IND application to the FDA. The Company is planning on two separate indications for NV-INF-1: High strength dosage form for hospitalized patients with severe influenza, and a single course therapy for the out-patients with less severe influenza. We are currently working on putting together the FluCide information in a pre-IND application to the US FDA.

In July 2011, we retained the Biologics Consulting Group to help us with our regulatory filings. This led to our pre-IND meeting request to the US FDA in December, 2011, and a pre-IND meeting with the US FDA in March, 2012.

In July 2012, we retained Australian Biologics Pty. Ltd., a regulatory affairs consulting firm, to coordinate the regulatory review and approval to conduct the first human trials in Australia for Flucide™, the Company's broad-spectrum anti-influenza drug. Australian Biologics will also facilitate clinical trial site(s) selection and development of the clinical trials agreements. Dr. Jim Ackland, the Manager of Australian Biologics Pty, Ltd, has extensive experience in this field. Prior to becoming managing director of this company, he was Vice-President, West Coast and Asia Pacific operations for the Biologics Consulting Group, the Company's US FDA regulatory affairs consulting group. In the 1990's, he was the Head of Regulatory Affairs, Vaccines, for the CSL Group in Australia. The CSL Group is a global, specialty biopharmaceutical company that researches, develops, manufactures and markets products to treat and prevent serious human medical conditions.

In August 2012, we reported that oral effectiveness of anti-influenza FluCide drug was demonstrated in a lethal animal model. Certain anti-influenza drug candidates under our FluCide™ program, when given orally, were nearly as effective as when administered as IV injections. Two different anti-influenza drug candidates were tested in Oral vs. IV comparison, and both of them showed similar results that indicated strong oral effectiveness. The results clearly demonstrated that oral administration of both of these FluCide drug candidates resulted in substantially superior animal protection compared to oseltamivir (Tamiflu®), a standard of care for influenza at present. The studies involved the same highly lethal animal model the Company has continued to use for its influenza drug development program.

One of the FluCide drug candidates, when administered orally, enabled the animals to survive as long as 347.4±4.6 hrs. (14.5 days), and when given as an injectable, it allowed the animals to combat the lethal influenza infection for 376.8±7.5 hrs. (15.7 days). Another drug candidate (with a different anti-viral ligand), when given orally, resulted in the animals surviving for as long as 301.3±5.2 hrs. (12.6 days), and when given as a tail-vein injection, for 349.0±3.9 hrs. (14.5 days). For comparison, untreated control animals died in 119.5±1 hrs. (5 days), and oseltamivir (Tamiflu®) treated animals died within just 181.7±4.6 hrs. (7.6 days).

The survival data clearly showed that oral as well as IV administration of FluCide drug candidates was substantially superior to oseltamivir. In addition, they showed that FluCide drug candidates when given orally had substantial efficacy, almost matching the effectiveness of the injectable form given at 0.3X of the oral dosage level.

One of the FluCide drug candidates, when administered orally, resulted in 1.30 log reduction (or 20X reduction) in lung viral load and matched the viral load reduction on the same drug candidate given as an IV injection. Another drug candidate resulted in 1.23 log viral load reduction when given orally and 1.31 log viral load reduction when given as an injectable. In contrast, oseltamivir (Tamiflu®, given orally at 40mg/kg/d) resulted in only 0.6 log viral load reduction (or only 4X reduction) compared to negative controls. These were the results of lung viral load measured at 108 hours post-infection (hpi). Further, at 180 hpi, the lung viral load remained controlled at about the same level as at 108 hpi with the nanoviricide® drug candidates. In contrast, lung viral load in the oseltamivir treated mice increased to the same level as the negative control (infected untreated) animals prior to their death and the oseltamivir group exhibited a survival of only 182±4 hours.

The number of lung plaques and plaque areas (resulting from the influenza virus infection) also were consistent with the data from the lung viral load, and were minimal in the case of the nanoviricide drug candidates whether given as IV or orally. Oseltamivir treatment did not protect the lungs of infected animals with the same effectiveness as the protection afforded by the FluCide drug candidates.

These data clearly demonstrated that both oral and IV treatment with nanoviricide drug candidates protected the lungs of the mice infected with influenza virus equally well. It is also clear that this lung protection was the result of the substantial decrease in the lung viral load. In addition, they show that FluCide drug candidates when given orally had substantial efficacy, almost matching the effectiveness of the injectable form given at 0.3X of the oral dosage level.

In addition to the antiviral effects, the oral FluCide drug candidates also led to generation of a strong antiviral antibody response. Two different anti-influenza drug candidates were tested in Oral vs. IV comparison. One of the FluCide drug candidates, when administered orally, resulted in  $1866 \pm 90$  micro-g/ml-plasma of anti-influenza antibody, and  $1258 \pm 59$  when administered as IV injections. Another FluCide candidate, when given orally, resulted in  $1491 \pm 37$  ug/ml plasma of anti-influenza antibody, and  $1151 \pm 53$  when administered as IV injections. The untreated infected animals had  $190 \pm 22$  ug/ml antibody response, which was the weakest of all, as expected. Of significance, oseltamivir (Tamiflu) resulted in only  $950 \pm 64$  ug/ml level of antibody response, which was far less than the two oral FluCide groups (p-value  $< 0.0003$ ), and also substantially less than the two IV FluCide groups (p-value  $< 0.04$ ). These p-values were determined for a comparison of FluCide groups against the oseltamivir group using the most stringent parameters, viz. two-tailed, paired, t-test. A smaller p-value indicates a greater confidence that the difference in observations cannot be a result of pure chance. These data also indicated that the antibody response was stronger when FluCide was given orally rather than as IV injection.



The generation of a strong antibody response is important. We believe that the strong reduction in viral load caused by FluCide treatment allows the immune system to function normally and generate appropriate antibodies. A strong antibody response implies that the FluCide drug candidates may also be useful as prophylactic therapy of uninfected health care workers and close associates of a patient in addition to treatment of infected patients.

All of these data also clearly demonstrated that both injectable and oral FluCide™ candidates were superior to oral oseltamivir (Tamiflu®, Roche), a current standard of care for influenza, in all parameters evaluated.

No adverse effects were found, indicating that the FluCide dose could be increased further to achieve much greater levels of effectiveness.

The oral FluCide candidate development was the result of chemistry optimization program that the Company has been working on.

In September 2012, we announced that the oral FluCide™ drug candidates demonstrated dramatically improved survival in animals administered a lethal dose of the H3N2 influenza A virus. Animals treated with the oral anti-influenza nanoviricide drug candidates survived for much longer as compared to Tamiflu® treated animals.

In this H3N2 infection study, animals treated with the best of the oral FluCide™ nanoviricide drug candidates survived 15.6 days while the animals treated with oral Tamiflu survived only 9.6 days. The control animals died within 5 days. The Company has previously reported that animals treated with these same oral anti-influenza nanoviricides protected mice infected with the H1N1 influenza A virus and were similarly substantially superior to oral oseltamivir (Tamiflu).

This is the first demonstration of efficacy of the Company's FluCide drug candidates against a completely unrelated type of influenza A virus (viz. H3N2) in contrast to the H1N1 Influenza A virus that the Company has used for its recent development work leading to its pre-IND application with the US FDA. H3N2 influenza virus is one of the multiple sub-types of influenza A that cause seasonal epidemics. According to the Center for Disease Control, influenza causes approximately 36,000 deaths every year in the U.S. alone. The Hong Kong Flu pandemic of 1968-1969, which killed an estimated one million people worldwide, was caused by a variant strain of H3N2. The Company believes an orally administered nanoviricide that protect against multiple influenza virus sub-types would be effective in season after season of influenza epidemics. Such a highly effective, broad-spectrum anti-influenza drug is widely anticipated to be highly successful.

The Company believes that the anti-influenza drug candidates it has developed are broad-spectrum, i.e. they should work against most if not all of influenza viruses. This is because, in spite of mutations and antigenic drift, all influenza viruses bind to the same cell surface receptor called sialic acid, and the Company has developed small chemical ligands that mimic this receptor, to attack the influenza viruses. These ligands are chemically attached to the Company's polymeric micelle backbones that mimic the cell membrane, to create the nanoviricides. The Company has previously shown effectiveness of its very early anti-influenza drug candidates against two different strains of H5N1 Bird Flu virus in cell culture studies. The Company has since then improved the ligands as well as the chemistries as reported from time to time.

The Company intends to develop data about effectiveness of its drug candidates against certain unrelated influenza A viruses using both cell culture studies and animal models in a reasonable manner. These data will be needed as part of the IND application that the Company is working on. An IND application will be required for the Company to enter into human clinical trials.

Previously, in June 2010, the Company reported successful studies in two different cell culture models of dengue virus type 2 infection. These studies were conducted at the Prof. Eva Harris lab at the UC Berkeley. Our results were later confirmed and extended to animal studies.

The Company reported that its anti-Dengue drug candidates demonstrated significant protection in the initial animal survival studies of Dengue virus infection, in an animal study protocol modeled to simulate the ADE syndrome. The best nanoviricide drug candidates demonstrated 50% animal survival in this uniformly lethal mouse model. The studies were performed in the laboratory of Dr. Eva Harris, Professor of Infectious Diseases at the University of California, Berkeley (UC Berkeley).

Based on this data, the Company believes that it is feasible to develop a single nanoviricide drug against all types of dengue viruses that circumvents the primary issue of antibody-dependent enhancement (ADE) of dengue virus infection. ADE is thought to result in severe dengue disease syndromes such as dengue shock syndrome (DSS) and dengue hemorrhagic fever (DHF).

In June, 2010, we also reported that our anti-HIV drug candidates demonstrated efficacy in the recently completed cell culture studies using two distinctly different HIV-1 isolates. These studies were performed in the laboratory of Carol Lackman-Smith at the Southern Research Institute, Frederick, Maryland. These results corroborated our previous findings in Animal Studies. The Company had reported that its best nanoviricide drug candidate against HIV was more than 25 times superior to a three drug combo anti-HIV cocktail based on biomarker test response in all parameters tested. The parameters included improvement in human T cell populations in the animal model and reduction in HIV viral load. The Company has since performed additional studies to optimize the HIV binding ligand and has found ligands that are superior to the one that yielded these strong results. The Company now plans to deploy this new anti-HIV ligand connected to the full strength polymeric micelle that we have also optimized as a new anti-HIV nanoviricide drug candidate. We plan to test this optimized anti-HIV drug candidate in animal studies. Anti-HIV studies are extremely expensive. As such, the Company's HIVCide program has been slowed down with the current slow financial markets.

In August 2010, we reported that our anti-HSV drug candidates exhibited almost complete inhibition of herpes simplex virus HSV-1 in cell culture studies conducted in Professor Ken Rosenthal lab at the Northeastern Ohio Universities Colleges of Medicine and Pharmacy. These studies employed the H129 strain of herpes simplex virus type 1 (HSV-1). H129 is an encephalitic strain that closely resembles a clinical isolate; it is known to be more virulent than classic HSV-1 laboratory strains.

In March through May 2011, the Company reported that further chemistry optimization led to dramatically improved antiviral efficacy with its optimized FluCide™ drug candidates in its most recent animal study. In the influenza mouse lethal infection model, animals treated with one of the optimized FluCide™ nanoviricide drug candidates survived beyond the stated full duration of study (21 days), and those treated with two additional drug candidates survived

almost the full duration of the study. Animals in these three groups survived significantly longer (20.2 to 22.2 days) as compared to the animals treated with Oseltamivir (Tamiflu®) only 8.3 days. In addition, the post-infection treatment with these optimized FluCide™ drug candidates resulted in dramatic reduction in the number of lung lesions that are caused by a lethal influenza virus infection. Four days post virus infection, animals treated with three of the optimized FluCide™ nanoviricide drug candidates exhibited greater than 95% reduction in the number of lung lesions as compared to the infected yet untreated control animals (p-values < 0.001). In contrast, animals treated with Oseltamivir (Tamiflu®, Roche) showed only a 50% reduction. In another significant finding, no increase in the number or size of the lung lesions was observed over the entire duration of the study in the FluCide™-treated animals. This was not the case for the Oseltamivir-treated animals. This demonstrated that treatment with FluCide drug candidates provided clear and strong protection against lung damage caused by the severe influenza infection. In addition, in this study, these optimized FluCide™ drug candidates achieved 1,000-fold reduction in the levels of infectious virus in the lungs of animals with a lethal level of influenza virus infection. The amount of infectious virus in the lungs of the infected animals treated with three of the optimized FluCide™ nanoviricide drug candidates was reduced by greater than 1000-fold as compared to the infected untreated control animals (p-values < 0.001), four days after virus infection. In contrast, animals treated with Oseltamivir (Tamiflu®, Roche) showed less than a 2-fold reduction in lung viral load at the same time point. This indicated a 500-fold greater reduction in viral load by FluCide drug candidates over Oseltamivir. Of great clinical significance is the fact that 2 of the optimized FluCide™ drug candidates maintained this greatly reduced lung viral load at 7, 13 and 19 days after virus infection in this 21 day study. Thus, treatment with the optimized FluCide drug candidates appeared to protect against the complete cycle of infection, virus expansion and spread of infection in the lungs that follows the initial virus infection. This was not the case for the Oseltamivir-treated animals. Animals treated with Oseltamivir (Tamiflu®, Roche) showed less than a 2-fold reduction in lung viral load at 4 days and the viral load was increased at 7 days to the same level as that found in the infected, untreated control animals shortly before their death.

In September 2011, we announced that we have selected a clinical candidate, designated NV-INF-1, for FDA submission in our highly successful FluCide™ anti-influenza therapeutics program. The Company submitted a pre-IND application to the FDA for this clinical candidate and held a pre-IND meeting with the US FDA in March, 2012. In addition, the Company is planning a high strength “piggy-back infusion” dosage form for hospitalized patients with severe influenza. The Company will continue the development of these two drug candidates towards an IND, based on the guidance it received in the first pre-IND meeting.

The studies of biological testing of materials provide information that is relatively easy to understand and therefore readily reported. In addition, we continue to engage in substantial work that is needed for the optimization of synthesis routes and for the chemical characterization of the nanoviricide drug candidates. We also continue to work on improving the drug candidates and the virus binding ligands where necessary. We continue to work on creating the information needed for the development of controlled chemical synthesis procedures that is vital for developing c-GMP manufacturing processes.

A fundamental PCT patent application, on which the nanoviricides® technology is based, has resulted in additional issued patents in Europe and Korea since our last update in March 2014. As with issuances in other countries including the USA, these patents have been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The corresponding original “pi-polymer” international application, namely, PCT/US06/01820, was filed under the Patent Cooperation Treaty (PCT) system in 2006. Several other patents have already been granted previously in this patent family in various countries and regions, including Australia, ARIPO, Canada, China, Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, OAPI, Philippines, Singapore, Vietnam and South Africa, and the USA. Prosecution in several other countries continues. In May 2012, the US Patent (No. 8,173,764) was granted for “Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers.” The US patent term is expected to last through October 1, 2028, including anticipated extensions in compensation for time spent in clinical trials. This US Patent has been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The disclosed structures enable self-assembling, biomimetic nanomedicines. Estimated expiry dates for these patents range nominally from 2026 to 2028 with various extensions accounting for delays in clinical trials. Additional issuances are expected in Europe, and in several other countries around the world.

In addition to this basic PCT application that covers the “pi-polymer” structure itself, another PCT application, PCT/US2007/001607, that discloses making antiviral agents from the TheraCour family of polymers and such structures is in various stages of prosecution in several countries, and has already issued in at least seven countries and regions. The counterparts of the international PCT application have issued as a granted patent in Australia, Japan, China, ARIPO, Mexico, New Zealand, OAPI, Pakistan, and, South Africa to date. Additional issuances are expected in Europe, USA, and in several other countries around the world. This patent application teaches antivirals based on the TheraCour polymeric micelle technologies, their broad structures and compositions of matter, pharmaceutical compositions, methods of making the same, and their uses. The nominal expiry dates are expected to range from 2027 to 2029.

The patents are being issued to the inventors Anil R. Diwan, PhD, Jayant G. Tatake, PhD, and Ann L. Onton, all of who are among the founders of NanoViricides, Inc. The patents have been assigned to AllExcel, Inc., the Company at which the ground-breaking work was performed. AllExcel, Inc. has contractually transferred this intellectual property to TheraCour Pharma, Inc.

NanoViricides, Inc. holds exclusive, worldwide, perpetual, licenses from TheraCour Pharma, Inc. to these technologies and patents for a broad range of antiviral applications and diseases that include all Influenzas including Asian Bird Flu Virus, Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Dengue viruses, Rabies virus, Ebola/Marburg viruses, Japanese Encephalitis virus, as well as viruses causing viral Conjunctivitis (a disease of the eye) and ocular herpes. NanoViricides currently holds two licenses in perpetuity to develop and sell drugs for the treatment of these viral diseases. These licenses are provided for all the intellectual property held by TheraCour Pharma, Inc. that relates to our antiviral licensed products. These licenses are not limited to underlying patents, but also include the know-how, trade secrets, and other important knowledge-base that is utilized for developing the drugs and making them successful. In addition, these extremely broad licenses are not limited to some specific chemical structures, but comprise all possible structures that we could deploy against the particular virus, based on these technologies. In addition, the licenses are held in perpetuity by NanoViricides for world-wide use. The licenses are also exclusively provided only to NanoViricides for the licensed products so NanoViricides is the only party that can further sublicense the resulting drugs to another party, if it so desires. TheraCour cannot further license anything in our licensed products areas because of the breadth of the license. The licenses can revert only in the case of a default by NanoViricides. The terms of default are such that effectively TheraCour would be able to take the licenses back only in the event that NanoViricides files bankruptcy or otherwise declares insolvency and inability to conduct its business. This structure is standard in the licensing world as it saves the intellectual property from being blocked from commercialization in lengthy and potentially fragmentary bankruptcy proceedings.

## **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION**

The following discussion should be read in conjunction with the information contained in the consolidated financial statements of the Company and the notes thereto appearing elsewhere herein and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in the Company's Annual Report on Form 10-K/A for the year ended June 30, 2014. Readers should carefully review the risk factors disclosed in this Form 10-K/A and other documents filed by the Company with the SEC.

As used in this report, the terms "Company", "we", "our", "us" and "NNVC" refer to NanoViricides, Inc., a Nevada corporation.

### **PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "NNVC believes," "management believes" and similar language. The forward-looking statements are based on the current expectations of NNVC and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report. Actual results may differ materially from results anticipated in these forward-looking statements. We base the forward-looking statements on information currently available to us, and we assume no obligation to update them.

Investors are also advised to refer to the information in our previous filings with the Securities and Exchange Commission (SEC), especially on Forms 10-K, 10-Q and 8-K, in which we discuss in more detail various important factors that could cause actual results to differ from expected or historic results. It is not possible to foresee or identify all such factors. As such, investors should not consider any list of such factors to be an exhaustive statement of all risks and uncertainties or potentially inaccurate assumptions.

### Overview

The nanomedicine technologies developed by TheraCour Pharma, Inc. serve as the foundation for our intellectual property. The Company holds a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex

Virus (HSV), Influenza and Asian Bird Flu Virus. The Company has entered into an Additional License Agreement with TheraCour granting the Company the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types: Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses. The Company may want to add further virus types to its drug pipeline. The Company would then need to negotiate with TheraCour an amendment to the Licensing Agreement to include those of such additional viruses that the Company determines it wants to follow for further development. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy.



The Company intends to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour Pharma, Inc., the exclusive source for these nanomaterials. The Company may manufacture these drugs itself, or under subcontract arrangements with external manufacturers that carry the appropriate regulatory licenses and have appropriate capabilities. The Company intends to distribute these drugs via subcontracts with distributor companies or in partnership arrangements. The Company plans to market these drugs either on its own or in conjunction with marketing partners. The Company also plans to actively pursue co-development, as well as other licensing agreements with other Pharmaceutical companies. Such agreements may entail up-front payments, milestone payments, royalties, and/or cost sharing, profit sharing and many other instruments that may bring early revenues to the Company. Such licensing and/or co-development agreements may shape the manufacturing and development options that the company may pursue. There can be no assurance that the Company will be able to enter into co-development or other licensing agreements.

To date, we have engaged in organizational activities; developing and sourcing compounds and preparing nano-materials; and experimentation involving preclinical studies using cell cultures and animals. Several of the Company's drug candidates have shown excellent levels of efficacy and preliminary safety in animal studies in many different animal models against many different viruses. The Company determined that its anti-Influenza program, "FluCide™", was the most advanced and obtained and held a pre-IND meeting with the US FDA for the same on March 29, 2012. The Company believes it has gained valuable guidance from the FDA that enables us to develop and execute a product development plan for our anti-influenza drug candidate with the goal of filing an Investigational New Drug (IND) application to the US FDA, and similar applications in other countries in the world.

As the Company's drug candidates progress towards human clinical studies, it has become necessary to enable that they can be produced under "current Good Manufacturing Practices" (cGMP) guidelines of the US FDA, and other applicable international guidelines (such as WHO and ICH guidelines, as well as other country-specific and region-specific guidelines). In the US, the US FDA requires that at least two validated and consistent batches of the drug be produced under cGMP conditions before any human clinical trials can be allowed. Some other countries may allow research product materials for certain phases of human clinical trials. The Company's management has studied the possibilities of contract manufacturing of its drug candidates over the last several years and has concluded that building a small pilot scale manufacturing facility where the special needs of the manufacture of its nanomedicines can be met is the most appropriate solution. This approach provides the highest level of control over the quality of the materials and also keeps the intellectual property of the Company well protected. However, the Company lacked the capital and financial resources to engage into such an expensive project. In 2011, Anil R. Diwan, the Company's co-founder, created a separate entity, Inno-Haven, LLC ("Inno-Haven"), and independently began the development of a nanomedicines manufacturing facility, to serve the interests of a number of pharmaceutical start-up clients as a contract-manufacturing organization (CMO), including NanoViricides, Inc. Inno-Haven purchased an 18,000 sq. ft. light manufacturing building on a 4.2 acre land lot in Shelton, Connecticut in August, 2011. The purchase and related costs were financed by Dr. Diwan. Dr. Diwan had also agreed to provide personal guarantees for potential loans and mortgages which could be drawn for the purpose of financing the building and construction costs.

No lease agreement had been perfected with Inno-Haven. The Company determined whether it would be more economically beneficial to the Company to either lease this facility or to purchase it outright from Inno-Haven, or to seek a different facility. Subsequently, the Company's Board of Directors authorized the acquisition of 1 Controls

Drive from Inno-Haven, LLC for the total costs and capital invested by Inno-Haven in acquiring and fitting out 1 Controls Drive. On December 31, 2014, the Company closed on the purchase of the property located in Shelton, Connecticut. The purchase price of this 18,000 sq. ft. cGMP compliant laboratory and clean room facility consisted of the repayment of Inno-Haven's acquisition and renovation expenses of \$4,222,549 and its closing costs of \$77,480. This purchase price does not include the additional costs that the Company has paid directly to vendors and consultants itself for the design and specialized infrastructure equipment that it needed for modifying the facility to suit its purposes of injectables nanomedicine drug AP [API = Active pharmaceutical ingredient.], drug substance, and drug product manufacture.

The Company does not currently have any revenue. All of the Company's products are in development stage and require successful development through regulatory processes before commercialization. We have generated funding through the issuances of debt and private placement of common stock and also the sale of our registered securities. The Company does not currently have any long term debt, other than convertible debentures as disclosed earlier. We have not generated any revenues and we may not be able to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or we may not become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations.

### **The Company's Drug Pipeline**

We currently have, in early, active development, (1) an Injectable FluCide™ for hospitalized patients with severe influenza; (2) Oral FluCide™ for outpatient – both of these drug candidates are expected to be active against Epidemic Influenzas including the current novel H1N1/2009 “Swine flu” virus, H5N1 and other Highly Pathogenic Avian Influenzas (H5N, H7N, H9N HPAI, Bird Flu), as well as common seasonal human Influenzas; (3) HIVCide, a potential “Functional Cure that is active against both the R5 and X4 strains of HIV, (4) Eye drops against viral diseases of the eye such as Epidemic Kerato-Conjunctivitis (EKC) and Herpes Keratitis, (5) HerpeCide against Herpes virus cold sores and genital Herpes, and (6) DengueCide against Dengue viruses.

In addition, the Company restarted its anti-Ebola nanoviricide drug program in response to the current epidemic.

The development of a highly effective therapeutic against Ebola and related viruses such as Marburg remains an important and urgent unmet medical need. We believe that NanoViricides is well poised to re-enter this field. We believe that this program will lead to an effective program against Ebola virus.

The epidemic and pandemic potential as well as the constantly changing nature of influenza viruses is well known. The HIV/AIDS worldwide epidemic and the “curse of slow death” nature of HIV viral infection is also well known. Adenoviral Epidemic Kerato-Conjunctivitis (EKC) is a severe pink eye disease that may lead to blurry vision in certain patients after recovery. Herpes simplex viral infections cause keratitis of the eye, and severe cases of infection may sometimes necessitate corneal transplants. Oral and genital herpes is also a well known disease. Dengue viral infection is also known as “break-bone fever”. What is worse, that when a patient is infected with a dengue virus a second time, if the virus is a different serotype, then it can cause a severe dengue disease, or dengue hemorrhagic syndrome, with very high morbidity and a high rate of fatality. This is because, the patient's immune system mounts an attack, but the antibodies that it generates, directed at the previous infecting virus, are not effective against the new infection, and instead the new infecting virus uses them to hitch a ride into host cells that it infects more severely. This phenomenon is called “Antibody-Dependent Enhancement” or “ADE” for short.

In addition, we initiated a research program for the development of a nanoviricide against the MERS Coronavirus (“Middle East Respiratory Syndrome”). MERS is a new coronavirus similar to the severe acute respiratory syndrome (“SARS”) virus. It first appeared in 2012 in the Middle East. Since then, about 400 cases have been reported to the World Health Organization; about a third have been fatal. While it has not spread easily between humans, there have been outbreaks within families and in hospitals, where patients have infected paramedics, nurses and doctors, reported the New York Times

([http://www.nytimes.com/2014/05/03/health/mers-virus-found-in-united-states-for-first-time.html?\\_r=0](http://www.nytimes.com/2014/05/03/health/mers-virus-found-in-united-states-for-first-time.html?_r=0)). The high fatality rate implies that if the virus changes such that its human-to-human transmission is more successful, then this virus can cause significant public health problem, including a potential epidemic. There are no known drugs or vaccines against the MERS coronavirus. No small animal models for testing MERS therapeutics were available until recently. Perlman and collaborators have recently reported a mouse model

(<http://www.pnas.org/content/early/2014/03/05/1323279111.abstract>). In this model, mice were infected with adenovirus carrying the DPP-IV gene to make them susceptible to the MERS virus.

We were able to create potentially useful drug candidates against MERS-CoV in a very rapid time frame, of less than two months, which included synthesis scale-up to multi-gram quantities. Similarly, we were able to design and synthesize potential drug candidates targeting the NPC1 binding site on Ebola virus glycoprotein in about four months, including scaling up to multi-gram quantities. This demonstrates how rapidly drugs can be developed using nanoviricides technology. The MERS epidemic did not expand further and therefore we have put this program on the back burner.

Both the safety and effectiveness of any drug has to be determined experimentally. The safety of a nanoviricide drug is expected to depend upon the safety of the nanomicelle portion as well as the safety of the antiviral ligand. If one of drug candidates results in a viable clinical candidate, this me be the fastest timeframe in which an antiviral drug has been designed, and advanced to clinical candidate level.

Given the high fatality rate associated with MERS infections, and small numbers of cases, the regulatory pathway for approval processes is uncertain. However, progress has been made with fatal diseases such as Ebola in defining clinical pathways, and we anticipate similar development model to be applied for MERS, if we restart this R&D program in the future.

We also have research programs against Rabies virus, Ebola/Marburg family of viruses, as well as other Viral hemorrhagic fevers. We also have a research program called ADIF<sup>(TM)</sup> which stands for “Accurate-Drug-In-Field”, that we believe is the only way to combat a novel viral threat right in the field before it becomes an epidemic like SARS, bird flu H5N1, Ebola, or other viral outbreaks. The Company’s ability to achieve progress in the drugs in development is dependent upon available financing and upon the Company’s ability to raise capital. The Company will negotiate with TheraCour to obtain licenses for additional viral diseases as necessary. However, there can be no assurance that TheraCour will agree to license these materials to the Company, or to do so on terms that are favorable to the Company.

#### Research and Development Costs

The Company does not maintain separate accounting line items for each project in development. The Company maintains aggregate expense records for all research and development conducted. Because at this time all of the Company’s projects share a common core material, the Company allocates expenses across all projects at each period-end for purposes of providing accounting basis for each project. Project costs are allocated based upon approximate labor hours performed for each project.

The Company has signed several cooperative research and development agreements with different agencies and institutions The Company expects to enter into additional cooperative agreements with other governmental and non-governmental, academic, or commercial, agencies, institutions, and companies. There can be no assurance that a final agreement may be achieved and that the Company will execute any of these agreements. However, should any of these agreements materialize, the Company will implement a system to track these costs by project and account for these projects as customer-sponsored activities and show these project costs separately.

#### Requirement for Additional Capital

As of March 31, 2015, we have cash and cash equivalents of approximately \$33.9 million which is more than sufficient to fund our operations through more than two years, or March 31, 2017, at the Company's current rate of expenditure, and including the projected expenditure for certain human clinical trials.

With our current funds we believe that we have sufficient funding available to continue to perform Toxicology Package studies and complete the same, and additional animal efficacy studies, to move at least one of our drug candidates into an Investigational New Drug Application ("IND") with the US FDA or a similar application with an international regulatory agency, and to conduct Phase I and Phase IIa human clinical trials of at least one of our drug candidates. In order to file an IND application, we also need to enable manufacturing of the drug under US FDA guidelines called cGMP. This was the underlying basis for the purchase of the cGMP manufacturing and R&D facility in Shelton, CT. This facility will enable cGMP manufacture of all of our drug substances.

We believe that we may also have sufficient additional funding in hand to take at least one more drug candidate into an IND application stage. These estimates are based on various preliminary discussions and "soft" quotes from contract research organizations that provide pre-clinical and clinical studies support. The estimates are also based on certain time estimates for achievement of various objectives. If we miss these time estimates or if the actual costs of the development are greater than the early estimates we have at present, our drug development cost estimates may be substantially greater than anticipated now. In that case, we may have to re-prioritize our programs and/or seek additional funding. Also, additional funding, if available, will allow us to move our other drug candidates towards IND filings. These additional funds will be needed to pay for additional personnel, increased subcontract costs related to the expansion and further development of our drug pipeline, and for additional capital and operational expenditures required to file IND applications. We will accelerate our business plans provided that we can obtain such additional funding. We believe that we currently have adequate financing for our current business plan of operations.

The Company does not have direct experience in taking a drug through human clinical trials. In addition, we depend upon external collaborators, service providers and consultants for much of our drug development work. As such our projections and estimates may be significantly off from actual future results both in terms of timeline and in terms of cost budgets.

We anticipate that we will incur the following additional expenses over the next 24 months:

1. Research and Development of \$12,000,000: Planned costs for in-vivo and in-vitro studies for pan-influenza FluCide, Eye nanoviricide, HIVCide, HerpeCide, Dengue, MERS-CoV, and Ebola/Marburg and Rabies programs.
2. Corporate overhead of \$4,000,000: This amount includes budgeted office salaries, legal, accounting, investor relations, public relations, and other costs expected to be incurred by being a public reporting company.
3. Capital costs of \$2,000,000: This is the estimated cost for equipment and laboratory improvements.
4. Staffing costs of \$4,000,000: This is the estimated cost of hiring additional scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to FDA compliance, as required for development of necessary data for filing an Investigational New Drug with the United States Food and Drug Administration.
5. If and when we initiate human clinical trials for Injectable FluCide, we anticipate approximately \$2 million in total costs for the Phase I clinical trials, and approximately \$5 million for the Phase IIa (virus challenge human efficacy study) clinical trials. In a subsequent year, if Phase I and Phase IIa are successful, we anticipate approximately \$10 million for Phase IIb human clinical trials. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional costs. These estimates assume that FluCide is highly effective and therefore would require relatively few patients in each arm of the each trial in order to establish statistically significant results.

We therefore believe that we have sufficient funds in hand to take Injectable FluCide through the initial human clinical trials.

Due to its current cash position, in addition to certain clinical trials for FluCide and another drug candidate, the Company anticipates that it will also be able to expedite development of its other drug candidates, namely, HerpeCide™,

DengueCide, Oral FluCide, HIVCide™, and EKCCide™ into the FDA approval process. In addition, the Company was also able to undertake R&D for a nanoviricide against the Ebola virus. We believe that, we should be able to attract funding from non-dilutive sources such as government grants and contracts, as well as from charitable organizations, for advancing a potential anti-Ebola nanoviricide into further drug development into the normal drug development pathway for a lethal disease, which follows the US FDA Animal Rule model.

The Company believes it will have sufficient access to capital even if it decides to develop FluCide through Phase IIb and Phase III on its own. The Company believes it will continue to be able to successfully raise financing as needed. If we are unable to obtain additional financing, our business plan will be significantly delayed.

The Company has limited experience with pharmaceutical drug development. Thus, our budget estimates are not based on experience, but rather based on advice given by our associates and consultants. As such these budget estimates may not be accurate. In addition, the actual work to be performed is not known at this time, other than a broad outline, as is normal with any scientific work. As further work is performed, additional work may become necessary or change in plans or workload may occur. Such changes may have an adverse impact on our estimated budget. Such changes may also have an adverse impact on our projected timeline of drug development.



We believe that this coming year's work-plan will lead us to obtain certain information about the safety and efficacy of some of the drugs under development in animal models. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further studies in animal models to obtain necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles of our drug candidates. We believe these data will then enable us to file an Investigational New Drug Application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

Most pharmaceutical companies expect 4 to 10 years of study to be required before a drug candidate reaches the IND stage. We believe that because we are working in the infectious agents area, our studies will have objective response end points, and most of our pre-clinical and studies will be of relatively short durations. Our business plan is based on these assumptions. If we find that we have underestimated the time duration of our studies, or we have to undertake additional studies, due to various reasons within or outside of our control, this will grossly and adversely impact both our timelines and our financing requirements.

Ability to manufacture our novel nanomedicines under cGMP conditions has been a limiting factor for us in advancing our drug candidates towards clinical trials. Once the Shelton facility is fully going and once we have produced several batches of at least one of our drug candidates at this facility under cGMP conditions, we will also have the ability to quickly develop cGMP manufacture of our other drug candidates. We believe that this will then enable us to move our drug candidates into clinical trials in rapid succession, limited only by the funding available and the personnel constraints that arise in small start-up pharma companies such as ours.

Management intends to use capital and debt financing, as required, to fund the Company's operations. Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain the additional capital resources necessary to fund its anticipated obligations beyond March 31, 2016. The Company currently has no long term debt other than the convertible debentures as disclosed.

## **Results of Operations**

The Company is a biopharmaceutical company and did not have any revenue for the three months ended March 31 2015 and 2014 and the nine months ended March 31, 2015 and 2014.

**Revenues** - The Company is a non-revenue producing entity.

**Operating Expenses** - Research and development expenses for the three months ended March 31, 2015 decreased \$79,273 to \$546,464 from \$625,737 and decreased \$656,126 to \$2,274,310 for the nine months ended March 31, 2015, from \$2,930,436 for the nine months ended March 31, 2014. This decrease in the cost of research and development is largely attributable to the decrease in costs of research and development expenditures of additional drug candidates offset by increased research and development payroll costs.

General and administrative expenses increased for the three months ended March 31, 2015 decreased \$31,455 to \$576,173 from \$607,628 and increased \$408,992 to \$2,352,115 for the nine months ended March 31, 2015, from \$1,943,123 for the nine months ended March 31, 2014. The increase resulted from the Company's general increase in the cost of non-research and development expenditures associated with development of its various drug candidates.

**Other Income (Expenses)** – Net interest income decreased \$19,780 for the three months ended March 31, 2015 to \$35,009 from \$54,789 for the three months ended March 31, 2014 and increased \$77,185 to \$156,035 for the nine months ended March 31, 2015 from \$78,850 for the nine months ended March 31, 2014.. Net interest income included interest on cash equivalent deposits in an interest-bearing account.

**Other Income (Expenses)** – Interest Expense for the three months ended March 31, 2015 decreased \$805,448 to (\$1,920,268) from (\$2,725,716) for the three months ended March 31, 2014. For the nine months ended March 31, 2015, Interest Expense decreased \$559,504 to (\$2,412,712) from (\$2,972,216) for the nine months ended March 31, 2014. The decrease is attributable to interest expense paid with a fixed number of the Company's securities which are at a lower valuation.

**Other Income (Expenses)** – Discount on convertible debentures for the three months ended March 31, 2015 increased \$154,255 to (\$297,276) from (\$143,051) for the three months ended March 31, 2014. For the nine months ended March 31, 2015, discount on convertible debentures increased \$441,149 to (\$860,454) from (\$419,305) for the nine months ended March 31, 2014. The increase reflects amortization of the discount on the Company's Series C Convertible Debentures.

**Other Income (Expenses)** – Change in fair value of derivatives for the three months ended March 31, 2015 decreased \$2,317,043 to \$3,054,154 from \$5,371,197 for the three months ended March 31, 2014. For the nine months ended March 31, 2015, the increase was \$4,878,028 to \$6,463,095 from \$1,585,067 for the nine months ended March 31, 2014.

**Income Taxes** – There is no provision for income taxes due to ongoing operating losses.

**Net Operating Loss** - For the nine months ended March 31, 2015, the Company had a net loss of (\$1,280,461), or \$ (\$0.07) per share (as adjusted) on a fully diluted basis compared to a net loss of (\$6,601,163), or (\$0.13) per share (as

adjusted) on a fully diluted basis for the nine months ended March 31, 2014.

The decrease resulted primarily from a decrease in the fair value of derivatives.

### ***Liquidity and Capital Reserves***

The Company had cash and cash equivalents of approximately \$33.9 million as of March 31, 2015 and accounts payable and accrued liabilities of approximately \$523,429.

Since inception, the Company has expended substantial resources on research and development. Consequently, we have sustained substantial losses. The Company has an accumulated deficit of \$53,181,861 at March 31, 2015.

While our cash and cash equivalent balance is sufficient for us to continue our operations through March 31, 2017, it is insufficient to fully execute the Company's business plan. If the Company is unable to obtain debt or equity financing to meet its cash needs it may have to severely limit, its business plan by reducing the funds it hopes to expend on pre-clinical studies and trials, the establishment of our own laboratory and/or research and development project.

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

We have not entered into any off-balance sheet arrangements during the nine months ended March 31, 2015.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Market risk is the risk of loss arising from adverse changes in market rates and prices, such as interest rates, foreign currency exchange rates and commodity prices. We currently have no foreign operations and are not exposed to foreign currency fluctuations. Our primary exposure to market risk is interest rate risk associated with our short term cash equivalent investments, which the Company deems to be non-material. The Company does not have any financial instruments held for trading or other speculative purposes and does not invest in derivative financial instruments, interest rate swaps or other investments that alter interest rate exposure. The Company does not have any credit facilities with variable interest rates.

### **ITEM 4. CONTROLS AND PROCEDURES**

(a) Evaluation of disclosure controls and procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Management has designed our disclosure controls and procedures to provide reasonable assurance of achieving the desired control objectives.

As required by Exchange Act Rule 13a-15(b), we have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2014.

(a) Based upon an evaluation of the effectiveness of disclosure controls and procedures, our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") originally concluded that as of the end of the period covered by the Annual Report on Form 10-K our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC and is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. However, in connection with the preparation of our unaudited financial statements for the quarter ended December 31, 2014, we determined that we inadvertently overlooked the anti-dilution provisions in certain warrants issued in connection with the company's private placements

of securities Specifically, the warrants issued contained certain anti-dilution ratchet provisions that provided for an adjustment to the exercise price of the warrants if the company issued any stock equivalent securities at a lower price in the future while the option was still outstanding.

As a result of this error we filed Form 10-K/A to restate our audited financial statements for the years ended June 30, 2014 and the three and six month ended December 31, 2013 and three months ended September 30, 2014 and 2013 and the three and nine months ended March 31, 2014.

Also in connection with the preparation of our unaudited financial statements for the quarter ended December 31, 2014 we determined that in preparing our unaudited financial statements for the quarter ended September 30, 2014, we inadvertently did not recognize a single compound embedded derivative included with the issuer's redemption rights in the Series C Convertible Debenture and the holders conversion right to receive coupon interest in common stock of the issuer. The Series C Convertible Debentures were issued on July 2, 2014. The Company has restated its financial statements for the three month period ended September 30, 2014.

(b) Changes in internal control over financial reporting. The Company has established an independent Board of Directors comprising three independent members. Under this Board the Company has established an Audit Committee, a Compensation Committee, a Nomination Committee, and an Executive Committee. The Company has met or exceeded corporate governance standards of the NYSE MKT, a national exchange.

#### Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a- 15(f) under the Securities Exchange Act of 1934, as amended. Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America ("GAAP"). We recognize that because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2014. To evaluate the effectiveness of our internal control over financial reporting, management used the criteria described in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Framework"). Based on its evaluation under the *Internal Control - Evaluation Framework*, management originally concluded that our internal control over financial reporting was effective as of June 30, 2014.

In connection with the restatement discussed in Note 2 of the Notes to Financial Statements included in this Form 10-Q/A, management, including our Chief Executive Officer and Chief Financial Officer, reassessed the effectiveness of our internal control over financial reporting as of June 30, 2014. Based on this reassessment, using the COSO criteria, management has concluded that we did not maintain effective internal control over financial reporting as of June 30, 2014 due to a deficiency in the controls over the review of accounting for complex debt and equity transactions. Management concluded that this deficiency was a material weakness as defined in the Securities and Exchange Commission regulations. This control deficiency resulted in the misstatement of the Company's derivative liability and the related financial disclosures for the year ended June 30, 2014 and the restatement of the unaudited financial information for the quarter ended September 30, 2014 and 2013. The Company has restated the Company's financial statements for the three and six months ended December 31, 2013 and the three and nine months ended March 31, 2014. The results of which are reported in this Form 10Q at Note 2 to the financial statements.

## **Remediation Plan**

We have proceeded to remediate this material weakness by, among other things, implementing a process of enhanced review by senior management of all financial transactions and the engagement of outside specialists to evaluate our financial transactions as they arise. The actions that we will be taking are subject to ongoing senior management review and Audit Committee oversight. Management believes the foregoing efforts when fully implemented will effectively remediate the material weakness. As we continue to evaluate and work to improve our internal control over financial reporting, management may execute additional measures to address potential control deficiencies or modify the remediation plan described above and will continue to review and make necessary changes to the overall design of our internal controls.

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

There were no material changes in our internal control over financial reporting (as defined in Rule 13a- 15(f) under the Exchange Act) that occurred during the quarter ended March 31, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

From time to time, we may be a party to legal proceedings in the ordinary course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

There are no current legal proceedings against the Company to the best of the Company's knowledge as of the date hereof and to the Company's knowledge, no action, suit or proceeding has been threatened against the Company.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

None.



**ITEM 6. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
31.1	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Executive Officer
31.2	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NANOIRICIDES, INC.**

/s/ Eugene Seymour, MD

Dated: May 15, 2015 Name: Eugene Seymour, M.D.  
Title: Chief Executive Officer and Director  
(Principal Executive Officer )

/s/ Meeta Vyas

Dated: May 15, 2015 Name: Meeta Vyas  
Title: Chief Financial Officer  
(Principal Financial Officer)