

NANOIRICIDES, INC.  
Form 10-Q  
February 09, 2016

**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 OF 1934.**

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

*Commission File Number: 333-148471*

**NANOIRICIDES, INC.**

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

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

**1 Controls Drive**

**Shelton, Connecticut 06484**

(Address of principal executive offices and zip code)

(203) 937-6137

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

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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 February 9, 2016 was approximately:  
57,823,000

NanoViricides, Inc.

FORM 10-Q

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NanoViricides, Inc.

## Balance Sheets

	December 31, 2015 (Unaudited)	June 30, 2015
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 28,237,621	\$ 31,467,748
Prepaid expenses	105,998	214,425
Total Current Assets	28,343,619	31,682,173
<b>PROPERTY AND EQUIPMENT</b>		
Property and equipment	13,527,861	13,496,851
Accumulated depreciation	(1,527,213 )	(1,534,203 )
Property and equipment, net	12,000,648,	11,962,648
<b>TRADEMARK</b>		
Trademark and patents	458,954	458,954
Accumulated amortization	(63,352 )	(59,217 )
Trademark and patents, net	395,602	399,737
<b>OTHER ASSETS</b>		
Service agreements	109,143	142,531
Total Assets	\$ 40,849,012	\$ 44,187,089
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 176,172	\$ 89,517
Accounts payable – related party	1,111,170	316,196
Accrued expenses	12,596	28,515
Deferred interest payable – current portion	166,668	166,667
Total Current Liabilities	1,466,606	600,895
Debentures payable - Series B, net of discount	5,075,012	4,700,582
Debentures payable – Series C, net of discount	2,789,845	2,480,605
Derivative liability-Series B debentures	99,469	366,764
Derivative liability-Series C debentures	240,482	476,289
Derivative liability-warrants	2,543,342	3,442,754
Deferred interest payable – long term portion	249,999	333,333

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Total Long Term Liabilities	10,998,149	11,800,327
Total Liabilities	12,464,755	12,401,222

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY:

Series A Convertible Preferred stock, \$0.001 par value, 4,000,000 shares designated, 4,000,000 and 3,583,445 shares issued and outstanding at December 31, 2015 and June 30, 2015, respectively	4,000	3,584
Common stock, \$0.001 par value; 150,000,000 shares authorized, 57,822,538 and 57,242,070 shares issued and outstanding at December 31, 2015 and June 30, 2015, respectively	57,822	57,242
Additional paid-in capital	86,504,253	85,824,613
Accumulated deficit	(58,181,818 )	(54,099,572 )
Total Stockholders' Equity	28,384,257	31,785,867
Total Liabilities and Stockholders' Equity	\$ 40,849,012	\$44,187,089

*See accompanying notes to the financial statements*

NanoViricides, Inc.

## Statements of Operations

(Unaudited)

	For the Three Months Ended December 31, 2015	For the Three Months Ended December 31, 2014	For the Six Months Ended December 31, 2015	For the Six Months Ended December 31, 2014
<b>OPERATING EXPENSES</b>				
Research and development	\$ 1,152,501	\$ 916,739	\$ 2,359,573	\$ 1,727,846
General and administrative	937,800	787,164	1,955,779	1,590,392
Total operating expenses	2,090,301	1,703,903	4,315,352	3,318,238
<b>LOSS FROM OPERATIONS</b>	<b>(2,090,301 )</b>	<b>(1,703,903 )</b>	<b>(4,315,352 )</b>	<b>(3,318,238 )</b>
<b>OTHER INCOME (EXPENSE):</b>				
Interest (expense) income	(4,562 )	(31,050 )	4,261	(64,525 )
Interest expense	(245,000 )	(247,444 )	(490,000 )	(492,444 )
Discount on convertible debentures	(349,962 )	(289,960 )	(683,670 )	(563,178 )
Change in fair value of derivatives	(85,467 )	391,216	1,402,515	3,408,941
Other (expense) income	(684,991 )	(177,238 )	233,106	2,288,794
<b>LOSS BEFORE INCOME TAX PROVISION</b>	<b>(2,775,292 )</b>	<b>(1,881,141 )</b>	<b>(4,082,246 )</b>	<b>(1,029,444 )</b>
<b>INCOME TAX PROVISION</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>NET LOSS</b>	<b>\$(2,775,292 )</b>	<b>\$(1,881,141 )</b>	<b>\$(4,082,246 )</b>	<b>\$(1,029,444 )</b>
<b>NET LOSS PER COMMON SHARE</b>				
- Basic	\$ (0.05 )	\$ (0.03 )	\$ (0.07 )	\$ (0.02 )
- Diluted	\$ (0.05 )	\$ (0.04 )	\$ (0.07 )	\$ (0.05 )
<b>Weighted average common shares outstanding</b>				
- Basic	57,588,081	56,557,352	57,431,198	56,066,776
- Diluted	57,588,081	59,224,019	57,431,198	58,733,443

*See accompanying notes to the financial statements*





NanoViricides, Inc.

## Statement of Changes in Stockholders' Equity

For the period from June 30, 2015 through December 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, 2015	3,583,445	\$ 3,584	57,242,070	\$57,242	\$85,824,613	\$(54,099,572)	\$31,785,867
Common Shares issued for employee stock bonus	-	-	1,295	1	3,299	-	3,300
Series A Preferred Shares issued for employee stock compensation	416,555	416	-	-	336,778	-	337,194
Share issued for consulting and legal services rendered	-	-	43,144	43	53,957	-	54,000
Warrants issued to Scientific Advisory Board	-	-	-	-	16,976	-	16,976
Common Shares issued for Directors fees	-	-	17,319	17	22,482	-	22,499
Common Shares issued upon stock option exercise	-	-	313,155	313	(313 )	-	-
Common Shares issued for debenture interest	-	-	205,555	206	246,461	-	246,667
Net loss	-	-	-	-	-	(4,082,246 )	(4,082,246 )
Balance, December 31, 2015	4,000,000	\$ 4,000	57,822,538	\$57,822	\$86,504,253	\$(58,181,818)	\$28,384,257

See accompanying notes to the financial statements

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NanoViricides, Inc.

## Statements of Cash Flows

(Unaudited)

	For the Six Months Ended December 31, 2015	For the Six Months Ended December 31, 2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,082,246	) \$ (1,029,444
Adjustments to reconcile net loss to net cash used in operating activities		
Series A Preferred shares issued as compensation	337,194	157,094
Common shares issued as compensation and for services	79,799	76,503
Common shares issued for interest	246,667	-
Warrants granted to Scientific Advisory Board	16,976	39,269
Depreciation	325,486	102,664
Amortization	4,135	4,386
Change in fair value of derivative liability	(1,402,515	) (3,408,941
Amortization of debt discount on convertible debentures	683,670	563,178
Changes in operating assets and liabilities:		
Prepaid expenses	108,426	(127,022
Other current assets	-	150,000
Deferred expenses	-	250,000
Other long term assets	33,388	-
Accounts payable	86,655	125,511
Accounts payable - related party	794,974	158,619
Accrued expenses	(15,919	) 69,940
Deferred interest payable	(83,333	) -
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(2,866,641</b>	<b>) (2,868,243</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(363,486	) (5,313,326
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of warrants	-	6,743,295
<b>NET CHANGE IN CASH</b>	<b>(3,230,127</b>	<b>) (1,438,274</b>
Cash at beginning of period	31,467,748	36,696,892
Cash at end of period	\$ 28,237,621	\$ 35,258,618

SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:

Interest paid	\$ 490,000	\$ -
Income tax paid	\$ -	\$ -

NON CASH FINANCING AND INVESTING ACTIVITIES:

Series A Preferred stock issued as discount on Debentures	\$ -	\$ 1,152,297
Common Stock issued upon cashless exercise of stock options	313	-
Reduction in leasehold improvements and fixtures and accumulated depreciation due to decommissioning of West Haven, CT facilities	332,476	-

*See accompanying notes to the financial statements*

**NANOIRICIDES, INC.**

**DECEMBER, 2015 AND 2014**

**NOTES TO THE FINANCIAL STATEMENTS**

**(Unaudited)**

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

NanoViricides, Inc. 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 Nanoviricides, Inc., a privately owned Florida corporation ("NVI"), pursuant to an Agreement and Plan of Share Exchange (the "Exchange"). Nanoviricides, 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 the Company 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. NanoViricides is unique in the bio-pharma field in that it possesses its own state of the art facilities for the design, synthesis, analysis and characterization of the nanomedicines that we develop, as well as for production scale-up, and e-GMP-like production in quantities needed for human clinical trials. The biological studies such as the effectiveness, safety, bio-distribution and Pharmacokinetics/Pharmacodynamics on our drug candidates are performed by external collaborators and contract organizations.

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”), to which we have the necessary exclusive licenses in perpetuity. The first agreement we executed with TheraCour on September 1, 2005, gave us an exclusive, worldwide license for the treatment of the following human viral diseases: Human Immuno deficiency 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 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 one time 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 Series A Preferred Stock 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 - 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 10 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 for the fiscal year ended June 30, 2015 filed with the SEC on September 14, 2015.

For a summary of significant accounting policies, see the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2015 filed on September 14, 2015.

*Net Income (Loss) per Common Share*

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	For the
Six Months	Six Months
Ended	Ended

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	December 31,2015	December 31, 2014
Stock options	-	535,715
Warrants	6,010,971	5,942,379
Total potentially outstanding dilutive common shares	6,010,971	6,478,094

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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 such 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. For the quarter ended December 31, 2015, two Holders of the Series B debentures elected to receive quarterly interest in restricted common stock of the Company. These two Holders are controlled by Dr. Milton Boniuk, a director of the Company.

At December 31, 2015, the 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.

The Company has also issued 4,000,000 shares Series A Preferred Stock to investors and others as of December 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 Preferred Stock is not convertible into Common Stock, and does not carry any dividend rights or any other financial effects. At December 31, 2015, the number of potentially dilutive shares of the Company's common stock into which these Series A Preferred shares can be converted into is 14,000,000 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. Coupon interest payable quarterly related to the Series C debenture is payable in cash or shares of common stock at the average of the open and close price. Such interest payment is due at the option of the Holder. For the quarter ended December 31, 2015, the Holder of the Series C Debenture elected to receive the quarterly interest in restricted common stock of the Company. The Holder is an entity controlled by Dr. Milton Boniuk, a director of the Company.

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At December 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 following represents a reconciliation of the numerators and denominators of the basic and diluted per share calculations for (loss) income from continuing operations:

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	For the three months ended		For the six months ended	
	December	December	December	December
	31,	31,	31,	31,
	2015	2014	2015	2014
Calculation of basic loss per share of common stock:				
Net loss attributable to common stockholders	\$ (2,775,292 )	\$ (1,881,141 )	\$ (4,082,246 )	\$ (1,029,444 )
Denominator for basic weighted average shares of common stock	57,588,081	56,557,352	57,431,198	56,066,776
Basic loss per share of common stock	\$ (0.05 )	\$ (0.03 )	\$ (0.07 )	\$ (0.02 )
Calculation of diluted loss per share of common stock:				
Net loss attributable to common stockholders	\$ (2,775,292 )	\$ (1,881,141 )	\$ (4,082,246 )	\$ (1,029,444 )
Add: Income impact of assumed conversion of Debentures	-	(222,053 )	-	(2,044,459 )
Net loss attributable to common stockholders plus assumed conversions	\$ (2,775,292 )	\$ (2,103,194 )	\$ (4,082,246 )	\$ (3,073,903 )
Denominator for basic weighted average shares of common stock	57,588,081	56,557,352	57,431,198	56,066,776
Incremental shares from assumed conversions of Debentures payable	-	2,666,667	-	2,666,667
Denominator for diluted weighted average shares of common stock	57,588,081	59,224,019	57,431,198	58,733,443
Diluted loss per share of common stock	\$ (0.05 )	\$ (0.04 )	\$ (0.07 )	\$ (0.05 )

Series B and Series C debentures were excluded from the loss per share calculation for the three and six months ended December 31, 2015 because the impact is anti-dilutive.

#### Recently Issued Accounting Pronouncements

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 2014-15 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 3- Financial Condition**

The Company's financial statements for the interim period ended December 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 a deficit accumulated from inception. 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 December 31, 2015 the Company had cash and cash equivalents of \$28,237,621. The Company has sufficient capital to continue its business, at least, through December 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 currently unplanned capital costs and additional staffing requirements, if they arise, 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 4 - 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 shareholder, Director  
 TheraCour Pharma, Inc. An entity owned and controlled by a significant stockholder  
 InnoHaven, LLC An entity owned and controlled by a significant stockholder  
 Milton Boniuk, MD Director and significant stockholder

Property and Equipment

	For the three months ended		For the six months ended	
	December 31, 2015	December 31, 2014	<b>December 31, 2015</b>	December 31, 2014
The Company acquired 1 Controls Drive, Shelton, Connecticut from InnoHaven, LLC		\$ 4,222,549		\$ 4,222,549
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	\$ 6,747	\$ 78,311	\$ 14,648	\$ 188,889

Account Payable – Related Party

As of  
December 31, 2015      June 30, 2015

Pursuant to an Exclusive 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. In consideration for obtaining this exclusive license, 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 or actual costs, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf. Accounts payable due TheraCour Pharma Inc. on the reporting date was

\$1,111,170      \$316,196

For the three months ended		For the six months ended	
December 31, 2015	December 31, 2014	<b>December 31, 2015</b>	December 31, 2014

## Research and Development Costs Paid to Related Parties

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 December 31, 2015 and 2014	\$ 996,398	\$ 520,955	\$2,012,614	\$ 1,290,140
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Long-Term Debentures Payable to a Director

	As of	
	December 31, 2015	June 30, 2015
Series B Convertible Debentures - Milton Boniuk	\$4,000,000	\$4,000,000
Series C Convertible Debentures - Milton Boniuk	5,000,000	5,000,000
Total Long Term Debentures Payable to a Director	\$9,000,000	\$9,000,000

	As of December 31, 2015	June 30, 2015
Debt Interest Paid to a Director		
<p>Coupon interest payable on \$5,000,000 Series C Convertible Debentures and deferred. The deferred interest is paid out quarterly over the remaining term of the debenture commencing September 30, 2015:</p>		
Deferred interest payable - short-term	\$166,668	\$166,667
Deferred interest payable - long-term	249,999	333,333

Coupon interest expense on the Series B Debentures to Dr. Milton Boniuk for the three months ended December 31, 2015 and 2014 was \$80,000 and \$80,000 respectively, and for the six months ended December 31, 2015 and 2014 was \$160,000 and \$160,000, respectively.

Coupon interest expense recognized on Series C Debentures to Dr. Milton Boniuk for the six months ended December 31, 2015 and 2014 was \$125,000 and \$125,000, respectively and for the six months ended December 31, 2015 and 2014 was \$250,000 and \$250,000, respectively.



**Note 5 - Property and Equipment**

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

	December 31, 2015	June 30, 2015
Land	\$ 260,000	\$260,000
GMP Facility	7,979,202	7,905,938
Office Equipment	68,579	65,241
Furniture and Fixtures	5,607	1,400
Lab Equipment	5,214,473	5,264,272
Total Property and Equipment	13,527,861	13,496,851
Less Accumulated Depreciation	(1,527,213 )	(1,534,203 )
Property and Equipment, Net	\$ 12,000,648	\$ 11,962,648

Depreciation expense for the three months ended December 31, 2015 and 2014 were \$163,880 and \$51,332 respectively and for the six months ended December 31, 2015 and 2014 were \$325,486 and \$102,664, respectively.

In the current reporting period the Company completed the transfer of laboratories and personnel from its previous laboratory facilities at 135 Wood Street, West Haven, CT to 1 Controls Drive, Shelton, CT. The Company recorded the abandonment of fully depreciated laboratory fixtures associated with the 135 Wood Street facility of \$332,476 as a reduction to Property and Equipment with a corresponding reduction to Accumulated Depreciation.

**Note 6 - Trademark and Patents**

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

	December 31, 2015	June 30, 2015
Trademarks and Patents	\$ 458,954	\$458,954
Less Accumulated Amortization	(63,352 )	(59,217 )
Trademarks and Patents, Net	\$ 395,602	\$ 399,737

Amortization expense amounted to \$2,067 and \$2,193 for the three months ended December 31, 2015 and 2014 respectively and \$4,135 and \$4,386 for the six months ended December 31, 2015 and 2014 respectively.

#### **Note 7 – 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 date of issuance, using the average of the open and close prices of the Company’s common stock on the date such interest payment is due. For the three months December 31, 2015, two holders of the Company’s Series B Convertible Debentures elected to receive quarterly coupon interest of \$80,000 in restricted common shares of the Company. The Board of Director authorized the issuance of 66,666 shares of the Company’s restricted \$0.001 par value common shares in payment of the coupon interest. Additional interest was 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 Series B Debenture payable, net of discount at December 31, 2015 and June 30, 2015. The debt discount is being accreted to interest expense over the term of the debenture:

	December 31, 2015	June 30, 2015
Proceeds	\$ 6,000,000	\$ 6,000,000
Debt discount for bifurcated derivative	(2,735,310 )	(2,735,310)
	3,264,690	3,264,690
Accumulated amortization of debt discount	1,810,322	1,435,892
Debenture payable - Series B, net	\$ 5,075,012	\$ 4,700,582

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.

The Company recognized amortization of this discount as an additional interest charge to “Discount on convertible debentures” for the three month periods ended December 31, 2015 and 2014 in the amount of \$190,803 and \$163,890, respectively. and for the six month periods ended December 31, 2015 and 2014 in the amount of \$374,430 and \$321,618, 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 December 31, 2015 and June 30, 2015, respectively.

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The following assumptions were used for the valuation of the compound embedded derivative at December 31, 2015 and June 30, 2015:

·The balance of the Series B Convertible Debenture as of December 31, 2015 and June 30, 2015 is \$6,000,000;

The underlying stock price was used as the fair value of the common stock; The stock price decreased to **\$1.18** at December 31, 2015 but higher projected annual volatility increased the warrant value with the \$3.50 exercise price. The stock price decreased to \$1.75 at June 30, 2015 which decreased the warrant value with the \$3.50 exercise price;

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

**1 year**

**12/31/2015 68.2%**

**6/30/15 62.1%**

·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 **20.0%** (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 be 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 **22.02%**.

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 December 31, 2015 and June 30, 2015 was \$99,469 and \$366,764, respectively.

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 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. In accordance with the debenture agreement, the interest for the initial year of the debenture shall be deferred and paid over the remainder of the term. The Holder at its option may choose to receive such coupon interest payment in shares of Common Stock calculated using the average of the open and close prices of the Company's common stock on the date such interest payment is due. For the three months ended December 31, 2015 the Holder of the Company's C Convertible Debenture elected to receive the quarterly coupon interest of \$166,667 in restricted common shares of the Company. The Board of Directors authorized the issuance of 138,889 share of the Company's restricted \$.001 par value common shares in payment of such coupon interest. 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 in the same amount as the 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. The Company recognized amortization of this discount as an additional interest charge to “Discount on convertible debentures” in the amount of \$159,159 and \$126,070 for the three month period ended December 31, 2015 and 2014 respectively and \$309,240 and \$241,560 for the six month periods ended December 31, 2015 and 2014 respectively.

The following represents the balance of the Debenture payable – Series C, net of discount at December 31, 2015 and June 30, 2015:

	December 31, 2015	June 30, 2015
Proceeds	\$ 5,000,000	\$ 5,000,000
Debt Discount:		
Series A Preferred	(1,152,297 )	(1,152,297)
Embedded derivative	(1,879,428 )	(1,879,428)
	1,968,275	1,968,275
Accumulated amortization of debt discount	821,570	512,330
Debenture payable - Series C, net	\$ 2,789,845	\$ 2,480,605

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 December 31, 2015 and June 30, 2015.

The following assumptions were used for the valuation of the compound embedded derivative at December 31, 2015 and June 30, 2015:

- The balance of the Series C Convertible Debenture as of December 31, 2015 and June 30, 2015 is \$5,000,000;

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The underlying stock price was used as the fair value of the common stock; The stock price decreased to **\$1.18** at December 31, 2015 but higher projected annual volatility increased the warrant value with the \$6.05 exercise price. The stock price decreased to \$1.75 at June 30, 2015 which decreased the warrant value with the \$6.05 exercise price;

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

**1 year**

**12/31/2015 68.2%**

**6/30/15 62%**

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

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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 22.02% and 21.97%, respectively.

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 December 31, 2015 and June 30, 2015 was \$240,482 and \$476,289, respectively.

## **Note 8 - Equity Transactions**

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Anil Diwan, the Company's president. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 of the Company's Series A preferred shares to Dr. Diwan. As of December 31, 2015 204,420 of these shares have been issued and 20,580 will be issued in a subsequent period. 75,000 shares will vest on June 30, 2016 and the remainder of the shares will vest over the three years of the employment agreement and are subject to forfeiture. The Company recognized a non cash compensation expense related to the issuance of the Series A Preferred Shares of \$77,336 for the three months ended December 31, 2015 and \$154,672 for the six months ended December 31, 2015.

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Eugene Seymour, the Company's Chief Executive Officer. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 of the Company's Series A preferred shares to Dr. Seymour. As of December 31, 2015 204,420 of these shares have been issued and 20,580 will be issued in a subsequent period. 75,000 shares will vest on June 30, 2016 and the remainder of the shares will vest over the three years of the employment agreement and are subject to forfeiture. The Company recognized a non cash compensation expense related to the issuance of the Series A Preferred Shares of \$77,336 for the three months ended December 31, 2015 and \$154,672 for the six months ended December 31, 2015.

The Company estimated the fair value of the Series A Preferred stock granted to various employees and others on the date of grant. The Series A Preferred stock fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; or 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 each issuance used the following inputs:

a. The common stock price was in the range \$1.16 to \$1.23

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 10.49% to 10.53% 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 for the issuances and a remaining restricted term of 1.33 to 1.17

f. The 7/21/15 Diwan & Seymour Preferred conversion value is based on the greater of the Change of Control in 4 years from 3/1/13 and the vesting on 6/30/16, 6/30/17, and 6/30/18 resulting in a remaining restricted term of **1.63** to **2.94** years;

**28.75%** to **27.14%** restricted stock discount (based on a restricted stock analysis and call-put analysis curve: <sup>g</sup> **64.42%** to **65.16%** volatility, **0.31%** to **0.51%** risk-free rate) applied to the converted common.

For the three and six months ended December 31, 2015 the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 17,148 shares of commons stock with an exercise price of \$1.50 per share expiring in August, 2019 and fully vested warrants to purchase 34,296 shares of common with a purchase price of 1.44 per share expiring November, 2019, respectively These warrants were valued at \$8,231 for the three months and \$16,976 for the six months periods and recorded as consulting expense.

For the three and six months ended December 31, 2015, the Company's Board of Directors authorized the issuance of 7,716 and 15,432 fully vested shares of its Series A Convertible Preferred stock for employee compensation. The Company recorded an expense of \$23,345 and 51,195 for the three months and six months respectively. 7,716 shares are to be issued in a subsequent period.

For the three and six months ended December 31, 2015, the Company's Board of Directors authorized the issuance of 1,295 fully vested shares of its common stock for employee compensation. The Company recorded an expense of \$3,300.

For the three months and six months ended December 31, 2015, the Company's Board of Directors authorized the issuance of 8,789 and 17,319 respectively, fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of \$ 11,250 and \$22,499.

For the three months and six months ended December 31, 2015, the Company's Board of Directors authorized the issuance of 22,689 and 43,144 respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$27,000. and \$54,000. Respectively.

On December 31, 2015 two Holders of the Company's Series B Debentures elected to receive the \$80,000 quarterly interest payable in restricted common stock of the Company. For the three months ended December 31, 2015 the Company's Board of Directors authorized the issuance of 66,666 shares of the Company's restricted common stock for interest payable to the Holders. The Holders are entities controlled by Dr. Milton Boniuk, a director of the Company.

On December 31, 2015 the Holder of the Company's Series C Debentures elected to receive the \$166,667 quarterly interest payable in restricted common stock of the Company. For the three months ended December 31, 2015 the Company's Board of Directors authorized the issuance of 138,889 shares of the Company's restricted common stock for interest payable to the Holder. The Holder is an entity controlled by Dr. Milton Boniuk, a director of the Company.

The expense recognized by the Company upon issuance of restricted common shares for compensation or services is determined by the average market value of the Company's common shares over the service period.

The Company estimated the fair value of the warrants granted 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	57.81 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	1.42 %

**Note 9 - Stock Options and Warrants**

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

	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Stock Options				
Outstanding and exercisable at June 30, 2015	535,715	\$ 0.35	0.23	\$2,094,643
Granted	-	-	-	-
Exercised	428,573	-	-	-
Expired	107,142	-	-	-
Canceled	-	-	-	-
Outstanding at December 31, 2015	-	\$ -	-	\$-

As of December 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 (\$)
Stock Warrants				
Outstanding and exercisable at June 30, 2015	5,976,675	\$ 5.14	3.20	\$ 19,000
Granted	34,296	1.50	3.63	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding and exercisable at December 31, 2015	6,010,971	\$ 5.12	2.70	\$ -

Of the above warrants, 345,713 expire in fiscal year ending June 30, 2016; 68,571 expire in fiscal year ending June 30, 2017; 68,577 in fiscal year ending June 30, 2018; 5,493,814 in fiscal year ending June 30, 2019 and 34,296 expire

in fiscal year ending June 30, 2020.

## **Note 10 – Fair Value Measurement**

### **Fair value measurements**

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

	Fair Value Measurements at December 31, 2015:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series B debentures	\$ -	-	\$ 99,469
Derivative liability – Series C debentures	-	-	240,482
Derivative liability – warrants	-	-	2,543,342
Total derivatives	\$ -	\$ -	\$ 2,883,293

	Fair Value Measurements at June 30, 2015:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series B debentures	\$ -	-	\$ 366,764
Derivative liability – Series C debentures	-	-	476,289
Derivative liability – warrants	-	-	3,442,754
Total derivatives	\$ -	\$ -	\$ 4,285,807

In conjunction with the Company's registered direct offerings of Units, consisting of the Company's common stock and warrants, on September 12, 2013 and January 24, 2014 the Company issued 2,945,428, and 2,479,935 warrants respectively, and, of which, 2,610,071 and 2,479,935 respectively are outstanding at December 31, 2015. Additionally, the Company issued 58,910 and 76,306 warrants, respectively, to the placement agents which are also outstanding at December, 31, 2015, for a total number of 5,425,222 warrants outstanding pursuant to the aforesaid registered direct offerings.

The Company accounts for stock purchase warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreements. Under applicable accounting guidance, stock warrants must be accounted for as derivative financial instruments if the warrants contain full-ratchet anti-dilution provisions, which preclude the warrants from being considered indexed to its own stock. The warrants described above contained a full-ratchet anti-dilution feature and are thus classified as a derivative liability.

The Company used a lattice model to calculate the fair value of the derivative warrants based on a probability weighted discounted cash flow model. This model is based on future projections of the various potential outcomes. The features that were analyzed and incorporated into the model included the exercise and full reset features.

The Warrants were valued as of December 31, 2015 and June 30, 2015 with the following assumptions:

- The 5 year warrants issued on 9/12/13 and 1/24/14 included Investor and Placement Agent Warrants with an exercise price of \$5.25 and \$6.05 (subject to adjustments-full ratchet reset).

- The stock price would fluctuate with the Company projected volatility.

- The Holder would exercise the warrant as they become exercisable (effective registration at issuance) at target prices of the higher of **2 times** the projected exercise/reset price or **2 times** the stock price.

- The next capital raise would fluctuate with an annual volatility. The projected volatility curve was based on historical volatilities of the Company for the valuation periods. The projected annual volatility for the valuation dates are:



1 Year	
6/30/15	62%
12/31/15	68%

The primary factors driving the economic value of options are stock price; stock volatility; reset events and exercise behavior. Projections of these variables over the remaining term of the warrant are either derived or based on industry averages. Based on the above, a probability was assigned to each scenario for each future period, and the appropriate derivative value was determined for each scenario. The option value was then probability weighted and discounted to the present.

The following tables present the activity for liabilities measured at estimated fair value using unobservable inputs for the six months ended December 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, 2015	\$366,764	\$476,289	\$3,442,754
Additions during the year	-	-	-
Change in fair value	(267,295)	(235,807)	(899,412 )
Transfer in and/or out of Level 3	-	-	-
Balance at December 31, 2015	\$99,469	\$240,482	\$2,543,342

#### Note 11 - Commitments and Contingencies

##### Operating Lease

The Company completed the relocation of its laboratory and office from 135 Wood Street, West Haven, Connecticut to 1 Controls Drive, Shelton, Connecticut around June, 2015. The Company was renting 135 Wood Street on a month-to-month basis.

Total rent expense at 135 Wood Street, West Haven, Connecticut amounted to \$0 and \$26,085 for the three months ended December 31, 2015 and 2014, respectively and \$0 and \$52,170 for the six months ended December 31, 2015 and 2014, respectively.

### License Agreements

The Company is dependent upon its license agreement with TheraCour Pharma, Inc. (See Note 4). If the Company lost the right to utilize any of the proprietary information that is the subject of the TheraCour Pharma license agreement on which it depends, the Company will incur substantial delays and costs in development of its drug candidates.

### Legal Proceedings

There are no pending legal proceeding 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.

### **Note 12 – Subsequent Events**

On January 23, 2016, the Company's Board of Directors and a majority of the holders of the Company's Series A Convertible Preferred Shares (the "Series A Shares") approved an amendment to the Certificate of Designation of the Series A Shares to increase the number of authorized Series A Shares from 4,000,000 to 8,500,000.

## **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, 2015. 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**

This Report contains forward-looking statements within the meaning of the federal securities laws. 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 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," "Company believes," "management believes" and similar language. 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 of these 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. The forward-looking statements are based on the current expectations of NanoViricides, Inc. and are inherently 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.

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.

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 such, 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.

## **ITEM I: BUSINESS**

### **Organization and Nature of Business**

#### **Overview**

NanoViricides, Inc. is a leading company in the application of 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 cells. Antibodies in contrast attack a virus particle at only a maximum of two attachment points per antibody. In addition, the nanoviricide technology also simultaneously enables attacking the rapid intracellular reproduction of the virus by incorporating one or more active pharmaceutical ingredients (APIs) within the core of the nanoviricide. The nanoviricide technology is the only technology in the world, to the best of our knowledge, that is capable of both (a) attacking extracellular virus thereby breaking the reinfection cycle, and simultaneously (b) disrupting intracellular production of the virus, thereby enabling complete control of a virus infection.

Our anti-viral therapeutics, that we call “nanoviricides®” are designed to look to the virus like the native host cell surface to which it binds. Since these binding sites for a given virus do not change despite mutations and other changes in the virus, we believe that our drugs will be broad-spectrum, i.e. effective against most if not all strains, types, or subtypes, of a given virus, provided the virus-binding portion of the nanoviricide is engineered appropriately.

NanoViricides, Inc. is one of a few bio-pharma companies that have all the capabilities needed from research and development to marketable drug manufacture in the small quantities needed for human clinical trials. With the completion of and relocation to our new campus at 1 Controls Drive, Shelton, CT, we now possess state of the art nanomedicines characterization facilities that enable us to perform IND-enabling nanomedicine analysis and characterization studies of any of our various drug candidates in house. In addition, we now have the ability to scale up production of any of our drug candidates, and implement state of the art in-process controls as well as post-process analysis controls in order to establish robust c-GMP-capable production methodologies. All of the biological testing and characterization of our drug candidates continues to be performed by external academic or institutional collaborators and contract research organizations (CRO).

The Company develops its drugs, that we call a nanoviricide®, using a platform technology. This 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. We believe 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.

With the recent success of our anti-HSV drug development program, the Company has determined that it is in the best interest of its shareholders to re-prioritize our drug development programs and focus on topical drug development against several indications related to infections by herpes family viruses. The Company recognized, after consultations with its FDA regulatory advisors, namely Biologics Consulting (of Alexandria, VA), and several other experts in the field, that the development of these topical drug candidates towards human clinical trials is likely to be considerably faster than the development of our anti-influenza systemic (injectable) drug candidate.

The Company believes that it will be developing drugs against four different topical indications in the HerpeCide™ program, namely: (a) skin cream/lotion for the topical treatment of “cold sores” (typically caused by HSV-1); (b) eye drops/gel for the treatment of ocular herpes keratitis (mostly caused by HSV-1, sometimes by HSV-2 primarily in neonates); (c) skin cream/lotion for the treatment of “genital lesions” caused by herpesvirus (typically HSV-2); and (d) skin cream/lotion for the treatment of shingles (caused by HHV-3 also known as VZV i.e the chickenpox virus).

Animal model studies of lethal herpesvirus infection using the highly pathogenic and neurotropic HSV-1 H129 strain in two different sites resulted in 85% to 100% survival in animals treated with certain anti-HSV nanoviricide drug candidates, while control animals uniformly died. We reported on these studies as the results became available in April 2015, from Professor Emeritus Ken Rosenthal’s lab at NEOMED, and in August 2015, from TransPharm Preclinical Solutions, LLC, Jackson, MI, a CRO. Previously, we have improved the anti-HSV drug candidates in cell culture studies and were able to achieve significant effectiveness before engaging into animal studies.

We re-designed the anti-HSV drug candidates so that the solutions would not run off the skin when applied. With this redesign, our drug candidates demonstrated complete survival of HSV-1 H129 lethally infected animals.

The Company thus has achieved animal studies efficacy proof of concept for HSV-1 skin topical treatment. The Company believes that the broad-spectrum nature of these drug candidates should allow effectiveness against related herpesvirus types such as HSV-2 as well as the more distantly related HHV-3.

The Company is in the process of establishing additional collaborations towards IND-enabling development of drug candidates against the four indications listed earlier.

Of these, the Company has announced on February 1, 2016, that it has entered into an agreement with the University of Wisconsin for the evaluation of its nanoviricides® drug candidates in models of ocular herpes virus infections.

The studies will be performed in the laboratory of Dr. Curtis Brandt, an expert in herpes simplex virus infections and in evaluating anti-viral agents. The Company has previously reported the successes of its nanoviricides drug candidates in pre-clinical studies of dermal herpes virus infections in mouse models. The studies in Dr. Brandt's laboratory will be critical in optimizing its anti-herpes drug candidates against ocular herpes virus infections. The goal of these studies will be to identify a drug development candidate as a treatment for ocular keratitis in humans caused by herpes simplex virus infections.

Dr. Brandt is Professor in the Departments of Ophthalmology and Visual Sciences, Medical Microbiology and Immunology, and Director of the Vision Research Core at the University of Wisconsin. The studies will be conducted by Collaborative Ophthalmic Research Laboratories, CORL, at the University.

The Company intends to test several drug candidates with different formulation consistencies in multiple animal studies in order to select a clinical development candidate for ocular herpes keratitis. Following identification of the clinical development candidate, the Company will engage into scaled up production of said drug candidate at our Scale-Up Lab in the new campus. The Scale-up Lab has been in operation since June 2015, and we have scaled most production operations to 200g scale.

The Company believes that a 200g batch production scale is sufficient for the quantities needed for further IND-enabling studies of the clinical drug candidate. These studies include formulation optimization studies, dose-response efficacy studies, efficacy studies with different viral strains, and preliminary safety/tox in small and medium size animals, followed by cGLP safety/tox in larger animals, and PK/PD studies (pharmacokinetics and

pharmacodynamics studies) in standard animal models.

The Company believes that all of these IND-enabling studies for each of the topical drug indications will be of a limited nature, and of short durations.

The Company is evaluating the possibility of performing Phase I and Phase II human clinical studies internationally. It is widely believed that Phase I studies can be performed in Australia more quickly than in the USA due to differences in regulatory procedures and guidelines.

Ocular infections with HSV-1 have been reported to be the leading cause of infectious blindness in the developed world, with recurrent episodes of viral reactivation leading to progressive scarring and opacity of the cornea. HSV epithelial keratitis afflicts the epithelium of the cornea. In some cases, the disease progresses to HSV stromal keratitis, which is a serious condition. HSV stromal keratitis involves the stroma, the layer of tissue in the cornea, which is deeper in the eye than the epithelium. Its pathology disease involves the HSV infection of stromal cells, and also involves the inflammatory response to this infection. It can lead to permanent scarring of the cornea resulting in diminished vision. More serious cases require corneal replacement surgery. About 75% of corneal replacements are known to fail in a 20 year time frame, due to graft versus host disease (i.e. rejection of the foreign implant by the body), requiring a new procedures, or resulting in blindness.



Ocular herpes keratitis incidence rates in the USA alone are reported to be in the range of 65,000 to 150,000 patients per year. Of these approximately 10,000 per year may be estimated as requiring corneal transplants. The incidence estimates vary widely based on source, and are also assumed to be underreported. A corneal transplant costs about \$15,000 to \$25,000 for the surgery, with additional costs for follow on drugs and treatments.

This scenario exists in spite of available drugs, namely the acyclovir class of drugs, trifluridine, and others, that are used for treatment of herpes keratitis. The failure of these drugs is primarily due to limited safety resulting in insufficient drug availability at the site of infection.

Thus, an effective drug with a good safety profile could have a dramatic impact on this disease. Merit-based compensation for the drug treatment would enable strong financial incentive and could result in potential revenues in the \$50 million to several hundreds of millions range, depending upon how good the drug is.

The Company believes that it has sufficient production capacity at its current site to supply the US requirement of the drug for treatment of (ocular) herpes keratitis upon drug licensure.

The Company believes that its anti-herpes drug candidate for the treatment of cold sores and for genital lesions should lead to effective control of the cold sores rapidly, and may also lead to a long lag time before a new recurrence episode occurs. This is because it is believed that recurrence rates increase by virtue of further infection of new nerve endings from the site of the herpesvirus outbreak which result in additional nerve cells harboring the virus. If this in situ infection is limited, which we believe is the primary mechanism of nanoviricide drugs, then it is expected that the number of HSV harboring reservoir cells should decrease, and recurrence rate should go down.

In the United States, approximately 1 million cases of shingles (i.e. zoster) occur annually. The risk of zoster increases with age, and with decreased immune system function. Zoster is characterized by pain and rash. Discrete cutaneous lesions occur in groups on the skin. The Company believes that this presentation enables topical therapy for control of the viral outbreak.

One in four patients develop zoster-related pain that lasts more than 30 days. If it persists more than 3 months, it is called post-herpetic neuralgia (PHN), and may persist for years. It is thought that zoster-associated pain and PHN is a result of chronic ganglionitis, i.e. continued low-grade production of the virus in the infected ganglia and related immune response. The Company believes that effective control of the virus production would minimize or eliminate PHN, a debilitating morbidity of zoster.

Zoster occurs mostly in the abdominal region. However, in 20% of cases, it occurs in the head area, with reactivation involving trigeminal distribution. These cases of zoster can lead to serious complications including hemorrhagic stroke (VZV vasculopathy), VZV encephalitis, ophthalmic complications, and may result in fatalities.

Currently available anti-herpes drugs have had limited impact on zoster. Thus, an effective drug with a good safety profile could have a dramatic impact on zoster as well as possibly PHN.

The Company believes that it will be able to expand its anti-herpes portfolio in the future to include many other herpesviruses such as cytomegalovirus (CMV), KSHV, and Epstein-Barr virus (EBV, cause of mononucleosis).

The Company thus continues to expand its portfolio of opportunities, while also making progress towards the clinical trials stage.

The Company continues to work on its anti-influenza drug candidates in parallel to its HerpeCide program. We are currently developing Injectable FluCide™ for hospitalized patients with severe influenza as our first, broad-spectrum anti-influenza drug candidate. We have demonstrated the very first effective orally available nanomedicine, namely oral FluCide™ for out-patients with influenza. The development of Oral FluCide is expected to follow behind Injectable FluCide.

Because of our limited resources, we have assigned lower development priorities to our other drug candidates in our pipeline such as 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)) and HIVCide™ (a potential “Functional Cure” for HIV/AIDS).

In addition, the Company has research programs to develop drugs against Rabies virus, Ebola and Marburg viruses, MERS Coronavirus (Middle-East Respiratory Syndrome), among others. 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, and in the range of \$100 Billion by some estimates.

Of these, our Injectable FluCide anti-influenza drug candidate for hospitalized patients and our anti-HSV-1 drug candidate for dermal herpes infections or “cold sores” are in advanced pre-clinical stage. Our remaining drug development programs are presently at pre-clinical stage. We continue to test several drug candidates under each program even though we may achieve extremely strong results with some of the candidates.

Both of our anti-influenza therapeutic candidates are designed to be “broad-spectrum”, i.e. they are expected to be effective against most if not all types of influenzas including the recently discovered novel strain of H7N9, Bird Flu H5N1, other Highly Pathogenic Influenzas (HPI/HPAI), Epidemic Influenzas such as the 2009 “swine flu” H1N1/A/2009, and Seasonal Influenzas including the recent H3N2 influenza. The Company has already demonstrated that our anti-influenza drugs have significantly superior activity when compared to oseltamivir (Tamiflu®) against two unrelated influenza A subtypes, namely, H1N1 and H3N2 in a highly lethal animal model.

Our position that an injectable drug against influenza is a viable option is now affirmed by the US FDA licensure of the very first injectable drug for influenza in December 2014, namely peramivir (Rapivab, by BioCryst). Interestingly, peramivir as an injection was approved even though it did not appear to provide significant additional benefits over other drugs in its class. Overall, patients who received 600 mg of peramivir had symptom relief 21 hours sooner, on average, than those who received the placebo, which is consistent with other drugs in the same class. Additionally, peramivir injection was found to be not effective for hospitalized patients with severe influenza.

Thus, an effective therapy for patients hospitalized with severe influenza continues to be an unmet need. In addition, a single injection treatment of non-hospitalized patients would be a viable drug if it provides superior benefits to existing therapies.

Both of our anti-influenza drug candidates can be used as prophylactics to protect at-risk personnel such as health-care workers and immediate family members and caretakers of a patient.

We are developing our anti-herpes drug candidates and the injectable FluCide for severely ill patients towards IND applications in parallel. We have engaged Biologics Consulting Group, a well-known group of regulatory consultants, to advise us on the regulatory pathways, and the studies required for the IND applications for the various indications.

In addition, the Company is developing broad-spectrum eye drops that are expected to be effective against a majority of the viral infections of the external eye. Most of these viral infections are from adenoviruses or from herpesviruses. The Company has shown excellent efficacy of its drug candidates against EKC (adenoviral epidemic kerato-conjunctivitis) in an animal model. In addition, the anti-HSV drug candidates have shown excellent efficacy in cell culture studies, as well as in a lethal skin infection animal model.

Topical treatment of herpesvirus infection is important because of the disfiguring nature of herpesvirus breakouts, the associated local pain, and the fact that the virus grows in these breakouts to expand its domain within the human host further. Topical treatment can deliver much higher local levels of drugs than a systemic treatment can, and thus can be more effective and safer at the same time. Systemic drug treatment results in side effects because of the high systemic drug concentrations that need to be achieved and the large drug quantities that must be administered. Since the virus remains mostly localized in the area of the rash and connected nerve apparatus, using high concentrations of drugs delivered in small quantities topically would allow maximizing the effectiveness while minimizing the side effects.

The Company is also developing an anti-HIV drug. The drug candidates in this HIVCide™ program were found to have effectiveness equal to that of a triple drug HAART cocktail therapy in the standard humanized SCID-hu Thy/Liv mouse model. Moreover, the nanoviricides were long acting. Viral load suppression continued to hold for more than four weeks after stopping HIVCide treatment. The Company believes that this strong effect and sustained effect together indicate that HIVCide can be developed as a single agent that would provide “Functional Cure” from HIV/AIDS. The Company believes that substantially all HIV virus can be cleared upon HIVCide treatment, except the integrated viral genome in latent cells. This would enable discontinuation of treatment until HIV reemerges from the latent reservoir, which may be several months without any drugs. Moreover, the Company believes that this therapy would also minimize the chances of HIV transmission. The Company is currently optimizing the anti-HIV drug candidates. These drug candidates are effective against both the R5 and X4 subtypes of HIV-1 in cell cultures. The Company believes that these drug candidates are “broad-spectrum”, i.e. they are expected to be effective against most strains and mutants of HIV, and therefore escape of mutants from our drugs is expected to be minimal.

Further, the Company is developing a broad-spectrum drug against Dengue viruses that is expected to be useful for the treatment of any of the four major serotypes of dengue viruses, including in severe cases of dengue (DSS) and dengue hemorrhagic fever (DHF). It is thought that DSS and DHF caused by prior antibodies against dengue that a patient’s body creates to fight a second unrelated dengue infection, and the second virus uses these antibodies effectively to hitch a ride into human cells, thereby causing a more severe infection than in naive patients. The Company has received an “Orphan Drug Designation” for our DengueCide™ drug from the USFDA as well as the European Medicines Agency (EMA). This orphan drug designation carries significant economic benefits for the Company.

In addition to these drugs in development, the Company also has research programs against Rabies virus, Ebola and Marburg viruses, the recently emerged Middle East Respiratory Syndrome coronavirus (MERS-CoV), and others. To date, the Company does not have any commercialized products. The Company continues to add to our existing portfolio of products through our internal discovery and clinical development programs and also seeks to do so through an in-licensing strategy.

We believe we have demonstrated that we can rapidly develop different types of formulations for different routes of administration, such as injectable, skin cream, lotion, gel, and even oral, because of the inherent strength of the nanoviricide platform tailorable technology. The technology also enables us to develop nasal sprays and bronchial aerosols. We plan to develop the appropriate formulations as necessary.

We have recently completed the development of a c-GMP capable facility in Shelton, Connecticut where we can manufacture multi-kilogram quantities of the c-GMP-like and c-GMP-compliant batches of drug substances as well as drug products (cGMP = “current Good Manufacturing Practices”). This multi-purpose facility can produce any of our nanoviricide drug candidates. Moreover, it can produce our drugs in any of the different formulations we have been working on including injectables, skin creams and lotions, eye drops and ocular gels, as well as oral syrups. This facility has the capability of production scales from several grams to a few kilograms per batch, depending upon the product. These quantities are more than sufficient for pre-IND studies, IND-enabling studies, and human clinical trials of all of the drug candidates we are currently focusing on towards IND.

With our new campus and c-GMP capable facility, we are now in a position to advance our drug candidates into clinical trials, produce the pre-clinical “tox package” batches, the clinical batches, as well as initial quantities of marketed drugs. This makes NanoViricides, Inc. one of very few drug developer companies that have the internal capability to support market entry. Until last year, we were limited to performing R&D to develop drug candidates capable of further clinical development, but did not have the capability to produce the drug candidates in a suitable manner and quantities required for the studies to advance them into an IND stage and human clinical trials.

In addition, our new facility is estimated to enable initial commercial manufacture of our drugs under cGMP guidelines, once licensed, in order to gain market entry. Any of our drugs once introduced to the market is estimated to generate revenues of several tens of millions of dollars. The market sizes of many of our drugs are in several billion dollars. Thus, we anticipate developing additional manufacturing capability for each of our drugs as they mature towards clinical products. We believe that we may be able to license the drugs to bigger pharmaceutical companies that can manufacture the drugs, or license the manufacture of the drugs to other commercial scale cGMP manufacturing facilities. The Company has kept its capital expenditures to a minimum in the past, and we intend to continue to do the same, in order to conserve our cash for drug development purposes, and in order to minimize additional capital requirements.

This versatile, customizable facility is designed to support the production of kilogram-scale quantities of any of our nanoviricides drugs. In addition, it is designed to support the production of the drug in any formulation such as injectable, oral, skin cream, eye drops, lotions, etc. The production scale is designed so that clinical batches for Phase I, Phase II, and Phase III can be made in this facility. The clean room suite contains areas suitable for the production of sterile injectable drug formulations, which require special considerations.

We have moved our existing equipment, and we have installed a substantial amount of additional equipment at the Shelton facility. We need to test and validate each piece of equipment. We will need to validate, test and verify that all the systems are functioning as needed for being able to make cGMP drug substance batches. Then we will need to run several batches, analyze the resulting products, and establish that our manufacturing processes are performing satisfactorily to produce the desired drug substance. A minimum of two reproducible batches are generally required to be made before submitting an Investigational New Drug application (IND) to the US FDA. In addition, we will also need to seek and obtain US FDA registration as a cGMP facility, after we successfully commission c- GMP-like production of at least one drug substance at this facility.

We expect the Company will be able to produce “cGMP-like” material in the new facility once the facility is validated, all of the protocols are finalized, standardized, and the standard protocols are documented in the manner needed for cGMP operation. A “cGMP-like” drug substance can be loosely defined as drug substance made using the same processes as c-GMP material but prior to undergoing the FDA registration process for the c-GMP facility. Such c-GMP-like product can be used for clinical batches for human clinical studies in most 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 contract manufacturers.

Our timelines depend upon several assumptions, many of which are outside the control of the Company, and thus are subject to delays.

### **Patents, Intellectual Property, and Licenses**

The nanomedicine technologies licensed from TheraCour Pharma, Inc. (“TheraCour”) 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.

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, West Nile Virus, 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 IP from being blocked from commercialization in lengthy and potentially fragmentary bankruptcy proceedings.



A fundamental Patent Cooperation Treaty (“PCT”) patent application, on which the nanoviricides® technology is based, has resulted in additional issued patents in Europe and Korea. As with issuances in other countries including the United States, 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 2027 to 2029 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.

### **Presentations and Conferences**

Our President, Dr. Anil Diwan, was recently invited to present a talk entitled “Critical Regulatory Issue in Nanomedicines Translation: Manufacture and Control - What, How, Why, When” in the session on “Enabling the Business Side of Translation of NanoMedicines”, moderated by Dr. Raj Bawa, on October 17, 2015, at the 5th Annual Meeting of the American Society for Nanomedicines, held in the Hilton Crystal City, Washington, DC..

Our CEO, Dr. Eugene Seymour presented an overview of the Company at the 2015 Rodman and Renshaw Conference held in New York City on September 9-10, 2015.

Our CEO, Dr. Eugene Seymour presented an overview of the Company at the 2016 Biotech ShowCase Conference held in San Francisco on January 13, 2016, subsequent to the reported period.

Our President, Anil R. Diwan, PhD, was invited to attend the prestigious JP Morgan Life Sciences Conference held in San Francisco, from January 11-14, 2016, subsequent to this report.

The Company also continues its efforts at connecting with additional investors and presenting in investor-oriented business conferences.

On January 23, 2016, the Company held its 2015 Annual Shareholders Meeting at the Sheraton Stamford, in Stamford, CT from 10am to 1:30pm, subsequent to the reporting period. Anil Diwan, PhD, Dr. Milton Boniuk and Professor Mukund Kulkarni were all re-elected as Class I Directors, each for a two-year term expiring at the 2017 annual meeting of stockholders and until each of their respective successors are duly elected and qualified or until each of their respective earlier resignation or removal. Also, the appointment of EisnerAmper LLP as the Company's independent registered public accounting firm for the fiscal year ending June 30, 2016, was ratified. After adjournment of the Business Meeting, Dr. Seymour, our CEO, and Dr. Diwan, our President gave presentations and engaged in discussions with investors.

Emphasis was placed on the Company's on-going transition from an R&D and "pre-clinical proof of concept" stage company to a true clinical-stage pharmaceutical company that could market its drugs on its own, thus maximizing potential value.

## **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 for the year ended June 30, 2015. Readers should carefully review the risk factors disclosed in our Form 10-K for the year ended June 30, 2015 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.

**Management Discussion - Accomplishments in Reported Quarter, Our Drug Development Programs and Current Drug Development Strategy**

During the reported quarter we have continued to focus our drug development work plans primarily on our lead Influenza drug candidate, and our anti-Herpes-virus programs.

We now have two advanced pre-clinical drug candidates, namely, our injectable FluCide for severely ill patients, and our HerpeCide skin treatment for oral herpes cold sores. In addition, our HerpeCide program is poised to produce additional advanced candidates against ocular herpes and shingles. Our animal efficacy studies are performed by third parties. We opt into drug developments against specific disease indications for which we have appropriate partners that can perform the necessary cell culture and animal efficacy studies.

We are developing the anti-herpes drug candidates and the injectable FluCide for severely ill patients towards IND applications in parallel. We have engaged Biologics Consulting of Alexandria, VA, a well-known group of regulatory consultants, to advise us on the regulatory pathways, and the studies required for the IND applications for the various indications.

NanoViricides technology is now maturing rapidly toward the clinical studies, with the new facility, expanded staff, and the financial strength that we have attained since uplisting to NYSE-MKT.

To this end, we have completed moving our operations to our new 18,000+ sqft campus at 1 Controls Drive, Shelton, CT, in a phased manner to minimize impact on current activities. In addition, we are working on scale-up of the nanomicelle polymer backbone to approximately 500g scale, and on establishing in-process control systems, as well as on developing post-process characterization assays for the same with the new instrumentation and analysis equipment we have acquired as we established our new facilities.

Our new campus comprises a state of the art pharmaceutical R&D synthesis laboratory, a chemistry translational scale-up laboratory, quality control and quality assurance laboratories, and a pilot-scale cGMP-capable pharmaceutical clinical drug manufacturing facility (“the cGMP Facility”).

The cGMP Facility in our new campus is capable of multi-kilograms of production per batch. Further, it is capable of producing the most stringent injectable materials from novel chemical synthesis, novel polymer production, to complete pharmaceutical drug substance and drug product manufacture. This highly customizable facility is capable of producing any of our nanoviricides nanomedicines, and in all of the formulations that we currently need, namely, injectable, oral, skin cream, lotion, eye drops, gels, etc.

We plan on using this facility to produce the drugs needed for our tox package studies and for our human clinical trials, as and when needed. In addition, we believe that this cGMP capability will allow rapid market introduction of our drug(s) once licensed. We estimate that the resulting sales could be in the range of several tens of millions of dollars to several hundreds of millions of dollars, depending upon the drug pricing and quantity of sales.

Having an in-house cGMP Facility for drug manufacture sets us apart and puts us in the company of a limited number of drug developers. This capability enables the possibility that NanoViricides could become a stand-alone pharma company, without any dependence on external big pharma collaborations or licensing/marketing arrangements for revenue generation.

It is well known in the pharma industry that investor value is maximized if a drug developer can become an independent pharma company with integrated manufacturing and marketing capabilities.

We believe that a 200g production scale would be sufficient for the tox package studies as well as initial clinical production for our anti-herpes virus drug candidates. After the 200 and 500g scale-up is completed, we will continue to scale the production to larger reactors, to approximately 1kg~2kg batch sizes. This larger scale has been estimated to be needed for production of our Injectable FluCide™ drug candidate for the tox-package safety studies as well as efficacy studies that are part of the pre-IND development of this drug candidate.

During the reported quarter we have continued to perform further optimization of our anti-HSV drug candidates. In April 2015, we reported dramatic improvement in clinical symptoms associated with a herpes simplex virus dermal infection in mice. The topical nanoviricide treatment significantly reduced the clinical disease, and led to >85% survival of the mice dermally infected with a highly aggressive, neurotropic, HSV-1 H129c strain, wherein all of the untreated mice had severe clinical morbidity and none of the untreated mice survived. Later in August 2015, we reported that these results were reproduced at a different laboratory, with 100% survival being observed. The repeat studies were conducted by Transpharm Preclinical Solutions, a pre-clinical services CRO in Jackson, MI.

We believe that these successes have positioned us to develop drugs against multiple herpesvirus indications. The potential broad-spectrum nature of our anti-HSV drug candidates is expected to enable several antiviral indications. Thus, HSV-1 primarily affects skin and mucous membranes causing “cold sores”. HSV-2 primarily affects skin and mucous membranes leading to genital herpes. HSV-1 infection of the eye causes herpes keratitis that can lead to blindness in some cases. In addition, human herpesvirus-3 (HHV-3), a.k.a. varicella-zoster virus (VZV), causes chickenpox in children and when reactivated in adults, causes shingles. Shingles breakouts are amenable to topical treatment, as are the HSV cold sores, genital lesions, and herpes keratitis of the eye. Most of these indications do not have satisfactory treatments at present, if any.

Topical treatment of herpesvirus infection is important because herpesviruses become latent in neuronal cells or in ganglia, and cause periodic localized breakouts that appear as skin rashes and lesions. Systemic drug treatment results in side effects because of the high systemic drug concentrations that need to be achieved and the large drug quantities that must be administered. Since the virus remains mostly localized in the area of the rash and connected nerve apparatus, using high concentrations of drugs delivered in small quantities topically would allow maximizing the effectiveness while minimizing the side effects.

We are now performing the studies necessary for selection of IND candidates for several indications related to herpes viruses under our HerpeCide™ program. These indications include ocular herpes keratitis, oral herpes (“cold sores”), genital herpes, and shingles. After initial achievement of efficacy in the HSV-1 dermal model, we are now working on establishing the best anti-HSV ligand for our anti-HSV drug candidate in this model. New ligands, based on a SAR (“structure-activity-relationship”) modeled after the successfully tested ones were developed using knowledge-based approaches including molecular modeling and bioinformatics studies in our laboratory. These novel ligands are entering final stages of synthesis and characterization as of this writing. Such SAR studies are undertaken after initial success and may often result in large improvements in efficacy and safety. In addition, we will test certain nanomicelle compositions to determine which composition is best suited for the dermal delivery. The nanomedicine technology enables tailor-made nanomicelle polymer compositions so that transport across skin layers and delivery to the site of action can be accomplished properly. Once these studies are successfully completed, we expect that we will be able to announce a broad-spectrum drug development candidate for the dermal HSV-1 infection, namely, “cold sores”.

We plan to replicate similar studies of our antiviral candidates in models for ocular HSV-1 infection, shingles, and genital HSV-2 infection. We are currently in the process of identifying collaborators with capabilities in these areas, and establishing appropriate collaborations, agreements, and contracts. We have recently signed an agreement with the Collaborative Ophthalmic Research Laboratories, CORL, at the University of Wisconsin, Madison, to perform studies intended to identify a drug development candidate as a treatment for ocular keratitis in humans caused by herpes simplex virus infections. The studies will be performed in the laboratory of Dr. Curtis Brandt, an expert in herpes simplex virus infections and in evaluating anti-viral agents.

We believe that our anti-herpes drug development program is thus maturing towards a franchise of drug candidates, such as eye drops and gel formulations for ocular herpes keratitis, skin creams for oral herpes “cold sores”, for genital herpes lesions, and for shingles (which is caused by the herpesvirus called Varicella-Zoster virus that also causes chickenpox in children).

The current market size for drugs for the treatment of herpes infections is about \$2~4 billion. We believe that when an effective topical treatment is introduced, the market size is likely to expand substantially.

We are also working on further developments in our FluCide™ anti-Influenza drug development project, and in particular, on our broad-spectrum anti-influenza drug for hospitalized, severely ill patients, Injectable FluCide™.

In addition, NanoViricides, Inc. is possibly the first company in the world in the entire field of nanomedicines to have developed a nanomedicine drug that is effective when taken orally (by mouth). Our oral anti-influenza drug candidate, NV-INF-2, has shown extremely high broad-spectrum effectiveness against two different influenza A viruses in animal models, in our FluCide™ program. We believe that the Oral FluCide drug development will follow the Injectable FluCide for hospitalized patients as the latter enters human clinical trials. We believe we now have the ability to manufacture sufficient drug material for initial market entry of our Injectable FluCide drug candidate when licensed by the FDA or another regulatory agency. However, an oral drug against influenza is expected to require very large manufacturing facility in order to address the large worldwide out-patient influenza market, comprising billions of cases every year. We intend to out-license the oral FluCide drug candidate when appropriate.



We have performed preliminary safety and toxicology studies on certain drug candidates in the FluCide program. In all of the studies conducted, the drug candidates were found to be extremely safe. Both mouse and rat models have been employed for these studies. Some of the earlier studies were performed at KARD Scientific, MA. Recent studies have been performed at BASi, Inc., a well regarded pre-clinical CRO for tox package studies. As a result of the strong safety, we have estimated a batch size requirement of about 2kg ~ 2.5kg of Injectable FluCide that will be needed to complete the full set of tox studies as well as efficacy studies in different influenza virus strains in cell cultures as well as in animal models. We have engaged in the scale up of production as described elsewhere.

We are continuing the CMC (Chemistry, Manufacture and Control) related work and scale-up as described earlier. This drug development phase is intensive in terms of workload for any drug candidate. In our case, and in general for nanomedicines, the workload in this phase is much more intensive than for small chemical drugs. This is because we have to perform this work for the small chemical anti-viral ligand, the nanomicelle, and for their chemical conjugate, which is our final nanoviricide drug candidate. FluCide drug candidate was our first drug candidate for which this work was undertaken. This work was delayed because of the significant delays in making our new facilities operational that were outside our control. Our new campus became operational around June 2015, and the scale-up and CMC program for Injectable FluCide has gained momentum since then. The knowledge and expertise gained in this project is helping with our anti-herpes drug candidate CMC development. Thus we anticipate the CMC program for our anti-herpes drug candidate to be significantly less time consuming.

We believe that because of the smaller quantity requirements and the less rigorous tox package studies needed for the dermal topical treatment, our anti-herpes drug candidates are likely to move more rapidly towards clinical stage, while we continue to work on our anti-influenza drug candidate.

We believe that we will perform development of the EKC adenovirus drug in the context of the ocular nanoviricide drug against herpes keratitis, with the goal of developing a single broad-spectrum drug candidate that works against both adenovirus infections as well as herpesvirus infections of the external eye. Our other important drug programs, namely DengueCide™ (anti-Dengue viruses drug development), and HIVCide™ (anti-HIV/AIDS drug development), are at a lower priority at present. In addition, we are watching with interest the recent development of Gilead Sciences and USAMRIID regarding the nucleotide analog GS-5734 as an anti-Ebola drug. We had re-engaged our anti-Ebola drug development program only because of the major pandemic threat posed to global health in the 2014 epidemic, when no viable drug candidates were around, although several drug candidates were in different stages. We also continue to work on several other research programs that we believe will feed our pipeline in the future.

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 recent Ebola virus epidemic, and the MERS coronavirus outbreak.

We continue to work on acquiring and establishing new resources including equipment and instrumentation at our new campus in Shelton CT. NanoViricides as well as our affiliates have added significant strength in our staffing, reaching a total staff strength of about 30 personnel, most of whom are scientists. Our new campus in Shelton has enabled this substantial expansion of our capabilities. This expansion is necessary to accomplish the substantial amount of scientific investigations, process engineering, quality engineering, large scale production and document preparation that goes towards filing investigational new drug applications (IND's) to the US Food and Drug Administration ("FDA"), and equivalent applications to regulatory agencies across the globe. This expansion has also enabled us to strengthen our novel platform technologies, and engage into further novel, application- oriented R&D work directed to the goal of eradication of viral diseases.

It is believed that the development of the topical anti-herpes drug candidates may be significantly faster and easier than the development of the injectable FluCide that we are currently working on. Therefore, we have planned on continuing the development of the HerpeCide drug candidates as well as the FluCide drug candidate towards clinical trials in parallel. With the expanded R&D labs, Analytical Labs, the new Bio labs, the new Process Scale-Up production facility, and the new cGMP-capable manufacturing facility established at our new Shelton campus, we are in a much stronger position than ever to move our drug development programs into the clinic rapidly.

The potential broad-spectrum nature of our anti-HSV drug candidates is expected to enable several antiviral indications. Thus, HSV-1 primarily affects skin and mucous membranes causing “cold sores”. HSV-2 primarily affects skin and mucous membranes leading to genital herpes. HSV-1 infection of the eye causes herpes keratitis that can lead to blindness in some cases. In addition, human herpesvirus-3 (HHV-3), a.k.a. varicella-zoster virus (VZV), causes chickenpox in children and when reactivated in adults, causes shingles. Shingles breakouts are amenable to topical treatment, as are the HSV cold sores, genital lesions, and herpes keratitis of the eye. Most of these indications do not have satisfactory treatments at present, if any. Further, the treatment of herpesvirus infections caused by acyclovir- and famciclovir- resistant mutants is currently an unmet medical need.

The childhood chickenpox vaccine has reduced the cases of chickenpox, but this is a live attenuated virus vaccine that persists in the body. All adults who have had chickenpox in childhood continue to harbor the chickenpox virus, and are expected to develop shingles at some time, with the risk of shingles increasing with age or weakening of the immune system surveillance. In addition to the shingles breakout itself, post-herpetic neuralgia (pain) (PHN) is a significant morbidity of shingles, and to a lesser extent, of oral and genital herpes. PHN is initially caused probably by the inflammation and immune response related to the local virus expansion, but persists well after the virus has subsided, the blisters have scabbed off, and the skin has recovered, due to the nerve damage that results from the local large viral load during infection. Current PHN treatments are symptomatic, affecting the pain signaling circuit (such as novocaine, pramoxine, capsaicin, etc.), and do not produce lasting control. An effective therapy that results in strong local control of the virus production during the breakout itself is expected to minimize the resulting immune responses and nerve damage, and thereby minimize or possibly eliminate PHN.

The Company thus believes that it can develop its broad-spectrum anti-herpes drug candidate towards at least four topical indications, namely, (a) oral herpes (“cold sores”), (b) genital herpes, (c) ocular herpes keratitis, and (d) shingles.

These nanoviricides are designed as topical treatment for the breakout of herpes sores. Our animal studies results are very significant considering that topical acyclovir in the form of a cream as well as an ointment, are approved for the treatment of cold sores. We believe our strong anti-herpes nanoviricide® drug candidates are capable of reaching approval as a drug for topical use against herpes cold sores, based on these datasets. Further drug development is necessary towards the goal of drug approval.

Existing therapies against HSV include acyclovir and drugs chemically related to it. These drugs must be taken orally or by injection. Available topical treatments, including formulations containing acyclovir or chemically related anti-HSV drugs, are not very effective. Currently, there is no cure for herpes infection.

The market size for existing herpes simplex virus treatments is in excess of \$2 billion annually. The Company believes that a drug that is superior to existing therapies would result in significantly expanded market size.

The Company has engaged with Transpharm Preclinical Solutions to perform the topical animal studies as well as cell culture studies for the herpesvirus topical treatments. Transpharm is a pre-clinical contract research services organization (CRO) that offers numerous types of studies for testing antimicrobials, antivirals, antifungals, antiparasitics, along with newer therapies using antibodies. TransPharm's scientists' skill set covers a broad range of Research and Development, enabling numerous services at the request of a client. TransPharm will perform the topical dermal efficacy studies for our anti-HSV drug candidates. In addition, we are also seeking CROs and other Institutes of merit where we can perform anti-HSV efficacy studies for other indications including ocular herpes keratitis, shingles, and genital herpes infections in small animal models, to broaden our anti-HSV franchise.

The Company met with its FDA advisory consulting group, namely, Biologics Consulting, of Alexandria, VA, to chart out the path towards approval of anti-HSV topical treatments. The Company believes, based on these meetings, that the drug approval process for a topical treatment would be significantly faster and less expensive compared to an injectable drug development. Therefore the Company has now put HerpeCide development at high priority. The Company intends to work on HerpeCide topical treatments in parallel to its FluCide injectable drug development.

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.

As part of the advanced IND-enabling development of our Injectable FluCide™ drug candidate, we performed initial safety-toxicology screening of an optimized FluCide™ drug candidate in a GLP-like toxicology study in rats. We reported that a good safety profile was observed for this drug candidate in rats, around the end of January 2015. 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.

No direct adverse clinical effects were found upon administration of this 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.

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 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.

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.

We have been actively studying different chemical processes and routes of synthesis of the backbone polymer, the ligand, and the nanoviricide drug itself, which is a chemical conjugate of the two. The objective of these studies 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 next phase of the toxicology package studies for our injectable influenza drug candidate will involve larger animals, and will require much larger quantities of the anti-influenza drug candidate. In order to accomplish this, we have continued to scale up our production processes for both the backbone polymer and the ligands at our new Shelton facility. 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. We have continued to work successfully towards large-scale production of this anti-Influenza drug candidate. The Scale-Up Laboratory in our new Shelton campus now has the necessary equipment for this scale up. Initial process engineering and in-process control schemes have been designed, and in-process control equipment required for this has been identified. Appropriate equipment has been ordered to test the suitability of the control procedures we have designed. Some of this equipment is being tested in practice now. Initial batches for each synthesis step are being committed.

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.

In the case of HIVCide™ we are close to completing the ligand optimization and are also in the process of further optimizing the polymer backbone. We have already identified certain polymeric backbone chemistries that appear to provide extended viral load suppression for as long as 30 days or more even after stopping the drug, in animal studies. Given the chronic nature of HIV/AIDS, such a drug that has long sustained effect is expected to provide significant benefits to the patient. We believe once a week dosing is possible. Anti-HIV drug development is both expensive and slow because of the nature of the animal studies that require SCID mice whose immune system is destroyed and then replaced by surgically implanting and growing human immune system tissues in the mouse body. Due to our limited resources, HIVCide development is further hampered. Nevertheless we have continued to make progress in the HIVCide program. We are also working on developing a total cure of HIV/AIDS. In addition to minimizing the viral load to achieve a "Functional Cure" with the HIVCide, a total cure would require development of a drug that hones in onto infected cells, and seeks to destroy only the HIV infected cells that harbor the HIV genome inside it. We believe we have excellent technologies for such site-directed, specific approaches. This program is in R&D stage and we expect that it will take some time before a drug candidate with the potential of totally curing HIV/AIDS can be identified.

Our anti-HIV program is conducted at a lower priority level because the Company lacks the resources needed to commit to the development of an anti-HIV drug. We will continue to advance this program albeit at a relatively slow pace in order to enable us to seek appropriate partnerships and/or non-dilutive funding.

Previously we have reported on certain anti-HIV studies in animals 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+, as well as double-positive 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.

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.

Our drug candidates against dengue viruses have previously achieved significant survival of mice in a lethal infection animal model of dengue disease. This model simulates antibody-dependent enhancement of dengue, which is believed to lead in humans to severe dengue, and dengue hemorrhagic fever. These studies were performed by Professor Eva Harris at the University of Berkeley.



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

In addition, we have now developed a state of the art, multi-purpose, customizable cGMP-capable manufacturing facility that can produce any of our drug candidates in sufficient quantities so that any of our drug candidates can now move into IND-enabling studies and production is no longer a constraint to our progress. Until now, we were hampered in our progress towards an IND due to the lack of ability to manufacture our drugs in large enough quantities and in a suitable cGMP-capable environment. We are now one of the very few small pharmaceutical drug innovators that possess their own cGMP or cGMP-capable manufacturing facility.

### **Intellectual Property and Patents**

We have previously announced certain important issuances of patents on the TheraCour® technology underlying our nanoviricides® drugs. A fundamental patent on the polymeric micelles composition, structure and uses was issued in the USA with substantially broad claims. This validates the novelty of our approach as well as our leadership position in the nanomedicines based on polymeric micelle technologies. This patent application has so far been issued, granted, and/or validated, with substantially similar broad claims as 52 different patents in different countries and multi-country intellectual property organizations. The Company announced in May 2012 that a fundamental patent, on which the nanoviricides® technology is based, is due to be issued in the USA on May 8, 2012. The US Patent (No. 8,173,764) is granted for “Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers.” It was issued on May 8, 2012. The 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. NanoViricides, Inc. holds exclusive, perpetual, worldwide licenses to these technologies for a broad range of antiviral applications and diseases. The other national and regional counterparts of the international Patent Cooperation Treaty (“PCT”) application number PCT/US06/01820, which was filed in 2006, have issued as a Singapore National Patent Publication, a South African patent, and also as an ARIPO regional patent, an OAPI regional patent (covering Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo). It has also issued as a granted patent in New Zealand, China, Mexico, Japan, Australia, Canada, several countries in Europe, Hong Kong, Indonesia, Israel, Korea, Malaysia, Philippines, Pakistan, and Vietnam among others. Estimated expiry dates range nominally from 2026 to 2027 prior to accounting for various extensions available in different regions and countries. Additional issuances are continuing in Europe, and in several other countries around the world.

Another fundamental patent application on the antivirals developed using the polymeric micelles has so far been issued, granted, and/or validated, with substantially broad claims as well, as 9 different patents. The counterparts of the international PCT application PCT/US2007/001607 have issued as a granted patent in ARIPO, Australia, China, Japan, Mexico, New Zealand, OAPI, South Africa, and Korea 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. Further patent prosecution in several other regions and countries is continuing.

A total of 61 patents have been issued globally as of August 23, 2015, on the basis of the two international PCT patent families that cover the fundamental aspects of our platform technology. Additional patent grants are expected to continue as the applications progress through prosecution processes. All of the resulting patents have substantially broad claims.

These patents have nominal expiry dates in 2026 to 2027. The dates can be further extended in several countries and regions for the additional allowances due to the regulatory burden of drug development process, or other local considerations, such as licensing to a local majority held company. Many countries allow up to five years extension for regulatory delays.

No patent applications have been filed for the actual drug candidates that we intend to develop as drugs as of now. We intend to file the patent application for FluCide and HerpeCide before entering human clinical trials. The estimated expiry date for the FluCide and HerpeCide patents, if and when issued, would be no earlier than 2035-2036.

With the achievement of extremely high levels of effectiveness in appropriate animal models for its current drug candidates listed above, the Company has progressed to advance its drugs into the IND-enabling studies needed to go into the clinical stage. Our drug development strategy now is to focus on the IND-enabling studies for at least one, possibly two, indications in the HerpeCide topical treatment program, and our injectable FluCide drug candidate for severely ill patients hospitalized with influenza (IND = Investigational New Drug application). In addition, the other programs will continue to progress at different priorities.

In March 2012, we held a pre-IND meeting with the United States Food & Drug Administration (“FDA”) for our anti-influenza drug candidate, NV-INF-1. We obtained valuable advice from the US FDA regarding the requirements for filing an Investigational New Drug (“IND”) for this anti-influenza drug candidate. The feedback from the FDA at this pre-IND meeting was very useful for our other anti-viral drug development programs as well.

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. In addition, we have engaged with TransPharm preclinical services for herpesvirus animal models. We have engaged Biologics Consulting Group, Inc., to help us with the 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.

The drugs are required to be manufactured in cGMP-compliant manner (cGMP = “current Good Manufacturing Practices”) for use in human clinical trials. We have now developed a facility where the drugs can be manufactured in such a fashion. In addition, the process of making the materials has to be optimized and appropriate analytical and quality control methods must be developed. This is a part of CMC (“Chemistry, Manufacture and Controls”) activities required before filing an Investigational New Drug application (IND) to allow human clinical studies. The Company is progressing steadily in satisfying the CMC requirements for its Injectable anti- Influenza drug candidates at present.

We are now optimizing the production processes at different scales of production. As part of this, we are designing, evaluating, and implementing various in-process controls. We are developing and implementing several tools and methods for the characterization of the materials we produce as part of making the final drug substance. Much of the work performed for the optimization of the polymer backbone of the nanoviricide would be applicable to several of our drug candidates. After the processes and methods are finalized, we will need to document the production processes as well as the specific characterization methods into standardized procedures. We will then need to manufacture at least two batches under the standardized protocols, and establish that the product meets the acceptance criteria. If the batches are not reproducibly acceptable, then we will need to further optimize the processes to eliminate

the problems. Once the batches are acceptable, the resulting product would be considered “c-GMP-like” and we would be able to use it in human clinical trials.

NanoViricides, Inc. 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 for the Injectable FluCide drug candidate. In addition, much of what we have learned is applicable other nanomedicine drug candidates we are developing for different indications including the various herpesvirus infection indications such as oral herpes infections, genital herpes infections, herpes keratitis (eye infections), and shingles. Our recent results in the dermal HSV-1 infection model suggest that our dermal herpesvirus drug candidates are now at an advanced pre-clinical stage of development. We anticipate that this will enable us to advance our anti-herpesvirus indications franchise rapidly through pre-clinical studies towards IND filings and human clinical development further towards licensure.

### **Collaborations, Agreements and Contracts**

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.

We have recently signed an agreement with the Collaborative Ophthalmic Research Laboratories, CORL, at the University of Wisconsin, Madison, to perform studies intended to identify a drug development candidate as a treatment for ocular keratitis in humans caused by herpes simplex virus infections. The studies will be performed in the laboratory of Dr. Curtis Brandt, an expert in herpes simplex virus infections and in evaluating anti-viral agents.

We have signed a Master Services Agreement with TransPharm Preclinical Services, Jackson, MI. TransPharm is currently performing evaluation of our anti-HSV drug candidates in a dermal model of HSV-1 infection.

We have an agreement with the Professor Eva Harris lab at the University of California at Berkeley for evaluation and development of our Denguecide drug candidates.

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 have 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 or advanced 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's Drug Pipeline in Brief**

We currently have, in early, active development, (1) HerpeCide™ skin cream/lotion against Herpes virus cold sores, (2) HerpeCide eye drops for ocular herpes keratitis treatment, (3) HerpeCide skin cream/lotion for treatment of herpes zoster aka shingles, (4) HerpeCide skin cream/lotion for the treatment of genital Herpes, in the HerpCide program; (5) an Injectable FluCide™ for hospitalized patients with severe influenza; (6) 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, in the FluCide program; (7) HIVCide, a potential “Functional Cure that is active against both the R5 and X4 strains of HIV, (8) Eye drops against viral diseases of the eye such as Epidemic Kerato-Conjunctivitis (EKC) and Herpes Keratitis, and (9) DengueCide against Dengue viruses. Of these, the HerpeCide program and the FluCide program are our highest priority programs.

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. 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. We have observed excellent safety of our injectable anti-influenza drug candidates. This leads us to believe that the nanomicelle backbones of these drug candidates that were evaluated in preliminary safety studies should be safe in most if not all routes of administration.

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™ “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 outbreak. 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.

## **Analysis of Financial Condition, and Result of Operations**

As of December 31, 2015, we had cash and equivalents of \$28,237,621 current prepaid expenses of \$105,998, and property, plant and equipment of \$12,000,648, net of depreciation of \$1,527,213. Long-term liabilities were \$10,998,149 and stockholders' equity is \$28,384,257 at December 31, 2015.

As of June 30, 2015, we had \$31,467,748 in hand, and additional assets of \$214,425 in the form of prepaid expenses. Property, plant and equipment stood at \$11,962,648 net of accumulated depreciation of \$1,534,203. Long term liabilities were \$11,800,327 and stockholders' equity was \$31,785,867 at June 30, 2015.

During the reporting quarter we spent approximately \$1,213,000 in cash toward operating expenses and approximately \$29,000 toward capital expenditures. For the six month period we spent approximately \$2,867,000 toward operating expenses and \$363,000 toward capital expenditures.

We do not anticipate any major capital costs going forward in the near future.

Based on the current rate of expenditures (excluding capital costs), we believe that we have sufficient funds in hand to last at least through December 31, 2017, or two years. In addition, in order to conserve cash expenditures, we also pay compensation in stock and stock instruments to various parties.



Thus, the Company believes that our spending continues to be in line with our estimates. We have not engaged in any additional raises after the “old warrant” conversion that closed in September 2014. We believe that we will not need to raise additional capital in the near future.

We project, based on various estimates that we have obtained, that our current available financing is sufficient for accomplishing the goal of filing one or possibly two IND or equivalent regulatory applications, and initial human clinical trials in at least one of our drug programs. Two of our drug programs, namely Injectable FluCide, and HerpeCide skin cream, are now in the late pre-clinical or IND-enabling studies stage. We anticipate that these drug candidates will move forward into IND or equivalent regulatory filings, and ensuing human clinical trials. As these drug candidates are advancing into the clinic, we believe that our additional drug candidates will also move forward into IND-enabling studies. We are thus poised for strong growth with a number of drug candidates in a number of disease indications.

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.

#### 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 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 need to 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 December 31, 2015, we have current assets of approximately \$28,344,000. This amount is more than sufficient for our operations through almost two years or December 31, 2017, at the Company's current rate of expenditure, and including the projected expenditure for certain human clinical trials.

While we now have the necessary funds based on our current operations to last more than the next 24 months, we anticipate undertaking additional expenditures to accelerate our progress to regulatory submissions. With our current funds we believe that we have sufficient funding available to perform Toxicology Package studies, 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, which we plan to perform at our new campus in 1 Controls Drive, Shelton, CT, which became operational around June 2015.

We anticipate that we have sufficient funding to take at least one of our drug candidates through initial Phase I and Phase II human clinical trials. At present, 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 as our drug candidates mature into human clinical trials:

1. Research and Development of \$9,000,000: Planned costs for in-vivo and in-vitro studies for the various HerpeCide program drug candidates, pan-influenza FluCide,, Eye nanoviricide, HIVCide, Dengue, and other research programs including Rabies.
2. Corporate overhead of \$2,000,000: 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 \$500,000: This is the estimated cost for additional equipment and laboratory improvements.
4. Staffing costs of \$1,500,000: 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 any one of the HerpeCide indications, we anticipate approximately \$1 million in total costs for the Phase I clinical trials, and approximately \$2 million for the Phase IIa (human efficacy study) clinical trials.

6. 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 \$4 million for the Phase IIa (virus challenge human efficacy study) clinical trials.

We believe that we have sufficient funding available to accomplish the steps 1 through 6 listed above with our current available cash.

In addition, in a subsequent year, if our anti-herpesvirus Phase I and Phase IIa are successful, we anticipate approximately \$5 million for anti-herpesvirus Phase IIb (human efficacy study in a larger group of patients) human clinical trials. Further, in a subsequent year, if Phase I and Phase IIa of our Injectable FluCide drug candidate are successful, we anticipate approximately \$7~8 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 our drug candidates, Injectable FluCide, and Dermal HerpeCide, are highly effective and therefore are estimated to require relatively few patients in each arm of each trial in order to establish statistically significant results. Actual costs may be material different than those set forth above which could cause the Company to modify its expected operations.

We therefore believe that we currently have sufficient funds in hand to take at least one more drug candidate through the initial human clinical trials, and at least one more drug candidate into initial human clinical trials.

The Company anticipates it will have sufficient access to capital even if it decides to develop ocular HerpeCide, dermal HerpeCide, or Injectable FluCide through 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 human clinical 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.

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 December 31, 2017. 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 six months ended December 31, 2015 and 2014.

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

**Operating Expenses** - Research and development expenses for the three months ended December 31, 2015 increased \$235,762 to \$1,152,501 from \$916,739 and for the six months ended December 31, 2015 increased \$631,727 to \$2,359,573 from \$1,727,846 for the six months ended December 31, 2014. This increase in the cost of research and development is largely attributable to the increase in research and development payroll costs, lab supplies and materials.

General and administrative expenses for the three months ended December 31, 2015 increased \$150,636 to \$937,800 from \$787,164 for the three months ended December 31, 2014 and increased \$365,387 to \$1,955,779 from \$1,590,392 for the six months ended December 31, 2014. The increase for the three months resulted from an increase in staff and expenses for our new facilities. The increase for the six months resulted from non cash compensation costs paid in corporate stock offset by lower rent and other operating expenses in general.

**Other Income (Expenses)** – Net interest income (expense) decreased \$26,488 for the three months ended December 31, 2015 to (\$4,562) from (\$31,050) for the three months ended December 31, 2014. Net interest income (expense) decreased \$68,788 for the six months ended December 31, 2015 to \$4,261 from (\$64,525) for the six months ended December 31, 2014. Net interest income included interest on cash equivalent deposits in interest-bearing accounts at market rates. The decrease is due to volatility in market rates that reduced the valuations of our deposits.

**Interest Expenses** – Interest expense for the three months ended December 31, 2015 and 2014 was \$245,000 and \$247,444. Interest expense was \$490,000 for the six months ended December 31, 2015 and \$492,444 for the six months ended December 31, 2014.

**Other Expenses** – Discount on convertible debentures for the three months ended December 31, 2015 increased \$60,002 to \$349,962 from \$289,960 for the three months ended December 31, 2014. Discount on convertible debentures for the six months ended December 31, 2015 increased \$120,494 to \$683,670 from \$563,178 for the six months ended December 31, 2014. The increase reflects amortization of the discount on the Company's Series B and Series C Convertible Debentures.

**Other Income** – Change in fair value of derivatives for the three months ended December 31, 2015 decreased \$476,683 to (\$85,467) from \$391,216 for the three months ended December 31, 2014. Change in fair value of derivatives for the six months ended December 31, 2015 decreased \$2,006,426 to \$1,402,515 from \$3,408,941 for the six months ended December 31, 2014. Change in the fair value of derivatives is a non cash item estimated based upon certain actuarial assumptions. See Footnote 7 to the Financial Statements.

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

**Net Loss** - For the six months ended December 31, 2015, the Company had a net loss of (\$4,082,246), or (\$0.07) per share (as adjusted) on a fully diluted basis compared to a net loss of (\$1,029,444), or (\$0.05) per share (as adjusted) on a fully diluted basis for the six months ended December 31, 2014. The Company does not have any revenue and reports its operating and other expenses resulting in a net operating loss for the current period. The net loss in the current period has been reduced, in part, from the change in the fair value of derivatives.

### **Liquidity and Capital Reserves**

The Company had cash and cash equivalents of approximately \$28,238,000 as of December 31, 2015 and accounts payable and accrued liabilities of approximately \$1,466,000. Additionally, \$6 million of the Company's Series B Convertible Debentures mature in February, 2017.

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 approximately \$58,182,000 at December 31, 2015.

Our cash and cash equivalent balance is sufficient for us to continue our operations through December 31, 2017 at our current rate of expenditure.

### *Off Balance Sheet Arrangements*

We have not entered into any off-balance sheet arrangements during the six months ended December 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**

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

Under the supervision and with the participation of the external firms that perform the finance and accounting functions for our Company, together with our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”) we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”).



Based on the evaluation of our controls and procedures, our CEO and CFO have concluded that as of the end of the period covered by this report our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were not 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 due to the material weakness in internal control over financial reporting described below.

Management concluded that the effectiveness of our internal controls over financial reporting as of the date of this report were not effective because of a material weakness in the reporting process due to the insufficient complement of personnel with the appropriate level of knowledge to identify and account for non-routine transactions such as derivative instruments. The Company disclosed and reported this material weakness in conjunction with its restatement of its annual and interim financial statements for the fiscal year ended June 30, 2014, and for the interim financial statements for the period ended September 30, 2014.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Although management has implemented certain initiatives as of December 31, 2015, and we believe that such initiatives will fully remediate the identified weakness, these initiatives have not been in operation for a sufficient period of time, nor has the Company initiated a new financial transaction containing derivatives, for the Company to obtain evidence of its operating effectiveness. Therefore Management has concluded that as of December 31, 2015, the material weakness in internal control over financial reporting described above has not been fully remediated for the current fiscal year, although the Company has made significant progress towards this goal.

Management has taken several steps to correct the material weakness identified. We have made additions to personnel and have improved corresponding internal control procedures. In particular, in May 2015, the Company added an Accounting Manager, reporting to our Controller. This person comes to us with over 30 years of experience in senior financial roles such as controller, divisional controller, and chief accounting officer, in large companies with multi-site operations. He has garnered experience with analysis and recording for complex agreements that required specific evaluations including evaluation of ratcheting rights provisions. This person is currently in additional training regarding SEC filing requirements. In addition, where needed, the Company may seek assistance from third parties to supplement current resources. With these additions, plus the experience gained by the Company officials in the process of identifying and correcting the derivative effects of our prior financing agreements over the last year, the Company is confident that it has taken the necessary steps to remediate the identified material weakness. The Company has not, and in the near future, does not intend to, perform additional financings. Our improved internal controls procedures along with our improved expertise level as described above have significantly upgraded our internal control over financial reporting and are expected to fully remediate the material weakness described above.

#### **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 for the quarter ended December 31, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than as discussed above.

## **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 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.**

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Anil Diwan, the Company's president. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 of the Company's Series A preferred shares to Dr. Diwan. As of December 31, 2015 204,420 of these shares have been issued and 20,580 will be issued in a subsequent period. 75,000 shares will vest on June 30, 2016 and the remainder of the shares will vest over the three years of the employment agreement and are subject to forfeiture. The Company recognized a non cash compensation expense related to the issuance of the Series A Preferred Shares of \$154,672 for the six months ended December 31, 2015.

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Eugene Seymour, the Company's Chief Executive Officer. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 of the Company's Series A preferred shares to Dr. Seymour. As of December 31, 2015 204,420 of these shares have been issued and 20,580 will be issued in a subsequent period. 75,000 shares will vest on June 30, 2016 and the remainder of the shares will vest over the three years of the employment agreement and are subject to forfeiture. The Company recognized a non cash compensation expense related to the issuance of the Series A Preferred Shares of \$154,672 for the six months ended December 31, 2015.

For the six months ended December 31, 2015, the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 34,296 shares of common stock with an exercise price of \$1.50 per share expiring in August, 2019. These warrants were valued at \$16,976 and recorded as consulting expense.

For the six months ended December 31, 2015, the Company's Board of Directors authorized the issuance of 7,716 fully vested shares of its Series A Convertible Preferred stock for employee compensation. The Company recorded an expense of \$27,850.

For the six months ended December, 2015, the Company's Board of Directors authorized the issuance of 1,295 fully vested shares of its common stock for employee compensation. The Company recorded an expense of \$3,300.

For the six months ended December 31, 2015, the Company's Board of Directors authorized the issuance of 17,319 fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of \$22,499.

For the six months ended December 31, 2015, the Company's Board of Directors authorized the issuance of 43,144 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$54,000.

On December 31, 2015 two Holders of the Company's Series B Debentures elected to receive quarterly interest payable in restricted common stock of the company. For the three months ended December 31, 2015 the Company's Board of Directors authorized the issuance of 66,666 shares of the Company's restricted common stock for interest payable to the Holders. The Holders are entities controlled by Dr. Milton Boniuk, a director of the Company.

On December 31, 2015 the Holder of the Company's Series C Debentures elected to receive quarterly interest payable in restricted common stock of the company. For the three months ended December 31, 2015 the Company's Board of

Directors authorized the issuance of 138,889 shares of the Company's restricted common stock for interest payable to the Holder. The Holder is an entity controlled by Dr. Milton Boniuk, a director of the Company.

All of the securities set forth above were issued by the Company pursuant to Section 4(2) of the Securities Act of 1933, as amended, or the provisions of Rule 504 of Regulation D promulgated under the Securities Act. All such shares issued contained a restrictive legend and the Holders confirmed that they were acquiring the shares for investment and without intent to distribute the shares. All of the purchasers were friends or business associates of the Company's management and all were experienced in making speculative investments, understood the risks associated with investments, and could afford a loss of the entire investment. The Company did not utilize an underwriter or a placement agent for any of these offerings of its securities.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

**Exhibit No. Description**

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
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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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: February 9, 2016 Name: Eugene Seymour, M.D.  
Title: Chief Executive Officer and Director  
(Principal Executive Officer )

/s/ Meeta Vyas

Dated: February 9, 2016 Name: Meeta Vyas  
Title: Chief Financial Officer  
(Chief Financial Officer)