

NANOIRICIDES, INC.  
Form 10-Q  
November 14, 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 September 30, 2016**

*Commission File Number: 333-148471*

**NANOIRICIDES, INC.**

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

NEVADA  
(State or other jurisdiction)  
of incorporation or organization)

76-0674577

(IRS Employer Identification No.)

**1 Controls Drive**

**Shelton, Connecticut 06484**

(Address of principal executive offices and zip code)

(203) 937-6137

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

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

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

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

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

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

Yes  No

As of November 14, 2016, there were approximately 58,203,000 shares of common stock of the registrant issued and outstanding.

NanoViricides, Inc.

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NanoViricides, Inc.

## Balance Sheets

	September 30, 2016 (Unaudited)	June 30, 2016
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 21,912,927	\$ 24,162,185
Prepaid expenses	207,563	219,458
Total Current Assets	22,120,490	24,381,643
<b>PROPERTY AND EQUIPMENT</b>		
Property and equipment	13,636,018	13,611,583
Accumulated depreciation	(2,014,102)	(1,850,816)
Property and equipment, net	11,621,916	11,760,767
<b>TRADEMARK AND PATENTS</b>		
Trademark and patents	458,954	458,954
Accumulated amortization	(69,554)	(67,487)
Trademark and patents, net	389,400	391,467
<b>OTHER ASSETS</b>		
Security deposits	3,515	3,515
Service agreements	87,348	96,026
Total Other Assets	90,863	99,541
Total Assets	\$ 34,222,669	\$ 36,633,418
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 269,388	\$ 96,524
Accounts payable – related parties	658,439	767,454
Debentures payable - Series B, net of discount	5,688,609	5,474,737
Derivative liability - Series B debentures	120,123	203,030
Accrued expenses	35,649	35,602
Deferred interest payable - current portion	166,667	166,667
Total Current Liabilities	6,938,875	6,744,014
<b>LONG TERM LIABILITIES:</b>		
Debentures payable - Series C, net of discount	3,323,258	3,133,668
Derivative liability - Series C, debentures	325,267	343,673
Derivative liability - warrants	3,285,204	3,197,182
Deferred interest payable - long term portion	124,999	166,667
Total Long Term Liabilities	7,058,728	6,841,190

Total Liabilities	13,997,603	13,585,204
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, \$0.001 par value, 8,500,000 shares designated, 4,098,810 and 4,091,094 shares issued and outstanding, at September 30, 2016 and June 30, 2016, respectively	4,099	4,091
Common stock, \$0.001 par value; 150,000,000 shares authorized, 58,202,708 and 58,179,699 shares issued and outstanding at September 30, 2016 and June 30, 2016, respectively	58,202	58,179
Additional paid-in capital	88,048,410	87,810,145
Accumulated deficit	(67,885,645	) (64,824,201 )
Total Stockholders' Equity	20,225,066	23,048,214
Total Liabilities and Stockholders' Equity	\$ 34,222,669	\$ 36,633,418

*See accompanying notes to the financial statements*

Nanoviricides, Inc.

## Statements of Operations

(Unaudited)

	For the Three Months Ended September 30, 2016	For the Three Months Ended September 30, 2015
<b>OPERATING EXPENSES</b>		
Research and development	\$ 1,452,137	\$ 1,282,072
General and administrative	988,312	942,979
Total operating expenses	2,440,449	2,225,051
<b>LOSS FROM OPERATIONS</b>	(2,440,449 )	(2,225,051 )
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	14,176	8,825
Interest expense	(245,000 )	(245,000 )
Discount on convertible debentures	(403,462 )	(333,710 )
Change in fair value of derivatives	13,291	1,487,982
Other (Expense) income, net	(620,995 )	918,097
<b>LOSS BEFORE INCOME TAXES</b>	(3,061,444 )	(1,306,954 )
<b>INCOME TAX PROVISION</b>	-	-
<b>NET LOSS</b>	\$ (3,061,444 )	\$ (1,306,954 )
<b>NET LOSS PER COMMON SHARE</b>		
- Basic	\$ (0.05 )	\$ (0.02 )
- Diluted	\$ (0.05 )	\$ (0.02 )
<b>Weighted average common shares outstanding</b>		
- Basic	58,179,949	57,274,315
- Diluted	58,179,949	57,274,315

*See accompanying notes to the financial statements*





NanoViricides, Inc.

Statement of Changes in Stockholders' Equity

For the period from July 1, 2016 through September 30, 2016

**(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, 2016	4,091,094	\$ 4,091	58,179,699	\$58,179	\$87,810,145	\$(64,824,201)	\$ 23,048,214
Series A Preferred Shares issued for employee stock compensation	7,716	8	-	-	182,890	-	182,898
Common Shares issued for consulting and legal services rendered	-	-	16,232	16	26,984	-	27,000
Warrants issued to Scientific Advisory Board	-	-	-	-	17,148	-	17,148
Common Shares issued for Directors fees	-	-	6,777	7	11,243	-	11,250
Net loss	-	-	-	-	-	(3,061,444 )	(3,061,444 )
Balance, September 30, 2016	4,098,810	\$ 4,099	58,202,708	\$58,202	\$88,048,410	\$(67,885,645)	\$ 20,225,066

See accompanying notes to the financial statements

Nanoviricides, Inc.

## Statements of Cash Flows

(Unaudited)

	For the Three Months Ended September 30, 2016	For the Three Months Ended September 30, 2015
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(3,061,444 )	\$(1,306,954 )
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation and for services	182,898	182,522
Common shares issued as compensation and for services	38,250	41,550
Warrants granted to Scientific Advisory Board	17,148	8,745
Depreciation	163,286	161,606
Amortization	2,067	2,067
Change in fair value of derivative liability	(13,291 )	(1,487,982 )
Amortization of debt discount on convertible debentures	403,462	333,710
Changes in operating assets and liabilities:		
Prepaid expenses	11,895	50,932
Other assets	8,678	19,449
Accounts payable	172,864	(30,975 )
Accounts payable - related party	(109,015 )	422,091
Accrued expenses	47	(8,920 )
Deferred interest payable	(41,668 )	(41,667 )
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(2,224,823 )</b>	<b>(1,653,826 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(24,435 )	(333,664 )
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(2,249,258 )</b>	<b>(1,987,490 )</b>
Cash and cash equivalents at beginning of period	24,162,185	31,467,748
Cash and cash equivalents at end of period	\$21,912,927	\$29,480,258
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>		

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Interest paid	\$286,667	\$286,667
Income tax paid	\$-	\$-
NON CASH FINANCING AND INVESTING ACTIVITIES:		
Common Stock issued upon cashless exercise of stock options	\$-	\$313

*See accompanying notes to the financial statements*

**NANOIRICIDES, INC.**

**September 30, 2016 AND 2015**

**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 ECMM by NVI, under the purchase method of accounting, and was treated as a recapitalization with NVI as the acquirer. Accordingly, the financial statements have been prepared to give retroactive effect to May 12, 2005 (date of inception), of the reverse acquisition completed on June 1, 2005, and represent the operations of NVI.

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

NanoViricides, Inc. (the “Company”), is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. 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 Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus.

On February 15, 2010 the Company executed an Additional License Agreement with TheraCour. Pursuant to the Additional License Agreement, the Company was granted exclusive licenses, in perpetuity, for technologies, developed by TheraCour, for the development of drug candidates for the treatment of Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes. As consideration for obtaining these exclusive licenses, we agreed to pay a onetime licensing fee equal to 2,000,000 shares (adjusted for the 3.5 to 1 reverse split) of the Company’s Series A Convertible Preferred Stock (the “Series A Preferred Stock”). The Series A Preferred Stock is convertible, only upon sale or merger of the Company, or the sale of or license of substantially all of the Company’s intellectual property, into shares of the Company’s common stock at the rate of 3.5 shares of common stock for each share of Series A Preferred Stock. The Series A Preferred Stock has a preferred voting preference at the rate of nine votes per share. The 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, 2016 filed with the SEC on September 16, 2016.

For a summary of significant accounting policies, see the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2016 filed on September 16, 2016.

*Net Loss per Common Share*

Basic net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed by dividing net 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 loss per common share calculation as they were anti-dilutive:

Potentially Outstanding Dilutive Common Shares	
For the	For the
Three Months	Three Months

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	Ended September 30, 2016	Ended September 30, 2015
Warrants	6,633,848	5,993,823
Total potentially outstanding dilutive common shares	6,633,848	5,993,823

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In addition, the Company has issued Convertible Debentures to investors. Coupon interest payable quarterly related to the Series B debentures is payable in cash or shares of Common Stock at the average of the open and close value on the date such interest payment is due at the option of the Holder. The Holders have elected to receive coupon interest in cash for the three months ended September 30, 2016 and 2015. Two of these Holders of the Series B debentures are controlled by Dr. Milton Boniuk, a director of the Company.

At September 30, 2016, 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. 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) – (iv), 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 value on the date such interest payment is due at the option of the Holder. At September 30, 2016, the number of potential dilutive shares of the Company's common stock into which the Series C debentures can be converted based upon the conversion provisions contained in the debenture is 952,381.

The Company has also issued 4,098,810 shares Series A Preferred Stock to investors and others as of September 30, 2016. 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 convertible Preferred Stock is not convertible into common stock, and does not carry any dividend rights or any other financial effects. At September 30, 2016, the number of potentially dilutive shares of the Company's common stock into which these Series A Preferred shares can be converted into is 14,345,835, and is not included in diluted earnings per share since the shares are contingently convertible only upon a Change of Control.

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



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	For the three months ended	
	September 30, 2016	September 30, 2015
Calculation of basic loss per share of common stock:		
Net loss attributable to common stockholders	\$ (3,061,444 )	\$ (1,306,954 )
Denominator for basic weighted average shares of common stock	58,179,949	57,274,315
Basic loss per share of common stock	\$ (0.05 )	\$ (0.02 )
Calculation of diluted loss per share of common stock:		
Net loss attributable to common stockholders	\$ (3,061,444 )	\$ (1,306,954 )
Add: Income impact of assumed conversion of Debentures	-	-
Net loss attributable to common stockholders plus assumed conversions	\$ (3,061,444 )	\$ (1,306,954 )
Denominator for basic weighted average shares of common stock	58,179,949	57,274,315
Incremental shares from assumed conversions of Debentures payable	-	-
Denominator for diluted weighted average shares of common stock	58,179,949	57,274,315
Diluted loss per share of common stock	\$ (0.05 )	\$ (0.02 )

Series B and Series C debentures were excluded from the loss per share calculation for the three months ended September 30, 2016 and September 30, 2015 because the impact is anti-dilutive.

Recently Issued Accounting Pronouncements

In March 2016, the FASB issued ASU No. 2016-09, "Stock Compensation (topic 718)", which includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The standard is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The Company is currently in the process of assessing the impact of the ASU on its financial statements.

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 November 2014, the FASB issued ASU 2014-16, "Derivatives and Hedging (Topic 815)." ASU 2014-16 addresses whether the host contract in a hybrid financial instrument issued in the form of a share should be accounted for as debt or equity. ASU 2014-16 is effective for annual periods beginning after December 15, 2015 and interim periods within those fiscal years. ASU 2014-16 did not have a material impact 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. This guidance does not have a material impact on our financial statements.

**Note 3 - Financial Condition**

The Company's financial statements for the interim period ended September 30, 2016 have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business.

The Company has an accumulated deficit at September 30, 2016 of \$67,885,645. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. 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 September 30, 2016 the Company had cash and cash equivalents of \$21,912,927. The Company's Series B Convertible Debenture, in the amount of \$6 million, matures on February 1, 2017. The Holder(s), at their option, may convert some or all of the principal balance and accrued interest if any, into a number of restricted shares of common stock of the Company equal to the outstanding balance being converted divided by 3.5. Any principal balance not being converted will be paid in cash on February 1, 2017. The Company has sufficient capital to continue its business for more than one year, 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 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 stockholder, 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

For the Three  
Months Ended  
SeptemberSeptember  
30, 30,  
2016 2015

Property and Equipment

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, \$17,995 \$ 7,901 to the Company

As of

September 30, 2016  
 June 30, 2016

Account Payable – Related Party

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 \$2,000 or actual costs each month, 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

\$658,439 \$767,454

For the Three Months  
Ended  
September 30,  
2016      September  
30,  
2015

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 September 30, 2016 and June 30, 2016.

\$861,616    \$1,016,216

	As of September 30, 2016	June 30, 2016
<u>Debentures Payable to a Director</u>		
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 Debentures Payable to a Director	\$9,000,000	\$9,000,000

	As of September 30 2016	June 30, 2016
<u>Debenture Interest Payable to a Director</u>		

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:

Deferred interest payable - short-term	\$166,667	\$166,667
Deferred interest payable - long-term	124,999	166,667
Total Debenture Interest Payable to a Director	\$291,666	\$333,334

Coupon interest expense on the Series B Debentures to Dr. Milton Boniuk for the three months ended September 30, 2016 and 2015 was \$80,000 and \$80,000, respectively.

Coupon interest expense on the Series C Debentures to Dr. Milton Boniuk for the three months ended September 30, 2016 and 2015 was \$125,000 and \$125,000, respectively.

**Note 5 - Property and Equipment**

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

	September 30, 2016	June 30, 2016
GMP Facility	\$ 7,996,402	\$ 7,996,402
Land	260,000	260,000
Office Equipment	46,897	46,897
Furniture and Fixtures	5,607	5,607
Lab Equipment	5,327,112	5,302,677
Total Property and Equipment	13,636,018	13,611,583
Less Accumulated Depreciation	(2,014,102 )	(1,850,816 )
Property and Equipment, Net	\$ 11,621,916	\$ 11,760,767

Depreciation expense for the three months ended September 30, 2016 and 2015 were \$163,286 and \$161,606, respectively.

#### **Note 6 - Trademark and Patents**

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

	September 30, 2016	June 30, 2016
Trademarks and Patents	\$ 458,954	\$458,954
Less Accumulated Amortization	(69,554 )	(67,487 )
Trademarks and Patents, Net	\$ 389,400	\$391,467

Amortization expense amounted to \$2,067 and \$2,067 for the three months ended September 30, 2016 and 2015 respectively.

#### **Note 7 - Convertible Debentures and Derivatives**

##### **Series B**

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 each of the three month periods ended September 30, 2016 and 2015, the Company paid cash interest of \$120,000 to the Holders of the Company's Series B Convertible Debentures. Additional interest was payable in restricted common stock of 571,429 shares at issuance, and on February 1, 2014 and 2015 and additional interest payable in 571,433 warrants on February 1, 2016. The investors can convert the principal of the debentures 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 September 30 and June 30, 2016. The debt discount is being amortized to interest expense over the term of the debenture:

	September 30, 2016	June 30, 2016
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	2,423,919	2,210,047
Debenture payable - Series B, net	\$ 5,688,609	\$5,474,737

The Company recognized amortization of this discount as an additional interest charge to “Discount on convertible debentures” for the three months ended September 30, 2016 and 2015, in the amounts of \$213,872 and \$183,629, respectively.

The debenture contains embedded derivatives which are not clearly and closely related to the host instrument. The embedded derivatives were 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 uses a lattice model that values the compound embedded derivatives bifurcated from the Series B Convertible Debenture based on a probability weighted discounted cash flow model at September 30, 2016 and June 30, 2016.

The following assumptions were used for the valuation of the compound embedded derivative at September 30, 2016 and June 30, 2016:

·The balance of the Series B Convertible Debenture as of September 30, 2016 and June 30, 2016 is \$6,000,000;

The underlying stock price was used as the fair value of the common stock. The stock price increased to **\$1.69** at September 30, 2016. The warrant value with the \$3.50 exercise price decreased due to the shorter term remaining and the difference between the exercise price and the stock price. The stock price decreased to \$1.60 at June 30, 2016 which decreased the warrant value with the \$3.50 exercise price;

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

**1 year**

**9/30/2016 85%**

**6/30/2016 83%**

·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 **21.90%**.

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 B Convertible Debenture at September 30, 2016 and June 30, 2016 was \$120,123 and \$203,030, respectively.

### Series C

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 for a total of \$500,000 shall be deferred and paid over the remainder of the term at \$166,667 per year. 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 each of the three month periods ended September 30, 2016 and 2015, the Company paid cash interest of \$125,000 to the Holders of the Company's Series C Convertible Debentures. 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 \$189,590 and \$150,081 for the three months ended September 30, 2016 and 2015, respectively.

The following represents the balance of the Debenture payable – Series C, net of discount at September 30, 2016 and June 30, 2016:

	September 30, 2016	June 30, 2016
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	1,354,983	1,165,393
Debenture payable - Series C, net	\$ 3,323,258	\$3,133,668

The Company uses 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 September 30, 2016 and June 30, 2016.

The following assumptions were used for the valuation of the compound embedded derivative at September 30 and June 30, 2016:

· The balance of the Series C Convertible Debenture as of September 30, 2016 and June 30, 2016 is \$5,000,000;

The underlying stock price was used as the fair value of the common stock; The stock price increased to **\$1.69** at September 30, 2016 with higher projected annual volatility. The warrant value with the \$6.05 exercise price decreased due the decreasing term remaining. The stock price decreased to \$1.60 at June 30, 2016 which decreased the warrant value with the \$6.05 exercise price;

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

**1 year**

**9/30/16 85%**

**6/30/16 83%**

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

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

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

The weighted cost of capital discount rate (based on the market value of the transaction at issuance) adjusted for changes in the risk free rate is 21.90%.

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 September 30, 2016 and June 30, 2016 was \$325,267 and \$343,673, 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 Series A preferred shares to Dr. Diwan. 75,000 shares vested 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 noncash compensation expense related to the issuance of the Series A Preferred Shares for the three months ended September 30, 2016 and September 30, 2015 of \$74,317 and \$77,336, respectively. The remaining balance of \$490,094 will be recognized as the remaining shares are vested over the term of the contract.

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 Series A preferred shares to Dr. Seymour. 75,000 shares vested 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 noncash compensation expense related to the issuance of the Series A Preferred Shares for the three months ended September 30, 2016 and September 30, 2015 of \$74,317 and \$77,336, respectively. The remaining balance of \$490,094 will be recognized as the remaining shares are vested over the term of the contract.

For the three months ended September 30, 2016, 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 \$34,264.

The fair value of the Series A Preferred stock was the following for the dates indicated:

Date	Shares	Value
7/31/2016	2,572	\$11,439
8/31/2016	2,572	11,978
9/30/2016	2,572	10,847
	7,716	\$34,264

There is currently no market for the shares of Series A Preferred Stock and they can only be converted into shares of common stock upon a Change of Control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the 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 \$1.74 to \$1.54;

b. The calculated weighted average number of shares of common stock in the period;

c. A 53.26% 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 10.25% to 10.81% of the total;

e. The conversion value is based on an assumption for calculation purposes only of a Change of Control in 4 years from March 1, 2013 and a remaining restricted term of 0.58 to 0.42 years;

f. 21.81% to 21.76% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 83.24% to 86.07% volatility, 0.37% to 0.47% risk free rate) applied to the converted common.

In August, 2016, the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 17,148 shares of common stock with an exercise price of \$2.04 per share expiring in August, 2020. The fair value of the warrants was valued at \$17,148 and was recorded as consulting expense for the three months ended September 30, 2016.

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	87.09%
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	1.00 %

For the three months ended September 30, 2016, the Company's Board of Directors authorized the issuance of 16,232 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$27,000, which was the fair value on the date of issuance.

For the three months ended September 30, 2016, the Company's Board of Directors authorized the issuance of 6,777 fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of \$11,250, which was the fair value on the date of issuance.

**Note 9 - Stock Warrants**Stock Warrants

Stock Warrants	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding and exercisable at June 30, 2016	6,616,700	\$ 4.96	2.55	\$ 4,459
Granted	17,148	2.04	3.83	-
Outstanding and exercisable at September 30, 2016	6,633,848	\$ 4.95	2.05	\$ 7,888

Of the above warrants, 414,284 expire in fiscal year ending June 30, 2017; 68,577 expire in fiscal year ending June 30, 2018; 6,065,247 expire in fiscal year ending June 30, 2019; 68,592 expire in fiscal year ending June 30, 2020 and 17,148 expire in fiscal year ending June 30, 2021.

**Note 10 - Fair Value Measurement****Fair value measurements**

At September 30, 2016 and June 30, 2016, 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 September 30, 2016 and June 30, 2016 the estimated fair values of the liabilities measured on a recurring basis are as follows:

Fair Value Measurements at  
September 30, 2016:  
(Level 1) (Level 2) (Level 3)

Derivative liability – Series B debentures	\$ -	-	\$ 120,123
Derivative liability – Series C debentures	-	-	325,267
Derivative liability – warrants	-	-	3,285,204
Total derivatives	\$ -	\$ -	\$ 3,730,594

Fair Value Measurements at  
June 30, 2016:  
(Level 1) (Level 2) (Level 3)

Derivative liability – Series B debentures	\$ -	-	\$ 203,030
Derivative liability – Series C debentures	-	-	343,673
Derivative liability – warrants	-	-	3,197,182
Total derivatives	\$ -	\$ -	\$ 3,743,885

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, 2,810,071 and 2,479,935, respectively, are outstanding at September 30, 2016. Additionally, the Company issued 58,910 and 76,306 warrants, respectively, to the placement agents which are also outstanding at September 30, 2016, for a total number of 5,425,222 warrants outstanding and issued 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 September 30, 2016 and June 30, 2016 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	
9/30/16	85%
6/30/16	83%

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 three months ended September 30, 2016:

	Fair Value Measurement Using Significant Unobservable Inputs		
	Derivative liability – Series B	Derivative liability – Series C	Derivative liability – warrant
Beginning balance at July 1, 2016	\$ 203,030	\$ 343,673	\$ 3,197,182
Additions during the year	-	-	-
Change in fair value	(82,907 )	(18,406 )	88,022
Transfer in and/or out of Level 3	-	-	-
Balance at September 30, 2016	\$ 120,123	\$ 325,267	\$ 3,285,204

#### **Note 11 - Commitments and Contingencies**

##### 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.

##### Employment Agreements

The Company and Dr. Diwan, President and Chairman of the Board of Directors, entered into an employment agreement effective July 1, 2015 for a term of three years. Dr. Diwan's compensation would be \$350,000 for the first year of employment, \$375,000 for the second year and \$400,000 for the final year. Additionally, Dr. Diwan was awarded a grant of 225,000 shares of the Company's Series A Preferred Stock. 75,000 shares vested on June 30, 2016 and the remainder of the shares will vest equally over the three years of the term of the employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Diwan. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017

The Company and Dr. Seymour, the Company's Chief Executive Officer and Director, entered into an employment agreement effective July 1, 2015, for a term of three years. Dr. Seymour's compensation would be \$350,000 for the first year of employment, \$375,000 for the second year and \$400,000 for the final year. Additionally, Dr. Seymour was awarded a grant of 225,000 shares of the Company's Series A Preferred Stock. 75,000 shares vested on June 30, 2016 and the remainder of the shares will vest equally over the three years of the term of the employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Seymour. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017.

On March 3, 2010, the Company entered into an employment agreement with Dr. Jayant Tatake to serve as Vice President of Research and Development. The employment agreement provides for a term of four years with a base salary of \$150,000. In addition, the Company issued 26,786 shares of Series A Preferred Stock and 35,715 shares of common stock upon entering into the agreement, and issued an additional 26,786 shares of Series A Preferred Stock and 35,715 shares of common stock on each anniversary date of the agreement. The shares of Series A Preferred Stock were issued in recognition of Dr. Tatake's work towards the achievement of several patents by the Company. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements.

On March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provided for a term of four years with a base salary of \$150,000. In addition, the Company issued 35,715 shares of common stock upon entering into the agreement, and issued an additional 35,715 shares of common stock on each anniversary date of the agreement. Dr. Tatake receives 26,736 shares of the Company's Series A Preferred Stock annually. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements.



On May 30, 2013, the Company entered into an Employment Agreement with Meeta Vyas to serve as its Chief Financial Officer. The employment agreement provided for a term of three years with a base salary of \$9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. On January 1, 2015, her compensation was increased to \$10,800 per month. The Agreement is renewable on an annual basis. On May 31, 2016, the Agreement was renewed for one year.

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.

## **PART I**

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

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, 2016. 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.

#### **PRELIMINARY NOTE REGARDING 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.

***Background - The Nanoviricide® Platform Technology***

NanoViricides, Inc. is a globally 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 we believe enable us to perform pre-IND nanomedicine analysis and characterization studies of any of our various drug candidates in house. In addition, we believe 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. We also have a Biological Safety Level 2 (BSL2) certified virological cell culture lab at our new campus. We are able to perform initial cell culture based screening of large numbers of drug candidates for effectiveness and safety against certain of the viruses that we have targeted for drug development. This capability boosts our drug development capabilities significantly. Other than this limited initial screening, 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). In particular, all of the animal studies are performed by our collaborators and CROs.

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 this 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.

### ***Our Product Pipeline***

We currently have eight different drug development programs, attesting to the strength of our platform technology.

The potential broad-spectrum nature of our anti-HSV drug candidates is enabling several anti-Herpes indications. Of these, our (i) Topical Treatment for Shingles (VZV) is currently moving most rapidly towards clinical stage. We believe that the other anti-Herpes drug candidates, would follow this lead drug to the clinical stage, namely, (ii) skin

cream for the treatment of orolabial herpes (“cold sores”) and recurrent herpes labialis (RHL) mostly caused by HSV-1, (iii) ocular eye drops treatment for external eye herpes keratitis (HK), caused by HSV-1 or HSV-2, and (iv) skin cream for the treatment of genital herpes caused by HSV2. In addition, we continue to work on our other drug candidates at lower priority levels. These include (v) Injectable FluCide™ for hospitalized patients with severe influenza, (vi) Oral FluCide™ for out-patients, (vii) 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 (viii) HIVCide™ for HIV/AIDS. In addition, the Company has research programs to develop drugs against Rabies virus, Ebola and Marburg viruses, and other viruses enabled by the robust nanoviricides platform technology.

To date, the Company does not have any commercialized products. The Company continues to add to its existing portfolio of products through our internal discovery and clinical development programs and also seeks to do so through an in-licensing strategy.

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, upon approval of a drug.

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.

All of our drug programs are established to target what we believe are unmet medical needs.

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, with no cure and existing treatments that are not very effective. Shingles, caused by VZV, a herpesvirus, does not have an effective treatment at present, although some drugs are approved for use in shingles. Adenoviral Epidemic Kerato-Conjunctivitis (EKC) is a severe pink eye disease that may lead to blurry vision in certain patients after recovery. 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. Dengue viral infection is also known as “break-bone fever”. What is worse, that when a patient is infected with a dengue virus a second time, if the virus is a different serotype, then it can cause a severe dengue disease, or dengue hemorrhagic syndrome, with very high morbidity and a high rate of fatality. This is because, the patient’s immune system mounts an attack, but the antibodies that it generates, directed at the previous infecting virus, are not effective against the new infection, and instead the new infecting virus uses them to hitch a ride into host cells that it infects more severely. This phenomenon is called “Antibody-Dependent Enhancement” or “ADE” for short.

In the United States alone, 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.

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.

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. Further, our anti-HSV drug candidates have shown excellent efficacy in cell culture studies, as well as in a lethal skin infection animal model.

Thus, an effective drug with a good safety profile could have a dramatic impact on ocular viral infections. Merit-based compensation for the herpes keratitis 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.

Topical treatment of herpesvirus infections 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.

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, leading to minimizing viral production at the site. Such effective local control of the virus titer is expected to lead to reduction in recurrence of herpesvirus “cold sores” or genital ulcers.

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) shingles, (b) ocular herpes keratitis, (c) oral herpes (“cold sores”), and (d) genital herpes.

Our nanoviricides in the HerpeCide™ program at present are designed as topical treatment for the breakout of shingles or 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. Currently, valacyclovir (Valtrex®) is approved as an oral drug for the treatment of severe shingles, but it has limited effectiveness. Another oral drug known as “FV-100” was studied in Phase II in clinical trials for the treatment of shingles by Bristol-Myers Squibb. This study has been completed in September 2015, but results are not available to us. Currently this drug is being further developed by Contravir Pharma. There is also a preventive vaccine for shingles that can be taken by adults over 55 years of age. Given the number of cases of severe shingles, we believe that there is an unmet medical need for developing a topical skin cream for the treatment of shingles. Local application should enable delivery of stronger, local doses of medicine, with a stronger patient benefit, than oral systemic dosing allows.

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.

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.

The current market size for drugs for the treatment of herpes infections is about \$2~4B. Similarly, the current market size for the treatment of influenza infections is in excess of \$4B, and that for HIV treatments is in excess of \$40B. The total market sizes for the drug development programs we have in progress are estimated at around \$100B.

We believe that when an effective topical treatment is introduced, the market size is likely to expand substantially, as has been demonstrated in the case of HIV as well as Hepatitis C.

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

We are currently focused 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.

We believe we are now one of the very few small pharmaceutical drug innovators that possess their own cGMP or cGMP-capable manufacturing facility (see below). With our new campus and pilot-scale c-GMP-capable manufacturing facility, we are now in a position to advance our drug candidates into clinical trials, produce the pre-clinical “tox package” batches, and the clinical drug substance batches.

**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 anti-Herpes-virus programs. In particular, we have focused on work plan related to identifying a clinical development candidate for the topical skin cream for the treatment of shingles outbreak. Because of the broad-spectrum nature of our anti-herpes drug candidates, we have also simultaneously continued further development of our drug candidates for the other three indications in the HerpeCide™ project, namely, cold sores, genital ulcers, and ocular viral infections. We have also continued to work on our anti-influenza drug development programs under the FluCide™ project.

Recent developments and our discussions with our regulatory advisors and consultants indicate that the shingles drug candidate may be likely to reach the human clinical evaluation phase earliest compared to the other drug candidates. Other drug candidates in the HerpeCide project are expected to follow into clinical stage rapidly thereafter. This is primarily because of the topical treatment nature of the drug candidates we have chosen to develop in these indications. The FluCide drug candidates are now expected to enter human clinical stage later than the HerpeCide drug candidates.

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 aka VZV or chickenpox/shingles virus.

The Company has established additional collaborations towards IND-enabling development of drug candidates against the four indications listed earlier. We now have collaboration agreements with the CORL at the University of Wisconsin, the Campbell Lab at the University of Pittsburgh, and, subsequent to the reporting period, the Moffat Lab at SUNY Upstate Medical Center, for the evaluation of our nanoviricides® drug candidates in models of ocular herpesvirus and adenovirus infections as well as VZV infections in *in vitro* and *ex vivo* models. TransPharm Preclinical Solutions, a CRO, will continue to perform testing of our anti-herpes drug candidates in dermal infection animal models. The Company also now has the ability to perform initial screening of our drug candidates in our BSL2

certified Virology Lab in Shelton, CT, against several viruses that include various strains and subtypes of HSV-1, HSV-2, VZV, and Influenza.

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.

The Company intends to test several drug candidates with different formulation consistencies in multiple studies in order to select a clinical development candidate for the topical treatment of shingles. 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 this 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 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.

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.

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).

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.

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.

### ***Our Campus and Facilities***

We have substantially completed our relocation to the new campus in Shelton, CT. We performed this transition smoothly and without affecting continuing operations by employing a staged relocation strategy.

We have built a c-GMP capable facility at our new campus in Shelton, Connecticut, where we will be able to 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, we believe the campus will be able to 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.

We have recently engaged a new Senior Virologist, namely Brian Friedrich, PhD. He has worked on drug development and drug screening for highly pathogenic viruses including alphaviruses, bunyaviruses, and filoviruses, at United States Army Medical Research Institute for Infectious Diseases (USAMRIID). He has also worked on HIV-1 and on flaviviruses such as West Nile Virus. Brian is trained in up to BSL-4 laboratory protocols in virology.

We are now able to perform certain initial *in vitro* drug candidates screening assays in cell culture for some of the viruses in our own BSL-2 Cell Culture Virology laboratories at our new campus. Certain non-lethal viruses such as



several Influenza strains, HSV, VZV, as well as Dengue viruses can be used in cell culture screening assays at low levels in our BSL-2 virology facility.

We believe that performing the initial drug screening as well as drug candidates screening during optimization studies in cell culture assays in our own facility will significantly improve our drug development capabilities. We have previously identified that our total dependence on external facilities even for cell culture-based screening has been causing significant delays in our drug development and drug candidate optimization efforts.

We will continue to employ external facilities for additional cell-culture screening of our drug candidates for different viruses. This will enable both confirmation of our in-house studies, and expansion of the studies to virus strains or virus types that we do not handle in house. In addition, all of our pre-clinical animal testing will continue to be performed by third parties.

We have thus significantly expanded our drug development capabilities with the addition of virological research capabilities.

We have moved our existing equipment and 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 consecutive reproducible batches are generally required to be made before qualifying a product, process, and facility under c-GMP. 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.

We continue to work on scale-up of the nanomicelle polymer backbone to approximately 500g scale, and on establishing in-process control systems, as well as post-process characterization assays for the same with the new instrumentation and analysis equipment we have acquired as we were establishing our new facilities. Many of the critical nanomedicine characterization assays needed for our nanoviricide drug candidates have now been developed, and will be perfected into standardized assays over the next several months.

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.

While we have expanded our staff significantly in the last two years, including the staff at our affiliates, we continue to operate with a relatively small team compared to the number of programs and the number of objectives in each program. We have continued to move forward in each of the objectives as we complete critical tasks at hand, using teams composed of substantially the same people. This serialization naturally extends the timeline for entry into the clinical phase. However, even if we increased staff, we would still need to train the new staff members into various proprietary techniques, which would take significant amount of time away from our current staff, and would also add to development costs substantially. We have therefore strategically chosen to continue development with the smaller but agile, highly flexible, and multi-talented team that we have now built.

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

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.

Our new facility is expected 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.

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.

*Current Status of the Company's Drug Development Programs*

All of our drug development programs are in pre-clinical or advanced pre-clinical stages.

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.

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.

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.

During the reported quarter we have continued to perform further optimization of our anti-HSV drug candidates. We have increased our efforts at characterization and study of each synthetic step in order to develop a knowledge base for further scale up of syntheses to larger scales. This process, as is well known in the industry, requires painstaking studies, and is time consuming. 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 contract research services organization (CRO), in Jackson, MI. We plan to replicate similar studies of our antiviral candidates in appropriate models for shingles, ocular HSV-1 infection and genital HSV-2 infection.

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.

We are now performing the studies necessary for selection of IND candidates (i.e. clinical drug candidates) for several indications related to herpes viruses under our HerpeCide™ program. These indications include shingles, ocular herpes keratitis, oral herpes (“cold sores”), and genital herpes. 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 our successfully tested earlier ligands were developed using knowledge-based approaches including molecular modeling and bioinformatics studies in our laboratory. Synthesis of these novel ligands has been substantially completed 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 clinical drug development candidate for the topical treatment of shingles outbreak. We believe that clinical candidates for the dermal topical treatment of HSV-1 and HSV-2 infections should be identified after an additional cycle of testing for effectiveness for these respective indications.

Our antiviral safety and efficacy studies are substantially performed by third party collaborators or contract organizations. To this end, we have engaged several new collaborations to help us finalize clinical candidates and develop IND-enabling pre-clinical data in our various programs this year. For our HerpeCide program, we have collaborations with the CORL at the University of Wisconsin for HSV-1 and HSV-2, with focus on small animal models for ocular disease; the Campbell Lab at the University of Pittsburgh for *in vitro* cell culture models of various ocular viruses including many adenovirus and herpesvirus strains, as well as animal models for ocular herpes keratitis (HK) and adenoviral epidemic kerato-conjunctivitis (EKC); and TransPharm, LLC, a contract research organization (CRO), for pre-clinical animal efficacy studies for our HSV-1 and HSV-2 skin cream drug candidates. In addition, we have a continuing relationship with BASi, a CRO for GLP and non-GLP safety/toxicology studies. We have engaged Biologics Consulting Group (BCG) for advice and help with regulatory affairs.

Subsequent to this reporting quarter, we have announced on October 31, 2016, that we have entered into an agreement with SUNY Upstate Medical University for the testing of our nanoviricides® drug candidates against VZV (varicella zoster virus), i.e. the shingles virus. The research will be performed in the laboratory of Dr. Jennifer Moffat and will include *in vitro*, *ex vivo* and possibly *in vivo* studies. Dr. Moffat has extensive experience in VZV infection and antiviral agent discovery. The goal of these studies is to help select a clinical drug development candidate for toxicology and safety evaluation intended for clinical trials for the treatment of shingles in humans.

A major impediment in VZV infection studies is a lack of suitable animal models because VZV is restricted to human tissue and only infects and replicates in human tissue. To overcome this problem, Dr. Moffat has developed an “*ex-vivo*” human skin organ culture VZV infection model for the evaluation of therapeutics. This model is a good representative model of natural VZV infection in humans as well as an important model for evaluating antiviral activity, because it demonstrates behavior similar to the skin lesions caused by VZV in human patients.

The *in vitro* studies will evaluate the effectiveness of the Company’s nanoviricides antiviral agents against VZV infection of certain human cells in culture. The *ex vivo* studies will evaluate the efficacy of the Company’s nanoviricides to inhibit VZV in human skin organ cultures. A limitation of this *ex vivo* model at present is the number of samples that can be studied at one time. We have planned several studies in sequence to overcome this issue. We are pleased to note that we have already started these studies. We have planned them such that they will help us identify a clinical drug candidate for the topical treatment of shingles when they are completed.

Dr. Moffat is an internationally recognized expert on varicella zoster virus, and her research has focused on the pathogenesis and treatment of infection by this virus. The National Institutes of Health has recognized this VZV model via a contract with Dr. Moffat’s lab for evaluating antiviral compounds against VZV. Dr. Moffat is the director of two research core facilities at SUNY Upstate, namely, the Center for Humanized Mouse Models and the core facility for *In Vivo* Imaging.

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).

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. 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. However, the HerpeCide program drug candidates are expected to require only 100g~500g scale batch production for toxicological and initial human clinical trials studies. We have therefore re-prioritized our programs last year and are now focused on the scale up studies for the HerpeCide drug candidates at approximately 200g scale of production. We will be able to continue further development of a 1kg~2kg per batch scale for FluCide drug candidates after we have completed the HerpeCide program scale up.

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.

We are continuing the CMC (Chemistry, Manufacture and Control) related work and scale-up for the HerpeCide program at present. 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. We anticipate the CMC program for our anti-herpes drug candidate to be significantly less time consuming as compared to our FluCide drug program, which will require scaling to a much larger scale of production. We generally plan our scale-up studies in small steps, going from ~1g to ~10g to ~50g to ~200g to ~500g to ~1kg. At each stage, we must collect parameters and observations from each batch, improve process control at the next batch, and make a replicate batch at the end when the process is relatively stabilized. We do not need to finalize the production processes before entering human clinical trials. However, we must develop appropriate quality characterization assays, quality control techniques, process control methods, and quality assurance assays so that we can make equivalent materials from batch to batch.

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.



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. 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. 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.

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.

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.

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.

### **NanoViricides Business Strategy in Brief**

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.

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.

### **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.

Subsequent to the reporting period, we have signed a collaboration agreement with the Professor Moffat Lab at SUNY Upstate Medical Center, Syracuse, NY, for evaluating safety and effectiveness studies of our drug candidates in cell culture and in animal models for shingles VZV infections.

We have signed a collaboration agreement with the CORL at the University of Wisconsin, Madison, WI, for HSV-1 and HSV-2, with focus on small animal models for ocular disease.

We have signed a collaboration agreement with the Campbell Lab at the University of Pittsburgh, Pittsburgh, PA for evaluating safety and effectiveness studies of our drug candidates in cell culture and in animal models for ocular infections by HSV-1, HSV-2 and Adenoviruses.

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

### **Intellectual Property and Patents**

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 existing 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 the 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.

More than 61 patents have been issued globally 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.

The patents are being issued to the inventors Anil R. Diwan, PhD, Jayant G. Tatake, PhD, and Ann L. Onton, all of whom 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.

Patents and other proprietary rights are essential for our operations. If we have a properly designed and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and intend to file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

The Company believes that the drugs by themselves, Shingles antiviral topical treatment, HerpeCide for Cold Sores, HerpeCide for genital ulcers, Antiviral nanoviricide eye drops, Injectable FluCide, Oral FluCide, DengueCide, HIVCide, RabiCide, and others, may be eligible for patent protection. The Company plans on filing patent applications for protecting these drugs when we have definitive results from in-vitro or in-vivo studies that enable further drug development and IND application filing.

The issued patents have nominal expiry dates in 2026 to 2029. 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 2037.

We may obtain patents for our compounds many years before we obtain marketing approval for them. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions, based on delays experienced in marketing products due to regulatory requirements. There is no assurance we would be able to obtain such extensions. The Company controls the research and work TheraCour performs on its behalf and no costs may be incurred without the prior authorization or approval of the Company.

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or reexamination proceedings regarding the enforcement or validity of our licensor, TheraCour Pharma Inc.'s existing patents or any future patents, could invalidate TheraCour's patents or substantially reduce their protection. In addition, the pending patent applications and patent applications filed by TheraCour, may not result in the issuance of any patents or may result in patents that do



not provide adequate protection. As a result, we may not be able to prevent third parties from developing the same compounds and products that we have developed or are developing. In addition, certain countries do not permit enforcement of our patents, and manufacturers are able to sell generic versions of our products in those countries.

We also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. In particular, a great deal of our material manufacturing expertise, which is a key component of our core material technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by the individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors.

## **Trademarks**

On April 20, 2010, the United States Patent and Trademark Office granted trademark registration number 3,777,001 to the Company for the standard character mark “nanoviricides” (the “Mark”) for International Class 5, pharmaceutical preparation for the treatment of viral diseases. The Mark was registered on the Principal Register and is protected in all its letter forms, including corresponding plural and singular forms, various forms of capitalization, and fonts and designs.

## **Presentations, Conferences, Recognition, and Investor Outreach**

On September 21, 2016, Dr. Anil Diwan, President and Chairman of the Company, was invited as panel participant to discuss “*Regulatory Landscape: What’s Needed to Drive Innovation*” in the “Anti-Infectives-Rx 2016” Conference organized by Boston Biotech Conferences and held at the Harvard Medical School - Joseph B. Martin Conference Center, Boston, MA.

On September, 19, 2016, Dr. Diwan was invited to present two talks at the “Public Health and Emerging Microbial Threats, 14th Annual International Conference” (PHEMT), held at the Albany College of Pharmacy and Health Sciences, Albany, NY 12208, USA.

Dr. Diwan presented a talk entitled “*Beyond Antibodies: Chemical Nanomachines to Combat Emerging Virus Threats*” about the Nanoviricides technology and accomplishments in the first session, and another talk on “*Nanomedicine Drug Development Regulatory Processes: Critical Issues*” in the second session at PHEMT.

On August 24, 2016, the Honorable U.S. Senator Chris Murphy visited the Company’s new campus in Shelton, CT.

On July 25, 2016, our President, Dr. Anil Diwan, was invited to participate in the prestigious 31st Annual Chief Executive of the Year Gala Reception & Dinner held at the New York Stock Exchange. In addition, he was also invited to participate in the CEO Roundtable Discussion on Innovation.

The Company continues its efforts at connecting with additional investors and presenting in investor-oriented business conferences, led by the Company’s CEO, Eugene Seymour, MD, MPH.

Earlier, on February 22, 2016, the Company announced that information on its novel, proprietary anti-virus platform technology has been published in the book “*Handbook of Clinical Nanomedicine, Vol. 1. Nanoparticles, Imaging, Therapy, and Clinical Applications*”, a CRC Press publication. The chapter entitled “Nanoviricides: Targeted Anti-Viral Nanomaterials” provides an in-depth presentation of the NanoViricides platform technology, evidence for how nanoviricides® are believed to act plus dramatic results of nanoviricides specifically targeting certain viral diseases, such as Influenza.

This chapter introduces the novel NanoViricides nanotechnology that possesses potent antiviral efficacy by targeting the mechanisms by which viruses attach or bind to cells. A nanoviricide is believed to act like a decoy of a human cell. When the virus sees the appropriate mimic of its cell binding site displayed on a nanoviricide, the virus binds to it. The Company believes that the flexible nanoviricide enables cooperative binding of the nanoviricide to additional sites on the virus surface in a velcro-like effect. This maximization of virus binding would lead to the nanoviricide spreading onto the virus particle, fusing with the virus surface, and then engulfing the virus. In the process, the coat proteins that the virus uses for binding to cells would be expected to become unavailable, and could fall off the virus surface. This highly targeted attack would lead to the loss of the viral coat proteins and the nanoviricide may further dismantle the engulfed virus capsid. The loss of virus particle integrity would neutralize the virus, making the virus non-infectious.

The *Handbook of Clinical Nanomedicine, Vol. 1. Nanoparticles, Imaging, Therapy, and Clinical Applications*, edited by Raj Bawa, PhD, Gerald F. Audette, PhD, and Israel Rubinstein, MD, is the first volume in a two volume set published by CRC Press; it is part of the Pan Stanford Series on Nanomedicine. The publisher states that Volume 1 “provides a comprehensive roadmap of basic research in nanomedicine as well as clinical applications. It not only highlights current advances in diagnostics and therapies but also explores related issues like nomenclature, terminology, historical developments, and regulatory aspects. While bridging the gap between basic biomedical research, engineering, medicine and law, the handbook provides a thorough understanding of nano’s potential to address (i) medical problems from both the patient and health provider's perspective, and (ii) current applications and their potential in a healthcare setting.” The CRC Press lists the official publication date as February 28, 2016. (<https://www.crcpress.com/Handbook-of-Clinical-Nanomedicine-Two-Volume-Set/Bawa-Audette-Rubinstein/9789814316170>)

### **NanoViricides, Inc. Annual Shareholders’ Meeting**

The Company’s 2016 Annual Shareholders Meeting is scheduled to be held at the Sheraton Stamford, in Stamford, CT, USA, on Sunday, December 11, 2016, from 9am to 12pm.

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

As of September 30, 2016, we had cash and equivalents of \$21,912,927, prepaid expenses of \$207,563, and property and equipment of \$11,621,916, net of accumulated depreciation of \$2,014,102. Long-term liabilities were \$7,058,728 and stockholders' equity was \$20,225,066 at September 30, 2016.

As of June 30, 2016, we had cash and equivalents of \$24,162,185, and \$219,458 in prepaid expenses. Property and equipment stood at \$11,760,767 net of accumulated depreciation of \$1,850,816. Long term liabilities were \$6,841,190 and the stockholders' equity was \$23,048,214 at June 30, 2016.

During the reporting quarter we used approximately \$2,225,000 in cash toward operating activities and approximately \$24,000 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 more than twelve months. In addition, in order to conserve cash, we also pay compensation in stock and stock instruments to various parties. The Company believes that our spending continues to be in line with our estimates.

We project, based on various estimates that we have obtained, that our current available financing is sufficient for accomplishing the goal of filing an IND or equivalent regulatory applications, and initial human clinical trials in at least one of our drug programs. Two of our drug programs, namely Shingles skin cream and Injectable FluCide, are now in the late pre-clinical or IND-enabling studies stage, with HerpeCide™ skin cream (for "cold sores" treatment) to follow. 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 wide variety of disease indications.

The Company does not currently have any revenue. All of the Company's products are in the 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 September 30, 2016, we have current assets of approximately \$22,100,000 that is more than sufficient for our operations for more than one year 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 one year, we anticipate undertaking additional expenditures for 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.

Our 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.

The Company anticipates it will have sufficient access to capital even if it decides to develop 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 this 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 such additional capital resources or that such financing will be on terms that are favorable to the Company.

## **Results of Operations**

The Company is a biopharmaceutical company and did not have any revenue for the three months ended September 30, 2016 and 2015.

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

**Operating Expenses** – Research and development expenses for the three months ended September 30, 2016 increased \$170,065 to \$1,452,137 from \$1,282,072 for the three months ended September 30, 2015. 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 Administration Expenses** – General and administrative expenses for the three months ended September 30, 2016 increased \$45,333 to \$988,312 from \$942,979 for the three months ended September 30, 2015. The increase resulted primarily from an increase in other operating expenses in general.

**Interest Income** – Interest income increased \$5,351 to \$14,176 for the three months ended September 30, 2016 from \$8,825 for the three months ended September 30, 2015. Interest income included interest on cash equivalent deposits in interest-bearing accounts at market rates. The increase is due to an increase in market rates.

**Interest Expense** – Interest expense for each of the three month periods ended September 30, 2016 and 2015 was \$245,000.

**Other Expenses** – Discount on convertible debentures for the three months ended September 30, 2016 increased \$69,752 to \$403,462 from \$333,710 for the three months ended September 30, 2015. 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 September 30, 2016 decreased \$1,474,691 to \$13,291 from \$1,487,982 for the three months ended September 30, 2015. Change in the fair value of derivatives is a non cash item estimate 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 three months ended September 30, 2016, the Company had a net loss of (\$3,061,444), or \$ (\$0.05) per share on a fully diluted basis compared to a net loss of (\$1,306,954) or (\$0.02) per share on a fully diluted basis for the three months ended September 30, 2015. 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 operating loss in the current period was greater than the net operating loss for the three months ended September 30, 2015, in part, from a decrease in the change in the fair value of derivatives.

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

The Company had cash and cash equivalents of approximately \$21,900,000 as of September 30, 2016 and accounts payable and accrued liabilities of approximately \$963,000.

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 \$67,886,000 at September 30, 2016.

Our cash and cash equivalent balance is sufficient for us to continue our operations for more than one year at our current rate of expenditure.

### *Off Balance Sheet Arrangements*

We have not entered into any off-balance sheet arrangements during the nine months ended September 30, 2016.

### **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 Disclosure controls and procedures.**

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the "SEC"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of September 30, 2016, we carried out an evaluation, with the participation of our management, including our chief executive officer and our chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

**Changes in internal control over financial reporting.**

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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

There are no 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.**

In August, 2016, the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 17,148 shares of common stock with an exercise price of \$1.50 per share expiring in August, 2020.

For the three months ended September 30, 2016, 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.

For the three months ended September 30, 2016, the Company's Board of Directors authorized the issuance of 16,232 fully vested shares of its common stock with a restrictive legend for consulting services.

For the three months ended September 30, 2016, the Company's Board of Directors authorized the issuance of 6,777 fully vested shares of its common stock with a restrictive legend for Director Services.

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

**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: November 14, 2016 Name: Eugene Seymour, M.D.  
Title: Chief Executive Officer and Director  
(Chief Executive Officer )

/s/ Meeta Vyas

Dated: November 14, 2016 Name: Meeta Vyas  
Title: Chief Financial Officer  
(Chief Financial Officer)