



(203) 937-6137

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

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

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

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

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

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

Yes  No

The number of shares outstanding of the Company's Common Stock as of November 14, 2014 was approximately:  
57,106,568

NanoViricides, Inc.

FORM 10-Q

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Nanoviricides, Inc.

## Balance Sheets

	September 30, 2014 (Unaudited)	June 30, 2014
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$41,120,652	\$36,696,892
Prepaid expenses	59,099	108,089
Prepaid expenses - related parties	424,402	709,221
Other current assets	-	150,000
<b>Total Current Assets</b>	<b>41,604,153</b>	<b>37,664,202</b>
<b>PROPERTY AND EQUIPMENT</b>		
Property and equipment	7,299,254	6,736,742
Accumulated depreciation	(1,291,318 )	(1,239,986 )
<b>Property and equipment, net</b>	<b>6,007,936</b>	<b>5,496,756</b>
<b>TRADEMARK</b>		
Trademark	458,954	458,954
Accumulated amortization	(52,889 )	(50,696 )
<b>Trademark, net</b>	<b>406,065</b>	<b>408,258</b>
<b>SECURITY DEPOSIT</b>	<b>1,000,000</b>	<b>1,000,000</b>
<b>Total Assets</b>	<b>\$49,018,154</b>	<b>\$44,569,216</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$155,978	\$376,446
Accounts payable – related parties	331,448	758,676
Accrued expenses	265,463	91,838
<b>Total Current Liabilities</b>	<b>752,889</b>	<b>1,226,960</b>
Debentures payable - Series B Net of discount	4,195,296	4,037,568
Derivative Liability	3,785,385	5,699,703
Debentures Payable - Series C, Net of discount	3,457,244	5,000,000

Total Long Term Liabilities	11,437,925	14,737,271
Total Liabilities	12,190,814	15,964,231
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, \$0.001 par value, 4,000,000 shares designated, 3,387,795 and 3,193,079 shares issued and outstanding, respectively	3,389	3,194
Series B Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, 0, and 0 shares issued and outstanding, respectively	-	-
Series C Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, 0 and 0 shares issued and outstanding, respectively	-	-
Common stock, \$0.001 par value; 85,714,285 shares authorized; 56,535,135 and 54,620,993 shares issued and outstanding, respectively	56,535	54,621
Additional paid-in capital	89,412,744	80,953,428
Accumulated deficit	(52,645,328)	(52,406,258)
Total Stockholders' Equity	36,827,340	28,604,985
Total Liabilities and Stockholders' Equity	\$49,018,154	\$44,569,216

See accompanying notes to the financial statements

Nanoviricides, Inc.

## Statements of Operations

(Unaudited)

	For the Three Months Ended September 30, 2014	For the Three Months Ended September 30, 2013
<b>OPERATING EXPENSES</b>		
Research and development	\$811,107	\$1,174,221
Refund credit research and development costs	-	-
General and administrative	876,026	714,561
Total operating expenses	1,687,133	1,888,782
<b>LOSS FROM OPERATIONS</b>	(1,687,133 )	(1,888,782 )
<b>OTHER INCOME (EXPENSE):</b>		
Interest income, net	39,323	9,560
Interest expense	(245,000 )	(120,986 )
Discount on convertible debentures	(260,578 )	(135,481 )
Beneficial conversion feature of convertible debentures	-	-
Change in fair market value of derivatives	1,914,318	(4,137,091 )
Other income (expense), net	1,448,063	(4,383,998 )
<b>LOSS BEFORE INCOME TAXES</b>	(239,070 )	(6,272,780 )
<b>INCOME TAX PROVISION</b>	-	-
<b>NET LOSS</b>	\$(239,070 )	\$(6,272,780 )
<b>NET LOSS PER COMMON SHARE</b>		
- BASIC AND DILUTED:	\$(0.004 )	\$(0.04 )
Weighted average common shares outstanding		
- basic and diluted	55,576,200	47,672,029

See accompanying notes to the financial statements



Nanoviricides, Inc.

## Statements of Cash Flows

(Unaudited)

	For the Three Months Ended September 30, 2014	For the Three Months Ended September 30, 2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(239,070 )	\$(6,272,780 )
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued for license		-
Series A Preferred shares issued as compensation	72,980	-
Common shares and warrants issued for services	38,250	32,250
Common shares issued for interest		
Warrants granted to scientific advisory board	22,292	106,050
Amortization of deferred compensation		-
Depreciation	51,332	52,719
Amortization	2,193	2,193
Change in fair value of derivative liability	(1,914,318 )	4,137,091
Amortization of deferred financing expenses		-
Discount convertible debentures	260,578	135,481
Beneficial conversion feature of convertible debentures		-
Changes in operating assets and liabilities:		
Prepaid expenses	48,990	(206,765 )
Prepaid expenses - Related parties	284,819	
Other current assets	150,000	-
Deferred expenses		-
Accounts payable - trade	(220,468 )	144,802
Accounts payable - related parties	(427,228 )	429,258
Accrued expenses	173,625	115,253
Accrued payroll to officers and related payroll tax expense		-
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(1,696,025 )</b>	<b>(1,324,448 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Security deposit	-	(1,000,000 )
Purchase of property and equipment	(562,512 )	(2,273,989 )
Purchase of trademark	-	



NET CASH USED IN INVESTING ACTIVITIES	(562,512 )	(3,273,989 )
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of convertible debentures		
Proceeds from issuance of Convertible Preferred Series B stock, net		
Proceeds from issuance of Convertible Preferred Series C stock, net		-
Proceeds from issuance of common stock and warrants in connection with private placements of common stock, net of issuance costs		9,690,450
Proceeds from exercise of stock options		-
Proceeds from exercise of warrants	6,682,297	185,624
Collection of stock subscriptions received		-
NET CASH PROVIDED BY FINANCING ACTIVITIES	6,682,297	9,876,074
NET CHANGE IN CASH	4,423,760	5,277,637
Cash at beginning of period	36,696,892	13,923,245
Cash at end of period	\$41,120,652	\$19,200,882
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	\$-	\$-
Income tax paid	\$-	\$-
NON CASH FINANCING AND INVESTING ACTIVITIES:		
Common stock issued for services rendered	\$38,250	\$32,250
Common stock for interest		
Preferred stock issued as compensation	72,980	-
Series A Preferred stock issued as discount on Debentures	1,645,606	
Stock options issued to the officers as compensation		-
Stock warrants granted to scientific advisory board	22,292	106,050
Stock warrants granted to brokers		113,696
Common stock issued for interest on debentures		-
Shares of common stock issued in connection with debenture offering		-
Common stock issued upon conversion of convertible debentures		-
Common stock issued upon conversion of Series B Preferred Stock		-
Common stock issued upon conversion of Series C Preferred Stock		-
Common stock issued for dividends on Series B Preferred Stock		-
Common stock issued for dividends on Series C Preferred Stock		-
Debt discount related to beneficial conversion feature of convertible debt		-
Stock Warrants issued in connection with Private Placement		-
Common stock issued for accounts payable		-
Common stock issued for equipment		-

See accompanying notes to the financial statements

**NANOIRICIDES, INC.**

**September 30, 2014 AND 2013**

**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 Nanoviricide, Inc., a privately owned Florida corporation ("NVI"), pursuant to an Agreement and Plan of Share Exchange (the "Exchange"). Nanoviricide, Inc. was incorporated under the laws of the State of Florida on May 12, 2005.

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

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

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

NanoViricides, Inc. (the “Company”), is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. 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 Pharma on September 1, 2005, gave us an exclusive, worldwide license for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus.

On February 15, 2010 the Company executed an Additional License Agreement with TheraCour Pharma, Inc. (“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 Preferred Series A do not contain any rights to dividends, have no liquidation preference, and are not to be amended without the holder’s approval. The 2,000,000 shares were valued at the par value of \$2,000 (adjusted for the reverse split).

We focus our research and clinical programs on specific anti-viral therapeutics. The Company's platform technology is based on novel biomimetic nanomedicine constructs, called nanoviricides®. A nanoviricide is designed to "fool" the virus into binding to the nanoviricide in the same fashion that it would bind to the host cell. Because the host cell receptor and how the virus binds to it does not change despite all the changes in the virus, the Company believes that our broad-spectrum nanoviricides should continue to work against the virus despite the viral mutations and other changes. We are seeking to add to our existing portfolio of products through our internal discovery and clinical development programs and through an in-licensing strategy.

The Company has held a pre-IND Meeting with the US FDA for its clinical drug candidate NV-INF-1 in the FluCide™ program. The Company is developing this injectable drug (NV-INF-1) for hospitalized patients with severe influenza, including immuno-compromised patients. The Company believes that this drug may also be usable as a single-dose injection in a medical office for less severe cases of influenza. The Company has also developed an oral anti-influenza drug candidate, NV-INF-2, with a very high degree of effectiveness when taken by mouth. This may be the first ever nanomedicine that is orally active. Both of these anti-influenza therapeutic candidates are "broad-spectrum", i.e. they are expected to be effective against most if not all types of influenzas including Bird Flu H5N1, 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 they 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. Both of these 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.

The Company's broad-spectrum drug candidate for the treatment of dengue viral infections, DengueCide™, has received "orphan drug" status from both the US FDA and the European Medicines Agency ("EMA"). This orphan drug status carries with it several tax benefits and other financial equivalent incentives. Notably, in the US, orphan drug status will enable us to gain a "Priority Review Voucher" that can be applied to another drug development program or can be sold for a consideration to another pharmaceutical company, once the drug is approved. The Company has therefore prioritized its Dengue drug development program.

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

The Company is also developing a broad-spectrum skin cream for the treatment of oral and genital herpesvirus infections (i.e. both HSV-1 and HSV-2).

In addition, the Company is also developing broad-spectrum eye drops that are expected to be effective against a majority of the viral infections of the external eye. Most of these viral infections are from adenoviruses or from herpesviruses. The Company has shown excellent efficacy of its drug candidates against EKC (adenoviral epidemic kerato-conjunctivitis) in an animal model. In addition, the anti-HSV drug candidates have shown excellent efficacy in cell culture studies. The Company is also developing a skin cream formulation for the treatment of herpes cold sores or genital warts. Further, the Company is also developing a broad-spectrum drug against Dengue viruses that is expected to be useful for the treatment of any of the four major serotypes of dengue viruses, including in severe cases of dengue (DSS) and dengue hemorrhagic fever (DHF). DSS and DHF are thought to be caused by prior antibodies against dengue that a patient's body creates to fight a second unrelated dengue infection, and the second virus uses these antibodies effectively to hitch a ride into human cells, thereby causing a more severe infection than in naive patients. In addition to these six drugs in development, the Company also has research programs against Rabies virus, Ebola and Marburg viruses, and others. To date, the Company does not have any commercialized products.

Thus, at present, the Company has six commercially important drug programs in its pipeline that have shown significant successes in cell culture as well as animal models. In addition, in August 2014, the Company announced that it has restarted our anti-Ebola drug development program, in response to the current Ebola epidemic. The Company's platform technology enables rapid development of drug candidates against novel infections. The Company believes that it will continue to expand its pipeline as available funds and opportunities permit.

The Company is also working on scaling up production processes, and enabling c-GMP-compliant manufacture of its drug candidates in order to provide clinical supplies for the future human clinical trials of our drug candidates. Construction of the modern, multi-product, state-of-the-art nanomedicines manufacturing facility built for this purpose was completed in July, 2014. Cleaning and Validation, as well as custom equipment fit-outs are in progress at present. The facility was built by Inno-Haven, LLC, a special-purpose company established for this purpose. Inno-Haven is controlled and managed by Dr. Anil Diwan, the Company's co-founder, President, and Chairman. Inno-haven purchased the building in 1 Controls Drive, Shelton, CT, in August 2011, with personal funds, and loans from family friends, at a time when NanoViricides was unable to support this critical endeavor. With the Company's improved finances, the Company now intends to purchase this facility from Inno-Haven.

## **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 8 of Regulation S-X of the Securities and Exchange Commission for Interim Reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim financial statements furnished reflect all adjustments (consisting of normal recurring accruals) which are, in the opinion of management, considered necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. The accompanying financial statements and the information included under the heading "Management's Discussion and Analysis or Plan of Operation" should be read in conjunction with our company's audited financial statements and related notes included in our company's form 10-K for the fiscal year ended June 30, 2014 filed with the SEC on September 30, 2014.

For a summary of significant accounting policies (which have not changed from June 30, 2014), see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

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

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

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

	Potentially Outstanding Dilutive Common Shares For the Three Months Ended September 30, 2014	For the Fiscal Year Ended September 30, 2013
Stock options		
Stock options issued on September 23, 2005 to the founders of the Company upon formation with an exercise price of \$0.35 per share expiring ten (10) years from the date of issuance	535,715	535,715
Sub-total: stock options	535,715	535,715
Warrants		
Warrants issued from June 15, 2006 to October 1, 2007 to investors in connection with the Company's equity financing with an exercise price of \$3.50 per share expiring August 15, 2014	-	513,143
Warrants issued on August 22, 2008 to investors in connection with the Company's equity financing with an exercise price of \$3.50 per share expiring August 15, 2014	-	466,486
Warrants issued from June 15, 2008 through May 15, 2010 to SAB for services with an exercise price from \$2.45 to \$9.38 per share expiring February 28, 2015	211,429	211,429
Warrants issued on June 30, 2009 to investors with an exercise price of \$3.50 per share expiring August 15, 2014	-	568,771
Warrants issued on September 30, 2009 to investors with an exercise price of \$3.50 per share expiring August 15, 2014	-	1,437,871
Warrants issued from August 16, 2010 to May 15, 2011 to SAB for services with an exercise price ranging from \$5.15 to \$6.34 per share expiring fiscal year ending June 30, 2015	65,714	65,714
Warrants issued from August 16, 2011 to May 15, 2012 to SAB for services with an exercise price ranging from \$2.80 to \$4.94 per share expiring fiscal year ending June 30, 2016	68,571	68,571
Warrants issued from August 16, 2012 to September 30, 2013 to SAB for services with an exercise price of \$5.17 per share expiring fiscal year ending June 30, 2017	68,571	68,571
Warrants issued on September 10, 2013 to investors with an exercise price of \$5.25 per share expiring September 10, 2018 less Warrants	2,810,071	2,910,071



exercised through September 30, 2014

Warrants issued on August 15, 2013 to SAB for services with an exercise price of \$5.17 per share expiring on August 15, 2017	17,143	17,143
Warrants issued on September 10, 2013 to Placement Agents as commissions with an exercise price of \$5.25 per share expiring September 10, 2018	58,910	58,910
Warrants issued on November 15, 2013 to SAB for services with an exercise price of \$6.56 per share expiring on November 15, 2017	17,143	
Warrants issued on January 24, 2014 to investors with an exercise price of \$6.05 per share expiring January 24, 2019	2,479,935	
Warrants issued on January 24, 2014 to investors with an exercise price of \$5.25 per share expiring January 24, 2019	76,306	
Warrants issued on February 14, 2014 to SAB for services with an exercise price of \$3.98 per share expiring on February 14, 2018	17,143	
Warrants issued on May 15, 2014 to SAB for services with an exercise price of \$4.11 per share expiring on May 15, 2018	17,148	
Warrants issued on August 15, 2014 to SAB for services with an exercise price of \$5.02 per share expiring on August 15, 2018	17,148	
Sub-total: warrants	5,925,231	6,386,680
Total potentially outstanding dilutive common shares	6,460,946	6,922,395

In addition the Company has issued Convertible Debentures, to investors. A portion of the interest required to be paid on the Debentures is payable in restricted shares of the Company's \$0.001 par value common stock or in warrants, according to the terms of the Debenture.

At September 30, 2014 the estimated number of potentially dilutive shares of the Company's common stock into which these Debentures can be converted is 1,960,785 based upon the Selling price of the Company's common stock on September 30, 2014 of \$3.06. At September 30, 2014 the estimated number of potentially dilutive shares of the Company's common stock arising from the payment of a portion of the future interest to be paid on the debentures in common shares or warrants is 1,142,858.

The Company has also issued 3,387,795 of \$0.001 par value Convertible Preferred A shares to investors and others. Only in the event of a “change of control” of the Company, each Series A preferred share is convertible to 3.5 shares of its new common stock. A “change of control” is defined as an event in which the Company’s shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition. In the absence of a change of control event, the Series A stock is not convertible into Common Stock, and does not carry any dividend rights or any other financial effects. At September 30, 2014, the estimated number of potentially dilutive shares of the Company’s common stock into which these Series A Preferred shares can be converted into, is 11,857,283.

#### Recently Issued Accounting Pronouncements

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.

The amendments in this Update remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage.

The amendments also clarify that the guidance in Topic 275, Risks and Uncertainties, is applicable to entities that have not commenced planned principal operations.

Finally, the amendments remove paragraph 810-10-15-16. Paragraph 810-10-15-16 states that a development stage entity does not meet the condition in paragraph 810-10-15-14(a) to be a variable interest entity if (1) the entity can demonstrate that the equity invested in the legal entity is sufficient to permit it to finance the activities that it is currently engaged in and (2) the entity’s governing documents and contractual arrangements allow additional equity investments.

The amendments in this Update also eliminate an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity on the basis of the amount of investment equity that is at risk. The amendments to eliminate that exception simplify U.S. GAAP by reducing avoidable complexity in existing accounting literature and improve the relevance of information provided to financial statement users by requiring the application of the same consolidation guidance by all reporting entities. The elimination of the

exception may change the consolidation analysis, consolidation decision, and disclosure requirements for a reporting entity that has an interest in an entity in the development stage.

The amendments related to the elimination of inception-to-date information and the other remaining disclosure requirements of Topic 915 should be applied retrospectively except for the clarification to Topic 275, which shall be applied prospectively. For public business entities, those amendments are effective for annual reporting periods beginning after December 15, 2014, and interim periods therein.

The company has limited operations and is considered to be in the development stage. The Company has elected to early adopt Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. The adoption of this ASU allows the company to remove the inception to date information and all references to development stage. The Company adopted this guidance from June 30, 2014

In June 2014, the FASB issued the FASB Accounting Standards Update No. 2014-12 *“Compensation—Stock Compensation (Topic 718) : Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period”* (“ASU 2014-12”).

The amendments clarify the proper method of accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The Update requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered.

The amendments in this Update are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The adoption of the ASU would not have a material effect on the accompanying financial statements.

In August 2014, the FASB issued the FASB Accounting Standards Update No. 2014-15 *“Presentation of Financial Statements— Going Concern (Subtopic 205-40) (Topic 718): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”* (“ASU 2014-15”).

The Update provides guidance to an organization’s management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes.

This Update is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures.

The amendments in this Update are effective for annual periods and interim periods within those annual periods beginning after December 15, 2016. Earlier adoption is permitted.

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the accompanying financial statements.

**Note 3 - Financial Condition**

The Company's financial statements for the interim period ended September 30, 2014 have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business. The Company has a deficit accumulated from inception. In addition, the Company has not generated any revenues and no revenues are anticipated in the short-term. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of September 30, 2014 the Company had cash and cash equivalents of \$41,120,652. The Company has sufficient capital to continue its business, at least, through September 30, 2016, at the current rate of expenditure. The Company therefore would not be considered to have risks relative to its ability to continue as a going concern within the applicable guidelines.

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.

On July 2, 2014, (the “Closing Date”), the Company accepted a subscription in the amount of \$5,000,000 for a 10% Coupon Series C Convertible Debenture (the “Debenture”) from Dr. Milton Boniuk, a member of the Company’s Board of Directors (the “Holder”). The \$5,000,000 funding of the Debenture had been received by the Company prior to June 30, 2014, the year end reporting period and the Company has reported the said Debenture in these financial statements under long term liabilities. The Debenture is due on June 30, 2018 (the “Maturity Date”) and is convertible, at the sole option of the Holder, into restricted shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”) at the conversion price of \$5.25 per share of Common Stock. The Debenture bears interest at the coupon rate of ten percent (10%) per annum, computed on an annual basis of a 365 day year, payable in quarterly installments on March 31, June 30, September 30 and December 31 of each calendar year until the Maturity Date. Interest for the first quarter ending September 30, 2014 shall be calculated on a per diem basis from the Closing Date. The Company has the right, but not the obligation, to repay the Debenture prior to the Maturity Date (the “Redemption Payment”) in cash or, at the option of the Holder, a number of shares of the Company’s Common Stock. 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 951,381 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, and additional interest of 7% per annum for the period from the Closing Date to the Redemption Date. As additional interest on the Debenture, the Company shall issue 187,000 shares of its restricted Series A Preferred Stock (the “Series A”) to the Holder. Each shares of Series A votes at 9 votes per share. In addition, only in the event of a “change of control” of the Company, each Series A preferred share is convertible to 3.5 shares of its new common stock. A “change of control” is defined as an event in which the Company’s shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition. In the absence of a change of control event, the Series A stock is not convertible into Common Stock, and does not carry any dividend rights or any other financial effects. The Offering was conducted directly by the Company without the use of a placement agent. Accordingly, no placement agent fees or other commissions were paid by the Company in connection with the Offering.

On September 5, 2014, NanoViricides, Inc. (the “Company”) accepted notices to exercise old warrants (*See Note 9*, below.) for the purchase of an aggregate of 2,136,655 shares of the Company’s common stock at the exercise price of \$3.50 per share for aggregate proceeds of \$7,478,292.50. On July 17, 2014, the Company filed a registration statement on Form S-3 (the “Form S-3”) registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009 (the “Old Warrants”), as described more fully in the Form S-3 (the “Registered Warrants”). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. As of August 15, 2014, any Registered Warrants as specified above and not previously exercised have expired.

As a result of the successful sale of the Company’s Common Shares, management believes that the Company has sufficient cash and cash equivalents to meet its budgeted expenditures through, at least, September 30, 2016 at current rate of expenditures.

Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral nanomedicines. The Company has not yet commenced any product commercialization. The Company has incurred significant losses from operations since its inception, resulting in an accumulated deficit of \$(52,645,328) at September 30, 2014 and expects recurring losses from operations 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. Despite the Company's financings in 2014 and 2013 and a cash and cash equivalent balance of \$41,120,652 at September 30, 2014, substantial additional financing will be required in future periods. The Company may require additional capital to finance planned and currently unplanned capital costs, and additional staffing requirements during the next twenty four months. The Company has, in the past, adjusted its priorities and goals in line with the cash on hand and capital availability. The Company believes it can adjust its priorities of drug development and its Plan of Operations as necessary, if it is unable to raise such additional funds.

**Note 4 - Related Party Transactions**

Related Parties

Related parties with whom the Company had transactions are:

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

Fixed Assets

	September 30, 2014	June 30, 2014
During the reporting period, InnoHaven, LLC, acquired fixed assets on behalf of the Company from third party vendors behalf of the Company at 1 Controls Drive, Shelton, Ct	\$ -	\$ 4,500,000
During the reporting Period, Thera Cour Pharma, Inc. acquired fixed assets on behalf of the Company from third party vendors	\$ 110,578	\$ 528,000

Account Payable – Related Party

September 30, 2014	June 30 , 2014
\$ 331,448	\$ 758,676



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

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## Research and Development Costs Paid to Related Parties

	September 30, 2014	September 30, 2013
Development 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. As of September 30, 2014, pursuant to its license agreement, the Company has paid a security advance of \$424,402 to and held by TheraCour Pharma, Inc. which is reflected in Prepaid Expenses. No royalties are due TheraCour from the Company's inception through June 30, 2014.	\$ 769,185	\$ 924,125

Long-Term Debentures Payable – Directors

	September 30, 2014	June 30, 2014
On February 1, 2013, the Company raised \$4M from a family investment office and a charitable foundation controlled by Dr. Milton Boniuk 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., an additional interest payable in restricted common stock of 0.33, 0.33, and 0.34 shares in year 1, 2, and 3 respectively, and an additional interest of 0.33 warrants to be issued in the fourth year, per \$1 of principal. The warrants are priced at \$3.50 and will be valid for 3 years after issuance. The investors can convert the principal and any accrued interest into common stock at a fixed price of \$3.50 per share. The Company can prepay the debentures, in which case the base interest rate shall increase by a 7% prepayment penalty. The Company agreed to use its best efforts to register the interest shares and the shares issuable from the interest warrants under a "shelf" registration statement provided same is available, in accordance with the provisions of the Securities Act.	\$ 4,000,000	\$ 4,000,000
Repayments from inception to date	-	-
Remaining balance	4,000,000	4,000,000
Subsequent to the reporting period the Company on July 2, 2014, (the "Closing Date"), the Company accepted a subscription in the amount of \$5,000,000 for a 10% Coupon Series C Convertible Debenture (the "Debenture") from Dr. Milton Boniuk, a member of the Company's Board of Directors (the "Holder"). The \$5,000,000 funding of the Debenture had been received by the Company prior to June 30, 2014, the year end reporting period and the Company has reported the said Debenture in these financial statements under long term liabilities. The	5,000,000	5,000,000

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. Interest for the first quarter ending September 30, 2014 has been accrued and will be paid over the remaining life of the Debenture commencing July 1, 2015.

Repayments from inception to date	-	-
Remaining balance	5,000,000	5,000,000
	\$ 9,000,000	\$ 9,000,000

Pursuant to an Exclusive License Agreement we entered into with TheraCour Pharma, Inc., (TheraCour), the Company was granted exclusive licenses in perpetuity for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. In consideration for obtaining this exclusive license, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed. (2) we will pay \$25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour, (3) we will pay \$2,000 or actual costs, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf. (4) we will make royalty payments (calculated as a percentage of net sales of the licensed drugs) of 15% to TheraCour Pharma, Inc. (5) and agreed that TheraCour Pharma, Inc. retains the exclusive right to develop and manufacture the licensed drugs. TheraCour Pharma, Inc. agreed that it will manufacture the licensed drugs exclusively for NanoViricides, and unless such license is terminated, will not manufacture such product for its own sake or for others.

**Note 5 - Concentrations**

Vendor purchase concentrations for September 30, 2014 and 2013 are as follows:

	Net Purchases				Accounts Payable			
	For the three months ended September 30, 2014		2013		As of September 30, 2014		2013	
TheraCour Pharma, Inc	769,185	45.6 %	924,126	48.9 %	331,448	68 %	1,139,825	73.6 %
Kard Scientific, Inc.	-	0 %	247,660	13.1 %	123,570	25.4 %	246,963	16.0 %
<b>Total Purchases</b>	<b>1,687,133</b>	<b>100 %</b>	<b>1,888,782</b>	<b>100 %</b>	<b>487,426</b>	<b>100 %</b>	<b>1,547,883</b>	<b>100 %</b>

**Note 6 - Property and Equipment**

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

	September 30, 2014	June 30, 2014
GMP Facility	\$ 3,551,713	\$3,099,780
Office Equipment	30,048	30,048
Furniture and Fixtures	1,400	1,400
Lab Equipment	3,716,093	3,605,514
Total Property and Equipment	7,299,254	6,736,742
Less Accumulated Depreciation	(1,291,318 )	(1,239,986)
Property and Equipment, Net	\$ 6,007,936	\$5,496,756

Depreciation expenses for the three months ended September 30, 2014 and 2013 were \$51,332 and \$52,719, respectively.

**Note 7 - Trademark and Patents**

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

	September 30, 2014	June 30, 2014
Trademarks and Patents	\$ 458,954	\$458,954
Less Accumulated Amortization	(52,889 )	(50,696 )
Trademarks and Patents, Net	\$ 406,065	\$408,258

Amortization expense amounted to \$2,193 and 2,193 for the three months ended September 30, 2014, and 2013, respectively.

**Note 8 - Prepaid Expenses**

Prepaid Expenses are summarized as follows:

	September 30, 2014	June 30, 2014
TheraCour Pharma, Inc.	\$ 424,402	\$709,221
Prepaid Others	59,099	108,089
	\$ 483,501	\$817,310

## Note 9 - Equity Transactions

On September 5, 2014, NanoViricides, Inc. (the "Company") accepted notices to exercise old warrants for the purchase of an aggregate of 2,136,655 shares of the Company's common stock at the exercise price of \$3.50 per share for aggregate proceeds of \$7,478,292.50. On July 17, 2014, the Company filed a registration statement on Form S-3 (the "Form S-3") registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009, ("old warrants") as described more fully in the Form S-3 (the "Registered Warrants"). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. As of August 15, 2014, any Registered Warrants as specified above and not previously exercised have expired.

### Unregistered Securities

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").

On July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debentures, the Company issued 187,000 Shares of its Series A Convertible Preferred stock to Dr. Milton Boniuk as additional interest, pursuant to the terms of the Debenture. The Company recognized a charge of \$1,645,606 as a discount of the Series C Debenture which will be amortized over the remaining life of the Debenture under the straight line method. For the three months ended September 30, 2014 the Company recognized \$102,850 amortization of this discount as a charge to "Discount on convertible debentures".

In August, 2014, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,148 shares of common stock at \$5.02 per share expiring in August, 2018. These warrants were valued at \$22,292 and recorded as consulting expense.

For the three months ended September 30, 2014, the Company's Board of Directors authorized the issuance of 7,716 shares of its Series A Convertible Preferred stock for employee compensation. The Company recorded an expense of \$72,980.

For the three months ended September 30, 2014, the Company's Board of Directors authorized the issuance of 2,059 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of

\$27,000.

For the three months ended September 30, 2014, the Company's Board of Directors authorized the issuance of 2,856 shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of \$11,250.

The Company estimated the relative fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

	August 15, 2014	
Expected life (year)	4	
Expected volatility	91.68	%
Expected annual rate of quarterly dividends	0.00	%
Risk-free rate(s)	1.2	%



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. The Company, therefore, estimated the relative fair value of the Preferred A shares granted to various Employees on the date of grant. The Preferred Series A shares fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; ii) the value of the voting rights since the holder would lose the voting rights upon conversion. The conversion of the shares is triggered either by the Company or a Change of Control. The valuations of the Series A Preferred Stock as of 9/30/14 used the following inputs:

a. The common stock price (post-reverse split) was in the range \$3.90 to \$4.16;

b. 54,614,930 to 56,450,000 shares outstanding and Series A Preferred shares with 2,572 (post-split 9/10/13) issued monthly ;

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

d. 63,899,777 to 65,193,001 total voting shares and the monthly shares representing voting rights of 2.425% to 2.448% 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 3/1/13 and a remaining restricted term of 2.59 to 2.42 years;

f. 35.53% to 31.95% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 87.68% to 91.87% volatility, 0.47% to 0.58% risk free rate) applied to the converted common.

## **Note 10 - Stock Options and Warrants**

### Stock Options

In September 2005, 142,857 stock options were granted to Eugene Seymour, our CEO under an employment agreement. Of these options, 71,429 were vested immediately and are exercisable from September 2005 until September 2015, and the remaining options vested annually on January 1, 2007 and 2008 in two equal amounts.

In September 2005, 285,715 stock options were granted to Anil Diwan, our Chairman and President under an employment agreement. Of these options, 95,238 were vested immediately and are exercisable from September 2005 until September, 2015, and the remaining options vested annually on January 1, 2007 and January 1, 2008 in two equal amounts.

In September 2005, 142,857 stock options were granted to Leo Ehrlich, our former CFO under an employment agreement. Of these options, 71,429 were vested immediately and are exercisable from September 2005 until September 2015, and the remaining options vest annually in two equal amounts. On May 16, 2007, Leo Ehrlich

resigned as the Company's Chief Financial Officer. At time of his resignation 107,143 options were vested and are exercisable from September 2005 until September 2015. The remaining options were forfeited.

The Company has accounted for these options granted to officers under the provisions of paragraph 718-10-30 of the FASB Accounting Standards Codification" and after giving effect to the 3.5 to 1 reverse split of September 9, 2013. Based on fair market value of these options, \$7,044 was recognized as stock based compensation expense for the years ended June 30, 2009. For the three months ended September 30, 2014 and 2013, the Company did not record any compensation expense related to these options.

The following table presents the combined activity of stock options issued for the reporting periods ended September 30, 2014 as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding at June 30, 2014	535,715	0.35	1.23	2,094,643
Granted	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding at September 30,2014	535,715	0.35	0.98	1,451,780

As of September 30, 2014 there was no unrecognized compensation cost.

#### Stock Warrants

Stock Warrants	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding at June 30, 2014	8,894,355	5.01	2.78	2,278,458
Granted	17,148	4.18	3.88	-
Exercised	1,926,656	-	-	-
Expired	1,059,616	-	-	-
Canceled	-	-	-	-
Outstanding at September 30,2014	5,925,231	5.15	3.86	113,571

Of the above warrants, 277,143 expire in fiscal year ending June 30, 2015; and 68,571 expire in fiscal year ended June 30, 2016; 68,571 expire in fiscal year ending June 30, 2017; 127,487 in fiscal year ending June 30,2018; 5,383,460 in fiscal year ending June 30, 2019.

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

Operating Lease

The Company's principal executive offices are located at 135 Wood Street, West Haven, Connecticut, and include approximately 7,000 square feet of office and laboratory space at a base monthly rent of \$8,695. The term of lease expired on February 28, 2011 and is now on a month-by-month basis.

Total rent expense at 135 Wood Street, West Haven, Connecticut amounted to \$26,085 and \$26,085 for the three months ended September 30, 2014 and 2013, respectively.

On February 11, 2013, the Company entered into a binding Memorandum of Understanding (“MOU”) with Inno-Haven, LLC, a Connecticut Limited Liability Company (“Inno-Haven”), to lease for a four-year term a 18,000 square foot building located at 1 Controls Drive, Shelton, Connecticut (the “Leased Premises”), and for Inno-Haven to initiate renovation of the facility at the Company’s direction. The Company has filled out and completed such renovations as it determined were necessary for its specific use as a laboratory and GMP clean room drug manufacturing. Inno-Haven is controlled by Anil Diwan, the Company’s founder, President and Chairman and controlling shareholder of TheraCour Pharma, Inc., the Company’s principal shareholder (“TheraCour”). The MOU is subject to a definitive lease agreement (the “Lease Agreement”) to be executed upon final determination of the cost of the laboratory and GMP clean room, and which would contain definitive terms regarding rent, taxes, utilities, maintenance and other, similar items. Pursuant to the MOU, the Company has agreed to provide up to \$2,000,000 in cash collateral for sums borrowed by Inno-Haven (collectively, the “Loans”) to complete the build-out and renovation of the Leased Premises for the benefit of the Company. The Company agreed to file a registration statement for shares of its restricted Common Stock, provided by TheraCour Pharma, Inc., as additional collateral for any or all of the Loans (the “Registrable Shares”). The Company shall file a registration statement within ninety (90) days of a closing of a Loan (a “Closing”) to cover such Registrable Shares and use its best efforts to have such registration statement declared effective no later than one hundred eighty (180) days following the Closing, and keep such registration statement effective until the termination of the respective collateral agreement, upon request to do so by Inno-Haven. The MOU further provides that, so long as there is no breach of the Lease Agreement by the Company, any distribution of the collateral in accordance with a Loan will first be made from the proceeds of life insurance policies (if applicable), then from the proceeds of the sale of the Registrable Shares, and then, should there be any balance still owing to the lender, from the cash collateral.

On February 11, 2013, pursuant to the provisions of the MOU, the Company transferred \$1,000,000 as cash collateral (the “Cash Collateral”) and agreed to register a number of shares of the Company’s Common Stock, which shares were provided by TheraCour Pharma, Inc., equal to \$1,000,000 (the “Collateral Shares”) as collateral pursuant to a Loan and Security Agreement entered into between Inno-Haven and a non-affiliated lender (the “Loan Agreement”) for a loan in the principal amount of \$2,000,000. On September 17, 2013, The Company transferred the remaining \$1,000,000 cash collateral to Inno-Haven. The value of the Collateral Shares shall be determined every three months and, in the event that the current number of shares of the Common Stock is less than \$1,000,000, Inno-Haven may deposit, and the Company shall register, additional shares to equal the aforesaid \$1,000,000. Alternatively, Inno-Haven may deposit cash equal to the difference between \$1,000,000 and the value of the Collateral Shares. Moreover, Inno-Haven is required to obtain a life insurance policy to insure the life of Dr. Diwan in the amount of \$2,000,000. If Dr. Diwan dies during the term of the Loan Agreement, the lender shall have the option to demand payment of the balance of the loan, but, shall be repaid first from the proceeds of any life insurance policy (if applicable), then from the proceeds of the sale of the Collateral Shares, and then, should there be any balance still owing to the lender, from the Cash Collateral. As of September 30, 2014, the Company has utilized approximately \$4.5 million for specific fixtures and improvements it required for the new laboratory and cGMP facilities.

No lease agreement has been perfected with Inno-Haven to date. The Company engaged external consultants to help determine whether to lease this facility or to purchase it outright from Inno-Haven. Subsequently, the Company’s Board of Directors has authorized the acquisition of 1 Controls Drive from Inno-Haven in an amount equal to its costs in acquiring and fitting out 1 Controls Drive on the Company’s behalf.

Total rent expense paid to Inno-Haven during this period amounted to \$-0- for the Three months ended September 30, 2014 and \$-0- since February 11, 2013.

### Legal Proceedings

On or about January 18, 2012, the Nevada Agency and Transfer Company, as agent for service of process for the Company in Nevada, was served with a Summons and Complaint in the case entitled Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and NanoViricides, Inc. (Case No. A-12-654437-B) answerable in the Eighth Judicial District Court of the State of Nevada – Clark County (“Court”). The Complaint seeks to compel inspection of the Company’s books and records. On or about February 14, 2012 we filed a Motion to Dismiss the Complaint for failure to state a claim upon which relief can be granted. The Complaint further seeks unspecified “injunctive relief” in furtherance of the demand for inspection to which it is not entitled. The Complaint by a holder of less than 1 percent of the common stock of the Company seeks to, inter alia, inspect documents and records of the company to which it is not entitled and in a form and manner the Company argues is not authorized by statute. Management believes that this lawsuit has no merit or basis and intends to vigorously defend it. Monetary damages have not been claimed and as a result no accrual has been made in relation to this litigation. On April 9, 2012, the Court dismissed the Complaint for failure to state a Claim for which relief could be granted.

On or about April 13, 2012, the Nevada Agency and Transfer Company, as agent for service of process for the Company in Nevada, was served with a Summons and Complaint in the case entitled Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and NanoViricides, Inc. (Case No. A-12-659535-B) answerable in the Eighth Judicial District Court of the State of Nevada – Clark County (“Court”). The Complaint seeks to compel inspection of the Company’s books and records. On or about May 2, 2012, the Company filed a Demand for Security of Costs. Upon filing of the Demand, proceedings relative to the Company are stayed pending posting of the demanded security (or plaintiff engages in motion practice about the Demand). The Company may seek dismissal of the complaint if plaintiff has not posted the demanded security (or engaged the court). The Complaint further seeks unspecified “injunctive relief” in furtherance of the demand for inspection to which the Company believes it is not entitled. The Complaint, by a holder of less than 1 percent of the common stock of the Company, seeks to, inter alia, inspect documents and records of the company to which it is not entitled and in a form and manner the Company argues is not authorized by statute. On or about July 18, 2012, the Plaintiff moved to amend its answer. On or about August 8, 2012, we filed our opposition to Plaintiff’s Motion to Amend and a Motion to Dismiss the Complaint for failure to state a claim upon which relief can be granted. On or about September 13, 2012 the court granted the Plaintiff’s Motion to Amend. On or about September 17, 2012 the Plaintiff served its “Second Amended Shareholder Derivative Complaint” upon our Counsel in Nevada. As in the prior two complaints that this Plaintiff has filed in this action, the Second Amended Complaint sought to compel inspection of the Company’s books and records, sought injunctive relief, an accounting and alleges breach of Fiduciary by Dr. Seymour and Dr. Diwan. On or about October 11, 2012, we filed a Motion to Dismiss the Second Amended Complaint for failure to state a claim upon which relief can be granted. On or about December 4, 2012, the Court granted the Company’s Motion to Dismiss with respect to Dr. Seymour and Dr. Diwan and ordered the case dismissed as to all claims but the Plaintiff’s request to compel documents required to be maintained by the Company’s registered agent in Nevada pursuant to NRS 78.105. On or about December 26, 2012, the Company provided the Plaintiff with each of the documents to which it is entitled. Management believes that the Plaintiff does not have a legal or good faith basis for inspection or copying of its shareholder’s list and intends to vigorously defend the production thereof. In May, 2013, the Plaintiff filed a motion for permission to file a third amended complaint. The Company subsequently filed a motion to dismiss and for Summary Judgment. The Court denied the Motion to Dismiss and for Summary Judgment and ordered the Plaintiff to file its Third Amended Complaint. On or about July 15, 2013 the Company Petitioned the Nevada Supreme Court for a Writ of Prohibition or Mandamus reversing the trial Court’s denial of Summary Judgment. Thereafter, on or about September 20, 2013, the Nevada Supreme Court denied the Company’s Writ Petition. The Company filed its answer to the Third Amended Complaint, which contains only one cause of action which is identical to the sole cause of action which was not dismissed from the Second Amended Complaint. Specifically, the Third Amended Complaint seeks only to compel production of books and records required to be maintained by the Company’s Registered Agent pursuant to NRS 78.105 Management believes that the Company’s registered Agent has provided the Plaintiff with all documents to which it is entitled pursuant to NRS 78.105 and that this lawsuit has no merit or basis. The Company has vigorously defended this lawsuit. Following cross-motions for summary judgment and certain discovery as limited by the court, the parties engaged in a settlement conference in March 2014, at which time an agreement was reached resolving the parties’ disputes in this matter. Pursuant to the Settlement Agreement, the Company deposited \$150,000 with its attorney to be released to reimburse the Plaintiff for a portion of its litigation expenses. However, disagreements later arose regarding the negotiated resolution, precipitating, among other things, the Company’s application for court intervention and repeated status hearings. Final settlement documents were fully exchanged on September 11, 2014. Upon the Plaintiff’s compliance with the terms of the Settlement Agreement, the Company authorized counsel to release the reimbursement amount to the Plaintiff. An order dismissing the foregoing lawsuit was entered on September 16, 2014.

On or about July 15, 2013 the same Plaintiff that had filed the repetitive complaints in the Nevada action as set forth in the preceding paragraphs (Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and NanoViricides, Inc.) filed a

Shareholder Derivative complaint with the United States District Court for the District of Colorado. The Plaintiff asserted the action is a shareholder derivative action and the Company is solely a nominal defendant. The Company maintains that it, as well as the individual defendants, Messrs. Seymour and Diwan, have not been served in the action. However, a default was filed against the Company, which has been vacated. The Complaint alleges that the Company has failed to deliver information requested by the Plaintiff, the identical information the Plaintiff is seeking inspection of in the Nevada action, and that the individual defendants, Messrs. Seymour and Diwan, breached their fiduciary duties to the Company and caused it financial harm. The Plaintiff demanded an order to inspect the Company's records, an order revoking Messrs. Diwan and Seymour from the Board of Directors, equitable relief, and consequential and punitive damages. The Company believes these claims had no merit and defended this action vigorously. The Company moved the District Court to dismiss the action in its entirety. No facts have been submitted to support the claimed vague consequential and punitive damages. Management has determined that such claims are specious and not relevant to the Company and no accrual has been made in relation to this litigation. The action was settled and dismissed with prejudice pursuant to the Settlement Agreement in the above referenced Nevada action. Similarly, upon the Plaintiff's compliance with the terms of the Settlement Agreement, the Company authorized counsel to release the reimbursement amount to the Plaintiff. An order dismissing the foregoing lawsuit was entered on September 16, 2014.



There are no other 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.

#### **Note 12 - Subsequent Events**

Management has evaluated all events that occurred after the balance sheet date through the date when these financial statements were issued to determine if they must be reported. The Management of the Company has determined that the following reportable subsequent event is required to be disclosed:

On October 31, 2014, the Company filed a Registration Statement on Form S-3 (the "Registration Statement") with the Securities and Exchange Commission (the "Commission"). The Registration Statement is a "universal" shelf registration statement for the registration of up to \$50 million of our common stock, preferred stock, warrants, debt securities and units comprised of any or all of such securities. If and when the Registration Statement is declared effective, the Company will be able to offer and sell, from time to time, up to \$50 million of securities, including shares of the Company's common stock and preferred stock, debt securities, warrants, and units, the terms of which will be described in prospectus supplements filed with the Commission, as applicable. Such securities may not be sold, nor may offers to buy be accepted, until the Registration Statement is declared effective by the Commission.

## **PART I**

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

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

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

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

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

### **ITEM I: BUSINESS**

**Organization and Nature of Business**

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

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

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

The Company develops its drugs, that we call a nanoviricide®, using 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. Many different kinds of viruses are likely to get destroyed in the process.

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

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

In August 2014, we announced that we restarted our anti-Ebola drug development program. An Ebola virus epidemic began in western Africa with an index case in December 2013. The epidemic was identified only in March/April 2014, as it began to spread into multiple countries. It has continued to expand rapidly geographically, and also to grow exponentially in spite of the serious efforts by the international community to contain it. As of November 4, 2014, the World Health Organization (WHO) has reported a total of 13,227 suspected cases and 5,285 deaths. The overall case fatality rate is estimated at 71%, based on clinical outcomes (See, Wikipedia article ([http://en.wikipedia.org/wiki/Ebola\\_virus\\_epidemic\\_in\\_West\\_Africa](http://en.wikipedia.org/wiki/Ebola_virus_epidemic_in_West_Africa))). Certain estimates by epidemiologists working with international organizations have projected that the epidemic may continue for another 12 to 18 months before it can be brought under control. This could cause not only major regional devastation, but also a significant global impact. Sporadic cases have occurred elsewhere in the world, including the United States, which were due to persons infected with Ebola virus traveling to other countries. Secondary infections from such patients mainly to health care workers have also occurred. However, these local outbreaks outside of West Africa have been successfully controlled so far with strong case management protocols as well as public health measures, including quarantine.

Currently there are neither any drugs nor vaccines against Ebola, although some vaccines and some drug candidates have advanced into clinical trials. The current epidemic Ebola virus, a Zaire Ebola virus variant, has been shown by to mutate in the field frequently. This raises significant doubts regarding the success of standard antiviral approaches including vaccines, antibodies, antisense technologies, and siRNA approaches. In spite of the mutations, however, the cognate receptor of the virus on the cells and how the virus binds to it does not change. Fortunately, this receptor has now been identified for Ebola virus, as the Niemann-Pick C1 protein (NPC1), a cholesterol transporter whose function is essential for health. An approach of blocking NPC1, similar to the development of maraviroc to block CCR5 and thereby affect HIV/AIDS, is unlikely to be successful, because NPC1 function is essential to human health. In contrast, the nanoviricides approach of attacking the virus by presenting to the virus like a cell membrane studded with the same binding sites which the virus binds to, namely its site on NPC1, shows significant promise. Sufficient

structural information has been elucidated recently about Ebola virus-NPC1 interaction that it has become possible for us to develop novel drug candidates against Ebola that the virus is unlikely to escape.

The Company has completed design of several anti-Ebola ligands based on this information as well as additional proprietary information. Anti-Ebola nanoviricide drug candidates based on these novel ligands are currently being synthesized.

In October 2014, the Company announced that it had signed a Cooperative Research and Development Agreement-Material Transfer Agreement (CRADA-MTA) with US Army Medical Research Institute for Infectious Diseases (USAMRIID). USAMRIID will be able to perform cell culture as well as animal testing of the Company's new anti-Ebola drug candidates under this Agreement. Should a successful candidate be identified, further development towards an Investigational New Drug (IND) Application and clinical studies as well as usage in the field in the current epidemic in West Africa is possible. The World Health Organization (WHO) has recently established guidelines for use of un-licensed novel anti-Ebola drug candidates in the field in an effort to help control the current epidemic.

The Company has the ability to produce requisite large quantities of such a drug candidate in its new cGMP-capable manufacturing facility in Shelton, CT.

We continue to achieve very strong performance in the testing of these drug candidates. All of our biological testing is conducted by third parties.

As part of the advanced IND-enabling development of our Injectable FluCide drug candidate, we have continued to scale up our production processes for both the backbone polymer and the ligands. We have been able to make up to 200g batches in our existing facility. We believe that we will be able to make as much as a few kilograms in a single batch in the new cGMP-capable facility. If the course of treatment of a successful Ebola drug candidate is assumed to be a few grams, we would be able to make as many as a thousand courses of treatment per batch. Our production capacity could thus be responsive to the current requirements for the containment of the Ebola epidemic in West Africa.

Much of our R&D work, until undertaking the Ebola program on a "war footing", was focused on the IND-enabling development of our anti-influenza drug candidate, Injectable FluCide. We have been actively studying different chemical processes and routes of synthesis of the backbone polymer, the ligand, and the nanoviricide drug itself, which is a chemical conjugate of the two. The objective of these studies is to develop pathways that will allow industrial manufacturing scale production of a well-defined drug substance, so that multiple batches will produce consistent product. Our studies also involve the development of methods of chemical and physical characterization of the materials at various stages in the entire production process. These studies also include performing the syntheses at different scales, and at least sufficiently characterizing the products at different stages to enable decision-making regarding different possible process variations. We are also continuing to develop additional tests that are needed for analyses of samples from animals that will be generated during the safety/toxicology studies, and later in the human clinical trials. Such tests are needed for estimating a drug's distribution pattern in the body as well as the time profile of the distribution. Such tests are also needed to decipher the metabolic fate of the drug. Since a nanoviricide drug is

not a simple small chemical or an antibody, development of these tests is relatively complex, and is taking a significant amount of time. The work on FluCide continues, albeit at a reduced pace, due to the urgency of the anti-Ebola drug development program.

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

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

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

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

The Company is currently performing process development and scale up studies on its FluCide drug candidate in its existing facilities. This activity is comprised of three parts: (a) Scale-up and characterization studies of the selected broad-spectrum anti-influenza ligand in FluCide; (b) Scale-up and characterization of the nanomicelle-forming



polymer in FluCide; and (c) Scale-up and characterization of the FluCide resulting from chemical conjugation of the ligand with the nanomicelle. The scale-up studies were necessitated to be performed at this early stage of our drug development because of the extremely high safety of FluCide that resulted in a very large quantity requirement for the GLP Safety/Toxicology studies. The limitations of the current laboratory facilities impose that we produce these materials in multiple batches at present, resulting in extended production and characterization time periods. We were able to perform production of 200g batch in our current facilities. This quantity allowed us to initiate certain safety studies.

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

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

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

We assembled a marquee team of experts to help with the design, engineering, architecture, and construction of this facility. Mr. Andrew Hahn continues to provide overall stewardship for this project. He was formerly Senior Director of Engineering, Pharmaceutical Facilities, Global Engineering, at the Bristol-Myers-Squibb Company Worldwide Medicines Group (BMS). He has almost 30 years of experience in architecture, design and project management in the creation of new and refurbished facilities at Bristol-Myers Squibb Company. Mr. Phil Mader and his firm, MPH Engineering, LLC (“MPH”), continue to help with the overall project management and design engineering of the laboratory and cGMP pilot production facility. Prior to founding MPH, from 2000 to 2007, Phil Mader served as the Senior Capital Project Manager at Bristol-Myers Squibb Company in Wallingford, CT (“BMS”). He was involved in the design, implementation, and commissioning of various biology and chemistry laboratory projects within budget and in a timely manner. Ms. Kathyann Cowles of ID3A, LLC, serves as the Principal Architect. Ms. Cowles, co-founder of Id3A, has over thirty years of experience as a licensed Architect and Senior Project Manager for diverse and complex design and construction projects in the academic, science, technology, corporate and research sectors. This team worked with the expert advice and guidance of the Company’s Scientific Advisor, Dr. Harmon Aronson. Dr. Aronson is a well-known cGMP consultant in the pharmaceutical industry, and was formerly Vice President of Quality Management at Biocraft Laboratories, a company that was acquired by Teva Pharmaceuticals.

We evaluated the lease versus purchase option regarding this facility. We commissioned an independent consultant report to help us with this decision. Based on this report, the Board of Directors has authorized the purchase of this facility. As such, the Company has not entered into a lease of the building as of the date of this report. Inno-Haven, LLC has agreed to sale of the building to the Company for the payment by the Company of all of Inno-Havens costs and expenses in acquiring and constructing the facility. The total costs of Inno-Haven are being determined in order to effect this purchase.

We will need to set up new equipment at this facility and ensure that its performance is adequate. Thereafter we will need to conduct several validation studies and also establish our new laboratories in the new facility. In addition, we will need to set up cGMP compliant systems for working in this new facility. We will need to establish the scaled up manufacturing processes of our drug candidates under cGMP guidelines in this facility. Only after that, the Company will be able to make cGMP-like material using the same processes as c-GMP material but prior to undergoing the FDA registration process. Such c-GMP-like product can be used for clinical batches for human clinical studies in

several countries around the world. The Company is currently investigating all such options in order to expedite the timeline to entering human clinical trials. The Company intends to contract out clinical batch fulfillments to outside established contract manufacturers.

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

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

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

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

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

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

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

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

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

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

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

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

We have continued to successfully raise financing. We had previously completed a \$6M convertible debentures placement with our prior investors with long positions in February, 2013. In addition, we completed a registered direct offering of approximately \$10M on September 9, 2013, after reverse-split of our common stock by a factor of 3.5 old common shares for 1 new common share. With the newly established stock price, subsequently, we met the eligibility criteria for both NASDAQ and NYSE MKT. On September, 25, 2013, the Company's common stock began trading on the NYSE MKT exchange under the symbol NNVC. This up-listing from OTC bulletin board was the culmination of a year long effort spearheaded by Dr. Anil R. Diwan, our founder. The Company had announced at its annual meeting on January 16, 2013, that it had undertaken an initiative to improve its corporate governance, build a stronger and independent board of directors, and prepare the Company for uplisting to a major national exchange. The Company studied and evaluated the processes and performance at the major national exchanges and determined that it was in the best interests of our shareholders to uplist to NYSE MKT. This uplisting was a major milestone for the Company and an important advance in the Company's corporate lifecycle. Subsequent to the uplisting, we raised approximately \$20M in January 2014, in a Registered Direct Offering. Later, in July, 2014, we sold convertible debentures worth \$5M. In addition, in September 2014, we accepted exercises of our old warrants at \$3.50 per share, for a total of approximately \$6.74M.

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

With these recent financings, as of September 30, 2014, the Company has current assets including security deposits and prepaid expenses of approximately \$42.6M. The Company continues to be frugal in its expenditures, and has successfully held the rate of operational cash expenditures at approximately \$1.69M this quarter. We believe we have sufficient funds in hand for more than two years of operations at the current rate of expenditure, and including the projected expenditures.

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

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

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

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

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

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

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

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

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

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



priority than our other drug development programs.

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

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

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

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

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

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

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

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

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

substantial efficacy, almost matching the effectiveness of the injectable form given at 0.3X of the oral dosage level.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In March through May 2011, the Company reported that further chemistry optimization led to dramatically improved antiviral efficacy with its optimized FluCide™ drug candidates in its most recent animal study. In the influenza mouse lethal infection model, animals treated with one of the optimized FluCide™ nanoviricide drug candidates survived beyond the stated full duration of study (21 days), and those treated with two additional drug candidates survived almost the full duration of the study. Animals in these three groups survived significantly longer (20.2 to 22.2 days) as compared to the animals treated with Oseltamivir (Tamiflu®) only 8.3 days. In addition, the post-infection treatment with these optimized FluCide™ drug candidates resulted in dramatic reduction in the number of lung lesions that are caused by a lethal influenza virus infection. Four days post virus infection, animals treated with three of the optimized FluCide™ nanoviricide drug candidates exhibited greater than 95% reduction in the number of lung lesions as compared to the infected yet untreated control animals (p-values < 0.001). In contrast, animals treated with Oseltamivir

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

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

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

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

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



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

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

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

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

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

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

This Report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "NNVC believes," "management believes" and similar language. The forward-looking statements are based on the current expectations of NNVC and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report. Actual results may differ materially from

results anticipated in these forward-looking statements. We base the forward-looking statements on information currently available to us, and we assume no obligation to update them.

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

The nanomedicine technologies developed by TheraCour Pharma, Inc. serve as the foundation for our intellectual property. The Company holds a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus. The Company has entered into an Additional License Agreement with TheraCour granting the Company the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types: Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses. The Company may want to add further virus types to its drug pipeline. The Company would then need to negotiate with TheraCour an amendment to the Licensing Agreement to include those of such additional viruses that the Company determines it wants to follow for further development. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy.

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

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

As the Company's drug candidates progress towards human clinical studies, it has become necessary to enable that they can be produced under "current Good Manufacturing Practices" (cGMP) guidelines of the US FDA, and other applicable international guidelines (such as WHO and ICH guidelines, as well as other country-specific and region-specific guidelines). In the US, the US FDA requires that at least two validated and consistent batches of the drug be produced under cGMP conditions before any human clinical trials can be allowed. Some other countries may allow research product materials for certain phases of human clinical trials. The Company's management has studied the possibilities of contract manufacturing of its drug candidates over the last several years and has concluded that building a small pilot scale manufacturing facility where the special needs of the manufacture of its nanomedicines can be met is the most appropriate solution. This approach provides the highest level of control over the quality of the materials and also keeps the intellectual property of the Company well protected. However, the Company lacked the capital and financial resources to engage into such an expensive project. In 2011, Anil R. Diwan, the Company's co-founder, created a separate entity, Inno-Haven, LLC ("Inno-Haven"), and independently began the development of a nanomedicines manufacturing facility. Inno-Haven purchased an 18,000 sq. ft. light manufacturing building on a 4.2 acre land lot in Shelton, Connecticut in August, 2011. The purchase and related costs were financed by Dr. Diwan through his personal savings, and the sale of NanoViricides common stock that he had acquired as a founder, that netted approximately \$900,000 after expenses and income taxes. Dr. Diwan disposed of his shares in accordance with a 10b5-1 trading plan which concluded in October, 2011. Inno-Haven has also obtained additional financing from certain other unrelated parties. Dr. Diwan had also agreed to provide personal guarantees for potential loans and mortgages which could be drawn for the purpose of financing the building and construction costs.

The Company agreed to provide Inno-Haven the specifications and plans for the cGMP pilot facility and laboratory and office spaces to be built by renovating the existing building. Subsequently, on February 11, 2013, the Company entered into a binding Memorandum of Understanding (“MOU”) with Inno-Haven, to lease these facilities for a four-year term. The MOU is subject to a definitive lease agreement (the “Lease Agreement”) to be executed upon final determination of the cost of the facilities. Pursuant to the MOU, the Company has agreed to provide up to \$2,000,000 in cash collateral for sums borrowed by Inno-Haven (collectively, the “Loans”) to complete the build-out and renovation of the Leased Premises for the benefit of the Company. The Company agreed to file a registration statement for the shares of restricted NNVC Common Stock owned and provided by TheraCour Pharma, Inc., as additional collateral for any or all of the Loans (the “Registrable Shares”). The MOU further provides that, so long as there is no breach of the Lease Agreement by the Company, any distribution of the collateral in accordance with a Loan will first be made from the proceeds of life insurance policies (if applicable), then from the proceeds of the sale of the Registrable Shares, and then, should there be any balance still owing to the lender, from the cash collateral. Also on February 11, 2013, pursuant to the provisions of the MOU, the Company transferred \$1,000,000 as cash collateral (the “Cash Collateral”) and agreed to register a number of shares of the Company’s Common Stock, which shares were provided by TheraCour Pharma, Inc., equal to \$1,000,000 (the “Collateral Shares”) as collateral pursuant to a Loan and Security Agreement entered into between Inno-Haven and a non-affiliated lender (the “Loan Agreement”) for a loan in the principal amount of \$2,000,000. On September 17, 2013, the Company transferred the remaining \$1,000,000 cash collateral to Inno-Haven. Moreover, Inno-Haven is required to obtain a life insurance policy to insure the life of Dr. Diwan in the amount of \$2,000,000. If Dr. Diwan dies during the term of the Loan Agreement, the lender shall have the option to demand payment of the balance of the loan, but, shall be repaid first from the proceeds of any life insurance policy (if applicable), then from the proceeds of the sale of the Collateral Shares, and then, should there be any balance still owing to the lender, from the Cash Collateral.

No lease agreement has been perfected with Inno-Haven to date. The Company engaged external consultants to help it determine whether it would be more economically beneficial to the Company to either lease this facility or to purchase it outright from Inno-Haven. Subsequently, the Company’s Board of Directors authorized the acquisition of 1 Controls Drive from InnoHaven, LLC for the total costs and capital invested by Inno-Haven in acquiring and fitting out 1 Controls Drive. Total rent expense paid to Inno-Haven during this period amounted to \$-0- for the three months ended September 30, 2014 and \$-0- since February 11, 2013.

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

## **The Company’s Drug Pipeline**

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

In addition, the Company restarted its anti-Ebola nanoviricide drug program in response to the current epidemic. We hope that this program may lead to an effective drug against Ebola virus. Currently there are no drugs or vaccines against Ebola.

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

In addition, we recently initiated a research program for the development of a nanoviricide against the MERS Coronavirus (“Middle East Respiratory Syndrome”). Recently, New York Times reported that the first case of MERS infection in the United States was in stable condition. This person, a healthcare worker, flew from Riyadh, Saudi Arabia to Chicago, and then by bus to Indiana ([http://www.nytimes.com/2014/05/03/health/mers-virus-found-in-united-states-for-first-time.html?\\_r=0](http://www.nytimes.com/2014/05/03/health/mers-virus-found-in-united-states-for-first-time.html?_r=0)). MERS is a new coronavirus similar to the SARS virus. It first appeared in 2012 in the Middle East. Since then, about 400 cases have been reported to the World Health Organization; about a third have been fatal. While it has not spread easily between humans, there have been outbreaks within families and in hospitals, where patients have infected paramedics, nurses and doctors, reported the New York Times. The high fatality rate implies that if the virus changes such that its human-to-human transmission is more successful, then this virus can cause significant public health problem, including a potential epidemic.

We were able to create potentially useful drug candidates against MERS-CoV in a very rapid time frame, of less than two months, which included synthesis scale-up to multi-gram quantities. This demonstrates how rapidly drugs can be developed using nanoviricides technology.

Using our platform technology, NanoViricides, Inc. has already developed novel drug candidates against the MERS virus that mimic the MERS virus binding to the host cell. The Company developed ligands that are designed to bind to the MERS coronavirus spike protein, in the same fashion that the cognate receptor of the virus, DPP-IV, binds to the virus. We performed the ligand design using well established molecular modeling techniques, based on published data regarding the MERS coronavirus spike protein and DPP-IV binding. The ligands were then chemically attached to the nanomicelle base polymer, thus making the nanoviricides drug candidates against the MERS virus. The Company has already successfully scaled up the synthesis to multi-gram scale, sufficient for animal testing, and can easily scale the processes to make kilogram quantities for widespread application in human patients if they are found to be effective and safe.

There are no known drugs or vaccines against the MERS coronavirus. No small animal models for testing MERS therapeutics were available until recently. Perlman and collaborators have recently reported a mouse model (<http://www.pnas.org/content/early/2014/03/05/1323279111.abstract>). In this model, mice were infected with adenovirus carrying the DPP-IV gene to make them susceptible to the MERS virus.

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

Given the high fatality rate associated with MERS infections, and small numbers of cases, the regulatory pathway for approval processes is uncertain. However, progress has been made with fatal diseases such as Ebola in defining

clinical pathways, and we anticipate similar development model to be applied for MERS.

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

#### 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 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, 2014, we have current assets plus security deposits of approximately \$42.6 MM that is more than sufficient our operations through more than two years or September 30, 2016, at the Company's current rate of expenditure, and including the projected expenditure for certain human clinical trials.

While we now have the necessary funds based on our current operations to last more than the next 24 months, we anticipate undertaking additional expenditures to accelerate our progress to regulatory submissions. With our current funds we believe that we have sufficient funding available to perform Toxicology Package studies, and additional animal efficacy studies, to move at least one of our drug candidates into an Investigational New Drug Application ("IND") with the US FDA or a similar application with an international regulatory agency, and to conduct Phase I and Phase IIa human clinical trials of at least one of our drug candidates. In order to file an IND application, we also need to enable manufacturing of the drug under US FDA guidelines called cGMP. We intend to purchase from Inno-Haven, LLC, the cGMP manufacturing and R&D facility in Shelton, CT, that was built to our specifications. This facility will enable cGMP manufacture of all of our drug substances. Inno-Haven is managed by its member Dr. Anil R. Diwan, who is our President and Chairman. Inno-Haven raised financing from Dr. Diwan and others, including some earlier investors of NanoViricides, Inc., and has renovated an 18,000 square foot building in Shelton, CT, on a 4.2 acre lot. Dr. Diwan raised additional financing through the sale of his NanoViricides stock that he had obtained as a founder under a 10b5-1 plan that was concluded in October, 2011. Inno-Haven has also raised significant amounts of additional financing through affiliated and un-affiliated parties. A purchase agreement has not been completed as of this report, and the Company is in the due diligence phase regarding this purchase.

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

that we can obtain such additional funding. We believe that we currently have adequate financing for our current business plan of operations.

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

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

1. Research and Development of \$10,000,000: Planned costs for in-vivo and in-vitro studies for pan-influenza FluCide, Eye nanoviricide, HIVCide, HerpeCide, Dengue, MERS-CoV, and Ebola/Marburg and Rabies programs.

2. Corporate overhead of \$2,000,000: This amount includes budgeted office salaries, legal, accounting, investor relations, public relations, and other costs expected to be incurred by being a public reporting company.

3. Capital costs of \$2,000,000: This is the estimated cost for equipment and laboratory improvements.

4. Staffing costs of \$2,000,000: This is the estimated cost of hiring additional scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to FDA compliance, as required for development of necessary data for filing an Investigational New Drug with the United States Food and Drug Administration.

5. Purchase of the 1 Controls Drive Facility. While the price has not yet been finalized, we have budgeted approximately \$5 million for this purchase, in addition to the approximately \$4.5 million we invested in equipment fixtures and the cGMP manufacturing facility.

6. If and when we initiate human clinical trials for Injectable FluCide, we anticipate approximately \$2 million in total costs for the Phase I clinical trials, and approximately \$5 million for the Phase IIa (virus challenge human efficacy study) clinical trials. In a subsequent year, if Phase I and Phase IIa are successful, we anticipate approximately \$10 million for Phase IIb human clinical trials. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional costs. These estimates assume that FluCide is highly effective and therefore would require relatively few patients in each arm of the each trial in order to establish statistically significant results.

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

Due to its current cash position, in addition to certain clinical trials for FluCide and DengueCide, the Company anticipates that it will also be able to expedite development of its four other drug candidates, namely, Oral FluCide, HerpeCide™, HIVCide™, and EKCCide™ into the FDA approval process. In addition, the Company was also able to undertake R&D for a nanoviricide against the Ebola virus.

The Company anticipates it will have sufficient access to capital even if it decides to develop 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 pharmacokinetic and pharmacodynamic profiles of our drug candidates. We believe these data will then enable us to file an Investigational New Drug Application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

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

Management intends to use capital and debt financing, as required, to fund the Company's operations. Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain the additional capital resources necessary to fund its anticipated obligations beyond September 30, 2016. The Company currently has no long term debt other than the convertible debentures as disclosed.

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

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

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

(a) Evaluation of disclosure controls and procedures.

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

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

(a) Based upon an evaluation of the effectiveness of disclosure controls and procedures, our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") have concluded that as of the end of the period covered by the Annual Report on Form 10-K our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC and is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in internal control over financial reporting. The Company has established an independent Board of Directors comprising three independent members. Under this Board the Company has established an Audit Committee, a Compensation Committee, a Nomination Committee, and an Executive Committee. The Company has met or exceeded corporate governance standards of the NYSE MKT, a national exchange. On September 25, 2013, the Company's common stock was listed and began trading on the NYSE MKT.

Management's Report on Internal Control Over Financial Reporting

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

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

#### Changes in Internal Control Over Financial Reporting

On May 13, 2013, the Company appointed Meeta Vyas as its Interim Chief Executive Officer, Meeta Vyas is a seasoned executive with large, public company experience.

In June 2013, the Company completed the process of accomplishing an independent board of directors. Simultaneously, the Company also expanded its Audit Committee, chaired by its Director, Mr. Stanley Glick, CPA, to include two additional Board Members, namely, Professor Mukund Kulkarni and Professor Dr. Milton Boniuk. In addition, the Company formalized its Compensation Committee, and Nomination Committee, with the same three independent board members serving on these committees. The Company further formulated an Executive Committee that reports directly to the Board of Directors. The Company’s CEO, Dr. Eugene Seymour, MD, MPH, and its President, Anil R. Diwan, PhD, are ex-officio members of the Executive Committee.

Other than as described above, there were no material changes in our internal control over financial reporting (as defined in Rule 13a- 15(f) under the Exchange Act) that occurred as of September 30, 2014, 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.

On or around January 18, 2012, the Nevada Agency and Transfer Company, as agent for service of process for the Company in Nevada, was served with a Summons and Complaint in the case entitled Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and NanoViricides, Inc. (Case No. A-12-654437-B) answerable in the Eighth Judicial District Court of the State of Nevada – Clark County (“Court”). The Complaint seeks to compel inspection of the Company’s books and records. On or about February 14, 2012 we filed a Motion to Dismiss the Complaint for failure to state a claim upon which relief can be granted. The Complaint further seeks unspecified “injunctive relief” in furtherance of the demand for inspection to which it is not entitled. The Complaint by a holder of less than 1 percent of the common stock of the Company seeks to, inter alia, inspect documents and records of the company to which it is not entitled and in a form and manner the Company argues is not authorized by statute. Management believes that this lawsuit has no merit or basis and intends to vigorously defend it. Monetary damages have not been claimed and as a result no accrual has been made in relation to this litigation. On April 9, 2012, the Court dismissed the Complaint for failure to state a Claim for which relief could be granted.



On or about April 13, 2012, the Nevada Agency and Transfer Company, as agent for service of process for the Company in Nevada, was served with a Summons and Complaint in the case entitled Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and NanoViricides, Inc. (Case No. A-12-659535-B) answerable in the Eighth Judicial District Court of the State of Nevada – Clark County (“Court”). The Complaint seeks to compel inspection of the Company’s books and records. On or about May 2, 2012, the Company filed a Demand for Security of Costs. Upon filing of the Demand, proceedings relative to the Company are stayed pending posting of the demanded security (or plaintiff engages in motion practice about the Demand). The Company may seek dismissal of the complaint if plaintiff has not posted the demanded security (or engaged the court). The Complaint further seeks unspecified “injunctive relief” in furtherance of the demand for inspection to which the Company believes it is not entitled. The Complaint, by a holder of less than 1 percent of the common stock of the Company, seeks to, inter alia, inspect documents and records of the company to which it is not entitled and in a form and manner the Company argues is not authorized by statute. On or about July 18, 2012, the Plaintiff moved to amend its answer. On or about August 8, 2012, we filed our opposition to Plaintiff’s Motion to Amend and a Motion to Dismiss the Complaint for failure to state a claim upon which relief can be granted. On or about September 13, 2012 the court granted the Plaintiff’s Motion to Amend. On or about September 17, 2012 the Plaintiff served its “Second Amended Shareholder Derivative Complaint” upon our Counsel in Nevada. As in the prior two complaints that this Plaintiff has filed in this action, the Second Amended Complaint sought to compel inspection of the Company’s books and records, sought injunctive relief, an accounting and alleges breach of Fiduciary by Dr. Seymour and Dr. Diwan. On or about October 11, 2012, we filed a Motion to Dismiss the Second Amended Complaint for failure to state a claim upon which relief can be granted. On or about December 4, 2012, the Court granted the Company’s Motion to Dismiss with respect to Dr. Seymour and Dr. Diwan and ordered the case dismissed as to all claims but the Plaintiff’s request to compel documents required to be maintained by the Company’s registered agent in Nevada pursuant to NRS 78.105. On or about December 26, 2012, the Company provided the Plaintiff with each of the documents to which it is entitled. Management believes that the Plaintiff does not have a legal or good faith basis for inspection or copying of its shareholder’s list and intends to vigorously defend the production thereof. In May, 2013, the Plaintiff filed a motion for permission to file a third amended complaint. The Company subsequently filed a motion to dismiss and for Summary Judgment. The Court denied the Motion to Dismiss and for Summary Judgment and ordered the Plaintiff to file its Third Amended Complaint. On or about July 15, 2013 the Company Petitioned the Nevada Supreme Court for a Writ of Prohibition or Mandamus reversing the trial Court’s denial of Summary Judgment. Thereafter, on or about September 20, 2013, the Nevada Supreme Court denied the Company’s Writ Petition. The Company filed its answer to the Third Amended Complaint, which contains only one cause of action which is identical to the sole cause of action which was not dismissed from the Second Amended Complaint. Specifically, the Third Amended Complaint seeks only to compel production of books and records required to be maintained by the Company’s Registered Agent pursuant to NRS 78.105 Management believes that the Company’s registered Agent has provided the Plaintiff with all documents to which it is entitled pursuant to NRS 78.105 and that this lawsuit has no merit or basis. The Company has vigorously defended this lawsuit. Following cross-motions for summary judgment and certain discovery as limited by the court, the parties engaged in a settlement conference in March 2014, at which time an agreement was reached resolving the parties’ disputes in this matter. Pursuant to the Settlement Agreement, the Company deposited \$150,000 with its attorney to be released to reimburse the Plaintiff for a portion of certain litigation expenses. However, disagreements later arose regarding the negotiated resolution, precipitating, among other things, the Company’s application for court intervention and repeated status hearings. Final settlement documents were fully exchanged on September 11, 2014. An order dismissing the foregoing lawsuit was entered on September 16, 2014.

On or about July 15, 2013 the same Plaintiff that had filed the repetitive complaints in the Nevada action as set forth in the preceding paragraphs (Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and NanoViricides, Inc.) filed a Shareholder Derivative complaint with the United States District Court for the District of Colorado. The Plaintiff

asserts the action is a shareholder derivative action and the Company is solely a nominal defendant. The Company maintains that it, as well as the individual defendants, Messrs. Seymour and Diwan, have not been served in the action. However, a default was filed against the Company, which has been vacated. The Complaint alleges that the Company has failed to deliver information requested by the Plaintiff, the identical information the Plaintiff is seeking inspection of in the Nevada action, and that the individual defendants, Messrs. Seymour and Diwan, breached their fiduciary duties to the Company and caused it financial harm. The Plaintiff demands an order to inspect the Company's records, an order revoking Messrs. Diwan and Seymour from the Board of Directors, equitable relief, and consequential and punitive damages. The Company believes these claims have no merit and the Company intends to defend this action vigorously. The Company intends to move the District Court to dismiss the action in its entirety. No facts have been submitted to support the claimed vague consequential and punitive damages. Management has determined that such claims are specious and not relevant to the Company and no accrual has been made in relation to this litigation. An order dismissing the foregoing lawsuit was entered on September 16, 2014.

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

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

On September 5, 2014, NanoViricides, Inc. (the “Company”) accepted notices to exercise old warrants for the purchase of an aggregate of 2,136,655 shares of the Company’s common stock at the exercise price of \$3.50 per share for aggregate proceeds of \$7,478,292.50. On July 17, 2014, the Company had filed a registration statement on Form S-3 (the “Form S-3”) registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009 as described more fully in the Form S-3 (the “Registered Warrants”). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. As of August 15, 2014, any Registered Warrants as specified above and not previously exercised have expired. The Company intends to use the proceeds from these offerings for working capital.

### Unregistered Securities

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”). On July 2, 2014, in conjunction with the issuance of the Company’s Series C Convertible Debentures, the Company issued 187,000 Shares of its Series A Convertible Preferred stock to Dr. Milton Boniuk as additional interest, pursuant to the terms of the Debenture.

In August 2014, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,148 shares of common stock at \$5.02 per share expiring in August 2018.

For the three months ended September 30, 2014, the Company’s Board of Directors authorized the issuance of 7,716 shares of its Series A Convertible Preferred stock for employee compensation.

For the three months ended September 30, 2014, the Company’s Board of Directors authorized the issuance of 2,059 shares of its common stock with a restrictive legend for consulting services.

For the three months ended September 30, 2014, the Company’s Board of Directors authorized the issuance of 2,856 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**

On November 7, 2014, the Company issued 571,433 shares of common stock as additional interest to the holders of its 8% Coupon Series B Convertible Debentures. The securities described were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act and Rule 506 of Regulation D promulgated thereunder. The agreements executed in connection with this sale contain representations to support the Company's reasonable belief that the holders had access to information concerning the Company's operations and financial condition, the holders acquired the securities for their own account and not with a view to the distribution thereof in the absence of an effective registration statement or an applicable exemption from registration, and that the holders are sophisticated within the meaning of Section 4(2) of the Securities Act and are "accredited investors" (as defined by Rule 501 under the Securities Act). In addition, the issuances did not involve any public offering; the Company's made no solicitation in connection with the sale other than communications with the holders; the Company obtained representations from the holders regarding their investment intent, experience and sophistication; and the holders either received or had access to adequate information about the Company in order to make an informed investment decision.

### **ITEM 6. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
31.1	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Executive Officer
31.2	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
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, 2014 Name: Eugene Seymour, M.D.  
Title: Chief Executive Officer and Director  
(Principal Executive Officer )

/s/ Meeta Vyas

Dated: November 14, 2014 Name: Meeta Vyas  
Title: Chief Financial Officer  
(Chief Financial Officer)