

NANOVIRICIDES, INC.  
Form 10-Q  
February 20, 2018

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended December 31, 2017**

*Commission File Number: 001-36081*

**NANOVIRICIDES, INC.**

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

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

**1 Controls Drive**

**Shelton, Connecticut 06484**

*(Address of principal executive offices and zip code)*

(203) 937-6137

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

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, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Yes  No

As of February 20, 2018, there were approximately 63,373,000 shares of common stock of the registrant issued and outstanding.



NanoViricides, Inc.

FORM 10-Q

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NanoViricides, Inc.

## Balance Sheets

	December 31, 2017 (Unaudited)	June 30, 2017
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 12,046,400	\$ 15,099,461
Prepaid expenses	239,532	190,166
Total Current Assets	12,285,932	15,289,627
<b>PROPERTY AND EQUIPMENT</b>		
Property and equipment	13,869,101	13,776,561
Accumulated depreciation	(2,838,422	) (2,505,501 )
Property and equipment, net	11,030,679	11,271,060
<b>TRADEMARK AND PATENTS</b>		
Trademark and patents	458,954	458,954
Accumulated amortization	(79,891	) (75,756 )
Trademark and patents, net	379,063	383,198
<b>OTHER ASSETS</b>		
Security deposits	3,515	3,515
Service agreements	26,900	55,414
Other Assets	30,415	58,929
Total Assets	\$ 23,726,089	\$ 27,002,814
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 75,820	\$ 135,786
Accounts payable – related parties	1,474,836	340,695
Obligation to issue registered shares	5,163,194	-
Debentures payable - Series C, net of discount	-	3,956,153
Derivative liability - Series C debentures	-	32,213
Accrued expenses	25,755	34,004
Deferred interest payable - current portion	-	166,667
Total Current Liabilities	6,739,605	4,665,518
<b>LONG TERM LIABILITIES:</b>		
Derivative liability - warrants	1,068,110	2,015,354
Total Liabilities	7,807,715	6,680,872
<b>COMMITMENTS AND CONTINGENCIES</b>		

STOCKHOLDERS' EQUITY:

Series A Convertible Preferred stock, \$0.001 par value, 8,500,000 shares designated, 4,364,176 and 4,348,744 shares issued and outstanding, at December 31, 2017 and June 30, 2017, respectively	4,364	4,349
Common stock, \$0.001 par value; 150,000,000 shares authorized, 63,372,681 and 63,306,774 shares issued and outstanding at December 31, 2017 and June 30, 2017, respectively	63,371	63,305
Additional paid-in capital	95,781,779	95,382,979
Accumulated deficit	(79,931,140)	(75,128,691)
Total Stockholders' Equity	15,918,374	20,321,942
Total Liabilities and Stockholders' Equity	\$ 23,726,089	\$27,002,814

*See accompanying notes to the financial statements*

Nanoviricides, Inc.

## Statements of Operations

(Unaudited)

	For the Three Months Ended December 31,		For the Six Months Ended December 31,	
	2017	2016	2017	2016
<b>OPERATING EXPENSES</b>				
Research and development	\$ 1,386,135	\$ 1,261,000	\$ 2,541,363	\$ 2,713,137
General and administrative	1,007,646	1,036,618	2,082,864	2,024,930
Total operating expenses	2,393,781	2,297,618	4,624,227	4,738,067
<b>LOSS FROM OPERATIONS</b>	(2,393,781 )	(2,297,618 )	(4,624,227 )	(4,738,067 )
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	24,970	11,734	49,362	25,911
Interest expense on convertible debentures	(60,275 )	(245,000 )	(185,274 )	(490,000 )
Loss on extinguishment of debt	(1,348,247 )	-	(1,348,247 )	-
Discount on convertible debentures	(119,863 )	(423,287 )	(359,214 )	(826,749 )
Change in fair value of derivatives	1,100,302	1,407,771	1,665,151	1,421,062
Other (expense) income	(403,113 )	751,218	(178,222 )	130,224
<b>LOSS BEFORE INCOME TAX PROVISION</b>	(2,796,894 )	(1,546,400 )	(4,802,449 )	(4,607,843 )
<b>INCOME TAX PROVISION</b>	-	-	-	-
<b>NET LOSS</b>	<b>\$(2,796,894 )</b>	<b>\$(1,546,400 )</b>	<b>\$(4,802,449 )</b>	<b>\$(4,607,843 )</b>
<b>NET LOSS PER COMMON SHARE</b>				
- Basic	\$(0.04 )	\$(0.03 )	\$(0.08 )	\$(0.08 )
- Diluted	\$(0.04 )	\$(0.03 )	\$(0.08 )	\$(0.08 )
<b>Weighted average common shares outstanding</b>				
- Basic	63,335,601	58,205,494	63,321,342	58,192,721
- Diluted	63,335,601	58,205,494	63,321,342	58,192,721



NanoViricides, Inc.

Statement of Changes in Stockholders' Equity

For the period from July 1, 2017 through December 31, 2017

(Unaudited)

	Series A Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2017	4,348,744	\$ 4,349	63,306,774	\$63,305	\$95,382,979	\$(75,128,691)	\$ 20,321,942
Series A Preferred Stock issued for employee stock compensation	15,432	15	-	-	312,192	-	312,207
Common stock issued for consulting and legal services rendered	-	-	46,530	47	53,953	-	54,000
Warrants issued to Scientific Advisory Board	-	-	-	-	10,174	-	10,174
Common shares issued for Directors fees	-	-	19,377	19	22,481	-	22,500
Net loss	-	-	-	-	-	(4,802,449 )	(4,802,449 )
Balance, December 31, 2017	4,364,176	\$ 4,364	63,372,681	\$63,371	\$95,781,779	\$(79,931,140)	\$ 15,918,374

See accompanying notes to the financial statements

Nanoviricides, Inc.

## Statements of Cash Flows

(Unaudited)

	<b>For the Six Months ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(4,802,449 )	\$(4,607,843 )
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	312,207	355,335
Common shares issued as compensation and for services	76,500	76,500
Warrants issued to Scientific Advisory Board	10,174	27,145
Common shares issued for interest	-	246,667
Common shares to be issued for debenture interest	60,274	-
Depreciation	332,921	325,720
Amortization	4,135	4,135
Change in fair value of derivative liability	(1,665,151 )	(1,421,062 )
Amortization of debt discount on convertible debentures	359,214	826,749
Loss on extinguishment of Series C Debenture	1,348,247	-
Changes in operating assets and liabilities:		
Prepaid expenses	(49,366 )	79,737
Other assets	28,514	23,375
Accounts payable	(59,966 )	29,535
Accounts payable - related party	1,134,141	(734,830 )
Accrued expenses	(8,249 )	15,987
Deferred interest payable	(41,667 )	(83,334 )
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(2,960,521 )</b>	<b>(4,836,184 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(92,540 )	(24,435 )
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,053,061 )</b>	<b>(4,860,619 )</b>
Cash and cash equivalents at beginning of period	15,099,461	24,162,185
Cash and cash equivalents at end of period	\$ 12,046,400	\$ 19,301,566
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>		
Interest paid	\$ 166,667	\$ 326,667
Non-cash Financing and Investing Activities:		
Obligation to issue shares for Series C debenture payment	\$ 5,739,337	\$ -

Obligation to issue shares for deferred interest	\$ 125,000	\$
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*See accompanying notes to the financial statements*

**NANOIRICIDES, INC.**

**December 31, 2017 AND 2016**

**NOTES TO THE FINANCIAL STATEMENTS**

**(Unaudited)**

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

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

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

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

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

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

to “NNVC”, respectively.

NanoViricides, Inc. is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. NanoViricides is unique in the bio-pharma field in that it possesses its own state of the art facilities for the design, synthesis, analysis and characterization of the nanomedicines that we develop, as well as for production scale-up, and c-GMP-like production in quantities needed for human clinical trials. The biological studies such as the effectiveness, safety, bio-distribution and Pharmacokinetics/Pharmacodynamics on our drug candidates are performed by external collaborators and contract organizations.

We are a company with several drugs in various stages of early development. Our drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. (“TheraCour”), to which we have the necessary exclusive licenses in perpetuity. The first agreement we executed with TheraCour on September 1, 2005, gave us an exclusive, worldwide license for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV-1 and HSV-2), Influenza and Asian Bird Flu Virus. Under the License Agreements, TheraCour Pharma will receive a royalty upon sale of resulting products from NanoViricides. There is no royalty payable to date.

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

## **Note 2 - Summary of Significant Accounting Policies**

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

The accompanying unaudited interim financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission for Interim Reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim financial statements furnished reflect all adjustments (consisting of normal recurring accruals) that 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, 2017 filed with the SEC on September 28, 2017.

For a summary of significant accounting policies, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2017 filed on September 28, 2017.

### *Net Loss per Common Share*

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Basic net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock and potentially outstanding shares of common stock during the period to reflect the potential dilution that could occur from common shares issuable through stock options, warrants, convertible preferred stock, and convertible debentures.

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

	Potentially Outstanding Dilutive Common Shares	
	For the Six Months Ended December 31, 2017	For the Six Months Ended December 31, 2016
Warrants	6,696,724	6,650,996
Total potentially outstanding dilutive common shares	6,696,724	6,650,996

The Company has also issued 4,364,176 shares of Series A Preferred Stock to investors and others as of December 31, 2017. 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 of the Company or the Company’s intellectual property. In the absence of a Change of Control event, the Series A convertible Preferred Stock is not convertible into common stock, and does not carry any dividend rights or any other financial effects. At December 31, 2017, the number of potentially dilutive shares of the Company’s common stock into which these Series A Preferred shares can be converted into is 15,274,616, and is not included in diluted earnings per share since the shares are contingently convertible only upon a Change of Control.

The following represents the basic and diluted per share calculations for loss from continuing operations:

	<b>For the three months ended</b>		<b>For the six months ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	2017	2016	2017	2016
Calculation of basic loss per share of common stock:				
Net loss attributable to common stockholders	\$(2,796,894 )	\$(1,546,400 )	\$(4,802,449 )	\$(4,607,843 )
Denominator for basic weighted average shares of common stock	63,335,601	58,205,494	63,321,342	58,192,721
Basic loss per share of common stock	\$(0.04 )	\$(0.03 )	\$(0.08 )	\$(0.08 )

Series C debentures were excluded from the fully diluted loss per share calculation for the three and six months ended December 31, 2017 because their inclusion is anti-dilutive. Series B and Series C debentures were excluded from the fully diluted loss per share calculation for the three and six months ended December 31, 2016 because their inclusion is anti-dilutive. On November 14, 2017 the Company entered into an agreement with the Holder of the Series C Debenture to redeem the Series C Debenture. See Footnote 7.

#### Recently Issued Accounting Pronouncements

In July 2017, the FASB issued Accounting Standards Update (“ASU”) No. 2017-11. “Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 revises the guidance for instruments with down round



features in Subtopic 815-40, Derivatives and Hedging – Contracts in Entity’s Own Equity, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for annual and interim periods beginning December 15, 2018, and early adoption is permitted, including adoption in an interim period. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of retaining earnings in the fiscal year and interim period adoption. The Company is currently in the process of assessing the impact of this ASU on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, “Stock Compensation (topic 718)”, which includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The standard is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The adoption of this standard on July 1, 2017 did not have a material effect on the Company’s financial position, results of operations or cash flows.

### **Note 3 - Financial Condition**

The Company's financial statements for the interim period ended December 31, 2017 have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business.

The Company has an accumulated deficit at December 31, 2017 of \$79,931,140. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of December 31, 2017, the Company had cash and cash equivalents of \$12,046,400.

Management believes that the Company's existing cash resources are sufficient for its operations at the current rate of expenditures to continue through February 2019. However, management believes that the available funds are insufficient for the Company's projected work, which is beyond our normal pre-clinical development operations, leading towards an Investigational New Drug Application (IND) filing with the U.S. Food and Drug Administration (FDA), to continue through February 2019. The Company has engaged investment banks to advise it as to raising further funding as the Company progresses towards human clinical trials. The Company believes that it can adjust its business plan according to its available resources. Further, the Company believes that it will be able to raise additional funding at an opportune time as it progresses towards human clinical trials. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. Further, the Company cannot provide assurances that it will be able to raise additional funding in a timely manner, and if it can, that it will be on terms favorable for the Company's current shareholders. The accompanying unaudited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

While the Company continues to incur significant operating losses with significant capital requirements, the Company has been able to finance its business through sale of its securities. The Company has in the past adjusted its priorities and goals in line with the cash on hand and capital availability. The Company believes it can adjust its priorities of drug development and its plan of operations as necessary, if it is unable to raise additional funds. The Company has sufficient capital to continue its business for more than one year, at the current rate of expenditure.

### **Note 4 - Related Party Transactions**

Related Parties

Related parties with whom the Company had transactions are:

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

For the three months ended		For the six months ended	
December 31, 2017	December 31, 2016	<b>December 31, 2017</b>	December 31, 2016

Property and Equipment

During the reporting period, TheraCour Pharma, Inc. acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, at cost, to the Company

\$	-	\$	-	\$	-	\$	17,995
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As of  
December  
31,  
2017      June 30,  
2017

Account Payable – Related Party

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

\$1,474,836    \$340,695

For the three months ended		For the six months ended	
December	December	December	December
31,	31,	31,	31,
2017	2016	2017	2016

Research and Development Costs Paid to Related Parties

Development fees and other costs charged by and paid to TheraCour pursuant to exclusive License Agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at December 31, 2017 and June 30, 2017

\$ 923,588	\$ 978,501	\$ 1,770,861	\$ 1,840,116
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As of  
December  
31, 2017      June 30,  
2017

Debentures Payable to a Director

Series C Convertible Debentures - Milton Boniuk    \$-    \$5,000,000

As of  
December  
31, 2017  
June 30,  
2017

Debenture Interest Payable to a Director

Coupon interest payable on \$5,000,000 Series C Convertible Debentures and deferred. The deferred interest was paid quarterly over the term of the debenture commencing September 30, 2015: \$- \$ 166,667

Coupon interest expense on the Series C Debenture to the IRA for Dr. Milton Boniuk for the three months ended December 31, 2017 and 2016 was \$60,275 and \$125,000, respectively, and for the six months ended December 31, 2017 and 2016 was \$185,274 and \$250,000, respectively. The Series C Debenture was redeemed on November 13, 2017.

Coupon interest expense on the Series B Debentures to Dr. Milton Boniuk for the three-months ended December 31, 2016 was \$80,000, and for the six months ended December 31, 2016 was \$160,000. The Series B debenture matured on February 1, 2017.

As of  
December  
31,  
2017  
June 30,  
2017

Securities Issuable to a Director in Redemption of Debentures

Obligation to issue Registered Shares-Milton Boniuk IRA (see footnote 7) \$5,163,194 \$ -

**Note 5 - Property and Equipment**

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

	December 31, 2017	June 30, 2017
GMP Facility	\$ 8,011,230	\$7,996,402
Land	260,000	260,000
Office Equipment	50,385	48,486
Furniture and Fixtures	5,607	5,607

Lab Equipment	5,541,879	5,466,066
Total Property and Equipment	13,869,101	13,776,561
Less Accumulated Depreciation	(2,838,422 )	(2,505,501 )
Property and Equipment, Net	\$ 11,030,679	\$ 11,271,060

Depreciation expense for the three months ended December 31, 2017 and 2016 were \$166,732 and \$162,433, respectively, and for the six months ended December 31, 2017 and 2016 were \$332,921 and \$325,720, respectively.

**Note 6 - Trademark and Patents**

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

	December 31, 2017	June 30, 2017
Trademarks and Patents	\$ 458,954	\$458,954
Less Accumulated Amortization	(79,891 )	(75,756 )
Trademarks and Patents, Net	\$ 379,063	\$383,198

Amortization expense amounted to \$2,067 and \$2,067 for the three months ended December 31, 2017 and 2016, respectively, and \$4,135 and \$4,135 for the six months ended December 31, 2017 and 2016 respectively.

**Note 7 - Convertible Debentures and Derivatives**

**Debentures - Series B**

The Series B debentures matured on February 1, 2017. For the three-month period ended December 31, 2016, the Company paid \$40,000 of coupon interest to Holders in cash and two additional Holders of the Company’s Series B Convertible Debentures elected to receive their \$80,000 of coupon interest payment in shares of the Company’s common stock. For the six-month period ended December 31, 2016, the Company paid \$160,000 of coupon interest to Holders in cash and two additional Holders of the Company’s Series B Convertible Debentures elected to receive their \$80,000 in shares of the Company’s common stock.

The debt discount had been amortized to interest expense over the term of the debenture. The Company recognized amortization of the discount as an additional interest charge to “Discount on convertible debentures” for the three and six months ended December 31, 2016, in the amount of \$222,226 and \$436,098, respectively. The debenture contained embedded derivatives that were not clearly and closely related to the host instrument. The embedded

derivatives were bifurcated from the host debt instrument and treated as a liability.

The fair value of the compound embedded derivatives of the Series B Convertible Debenture at December 31, 2016 was \$28,284. For the three and six months ended December 31, 2016 the change in fair value was \$(91,839) and \$(174,746), respectively, which is included in the change in fair value of derivatives on the statement of operations.

### **Debenture - Series C**

On July 2, 2014 (the "Closing Date"), the Company accepted a subscription in the amount of \$5,000,000 for a 10% Coupon Series C Convertible Debenture (the "Debenture") from Dr. Milton Boniuk, a member of the Company's Board of Directors (the "Holder"). The Debenture was due on June 30, 2018 (the "Maturity Date") and was 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 bore interest at the coupon rate of ten percent (10%) per annum, computed on an annual basis of a 365 day year, payable in quarterly installments on March 31, June 30, September 30 and December 31 of each calendar year until the Maturity Date. In accordance with the debenture agreement, the interest for the initial year of the debenture for a total of \$500,000 was deferred, to be paid over the remainder of the term at \$166,667 per year. The Holder at its option may choose to receive such coupon interest payment in shares of Common Stock calculated using the average of the open and close prices of the Company's common stock on the date such interest payment is due. For the three-month period ended December 31, 2017, the Holder of the Company's Series C Convertible Debentures elected to receive \$60,274 (through November 13, 2017) of their coupon interest payment and \$125,000 of deferred interest payment in shares of the Company's common stock. For the three-month period ended December 31, 2016, the Holder of the Company's Series C Convertible Debentures elected to receive \$125,000 of its coupon interest payment and \$41,667 of its deferred interest payment in shares of the Company's common stock. For the six-month period ended December 31, 2017, the Holder elected to receive \$60,274 (through November 13, 2017) of its coupon interest payment and \$125,000 of deferred interest payment in common stock of the Company and \$125,000 of its coupon interest payment and \$41,667 of its deferred interest payment in cash. For the six month period ended December 31, 2016, the Holder elected to receive \$125,000 of its coupon interest payment and \$41,667, of its deferred interest payment in shares of the Company's common stock and 125,000 of their coupon interest payment and \$41,667, of its deferred interest payment in cash.



On July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debentures, the Company issued 187,000 shares of its Series A Convertible Preferred stock (the "Series A") to Dr. Milton Boniuk, pursuant to the terms of the Debenture. Proceeds received in a financing transaction are allocated to the instruments issued prior to evaluating hybrid contracts for bifurcation of embedded derivatives. Since the Series A Convertible Preferred Stock is classified as equity, the proceeds allocated to the Preferred Stock are recorded at relative fair value. The fair value of the Series A was \$1,645,606 at issuance and the relative fair value was calculated as \$1,152,297. The remaining amount of the proceeds was allocated to the Debenture and a debt discount of \$1,152,297 was recorded to offset the amount of the proceeds allocated to the Series A. Then, the embedded derivative was bifurcated at its fair value of \$1,879,428 with the remaining balance allocated to the host instrument (Debenture). The total debt discount will be amortized over the term of the Debenture using the effective interest method.

The Company recognized amortization of this discount as an additional interest charge to "Discount on convertible debentures" in the amount of \$119,863 and \$201,061 for the three month periods ended December 31, 2017 and 2016, respectively, and \$359,214 and \$390,651 for the six month periods ended December 31, 2017 and 2016, respectively.

The Holder of the Series C Debenture and the Company agreed on November 13, 2017 that the Debenture would be redeemed for the Company's common stock, as described further below. The Holder waived all early redemption payments provided for in the Debenture in consideration for 150,000 shares of the Company's Series A Preferred shares.

The following represents the balance of the Debenture payable – Series C, net of discount at November 13, 2017 and June 30, 2017. The debt discount has been amortized to interest expense over the term of the debenture.

	<b>November 13, 2017</b>	<b>June 30, 2017</b>
<b>Proceeds</b>	\$ 5,000,000	\$ 5,000,000
Debt Discount:		
Series A Preferred	(1,152,297 )	(1,152,297 )
Embedded derivative	(1,879,428 )	(1,879,428 )
	1,968,275	1,968,275
Accumulated amortization of debt discount	2,347,092	1,987,878
<b>Debenture payable - Series C, net</b>	<b>\$ 4,315,367</b>	<b>\$ 3,956,153</b>

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The Company uses a lattice model that values the compound embedded derivatives of the Series C Convertible Debenture based on a probability weighted discounted cash flow model at November 13, 2017.

The following assumptions were used for the valuation of the compound embedded derivative at November 13, 2017:

- The balance of the Series C Convertible Debenture as of November 13, 2017 is \$5,000,000;

The underlying stock price was used as the fair value of the common stock; The stock price decreased to **\$1.00** at November 13, 2017 with lower projected annual volatility. The warrant value with the \$6.05 exercise price decreased due to the decreasing term remaining;

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

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

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

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

The weighted cost of capital discount rate (based on the market value of the transaction at issuance) adjusted for changes in the risk free rate is 21.99%.

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

The fair value of the compound embedded derivatives of the Series C Convertible Debenture at November 13, 2017 and June 30, 2017 was \$15,449 and 32,213, respectively.

The Company's Series C Debenture in the amount of \$5,000,000 was due to mature on June 30, 2018. On November 13, 2017, the Company entered into a Debenture Redemption Agreement (the "Agreement") with the Holder, to redeem (the "Redemption") its \$5,000,000 Series C Convertible Debenture (the "Debenture") for an aggregate of 5,500,000 shares of the Company's \$0.001 par value Common Stock ("Purchase Price") comprising 5,000,000 shares for the principal of the Debenture and 500,000 shares for unpaid coupon interest from October 1, 2017 through June 30, 2018. The unpaid interest included \$60,274 of accrued interest through November 13, 2017, \$314,726 in coupon interest through June 30, 2018 and \$125,000 of unpaid deferred interest. The price per share was equal to the closing price of the Company's stock on Friday, November 10, 2017 of one (\$1.00) dollar per share. The Holder waived all early redemption penalty payments provided for in the Debenture for consideration of 150,000 shares of the Company's \$0.001 par value Series A Convertible Preferred Stock. The Company did not incur placement agent fees in redemption of the Series C Convertible Debenture. The Company recognized a non-cash loss on extinguishment of debt of \$1,348,247 on the extinguishment of the aforesaid principal attributable to the Series C Debentures into the Company's Common and Preferred stock. The loss on extinguishment arises from, the obligation to issue 150,000 shares of the Company's Series A Preferred shares with a fair value of \$364,337, as of November 13, 2017, obligation to issue 314,726 shares of the Company's \$0.001 par value Common Stock with a fair value of \$314,726 as of November 13, 2017, in consideration of Debenture coupon interest from the redemption date through June 30, 2018, and unamortized discount of \$684,633 as of the redemption date, offset by the derivative liability of (\$15,449) as of the redemption date. Therefore the balance is included in the Obligation to issue registered shares.

Pursuant to the redemption agreement for the Company's Series C Debenture, the Company is obligated to issue 5,500,000 of its registered Common Stock, from its shelf registration and the shares of Series A Preferred Stock upon receiving consent to issue the shares pursuant to New York Stock Exchange ("NYSE") regulations, the Company submitted a request for authorization to issue the Common Stock and Series A Preferred Shares to the NYSE. The Company is currently awaiting NYSE consent to issue the aforesaid securities.

The Company has recognized a derivative liability arising from the change in value of the securities to be issued in settlement of the redemption of the Company's Series C Debenture. The fair value of the 5,500,000 of the Company's Common shares was \$5,500,000 and the fair value of the 150,000 of the Company's Series A Preferred shares to be issued was \$364,337, totaling \$5,864,337, as of November 13, 2017. These values were offset by a decrease in the fair value of the derivative liability of \$701,143 as of December 31, 2017. The decrease in the value of the 5,500,000 shares was calculated as the difference between the value of the Common shares stipulated in the redemption agreement of one (\$1.00) per share and the closing price of the Common stock on December 31, 2017, of \$0.88 dollar per share, resulting in a decrease in the derivative liability of \$660,000. This was recognized as a gain in the fair value of the derivative liability. The change in the fair value of the obligation to issue 150,000 of the Company's Series A Preferred shares is based on the change in the fair value from November 13, 2017 to December 31, 2017. The value of the preferred shares decreased and a gain of \$41,143 was recognized in the change in the fair value of derivative liability.

The Series A Preferred fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the Holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a Change of Control. The valuations of the Series A Preferred Stock at each issuance used the following inputs:

- a. The common stock price was in the range \$1.14 to \$1.00;
- b. The calculated weighted average number of shares of common stock in the period;
- c. A 26.63% premium over the common shares for the voting preferences;
- d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 12.27% to 12.30% 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 October 31, 2016 and a remaining restricted term of 3.00 to 2.84 years;
- f. 31.69% to 30.43% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 58.33% to 52.49% volatility, 1.62% to 1.78% risk free rate) applied to the converted common.

**Note 8 - Equity Transactions**

On July 21, 2015, the Board of Directors approved the employment agreement with Dr. Anil Diwan, the Company's President. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 Series A Preferred shares to Dr. Diwan. 75,000 shares vested on June 30, 2016 and 75,000 shares vested on June 30, 2017. The remainder of the shares will vest over the remaining term of the employment agreement ending, June 30, 2018 and are subject to forfeiture. The Company recognized a noncash compensation expense related to the issuance of the Series A Preferred Shares for the three and six months ended December 31, 2017 of \$66,786 and \$133,572, respectively and for the three and six months ended December 31, 2016 of \$74,317 and \$148,633, respectively. The balance of \$133,572 will be recognized as the remaining shares are vested.

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Eugene Seymour, the Company's Chief Executive Officer. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 Series A Preferred shares to Dr. Seymour. 75,000 shares vested on June 30, 2016 and 75,000 shares vested on June 30, 2017. The remainder of the shares will vest over the remaining term of the employment agreement ending, June 30, 2018 and are subject to forfeiture. The Company recognized a noncash compensation expense related to the issuance of the Series A Preferred Shares for the three and six months ended December 31, 2017 of \$66,786 and \$133,572, respectively and for the three and six months ended December 31, 2016 of \$74,317 and \$148,633, respectively. The balance of \$133,572 will be recognized as the remaining shares are vested.

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 7,716 and 15,432, respectively, fully vested shares of its Series A Convertible Preferred stock for employee compensation. The Company recorded expense of \$19,836 and \$45,063, respectively, for the three and six months ended December 31, 2017.

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

Date	Shares	Value
7/31/2017	2,572	\$8,242
8/31/2017	2,572	8,397
9/30/2017	2,572	8,588
10/31/2017	2,572	7,010
11/30/2017	2,572	6,313
12/31/2017	2,572	6,513
	15,432	\$45,063

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

- a. The common stock price was in the range \$1.14 to \$1.00;

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

c. A 26.63% premium over the common shares for the voting preferences;

d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 12.27% to 12.30% 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 October 31, 2016 and a remaining restricted term of 3.00 to 2.84 years;

f. 31.69% to 30.43% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 58.33% to 52.49% volatility, 1.62% to 1.78% risk free rate) applied to the converted common.

For the six months ended December 31, 2017, the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 11,432 shares of common stock with an exercise price of \$1.17 per share expiring in November 2021 and 11,432 fully vested warrants to purchase shares of common stock with an exercise price of \$1.56 per share expiring in August 2021. The fair value of the warrants was \$4,401 for the three months and \$10,174 for the six months ended December 31, 2017 and was recorded as consulting expense.

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

Expected life (year)	4	
Expected volatility	55.56-56.10%	
Expected annual rate of quarterly dividends	0.00	%
Risk-free rate(s)	1.67-1.92	%

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 26,468 and 46,530, respectively fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$27,000 and \$54,000 for the three and six months, respectively, which was the fair value on the dates of issuance.

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 11,019 and 19,377, respectively, fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of \$11,250 and \$22,500 for the three and six months, respectively, which was the fair value on the dates of issuance.

## Note 9 - Stock Warrants

### Stock Warrants

Stock Warrants	Number of Shares	Weighted Average Exercise	Weighted Average Remaining	Aggregate Intrinsic Value (\$)
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		Price per share (\$)	Contractual Term (years)		
Outstanding and exercisable at June 30, 2017	6,673,860	\$ 4.93	1.36	\$	-
Granted	22,864	1.37	3.71		-
Outstanding and exercisable at December 31, 2017	6,696,724	\$ 4.92	0.93	\$	-

Of the above warrants, none expire in fiscal year ending June 30, 2018; 6,548,108 expire in fiscal year ending June 30, 2019; 68,592 expire in fiscal year ending June 30, 2020, 57,160 expire in fiscal year ending June 30, 2021 and 22,864 expire in the fiscal year ending June 30, 2022.

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

At December 31, 2017 and June 30, 2017, the fair value of derivative liabilities is estimated using a lattice model that is based on the individual characteristics of our warrants, preferred and common stock, the derivative liability on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate and, in some cases, credit spread. The derivative liabilities are the only Level 3 fair value measures.

At December 31, 2017 and June 30, 2017 the estimated fair values of the liabilities measured on a recurring basis are as follows:

	Fair Value Measurements at December 31, 2017:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series C debentures	\$ -	-	\$ -
Obligation to issue registered shares	-	-	5,163,304
Derivative liability – warrants	-	-	1,068,110
Total derivatives	\$ -	\$ -	\$ 6,231,414

	Fair Value Measurements at June 30, 2017:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series C debentures	\$ -	-	\$ 32,213
Derivative liability – warrants	-	-	2,015,354
Total derivatives	\$ -	\$ -	\$ 2,047,567

In conjunction with the Company's registered direct offerings of Units, consisting of the Company's common stock and warrants, on September 12, 2013 and January 24, 2014 the Company issued 2,945,428, and 2,479,935 warrants, respectively, and of which, 2,810,071 and 2,479,935, respectively, are outstanding at December 31, 2017. Additionally, the Company issued 58,910 and 76,306 warrants, respectively, to the placement agents which are also outstanding at December 31, 2017, for a total number of 5,425,222 warrants outstanding and issued pursuant to the aforesaid registered direct offerings.

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

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

The Warrants were valued as of December 31, 2017 and June 30, 2017 with the following assumptions:

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

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

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

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

1 Year	
12/31/17	52%
6/30/17	60%

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

The following tables present the activity for liabilities measured at estimated fair value using unobservable inputs for the three months ended December 31, 2017:

	Fair Value Measurement Using Significant		
	Unobservable Inputs		
	Derivative	Derivative	Obligation
	Liability-	Liability-	to issue
	Series C	Warrant	shares
Beginning balance at July 1, 2017	\$32,213	\$2,015,354	\$-
Additions during the year	-	-	5,864,337
Change in fair value	(16,764)	(947,244 )	(701,143 )
Transfer in and out of Level 3	(15,449)	-	-
Balance at December 31, 2017	\$-	\$1,068,110	\$5,163,194

#### Note 11 - Commitments and Contingencies

##### Legal Proceedings

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

### Employment Agreements

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

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

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

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

On May 30, 2013, the Company entered into an Employment Agreement with Meeta Vyas to serve as its Chief Financial Officer. The employment agreement provided for a term of three years with a base salary of \$9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. On January 1, 2015, her cash compensation was increased to \$10,800 per month. The Agreement is renewable on an annual basis. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements.

### License Agreements

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

### **Note 12 – Income Taxes**

The Company calculates income tax expense based on an annual effective tax rate forecast, including estimates and assumptions. We have not recorded tax benefits on our loss before income taxes because we have provided for a full valuation allowance that offsets potential deferred tax assets resulting from net operating loss carry forwards,

reflecting our inability to use such loss carry forwards.

The Company's effective tax rate for the six months ended December 31, 2017 and 2016 was 0% and 0%.

The Tax Cut and Jobs Act of 2017 was enacted in December 2017. Among other things, the Act reduces the U.S. federal corporate tax rate from 34% to 21% and eliminates the alternative minimum tax ("AMT") for corporations. Since the deferred tax assets are expected to reverse in a future year, it has been tax effected using the 21% federal corporate tax rate. As a result of the reduction in the corporate income tax rate, the Company wrote down approximately \$5.3 million of the gross deferred tax assets and valuation allowance as of December 31, 2017, which has no impact on the financial statements for the three and six months ended December 31, 2017.

### **Note 13 - Subsequent Events**

The Management of the Company has determined that there was a reportable subsequent event to be disclosed as follows:

On January 27, 2018, the Company's Chief Executive Officer, Dr. Eugene Seymour, resigned as the Chief Executive Officer and as a Director of the Company to allow a successor with pharmaceutical experience to serve in this capacity. Subject to the entry into a Severance Agreement, Dr. Seymour will assume the role of Chief Executive Officer Emeritus. The Board of Directors previously commenced a search for a permanent replacement for Dr. Seymour, which is ongoing. The Board of Directors has appointed Dr. Anil Diwan, the Company's President, as Interim Chief Executive Officer.

## **PART I**

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

The following discussion should be read in conjunction with the information contained in the financial statements of the Company and the notes thereto appearing elsewhere herein and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in the Company's Annual Report on Form 10-K for the year ended June 30, 2017. Readers should carefully review the risk factors disclosed in this Form 10-K and other documents filed by the Company with the SEC.

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

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

This Report contains forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical fact made in this report are forward looking. In particular, the statements herein regarding industry prospects and future results of operations or financial position are forward-looking statements. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "Company believes," "management believes" and similar language. These forward-looking statements can be identified by the use of words such as "believes," "estimates," "could," "possibly," "probably," "anticipates," "projects," "expects," "may," "will," or "should," or other variations of these words. No assurances can be given that the future results anticipated by the forward-looking statements will be achieved. Forward-looking statements reflect management's current expectations and are inherently uncertain. The forward-looking statements are based on the current expectations of NanoViricides, Inc. and are inherently subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report. Actual results may differ materially from results anticipated in these forward-looking statements.

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



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

NanoViricides, Inc. is a globally leading company in the application of nanomedicine technologies to the complex issues of viral diseases. The nanoviricide® technology enables direct attacks at multiple points on a virus particle. It is believed that such attacks would lead to the virus particle becoming ineffective at infecting cells. Antibodies in contrast attack a virus particle at only a maximum of two attachment points per antibody. In addition, the nanoviricide technology also simultaneously enables attacking the rapid intracellular reproduction of the virus by incorporating one or more active pharmaceutical ingredients (APIs) within the core of the nanoviricide. The nanoviricide technology is the only technology in the world, to the best of our knowledge, that is capable of both (a) attacking extracellular virus, thereby breaking the reinfection cycle, and simultaneously (b) disrupting intracellular production of the virus, thereby enabling complete control of a virus infection.

Our anti-viral therapeutics, that we call “nanoviricides®” are designed to appear to the virus like the native host cell surface to which it binds. Since these binding sites for a given virus do not change despite mutations and other changes in the virus, we believe that our drugs will be broad-spectrum, i.e. effective against most if not all strains, types, or subtypes, of a given virus, provided the virus-binding portion of the nanoviricide is engineered appropriately. Viruses would not be able to escape the nanoviricide drugs so designed by mutations since they continue to bind to the same cellular receptor and thus would be captured by the nanoviricides. Virus escape by mutations is a major problem in the treatment of viral diseases using conventional drugs.

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

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

NanoViricides, Inc. is one of a few bio-pharma companies that has all the capabilities needed from research and development to marketable drug manufacture in the small quantities needed for human clinical trials. At our campus at 1 Controls Drive, Shelton, CT, we possess state of the art nanomedicines characterization facilities that we believe enable us to perform pre-IND nanomedicine analysis and characterization studies of any of our various drug candidates in house. In addition, we believe we now have the ability to scale up production of any of our drug

candidates, and implement state of the art in-process controls as well as post-process analysis controls in order to establish robust c-GMP-capable production methodologies. We also have a Biological Safety Level 2 (BSL2) certified virological cell culture lab at this campus. We are able to perform initial cell culture based screening of large numbers of drug candidates for effectiveness and safety against certain of the viruses that we have targeted for drug development. This capability boosts our drug development capabilities significantly. Other than this limited initial screening, all of the biological testing and characterization of our drug candidates continues to be performed by external academic or institutional collaborators and contract research organizations (CRO). In particular, all of the animal studies are performed by our collaborators and CROs.

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

We have focused our efforts almost exclusively on the HerpeCide program, given our budgets and current financial condition.

We currently have at least eight different drug development programs, attesting to the strength of our platform technology. Of these, 4 of the indications are under the HerpeCide™ program. We are currently working on 3 of these indications (VZV, HSV-1 and HSV-2) in parallel, as explained below (priority level 1). The v-ARN program is at a lower priority level. In addition, we continue to work on the FluCide™ program at the lower priority 3. HIVCide™ program is at priority level 4. We will continue to seek funding for further development in the remaining programs, namely Dengue and Ebola/Marburg antivirals.

The potential broad-spectrum nature of our anti-HSV drug candidates is enabling several anti-Herpes indications under our HerpeCide™ program. Of these, our (i) Topical Treatment for Shingles (VZV) is currently moving most rapidly towards clinical stage. We believe that the other anti-Herpes drug candidates, would follow this lead drug to the clinical stage, namely, (ii) skin cream for the treatment of orolabial herpes (“cold sores”) and recurrent herpes labialis (RHL) mostly caused by HSV-1, (iii) ocular eye drops treatment for external eye herpes keratitis (HK), caused by HSV-1 or HSV-2, and (iv) skin cream for the treatment of genital herpes caused by HSV-2.

In addition, we announced that we have begun preclinical drug development work on a fifth indication under the HerpeCide program, namely (v) viral Acute Retinal Necrosis (v-ARN), intravitreal injection.

The Company reports that it is close to identifying a clinical candidate for VZV shingles skin cream topical treatment. Recently, we have been able to scale up production to make sufficient amounts of the lead candidates for a preliminary rat toxicology study.

The Company announced on December 6, 2017, that it has begun an initial safety and toxicology evaluation of its optimized nanoviricides® drug candidates developed against varicella-zoster virus (VZV), the shingles virus. This preliminary safety/toxicology study in the rat animal model is an important step in the drug development pathway for a treatment for shingles, a debilitating infection of human skin by VZV. The results of this study are expected to help us finalize the clinical lead. In addition, these results are expected to lead to refining and commissioning the GLP safety and toxicology study (“Tox Package” study) as required for filing an IND.

We believe that, additionally, the results of this preliminary rat safety/tox study will also be applicable to the dermal topical treatments we are developing for the treatment of HSV-1 cold sores, and HSV-2 genital ulcers.

The non-GLP safety and toxicology study in rats is being conducted at AR Biosystems, Beverly, MA. The study is designed to (i) evaluate the direct effects of topical delivery of the drug candidates on the skin, (ii) assess if the drugs attain detectable levels in the blood, and also (iii) evaluate whether there are any effects on the blood and primary organs, in uninfected animals. The results of this study will provide the basis and focus for the IND-enabling GLP safety and toxicology studies that are required for the IND submission to the U.S. FDA. As a result of the success of its drug lead optimization process, the Company has selected two clinical development candidates for further evaluation in this initial safety/toxicology study.

Subsequent to this reporting period, the animal experiment portion of this study has been completed as of the end of January 2018. We have received initial verbal communications that indicate that our drug candidates were non-toxic in terms of behavioral and other observable signs during the study. We are awaiting a final report from the CRO,

which is due shortly, and further discussion of next steps in the development of one of these drug candidates as the final clinical candidate for the treatment of shingles.

We have already begun to scale up production of these tested candidates to the larger amounts as estimated to be required for the ensuing Tox Package studies. We have estimated that approximately 500g of the candidate will be needed for such a study, based on discussions with BASi, Inc., IN, the service provider, and Biologics Consulting Group, VA, our regulatory consultants.

The market size for anti-shingles drugs is currently estimated to be in the range of several billions of dollars, even after a new shingles vaccine, Shingrix® (GlaxoSmithKline) has become available, based on a recent report by Dr. Myers of BioEnsemble, LLC, pharma industry consultants, commissioned by the Company.

More specifically, the report estimated that our anti-shingles drug could reach peak annual sales of as much as \$2 Billion, depending upon the effectiveness determined in clinical trials, at an assumed 50% market penetration. Based on current pre-clinical data, we believe that there is a very strong probability that our shingles treatment would significantly minimize the shingles pain, accelerate healing, and minimize nerve damage, thereby minimizing the occurrence and severity of post-herpetic neuralgia (PHN). Our pre-clinical drug design efforts have been aimed at developing a treatment for shingles that would have pain reduction effects as well as healing effects on skin. If our anti-VZV drug candidate is as effective in human clinical studies as we see in the skin patch studies and in the cell culture studies, it would be reasonable to anticipate that the substantial reduction in viral load at the site of application would significantly minimize the shingles pain, accelerate healing, and minimize nerve damage, thereby minimizing the occurrence and severity of post-herpetic neuralgia (PHN). If this were borne out in clinical trials, the potential market could be closer to the \$2 billion mark. However, initially, we do not plan on performing clinical trials aimed at proving PHN effectiveness, but rather, we plan on performing clinical trials based on VZV related biomarkers and clinical pathology, which we believe would be sufficient for a first indication for approval of the drug for treatment of shingles by the US FDA. We plan on performing observations regarding PHN in these clinical trials so that an informed PHN clinical trial may be performed later.

We have developed strong chemical manufacturing process controls that enable us to produce the backbone polymers with highly restricted and reproducible molecular size range. In fact, we have achieved highly reproducible and scalable processes that have yielded the same polymer molecular sizes across production scales from 10g to 500g. In other words, we are now able to control the length of the backbone polymer to within one monomer unit, irrespective of production scale (at least up to about 1 kg scale).

We believe that this is a remarkable and possibly unmatched achievement in the field of nanomedicines. We plan on scaling up the production of the polymer backbone “nanomicelle” to kilogram scales and do not anticipate any manufacturing constraints at present.

Typically, the synthesis of small chemicals, such as the ligands we use to direct the nanoviricide against a specific type of virus, is substantially easier to scale up than the synthesis of polymers. We have been able to scale up production of the two different ligands under potential clinical development consideration for VZV shingles treatment to approximately 200g scale already. We anticipate being able to scale up to approximately 500g level or more, as necessary, in the next few months.

The process of chemically covalently connecting the ligands to the polymer backbone, to produce the nanoviricides, is now being investigated further to change the operations involved to scalable chemistries and unit operations. At present, we have been able to make research quantities of the anti-VZV nanoviricides at approximately 10~20g scale in a fairly reproducible manner.

Our polymer backbone is designed based on the route of application. In the case of the shingles drug candidate, as well as for HSV-1 cold sores, and for HSV-2 genital ulcers, the route is dermal topical application. We are now in the final stages of screening two different polymer backbones for best suitability for this purpose.

We were able to formulate our anti-shingles nanoviricides into skin ointment formulation within a matter of a single week. This is the inherent advantage of our platform technology – that the formulation challenge is addressed head-on in the design of the drug itself. Typically companies estimate between 1 to 2 years for final formulation development. We believe we can achieve this in only the time-frame required for external biological characterization of effectiveness of the formulation, because of the inherent strength of the technology and the ease of formulation as skin ointment of the current drug candidates designed for this purpose.

Thus we are on course to be able to manufacture the required quantities of materials for the Tox Package studies. We believe that this same Tox Package study performed for the indication of (i) shingles treatment, will be applicable for the development of (ii) our anti-HSV-1 skin ointment for the treatment of cold sores, as well as (iii) our anti-HSV-2 skin ointment for the treatment of genital ulcers, provided that the same API can be shown to be sufficiently effective against all three in relevant disease models. Dr. Brandt's Lab at CORL, the University of Wisconsin, Madison, WI, is currently in the process of validating animal models for the study and evaluation of relative efficacies of different treatments for HSV-1 infection in mice as well as for HSV-2 infection in mice. If their animal models are successful in differentiating effectiveness of different drug candidates, then we will be able to evaluate our drug candidates for the treatment of HSV-1 cold sores as well as for the treatment of HSV-2 genital ulcers, in addition to the VZV testing being performed.

The ligands currently in use for the nanoviricide drug candidates against VZV shingles were actually developed using computer models of HSV binding to its cellular receptor, and not against VZV itself. Our program shifted to advance VZV candidate as our first indication because of several advantages that would enable earlier entry into clinical trials for the shingles candidate, and additionally because of the speed with which this drug development program moved

forward. The shingles drug development program has been moving rapidly primarily because of the quick turnaround time and high responsiveness of the Dr. Moffat Lab at SUNY Syracuse, our critical collaborator for human skin effectiveness studies of our drug candidates.

One of the advantages of the shingles program is that the pre-clinical drug development is performed directly in a human skin model, bypassing any animal model, providing significant confidence that a human clinical studies outcome would parallel the preclinical study outcome. VZV does not infect animals other than humans.

If the same anti-VZV/shingles drug candidates also demonstrate efficacy against the HSV-1 and HSV-2 animal models, then we will be ready to go into IND applications and clinical stage for these indications as well in relatively short time frames of six months to a year, after the first IND filing, depending upon the availability of funding. We had previously demonstrated significant efficacy of an anti-HSV-1 nanoviricide in animal models using nanoviricides based on closely related ligands and polymer that were not yet optimized. The drugs employed in those studies were, however, very complex, and would have required significantly extensive regulatory pathway studies in the clinical stage. We have therefore engaged in further optimization and simplification process starting from those anti-HSV drugs that has now resulted in the current anti-VZV shingles treatment candidates.

Thus we have made significant and substantial progress in the reporting quarter towards the goal of filing our first IND application, and we continue to build on this progress.

Our progress towards IND stage is now constrained severely by the small number of scientists in our team. We have been unable to expand the staffing due to budgetary constraints. The same staff is currently moving from synthesis to process studies to large-scale production as well as chemical characterization studies, in a serial fashion. Many of these tasks could have been readily parallelized, thereby reducing the time to filing an IND, if we had sufficient financing available for hiring and retaining additional competent scientific talent.

NanoViricides, Inc. reported in July 2017, that its anti-shingles nanoviricides® drug candidates achieved dramatic reduction in infection of human skin by the varicella-zoster virus (VZV), the shingles virus. These findings corroborate the previously reported findings of inhibition of VZV infection of human cells in culture. VZV is restricted to human tissue and only infects and replicates in human tissue.

Over the time course of VZV infection, the nanoviricides® drug candidates showed marked inhibition of VZV infection, replication and spread in human skin cultured *ex vivo*. The data suggest that select nanoviricides® drug candidates may have direct virucidal activity based on their antiviral effects within the first 24 hours after viral infection.

The antiviral effect of certain nanoviricide drug candidates was substantially greater than the effect of the standard positive control of cidofovir added into media. Even more remarkably, the effect of these nanoviricides drug candidates was equivalent to a topical formulation of 1% cidofovir applied directly onto the skin patch. A topical skin cream containing 2% cidofovir is clinically used in very severe cases of shingles. However, the cytotoxicity of cidofovir is known to cause ulceration of the skin to which it is applied, followed by natural wound healing. We are awaiting histopathology studies at present.

Since VZV causes skin lesions as a result of direct attack of the re-awakened virus released from nerve endings onto the human skin cells, this *ex vivo* human skin patch model involving VZV infection of cultured human skin *ex vivo* is considered to be a close representation of natural course of shingles.

The Company has previously reported that these same nanoviricides® compounds displayed potent inhibition of VZV infection of a human retinal epithelial pigment cell line in an *in vitro* cell culture virus infection model with no evidence of toxicity to the cells. These *ex vivo* and *in vitro* studies are a critical step in the selection of final clinical drug development candidates for safety and toxicology studies with the goal of an IND submission to the FDA for the topical treatment of shingles in humans.

These human skin studies were performed in the laboratory of Dr. Jennifer Moffat at SUNY Upstate Medical University in Syracuse, NY. The Company previously reported the collaboration with Dr. Moffat, an internationally recognized expert on varicella-zoster virus. She has extensive experience in varicella-zoster virus (VZV) infection, pathogenesis, and anti-viral agent discovery. The National Institutes of Health has a contract with Dr. Moffat's lab for evaluating anti-viral compounds against VZV, although the Company chose to set up a direct collaboration with Dr. Moffat rather than going through the NIH program.

Dr. Vivien Boniuk, Consultant in Ophthalmology at the Company, presented the successful results of certain anti-herpes nanoviricide treatments for v-ARN at the 2017 Annual meeting of the Ocular Microbiology and Immunology Group (OMIG) of the American Academy of Ophthalmology held in New Orleans, LA, on November 10, 2017. In this study, HSV-2 infection was given to mice as a single injection to cause v-ARN. The mice that received either of two nanoviricides drug candidates simultaneously with the virus in this single injection, showed significant improvements using a number of parameters. In contrast, mice that received foscarnet injection simultaneously with the virus did not show any improvements. Of note, foscarnet is a current standard of treatment, although the treatment is long in duration and arduous, being multiple intravitreal injections. In addition, another

group of HSV-2 infected animals received acyclovir by intraperitoneal injection (50mg/kg), twice daily for 7 days, as a positive control. Acyclovir and its derivatives are also used currently for treating v-ARN, although the clinical efficacy is limited and generally requires long durations of treatment. Vehicle treated and untreated negative controls also were employed. These studies were performed in the lab of Dr. Curtis Brandt at CORL, University of Wisconsin, Madison, WI.

Both nanoviricides tested showed remarkable efficacy using multiple parameters. In particular, nanoviricide-A treated group showed viral load going down to undetectable levels by day 7 itself (approximately 4 logs viral load reduction from baseline), whereas acyclovir group showed no reduction in viral load from baseline at day 7, but approximately 2 logs reduction at day 9, indicating a much lower efficacy.

Both nanoviricides A and B resulted in 100% maintenance of body mass by day 9, indicating complete control of infection. However, the acyclovir group showed a loss of at least 10% body mass, close to the nearly 15% loss in the negative controls, indicating that it was either much less effective than the nanoviricides A and B or was somewhat toxic to the animals.

The mean disease score for the vitreous infiltrate (fluid inside the eye) was zero (best) for 9 days with nanoviricide A treatment, and was about 0.5 for acyclovir treated group, whereas it was about 4 (worst) in untreated and vehicle groups, indicating that nanoviricide A was more effective than the acyclovir treatment in this model.

In both nanoviricide A and nanoviricide B groups, the retina was protected fully from viral damage, which is very significant. In contrast, the acyclovir treated group showed retinal damage approximately similar to the vehicle treated group, in spite of reduced viral load in the acyclovir group, indicating that acyclovir may have been toxic. These results were also confirmed by histological staining of retinal sections.

Taken together, both nanoviricide A and nanoviricide B had substantial effectiveness in protecting the retina, in spite of the high infectious dose of HSV-2 employed in this model. Significantly, they were both substantially more effective than foscarnet (single injection) or acyclovir (bid 7days) in this particular study. If these results are reproducible, then the Company would be able to identify a clinical candidate for v-ARN as well.



Of note, both nanoviricides tested against v-ARN are closely chemically related to the ones that have shown significant efficacy against varicella zoster virus (VZV) in the human skin patch model in Professor Moffat's lab at the Upstate Medical Center, SUNY, Syracuse, NY. We have previously shown that closely chemically related nanoviricides were also effective against HSV-1 in animal models as well as in cell culture models. This is important because about 50% of v-ARN cases are caused by VZV, about 40+% caused by HSV-2, with HSV-1 and CMV accounting for a small percentage of cases. VZV does not infect mice, and therefore the HSV-2 v-ARN model should be indicative model for our drug development. Thus the broad-spectrum activity of our nanoviricides against multiple different herpesvirus types has been instrumental in rapid expansion of our HerpeCide program.

Additional successful studies on v-ARN are expected to add a fifth indication to the Company's growing portfolio of anti-herpes drug indications, further expanding the potential market. The Company intends to maximize shareholder value from its broad-spectrum anti-herpes nanoviricides asset by aggressively expanding its portfolio of herpesvirus indications.

v-ARN is a disease of the retina of the eye caused by various herpes viruses that leads to severe loss of vision and blindness. The infecting agent in this study was herpes simplex virus-2 (HSV-2), the type of herpes virus that also causes genital herpes.

Acute Retinal Necrosis is characterized by severe ocular inflammation, retinal necrosis, and a high incidence of retinal detachment (RD) leading to visual loss and blindness. This disease is caused by members of the herpesvirus family, including, herpes simplex virus-2 (HSV-2), varicella zoster virus (VZV), and herpes simplex virus (HSV-1). An estimated 50,000 new and recurrent cases of viral ARN per year are reported in the United States alone. We anticipate that v-ARN may qualify for an orphan disease indication.

However, the development path for an intra-vitreous injection is significantly different from that for a skin ointment or skin cream, requiring modifications in the polymer chemistry, possibly in the ligand chemistry, and also in the production processes in order to make the aqueous humor-soluble form of API in a sterile manner for intra-vitreous injections. Our current development has focused on API suitable for formulating into a skin ointment for the treatment of VZV shingles, HSV-1 cold sores, or HSV-2 genital ulcers.

We have recently reported that we have extended the contracts with both the Moffat Lab, UMC, SUNY Syracuse, as well as the Brandt Lab, CORL, UW, Madison to continue to perform more advanced studies in preparation of an IND for shingles topical treatment and for v-ARN intravitreal treatment, respectively. The Brandt Lab will also be able to do animal model studies for genital herpes, when we initiate that program.

In addition, we have continued work on our other drug candidates albeit at a very low priority. These include (vi) Injectable FluCide™ for hospitalized patients with severe influenza, (vii) Oral FluCide™ for out-patients, (viii) DengueCide™, a broad spectrum nanoviricide designed to attack all types of dengue viruses and expected to be effective in the Severe Dengue Disease syndromes including Dengue Hemorrhagic Fever (DHS) and Dengue Shock Syndrome (DSS), and (ix) HIVCide™ for HIV/AIDS. In addition, the Company has research programs, enabled by the robust nanoviricides platform technology, to develop drugs against Rabies virus, Ebola and Marburg viruses, and other viruses.

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

The Company has received an “Orphan Drug Designation” for our DengueCide™ drug from the USFDA as well as the European Medicines Agency (EMA). This orphan drug designation carries significant economic benefits for the Company, upon approval of a drug.

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

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

Herpes simplex viral infections cause keratitis of the eye, and severe cases of infection may sometimes necessitate corneal transplants. Oral and genital herpes is also a well-known disease, with no cure and existing treatments that are not very effective. Shingles, caused by VZV, a herpesvirus, does not have an effective treatment at present, although some drugs are approved for use in shingles. Adenoviral Epidemic Kerato-Conjunctivitis (EKC) is a severe pink eye disease that may lead to blurry vision in certain patients after recovery. The epidemic and pandemic potential as well as the constantly changing nature of influenza viruses is well known. The HIV/AIDS worldwide epidemic and the “curse of slow death” nature of HIV viral infection are also well known. Dengue viral infection is also known as “breakbone fever”. What is worse, is that when a patient is infected with a dengue virus a second time, if the virus is a different serotype, then it can cause a severe dengue disease, or dengue hemorrhagic syndrome, with very high morbidity and a high rate of fatality. This is because, the patient’s immune system mounts an attack, but the antibodies that it generates, directed at the previous infecting virus, are not effective against the new infection, and instead the new infecting virus uses them to hitch a ride into host cells that it infects more severely. This phenomenon is called “Antibody-Dependent Enhancement” or “ADE” for short.

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

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

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

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

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

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

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

insufficient drug availability at the site of infection.

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

Thus, an effective drug with a good safety profile could have a dramatic impact on ocular viral infections. Merit-based compensation for the herpes keratitis treatment would enable strong financial incentive and could result in potential revenues in the several hundreds of millions range, depending upon the effectiveness of the drug. The Company believes that it has sufficient production capacity at its current site to supply the US requirement of the drug for treatment of (ocular) herpes keratitis upon drug licensure.

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

Herpesviruses become latent in neuronal cells or in ganglia, and cause periodic localized breakouts that appear as skin rashes and lesions. Systemic drug treatment results in side effects because of the high systemic drug concentrations that need to be achieved and the large drug quantities that must be administered. Since the virus remains mostly localized in the area of the rash and connected nerve apparatus, using high concentrations of drugs delivered in small quantities topically would allow maximizing the effectiveness while minimizing the side effects, leading to minimizing viral production at the site. Such effective local control of the virus titer is expected to lead to reduction in recurrence of herpesvirus “cold sores” or genital ulcers.

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



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

The Company thus believes that it can develop its broad-spectrum anti-herpes drug candidate towards at least four topical indications, namely, (a) shingles, (b) ocular herpes keratitis, (c) oral herpes (“cold sores”), and (d) genital herpes. As the HerpeCide™ program progresses, it is likely that additional herpesvirus related pathologies may become amenable to treatment with our herpesvirus drug candidates.

Our nanoviricides in the HerpeCide™ program at present are designed as topical treatment for the breakout of shingles or herpes sores. Our animal studies results are very significant considering that topical acyclovir in the form of a cream as well as an ointment, are approved for the treatment of cold sores. We believe our strong anti-herpes nanoviricide® drug candidates are capable of reaching approval as a drug for topical use against herpes cold sores, based on these datasets. Further drug development is necessary towards the goal of drug approval. Currently, valacyclovir (Valtrex®) is approved as an oral drug for the treatment of severe shingles, but it has limited effectiveness. Another oral drug known as “FV-100” was studied in Phase II in clinical trials for the treatment of shingles by Bristol-Myers Squibb. This study had been completed in September 2015, but results are not available to us. Currently this drug is being further developed by ContraVir Pharma. There is also a preventive vaccine for shingles that can be taken by adults over 55 years of age. Given the number of cases of severe shingles, we believe that there is an unmet medical need for developing a topical skin cream for the treatment of shingles. Local application should enable delivery of stronger, local doses of medicine, with a stronger patient benefit, than oral systemic dosing allows.

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

Both the safety and effectiveness of any new drug has to be determined experimentally. The safety of a nanoviricide drug is expected to depend upon the safety of the nanomicelle portion as well as the safety of the antiviral ligand. We have observed excellent safety of our injectable anti-influenza drug candidates. This leads us to believe that the nanomicelle backbones of these drug candidates that were evaluated in preliminary safety studies should be safe in

most if not all routes of administration.

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

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

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

We are currently focused on topical drug development against several indications related to infections by herpes family viruses. The Company recognized, after consultations with its FDA regulatory advisors, namely Biologics Consulting Group (of Alexandria, VA), and several other experts in the field, that the development of these topical drug candidates towards human clinical trials is likely to be considerably faster than the development of our anti-influenza systemic (injectable) drug candidate.

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

### **Management Discussion - Current Drug Development Strategy**

During the reported quarter we have continued to focus our drug development work plans primarily on our lead anti-Herpes-virus programs. In particular, we have focused on a work plan related to identifying a clinical development candidate for the topical skin ointment for the treatment of shingles outbreak. Because of the broad-spectrum nature of our anti-herpes drug candidates, we have also simultaneously continued further development of our drug candidates for four additional indications in the HerpeCide™ project, namely, cold sores, genital ulcers, external ocular viral infections, and viral acute retinal necrosis. We have also continued to work on our anti-influenza drug development programs under the FluCide™ project at a slow pace. The FluCide program is expected to be quite expensive for development, based on our pre-IND discussions with the US FDA. Given the limited financing we have available, the Company has determined that its best chance of filing its first IND application in the shortest time frame would be for the shingles indication in the HerpeCide program. We have therefore prioritized our resources accordingly.

NanoViricides has licenses from TheraCour Pharma, Inc., (TheraCour) our development partner and where the intellectual property has originated, for HSV-1 and HSV-2 but not for the remaining herpesviruses. NanoViricides in the past has asked TheraCour to work on unlicensed viruses in order to determine the feasibility of fully engaging into a program before licensing it. This has been the case with Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Ebola and Marburg viruses, as well as SARS, MERS, and VZV, to name a few. TheraCour initiates work on a given virus or program only after NanoViricides asks for such work to be done. Historically, these requests have been verbal, usually based on meetings of the senior level scientists and executives. Of these programs, we ended up licensing Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Ebola and Marburg viruses, in the additional license agreement. NanoViricides has disclosed our intention to obtain licenses for VZV as well as other remaining unlicensed herpesvirus indications from TheraCour Pharma. As is the standard process with such agreements, and the process that we have followed in the past, the Company needs to obtain a valuation of the assets under consideration. We have retained Dr. Carolyn Myers of BioEnsemble LLC, an expert in in-licensing, out-licensing, valuations, and M&A in pharmaceutical industry to help with the valuations and related matters. Dr. Myers was tasked with (i) valuation of the assets under consideration, (ii) potential timelines for the drug development programs, and (iii) anticipated financing needed for at least the first program through different human clinical stages into FDA approval. Dr. Myers presented her initial report to our Board of Directors on December 9, 2017. Thereafter, we have asked that further modeling and analysis be performed incorporating additional assumptions that reflect our situation more closely than in the model that was presented.

Thereafter, we anticipate license agreements will be drafted and the terms and conditions will be negotiated. TheraCour has in the past not denied any licenses for any virus programs that we initiated. We have retained counsel to prepare and negotiate the new license agreement on our behalf. If we cannot come to an agreement with TheraCour for the shingles license, we will continue and accelerate our work on the HSV-1 (cold sores) and HSV-2 (genital ulcers) indications, which we believe will be using essentially the same or closely related dermal topical drug candidates as in development under the VZV banner at present in the HerpeCide™ program. The Company already has licenses for these indications.



The Company has continued the development of anti-HSV-1 and anti-HSV-2 drug candidates, and has tested the same against VZV in cell cultures, in addition to against HSV-1 and HSV-2. Since the candidates showed preliminary efficacy against VZV as well, the Company added shingles as an additional indication to pursue under the HerpeCide™ program.

Our earlier animal studies for efficacy testing of HSV-1 drug candidates in a mouse dermal model of the infection were performed by Professor Ken Rosenthal's Lab at NEOUCOM/NEOMED. Professor Rosenthal has retired and his lab has closed down. We performed another confirmatory study of efficacy of our drug candidates against HSV-1 in this dermal infection mouse model at TransPharm Preclinical services, a CRO, thereafter. TransPharm was not able to meet our aggressive scheduling requirements for the development of this HSV-1 drug candidate.

We have therefore engaged Dr. Brandt's Lab at CORL, University of Wisconsin, Madison, WI, to further develop their animal models of dermal HSV-1 and HSV-2 infections in mice and to make them suitable for screening of drugs for relative efficacy. They have recently started working on validating their HSV-1 mouse model for discriminative efficacy of different existing drugs. Once they can establish that the model distinguishes different effective drugs, we will be able to use the model for testing our HerpeCide drug candidates against HSV-1, and optimizing the same only if necessary. Following HSV-1 model development, we have commissioned them to perform similar studies for their HSV-2 genital infection mouse model as well. Dr. Brandt's Lab developed the mouse model of viral Acute Retinal Necrosis (v-ARN) caused by HSV-1 that we have tested some of our drug candidates in as reported elsewhere.

The process for developing a license agreement for the remaining herpesviruses (other than HSV-1 and HSV-2) has officially started only around September 2017, when the Company initiated our search for an appropriate party to perform the valuation. At the same time, the anti-VZV drug development program has moved rapidly towards clinical candidate declaration stage because of several factors, namely (a) that it was simply the existing HSV-1 drug program in which the existing candidates were re-tested for effectiveness against VZV, (b) that we have had a highly successful collaboration with Dr. Moffat Lab at SUNY Syracuse with rapid turnaround times, and (c) the drug candidates were found to be highly effective against VZV in these studies.

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

Animal model studies of lethal herpesvirus infection using the highly pathogenic and neurotropic HSV-1 H129 strain in two different sites resulted in 85% to 100% survival in animals treated with certain anti-HSV nanoviricide drug candidates, while control animals uniformly died. We reported on these studies in April 2015, from Professor Emeritus Ken Rosenthal's lab at NEOMED, and in August 2015, from TransPharm Preclinical Solutions, LLC,

Jackson, MI (TransPharm), a CRO. Previously, we have improved the anti-HSV drug candidates in cell culture studies and were able to achieve significant effectiveness before engaging into animal studies. We re-designed the anti-HSV drug candidates so that the solutions would not run off the skin when applied. With this redesign, our drug candidates demonstrated complete survival of HSV-1 H129 lethally infected animals.

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

The Company has established additional collaborations towards IND-enabling development of drug candidates against the four indications listed earlier. We now have collaboration agreements with the CORL at the University of Wisconsin, the Campbell Lab at the University of Pittsburgh, and, the Moffat Lab at SUNY Upstate Medical Center, for the evaluation of our nanoviricides® drug candidates in models of ocular herpesvirus and adenovirus infections as well as VZV infections in *in vitro* and *ex vivo* models. The Company also now has the ability to perform initial screening of our drug candidates in our BSL2 certified Virology Lab in Shelton, CT, against several viruses that include various strains and subtypes of HSV-1, HSV-2, VZV, and Influenza.

The Company has previously reported the successes of its nanoviricides drug candidates in pre-clinical studies of dermal herpes virus infections in mouse models. The studies in Dr. Brandt's laboratory, namely CORL, at the University of Wisconsin will be critical in optimizing our anti-herpes drug candidates against ocular herpes virus infections. The goal of these studies will be to identify a drug development candidate as a treatment for ocular keratitis in humans caused by herpes simplex virus infections. We anticipate undertaking these studies as we are testing our HerpeCide drug candidates developed as skin ointment/cream against all three of dermal HSV-1, genital HSV-2, and VZV models. The treatment of ocular keratitis requires an eye drops formulation. We have tested certain of our polymer backbones in eye drop formulation application successfully previously. However, we are at present constrained by resource availability and the workload of moving our first drug candidate into IND stage.

The Company has continued to test several drug candidates with different formulation consistencies in multiple studies in order to select a clinical development candidate for the topical treatment of shingles. Following identification of the clinical development candidate, the Company will engage into scaled up production of said drug candidate at our Scale-Up Lab in the new campus. The Scale-up Lab has been in operation since June 2015, and we have scaled most production operations to 200g scale previously, and some steps to 500g~700g scales recently.

Once we identify the clinical drug candidate for the treatment of shingles, we will need to manufacture it in sufficient quantities to enable further IND-enabling studies. These studies include formulation optimization studies, dose-response efficacy studies, efficacy studies with different viral strains, and preliminary safety/tox in small animals, followed by cGLP safety/tox in larger animals, and PK/PD studies (pharmacokinetics and pharmacodynamics studies) in standard animal models.

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

The Company believes that its anti-herpes drug candidates for the treatment of cold sores and for genital lesions should lead to effective control of the cold sores rapidly, and may also lead to a long lag time before a new recurrence episode occurs. This is because it is believed that recurrence rates increase by virtue of further infection of new nerve

endings from the site of the herpesvirus outbreak which result in additional nerve cells harboring the virus. If this in situ re-infection is limited, which we believe is the primary mechanism of nanoviricide drugs, then it is expected that the number of HSV harboring reservoir cells should decrease, and recurrence rate should go down.

The Company believes that it will be able to expand its anti-herpes portfolio in the future to include many other herpesviruses such as cytomegalovirus (CMV), HHV-6A, HHV-6B, KSHV, and Epstein-Barr virus (EBV, cause of mononucleosis). This would lead to a very large number of therapeutic indications beyond the four or five indications we are currently targeting.

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

The Company continues to work on its anti-influenza drug candidates in parallel to its HerpeCide program. We are developing Injectable FluCide™ for hospitalized patients with severe influenza as our first, broad-spectrum anti-influenza drug candidate. We have demonstrated the very first effective orally available nanomedicine, namely oral FluCide™ for outpatients with influenza. The development of Oral FluCide is expected to follow behind Injectable FluCide. These programs are being conducted at a much lower priority, with the highest priority being given to the various indications in the HerpeCide programs. Development of an anti-Influenza drug candidate has been estimated to be an extremely expensive process with a long drug development timeframe. This is because of the large number of virus types and subtypes that change rapidly within and over seasons. The Company at present does not have the resources to engage into a full-fledged anti-Influenza drug development program.

Because of our limited resources, we have assigned lower development priorities to our other drug candidates in our pipeline such as DengueCide™ (a broad spectrum nanoviricide designed to attack all types of dengue viruses and expected to be effective in the Severe Dengue Disease syndromes including Dengue Hemorrhagic Fever (DHS) and Dengue Shock Syndrome (DSS)) and HIVCide™ (a potential “Functional Cure” for HIV/AIDS).

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

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

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

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

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

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

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

### **Our Campus in Shelton, CT**

We are happy to report that our new campus at Shelton, CT, is mostly operative. With the expanded R&D labs, Analytical Labs, the new Bio labs, the new Process Scale-Up production facility, and the new cGMP-capable manufacturing facility established at our new Shelton campus, we are in a much stronger position than ever to move our drug development programs into the clinic rapidly.

#### *Process Scale-Up Production Capability*

The Process Scale-up area is operational at scales of about 200g to 1kg per step for different chemical synthesis and processing steps. It comprises reactors and process vessels on chassis or skids, ranging from 1L to 30L capacities, as needed. Many of the reactors or vessels have been designed by us for specific tasks.

#### *cGMP Production Capability*

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

We have planned certain minimal infrastructure modifications to improve the capabilities of the cGMP-compliant facility, based on our experience in the Scale-up operations. Certain of these improvements are expected to add a separate production suite for the manufacture of skin cream in an area that was designated for such further expansion. These infrastructure improvements will be undertaken only after appropriate level of funding becomes available, of which there can be no assurance.

After these infrastructure improvements, we plan to produce at least three consecutive batches of a drug product and satisfy that said drug product is within our own defined specifications. After we are satisfied with such strong reproducibility of our processes, we plan to register the facility as a cGMP manufacturing facility with the US FDA.

At present, we plan on moving operations to our cGMP-capable manufacturing suite as the operational steps are developed to the level needed for moving them into this facility. This requires the development of draft-level Standard Operating Procedures, training, and drill-through of operations. We will also need to establish a Quality Assurance and Quality Control Department. As yet we have not hired any dedicated Quality Assurance and Quality Control personnel due to constraints on our budget. Our current staff is busy developing our pre-clinical HerpeCide programs.

Given the limited financing, we have not been able to attract the necessary talent for replacing the lost staff and for building out the necessary additional resources such as QA/QC. We have been working with our extremely versatile and multi-talented team, in a task-serialized fashion, over the last several years. While the versatility of the team has enabled us to develop and establish most of the required quality assays and methods, we will be severely limited in our abilities in producing a cGMP product until the staffing is enhanced.

After we are able to attract and hire quality candidates that we severely need, we anticipate that it will take at least six months to one year for each such person to be fully productive as an integrated part of our team. In the past, we have been very fortunate that newly hired personnel were immediately productive in tasks delineated to them, and they were productively integrated within a short time frame of several months into independent but integrated parts of our team. However, this is not always the case.

We operate in a completely novel area of medicines, which is broadly described as polymeric-micelle based drug conjugates and complex nanomedicines. Our technologies are also completely novel, and unmatched in the industry. As such, we anticipate a longer training period for new employees than in normal small chemical or biological drugs. We continue to seek talented scientists and engineers with specialized training. However, it is difficult to attract such talent for a small, pre-revenue pharma company such as ours.

We employ the same team that developed the small-scale synthesis chemistry for translation of those chemical syntheses into clinical-scale processes, and also to perform the related chemical engineering, quality control, quality assurance, and regulatory tasks along the way. Because of the small size of our scientific staff, this results in significant serialization of efforts. However, the personnel cost, as well as the time and expense cost of transfer of knowledge and training of a separate dedicated team is avoided because the same expert scientists who have developed the chemistries are also involved in scaling them up into process scale. To enable such extensive multi-tasking, we have a continuous training program in place, with both formal and informal components. We believe that this approach helps us keep drug development costs as low as possible.

#### *Our BSL-2 Certified Virology Lab*

Most importantly, we have significantly enhanced our internal anti-viral cell culture testing capabilities at our Shelton campus. We have achieved BSL-2 (Biological Safety Level 2) certification from the State of Connecticut for our Virology suite at the new campus. This suite comprises three individual virology workrooms, enabling us to work on several different viruses and strains at the same time. This facility is designed only for cell culture studies on viruses, and no animal studies can be conducted at any of our own facilities. We have brought in Brian Friedrich, Ph.D. as the Company's Virologist. Dr. Friedrich has previously performed drug screening of hundreds of candidates against several viruses including alphaviruses, bunyaviruses, and filoviruses (namely, Ebola and Marburg, which are BSL-4), to discover potential therapeutics, while he was at United States Army Medical Research Institute of Infectious Diseases (USAMRIID). Brian has also worked extensively on Flaviviruses, specifically West Nile Virus, while at University of Texas Medical Branch (UTMB). He has also worked on HIV as part of his PhD thesis. Dengue viruses as well as the Zika virus belong to the Flavivirus family.

Dr. Friedrich has already established several different types of assays for screening of candidates against VZV, HSV-1 and HSV-2 in our lab. He is now in the process of establishing assays for Influenza viruses and HIV. We believe that having developed the internal capabilities for cell culture testing of our ligands and nanoviricides against a variety of viruses has substantially strengthened our drug development programs. We believe that this internal screening enables speedy evaluation of a much larger number of candidates than external collaborations allow. This has significantly improved our ability of finding highly effective ligands and performing structure-activity-relationship studies of the same in a short time period.



*Manufacturing Requirements of Some of Our Drug Candidates*

The HerpeCide program drug product batch requirements are estimated to be fairly modest because of the topical nature of treatment. In consultation with BASi and BCG, we have currently estimated a batch size of approximately 500g will be sufficient for the “Tox Package” (i.e. safety and toxicology) studies of our dermal topical shingles drug candidate. We are estimating that a ~500g batch will be more than sufficient for initial Phase-I human clinical studies as well. Our current estimate for a Phase IIa human clinical efficacy study is also in the range of a ~500g batch requirement. We already have the facilities for producing up to 1kg per batch or more. Many of our synthesis steps have already been scaled up to 200g~500g scales. The “nanomicelle” polymer manufacture is now scaled to ~500-750g scale. Some of the synthetic steps have also been tested successfully at kg scales. Thus we believe that we have sufficient production capability for the amounts of the HerpeCide drugs that would be needed for tox package as well as clinical studies.

As we move our drug candidates into clinical studies, we plan to perform further scale-up studies to get to about 1kg per batch production scale. In the current facility, we may be able to manufacture about 10kg to 20kg of cGMP product annually. Depending upon the drug’s potency and indication, this production size may fetch modest revenues of around \$50M to \$500M, depending upon the cost metrics, enabling profitable market entry. Such initial commercialization would allow the Company to turn itself into a stand-alone pharmaceutical company, by enabling capital formation for larger scale manufacturing facilities and fueling further growth.

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

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

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

Our animal efficacy studies are performed by third parties. We opt into drug developments against specific disease indications for which we have appropriate partners that can perform the necessary cell culture and animal efficacy studies.

NanoViricides technology is now maturing rapidly toward the clinical studies. However, as is true with other pre-revenue biopharma drug development companies, we will need to raise additional capital to meet our clinical drug development goals.

During the reported quarter we have continued to perform further optimization of our anti-HSV-1, anti-HSV-2, and anti-VZV drug candidates. We have increased our efforts at characterization and study of each synthetic step in order to develop a knowledge base for further scale up of syntheses to larger scales. This process, as is well known in the industry, requires painstaking studies, and is time consuming. In April 2015, we reported dramatic improvement in clinical symptoms associated with a herpes simplex virus dermal infection in mice. The topical nanoviricide treatment significantly reduced the clinical disease, and led to >85% survival of the mice dermally infected with a highly aggressive, neurotropic, HSV-1 H129c strain, wherein all of the untreated mice had severe clinical morbidity and none of the untreated mice survived. Later in August 2015, we reported that these results were reproduced at a different laboratory, with 100% survival being observed. The repeat studies were conducted by Transpharm Preclinical Solutions, a pre-clinical contract research services organization (CRO), in Jackson, MI. We plan to replicate similar studies of our antiviral candidates in appropriate models for shingles, ocular HSV-1 infection and genital HSV-2 infection.

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

We are currently performing the studies necessary for selection of IND candidates (i.e. clinical drug candidates) for several indications related to herpes viruses under our HerpeCide™ program. These indications include shingles, ocular herpes keratitis, oral herpes (“cold sores”), genital herpes, and v-ARN. After initial achievement of efficacy in the HSV-1 dermal model, we are now working on establishing the best anti-HSV ligand for our anti-HSV drug candidate in this model. New ligands, based on a SAR (“structure-activity-relationship”) modeled after our successfully tested earlier ligands were developed using knowledge-based approaches including molecular modeling and bioinformatics studies in our laboratory. We are now scaling up the synthesis of the two most broadly applicable and successful ligands active against the tested herpesvirus indications. We are also performing CMC studies required as part of the IND package for these ligands as well as appropriate backbone polymers.

The nanomedicine technology enables tailor-made nanomicelle polymer compositions so that transport across skin layers and delivery to the site of action can be accomplished properly. Different nanomicelle compositions may be better suited for intravitreal delivery.

Once these studies are successfully completed, we expect that we will be able to announce a broad-spectrum clinical drug development candidate for the topical treatment of shingles outbreak. We believe that clinical candidates for the dermal topical treatment of HSV-1 and HSV-2 infections should be identified after further testing for effectiveness in appropriate animal models of the disease for these respective indications.

We had discussions with BASi, Toxicology Services of West Lafayette, IN (“BASi”), a CRO for GLP and non-GLP safety/toxicology studies recently regarding the Safety/toxicology studies that would be needed for our topical dermal skin cream for the treatment of various herpesvirus skin infections including zoster (shingles), herpes labialis, and herpetic genital ulcers. We have also held discussions with other experts in the industry. We have developed a plan for the required studies, and are in the process of estimating the drug product requirements. We believe that we have the facilities for producing the drug product batches needed for the safety/tox studies as well as the initial human clinical trials.

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

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

A major impediment in VZV infection studies is a lack of suitable animal models because VZV is restricted to human tissue and only infects and replicates in human tissue. To overcome this problem, Dr. Moffat has developed an “*ex-vivo*”

human skin organ culture VZV infection model for the evaluation of therapeutics. This model is a good representative model of natural VZV infection in humans as well as an important model for evaluating antiviral activity, because it demonstrates behavior similar to the skin lesions caused by VZV in human patients.

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

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

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

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

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

We have performed preliminary safety and toxicology studies on certain drug candidates in the FluCide program. In all of the studies conducted, the drug candidates were found to be extremely safe. Both mouse and rat models have been employed for these studies. Some of the earlier studies were performed at KARD Scientific. Recent studies have been performed at BASi, Inc., a well-regarded pre-clinical CRO for tox package studies. As a result of the strong safety, we have estimated a batch size requirement of about 2kg ~ 2.5kg of Injectable FluCide that will be needed to complete the full set of tox studies as well as efficacy studies in different influenza virus strains in cell cultures as well as in animal models. However, the HerpeCide program drug candidates are expected to require only 100g~500g scale batch production for toxicological and initial human clinical trials studies. We have therefore re-prioritized our programs last year and are now focused on the scale up studies for the HerpeCide drug candidates at approximately 200g scale of production. We will be able to continue further development of a 1kg~2kg per batch scale for FluCide drug candidates after we have completed the HerpeCide program scale up.

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

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

We believe that because of the smaller quantity requirements and the less rigorous tox package studies needed for the dermal topical treatment, our anti-HSV-1, anti-HSV-2, and anti-VZV drug candidates are likely to move more rapidly towards clinical stage, while we continue to work on our anti-influenza drug candidate.

As part of the advanced IND-enabling development of our Injectable FluCide™ drug candidate, we performed initial safety-toxicology screening of an optimized FluCide™ drug candidate in a GLP-like toxicology study in rats. We reported that a good safety profile was observed for this drug candidate in rats, around the end of January 2015. These results are extremely important since they indicate that FluCide continues to look very promising as one of the most advanced candidates in the Company's drug development pipeline.

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

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

The study was conducted at BASi. The study was performed in a cGLP-like fashion, compliant with BASi Evansville standard operating procedures. BASi has over 40 years of experience providing contract research services and niche instrumentation to the life sciences, primarily drug research and development. This study was developed in collaboration with BASi and conducted by BASi in a c-GLP-like fashion in order to understand the safety parameters of FluCide intravenous dosing.

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

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

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

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

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

The Company has kept its capital expenditures to a minimum in the past, and we intend to continue to do the same, in order to conserve our cash for drug development purposes, and in order to minimize additional capital requirements.

**Collaborations, Agreements and Contracts**

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

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

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

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

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

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

In addition, we have signed a Master Services Agreement with Public Health England (PHE), UK.

We have a CRADA-Materials Transfer Agreement with USAMRIID for the evaluation of our anti-Ebola nanoviricide drug candidates.



We anticipate completing master services agreements, after performing our due diligence, with additional parties in furtherance of our anti-viral drug development programs.

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

### **Patents, Trademarks, Proprietary Rights: Intellectual Property**

The nanomedicine technologies licensed from TheraCour Pharma, Inc. (“TheraCour”) serve as the foundation for our intellectual property. NanoViricides 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 NanoViricides 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. NanoViricides may want to add further virus types to its drug pipeline, which would require negotiation with TheraCour for the same.

NanoViricides, Inc. holds exclusive, worldwide, perpetual, licenses from TheraCour Pharma, Inc. to these technologies and patents for a broad range of antiviral applications and diseases that include all Influenzas including Asian Bird Flu Virus, Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Dengue viruses, West Nile Virus, Rabies virus, Ebola/Marburg viruses, Japanese Encephalitis virus, as well as viruses causing viral Conjunctivitis (a disease of the eye) and ocular herpes. NanoViricides currently holds two licenses in perpetuity to develop and sell drugs for the treatment of these viral diseases.

These licenses are provided for all the intellectual property held by TheraCour Pharma, Inc. that relates to our antiviral licensed products. These licenses are not limited to underlying patents, but also include the know-how, trade secrets, and other important knowledge base that is utilized for developing the drugs and making them successful.

In addition, these extremely broad licenses are not limited to some specific chemical structures, but comprise all possible structures that we could deploy against the particular virus, based on these technologies. In addition, the licenses are held in perpetuity by NanoViricides for worldwide use. The licenses are also exclusively provided to

NanoViricides for the licensed products so NanoViricides is the only party that can further sublicense the resulting drugs to another party, if it so desires. TheraCour cannot further license anything in our licensed products areas because of the breadth of the license. The licenses can revert only in the case of a default by NanoViricides. The terms of default are such that, effectively, TheraCour would be able to take the licenses back only in the event that NanoViricides files bankruptcy or otherwise declares insolvency and the inability to conduct its business. This structure is standard in the licensing world as it saves the IP from being blocked from commercialization in lengthy and potentially fragmentary bankruptcy proceedings.

A fundamental Patent Cooperation Treaty (“PCT”) patent application, on which the nanoviricides® technology is based, has resulted in additional issued patents in Europe and Korea. As with issuances in other countries including the United States, these patents have been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The corresponding original “pi-polymer” international application, namely, PCT/US06/01820, was filed under the Patent Cooperation Treaty (PCT) system in 2006. Several other patents have already been granted previously in this patent family in various countries and regions, including Australia, ARIPO, Canada, China, Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, OAPI, Philippines, Singapore, Vietnam, South Africa, and the USA. Prosecution in several other countries continues. In May 2012, the US Patent (No. 8,173,764) was granted for “Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers.” The US patent term is expected to last through October 1, 2028, including anticipated extensions in compensation for time spent in clinical trials. This US Patent has been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The disclosed structures enable self-assembling, biomimetic nanomedicines. Estimated expiry dates for these patents range nominally from 2027 to 2029 with various extensions accounting for delays in clinical trials. Additional issuances are expected in Europe, and in several other countries around the world.

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

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

The patents are 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 groundbreaking work was performed. AllExcel, Inc. has contractually transferred this intellectual property to TheraCour Pharma, Inc.

The Company has an exclusive license in perpetuity for technologies developed by TheraCour for the following virus types: HIV, Hepatitis C Virus, HSV, Asian (bird) flu, Influenza, and rabies. 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 for Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses. (Also please see under “Significant Alliances: Related Parties: TheraCour Pharma”).

NanoViricides has entered into a Memorandum of Understanding with TheraCour, whereby TheraCour will initiate discovery and development for drug candidates for a new virus or indication upon request. If the resulting drug candidates are worthy of further drug development, NanoViricides may determine that it should enter into a licensing agreement with TheraCour. In such a case, NanoViricides would obtain an independent asset valuation for the asset(s) to be licensed from a party experienced in such valuations. NanoViricides and TheraCour would thereafter negotiate the terms of compensation for the new license agreement. However, there can be no assurance that an agreement for licenses for new viruses will be entered into on terms that are favorable to NanoViricides. We believe this process has been extremely beneficial for NanoViricides, since this process saves NanoViricides from the cost of acquiring and paying for licenses that it may not want to pursue further. At present, TheraCour has licensed to NanoViricides HSV-1 and HSV-2, but has not licensed the VZV area, nor has it licensed any of the remaining herpesviruses. Licensing of these assets is currently in process as described earlier.

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

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

The issued patents have nominal expiry dates in 2026 to 2029. The dates can be further extended in several countries and regions for the additional allowances due to the regulatory burden of drug development process, or other local considerations, such as licensing to a local majority held company. Many countries allow up to five years extension for regulatory delays.

No patent applications have been filed for the actual drug candidates that we intend to develop as drugs as of now. We intend to file the patent application for FluCide and HerpeCide before entering human clinical trials. The estimated expiry date for the FluCide and HerpeCide patents, if and when issued, would be no earlier than 2037.

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

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or reexamination proceedings regarding the enforcement or validity of our licensor, TheraCour Pharma Inc.'s existing patents or any future patents, could invalidate TheraCour's patents or substantially reduce their protection. In addition, the pending patent applications and patent applications filed by TheraCour, may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing the same compounds and products that we have developed or are developing. In addition, certain countries do not permit enforcement of our patents, and manufacturers are able to sell generic versions of our products in those countries.



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

## **Trademarks**

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

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

As of December 31, 2017, we had cash and equivalents of \$12,046,400, prepaid expenses of \$239,532, and property and equipment of \$11,030,679, net of accumulated depreciation of \$2,838,422. Long-term liabilities were \$1,068,110 and stockholders' equity was \$15,918,374 at December 31, 2017.

In comparison, as of June 30, 2017, we had cash and equivalents of \$15,099,461, and \$190,166 in prepaid expenses. Property and equipment stood at \$11,271,060 net of accumulated depreciation of \$2,505,501. Long-term liabilities were \$2,015,354 and the stockholders' equity was \$20,321,942 at June 30, 2017.

During the six-month period ended December 31, 2017 we used approximately \$2,961,000 in cash toward operating activities.

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

Based on the current rate of expenditures (excluding capital costs), we believe that we have sufficient funds in hand to last more than twelve months. In addition, in order to conserve cash, we also pay compensation in stock and stock instruments to various parties. The Company believes that our spending continues to be in line with our estimates. Management believes that it will have to raise additional capital to fund and perform additional projected work, which is beyond normal pre-clinical development operations, leading towards an Investigational New Drug Application (IND) filing with the U.S. Food and Drug Administration (FDA), to continue through and beyond February 2019.

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

#### Research and Development Costs

The Company does not maintain separate accounting line items for each project in development. The Company maintains aggregate expense records for all research and development conducted. Because at this time all of the Company's projects share a common core material, the Company allocates expenses across all projects at each period-end for purposes of providing accounting basis for each project. Project costs are allocated based upon labor hours performed for each project. Far fewer man-hours are spent on the projects at low priority than the projects at high priority. In this quarter, we have focused primarily on our HerpeCide program drug candidates, while continuing limited work on our FluCide program

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

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 one of the drugs under development in animal models. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further studies in animal models to obtain necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles of our drug candidates, provided that appropriate levels of funding become available. We believe this data will then enable us to file an Investigational New Drug Application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

Most pharmaceutical companies expect 4 to 10 years of study to be required before a drug candidate reaches the IND stage. We believe that because we are working in the infectious agents area, our studies will have objective response end points, and most of our human clinical studies will be of relatively short duration. 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.

## **Results of Operations**

The Company is a biopharmaceutical company and did not have any revenue for the three and six month periods ended December 31, 2017 and 2016.

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

**Research and Development Expenses** – Research and development expenses for the three months ended December 31, 2017 increased \$125,135 to \$1,386,135 from \$1,261,000 for the three months ended December 31, 2016, and for the six months ended December 31, 2017 decreased \$171,774 to \$2,541,363 from \$2,713,137 for the six months ended December 31, 2016. The increase in the cost of research and development for the three months ended December 31, 2017 is largely attributable to the increase in outside laboratory fees to collaborators, lab supplies and materials during the three month period ended December 31, 2017. The Company began laboratory studies with its collaborators in the



quarter ended December 31, 2017. No outside laboratory studies were incurred in the three month period ended September 30, 2017 which is in contrast to the prior year when lab fees paid to our collaborators amounted to approximately \$222,000 in the three months ended September 30, 2016 and were lower in the three months ended December 31, 2016.

**General and Administration Expenses** – General and administrative expenses for the three months ended December 31, 2017 decreased \$28,972 to \$1,007,646 from \$1,036,618 for the three months ended December 31, 2016 and for the six months ended December 31, 2017 increased \$57,934 to \$2,082,864 from \$2,024,930 for the six months ended December 31, 2016. The decrease over the three month period and the increase over the six month period resulted primarily from changes in operating expenses in general.

**Interest Income**– Interest income increased \$13,236 to \$24,970 for the three months ended December 31, 2017 from interest income of \$11,734 for the three months ended December 31, 2016. Interest income increased \$23,451 to \$49,362 for the six months ended December 31, 2017 from \$25,911 for the six months ended December 31, 2016. Interest income included interest on cash equivalent deposits in interest-bearing accounts at market rates. The increase is due to an increase in market interest rates received on our investments.

**Interest Expense on Convertible Debentures** – Interest expense decreased \$184,725 to \$60,275 for the three months ended December 31, 2017, from \$245,000 for the three months ended December 31, 2016. Interest expense decreased \$304,726 to \$185,274 for the six months ended December 31, 2017 from \$490,000 for the six months ended December 31, 2016. The decreases are a result of the repayment of the Company's Series B Debenture on February 8, 2017 and the redemption of the Company's Series C Debenture on November 13, 2017.

**Other Expenses** – Discount on convertible debentures for the three months ended December 31, 2017 decreased \$303,424 to \$119,863 from \$423,287 for the three months ended December 31, 2016. Discount on convertible debentures for the six months ended December 31, 2017 decreased \$467,535 to \$359,214 from \$826,749 for the six months ended December 31, 2016. The decreases in amortization are a result of the repayment of the Company's Series B Debenture on February 8, 2017 and the redemption of the Company's Series C Debenture on November 13, 2017. The Company recorded a loss of (\$1,348,247) on the redemption of the Series C Debentures for the three and six months ended December 31, 2017.

**Other Income** – Change in fair value of derivatives for the three months ended December 31, 2017 decreased \$307,469 to \$1,100,302 from \$1,407,771 for the three months ended December 31, 2016. Change in fair value of derivatives for the six months ended December 31, 2017 increased \$244,089 to \$1,665,151 from \$1,421,062 for the six months ended December 31, 2016. Change in the fair value of derivatives is a non-cash item. It includes an estimate of the change in the Warrant liability based upon certain actuarial assumptions, see Footnote 10 to the Financial Statements and the change in the value of the shares to be issued for the redemption of the Series C Convertible Debenture. The value of 5,500,000 common shares and 150,000 shares of the Company’s Series A Convertible Preferred Stock decreased \$660,000 and \$41,143, respectively for the three and six months ended December 31, 2017.

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

**Net Loss** - For the six months ended December 31, 2017, the Company had a net loss of (\$4,802,449), or \$ (\$0.08) per share on a fully diluted basis compared to a net loss of (\$4,607,843) or (\$0.08) per share on a fully diluted basis for the six months ended December 31, 2016. The Company does not have any revenue and reports its operating and other expenses resulting in a net operating loss for the current period. The net operating loss in the current period was more than the net operating loss for the six months ended December 31, 2016, due to the loss on the redemption of the Company’s Series C Debenture offset by decreases in interest expense and discount amortization.

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

The Company had cash and cash equivalents of approximately \$12,046,000 as of December 31, 2017 and accounts payable and accrued liabilities of approximately \$102,000. The Company had account payables due to a related party, TheraCour Pharma, Inc. of approximately \$1,475,000 and accrued liabilities to a related party, an IRA owned by Dr. Milton Boniuk, a Director of the Company, of approximately \$5,163,000. This accrued liability was incurred when the Company redeemed the Company’s Series C Convertible Debenture and accrued and deferred interest for the Company’s \$0.001 par value Common Stock (See Note 7 to the financial statements). The Company estimates that the redemption of the Series C Convertible Debenture permits the Company to retain approximately \$5,500,000 of cash that would have been otherwise paid to the Holder. The Company is currently awaiting the New York Stock Exchange authorization to issue the common stock in redemption of the debenture.

Since inception, the Company has expended substantial resources on research and development. Consequently, we have sustained substantial losses. The Company has an accumulated deficit of approximately \$79,931,000 at December 31, 2017.

Management believes that the Company's existing cash resources are sufficient for its operations at the current rate of expenditures to continue through February 2019. However, management believes that the available funds are insufficient for the Company's projected work, which is beyond normal pre-clinical development operations, leading towards an Investigational New Drug Application (IND) filing with the U.S. Food and Drug Administration (FDA), to continue through February 2019. The Company has engaged investment banks to advise it as to raising further funding as the Company progresses towards human clinical trials. The Company believes that it can adjust its business plan according to its available resources. Further, the Company believes that it will be able to raise additional funding at an opportune time as it progresses towards human clinical trials. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. Further, the Company cannot provide assurances that it will be able to raise additional funding in a timely manner, and if it can, that it will be on terms favorable for the Company's current shareholders. The accompanying unaudited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

While the Company continues to incur significant operating losses with significant capital requirements, the Company has been able to finance its business through sale of its securities. The Company has in the past adjusted its priorities and goals in line with the cash on hand and capital availability. The Company believes it can adjust its priorities of drug development and its plan of operations as necessary, if it is unable to raise additional funds. The Company has sufficient capital to continue its business for more than one year, at the current rate of expenditure.

We anticipate undertaking additional expenditures towards the goal of filing at least one Investigational New Drug application (IND) with the US FDA or another regulatory agency. We anticipate that we will need to raise additional funds to support these activities as well as the human clinical trials that would follow. Further development of other drug candidates in our drug pipeline will depend upon the availability of appropriate levels of additional funding. 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.

Our estimates for external costs 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.

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.

Management intends to use capital and debt financing, as required, to fund the Company's operations. Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain such additional capital resources or that such financing will be on terms that are favorable to the Company.

### *Off Balance Sheet Arrangements*

We have not entered into any off-balance sheet arrangements during the six months ended December 31, 2017.

### *Subsequent Event*

Effective January 27, 2018 the Company's Chief Executive Officer, Dr. Eugene Seymour, resigned as the Chief Executive Officer and as a Director of the Company to allow a successor with pharmaceutical experience to serve in this capacity. Subject to the entry into a Severance Agreement, Dr. Seymour will assume the role of Chief Executive Officer Emeritus. The Board of Directors commenced a search for a permanent replacement for Dr. Seymour, which is ongoing. Pending the appointment of a permanent Chief Executive Officer, the Board of Directors appointed Dr. Anil Diwan, the Company's President, as interim Chief Executive Officer. As of the date of this report, the Company and Dr. Seymour have not yet entered into a Severance Agreement.

The Company is now actively looking for a CEO with pharmaceutical industry novel chemical entity drug development experience to lead us to our next stage, namely clinical development and, assuming success in the clinic, further commercialization of our drugs. The Company has begun the interview process for the next CEO. However, interviewing multiple candidates, due diligence, selection and offer to a candidate, and the contractual paperwork may take some time to complete.

Meanwhile, the Company's progress is expected to continue unaffected by the loss of the previous CEO, with Dr. Diwan, who has served as the Company's President since 2005, assuming additional duties as interim CEO. Dr. Diwan has been performing several of the CEO duties increasingly since the 2013 uplisting from the OTC Markets to our NYSE listing. Dr. Diwan was instrumental in the design, development, and financing of our modern, state of the art nanomedicines synthesis, characterization, and production facility. Further, Dr. Diwan led several of the Company's financing efforts with Dr. Seymour including two registered direct offerings conducted in September 2013 and January 2014 respectively, that raised approximately \$30 million.

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

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

**ITEM 4. CONTROLS AND PROCEDURES - Disclosure controls and procedures.**

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

As of December 31, 2017, we carried out an evaluation, with the participation of our management, including our chief executive officer and our chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

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

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Subsequent to the reporting period, due to the resignation of the CEO and appointment of Dr. Diwan as Interim CEO, the Company has adopted temporary modified procedures for the treatment of related party invoices, namely, those from TheraCour Pharma, Inc. The TheraCour Pharma invoices, upon the normal review and approval by the Company’s Controller, will be submitted, rather than to the Company’s CEO for review and approval (which is the

normal process), to the Audit Committee for further examination, review, and recommendation by the Board for approval. The procedure will revert to review and approval by the CEO, once a permanent CEO is appointed.

## **PART II. OTHER INFORMATION**

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

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

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

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

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 7,716 and 15,432, respectively, fully vested shares of its Series A Convertible Preferred stock for employee compensation.

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 26,468 and 46,530, respectively, fully vested shares of restricted common stock for consulting services.

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 11,019 and 19,377, respectively, fully vested shares of its restricted common stock for Director Services.

All of the securities set forth above were issued by the Company pursuant to Section 4(a)(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**

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 26,468 and 46,530, respectively, fully vested shares of restricted common stock for consulting services.

For the three and six months ended December 31, 2017, the Company's Board of Directors authorized the issuance of 11,019 and 19,377, respectively, fully vested shares of its restricted common stock for Director Services.

Effective January 27, 2018, the Company's Chief Executive Officer, Dr. Eugene Seymour, resigned as the Chief Executive Officer and as a Director of the Company for personal reasons. Subject to the entry into a Severance



Agreement, Dr. Seymour will assume the role of Chief Executive Officer Emeritus. The Board of Directors commenced a search for a permanent replacement for Dr. Seymour, which is ongoing. Pending the appointment of a permanent Chief Executive Officer, the Board of Directors appointed Dr. Anil Diwan, the Company's President, as Interim Chief Executive Officer. As of the date of this report, the Company and Dr. Seymour have not yet entered into a Severance Agreement.

## ITEM 6. EXHIBITS

### Exhibit No. Description

31.1            Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Executive Officer

31.2            Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Financial Officer

32.1            Section 1350 Certification of Chief Executive Officer

32.2            Section 1350 Certification of Chief Financial Officer

101.INS        XBRL Instance Document

101.SCH        XBRL Taxonomy Extension Schema Document

101.CAL        XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF        XBRL Taxonomy Extension Definition Linkbase Document

101.LAB        XBRL Taxonomy Extension Label Linkbase Document

101.PRE        XBRL Taxonomy Extension Presentation Linkbase Document

**SIGNATURES**

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

**NANOIRICIDES, INC.**

/s/ Anil R. Diwan

Dated: February 20, 2018 Name: Anil R. Diwan  
Title: President, Chairman of the Board and Interim Chief Executive Officer  
(Chief Executive Officer)

/s/ Meeta Vyas

Dated: February 20, 2018 Name: Meeta Vyas  
Title: Chief Financial Officer  
(Chief Financial Officer)