NANOVIRICIDES, INC. Form 10-O November 19, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION	N
Washington, D.C. 20549	

FORM 10 - Q

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

For the quarterly period ended September 30, 2008

Commission File Number: 0001379006

# NANOVIRICIDES, INC.

(Exact name of registrant as specified in its charter)

**NEVADA** 

76-0674577 (IRS Employer Identification No.)

(State or other jurisdiction)

of incorporation or organization)

135 Wood Street, Suite 205 West Haven, Connecticut 06516 (Address of principal executive offices and zip code) (203) 937-6137 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (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 registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes £ No T

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

Large accelerated filer £ Accelerated filer £

Non-accelerated filer £ Smaller reporting company T

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

Yes £ No T

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes £ No T
The number of shares outstanding of the Registrant's Common Stock as of November 10, 2008 was 122,705,10 shares.
1

# NanoViricides, INC. FORM 10-Q INDEX

# PART I FINANCIAL INFORMATION

Item 1.	Financial Statements							
Balance Sheets – September 30, 2008 (Unaudited) and June 30, 2008 (Audited) 3								
Statements of Operations (Unaudited) - For the Three Months Ended September 30, 2008 and 2007, and for the Cumulative Period May 12, 2005 (Inception) through September 30, 2008.								
Statements of Cash Flows (Unaudited) Cumulative Period May 12, 2005 (Incompared to the Compared to the Compare	) - For the Three Months Ended September 30, 2008 and 2007, and for the eption) through September 30, 2008.	5						
Notes to Financial Statements (Unaudi	ited)	7						
Item 2.	Management's Discussion and Analysis of Financial Condition and Plan of Operation	14						
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	19						
Item 4.	Controls and Procedures	20						
PART II OTHER INFORMATION								
Item 1.	Legal Proceedings	21						
Item 2.	Changes in Securities	21						
Item 3.	<u>Defaults Upon Senior Securities</u>	21						
Item 4.	Submission of Matters to a Vote of Security Holders	21						
Item 5.	Other Information	21						
Item 6.	Exhibits and Reports on Form 8-K	22						
<u>Signatures</u>		23						
Certifications		24						
2								

# <u>Index</u>

# NANOVIRICIDES, INC. (A DEVELOPMENT STAGE COMPANY) BALANCE SHEETS

	Se	eptember 30, 2008		June 30, 2008
		Unaudited		
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	2,985,247	\$	816,386
Prepaid expenses		426,735		328,544
Other current assets		102,873		102,873
Total current assets		3,514,855		1,247,803
Property and equipment, net		562,436		133,738
OTHER ACCETS				
OTHER ASSETS				
Conveity demonit		69,000		90,000
Security deposit Trademarks, net		68,000 6,583		80,000 6,709
Total Other Assets		74,583		86,709
Total Other Assets		74,363		80,709
TOTAL ASSETS	\$	4,151,874	\$	1,468,250
TOTAL ASSLIS	Ψ	4,131,074	Ψ	1,700,230
LIABILITIES AND SHAREHOLDERS' EQUITY				
EMBIETIES AND SIMMERICEDERO EQUITI				
CURRENT LIABILITIES:				
Accounts payable – trade	\$	269,133	\$	295,555
Accounts payable – related parties		546,749		374,394
Accrued expenses		93,000		96,130
Accrued payroll to officers and related payroll tax expense		92,756		258,432
• • • • • • • • • • • • • • • • • • • •				
TOTAL CURRENT LIABILITIES		1,001,638		1,024,511
COMMITMENTS AND CONTINGENCIES				
SHAREHOLDERS' EQUITY				
Common stock, \$0.001 par value; 300,000,000 shares authorized at September 30,				
2008; issued and outstanding:.122,705,105, and 119,270,677 at September 30, 2008				
and June 30, 2008 respectively		122,705		119,271
Additional paid-in capital		12,980,025		9,532,205
Deficit accumulated during the development stage		(9,952,494)		(9,207,737)
TOTAL GUARENOL DEDGLEOLUTY		0.150.005		4.40. = 2.6
TOTAL HARH ITIES AND SHAPEHOLDERS' FOLUTY	ф	3,150,236	ф	443,739
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	4,151,874	\$	1,468,250

The accompanying notes are an integral part of these financial statements.

# <u>Index</u>

# NANOVIRICIDES, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF OPERATIONS (Unaudited)

		Three Mont Septemb		Po M	For the Cumulative eriod From ay 12, 2005 Inception) through ptember 30, 2008
		2008	2007		
Revenues	\$	-	\$ -	\$	-
Operating expenses:					
operating expenses.					
Research and development		230,750	158,814		2,932,647
Refund credit for research and development costs		_	_		(200,190)
General and administrative (of this amount \$73,700, \$36,357, and \$1,136,322 was for stock and option based compensation to					(=00,170)
consultants and officers for each period presented)		526,084	423,832		6,561,183
Total operating expenses		756,834	582,646		9,293,640
Loss from operations		(756,834)	(582,646)		(9,293,640)
Other income (expense):					
Interest income		12,077	7,914		128,155
Non cash interest on convertible debentures		-	-		(73,930)
Non cash interest expense on beneficial conversion feature of convertible debentures					(712.070)
Total other income (expense)		12,077	7,914		(713,079) (658,854)
Total other income (expense)		12,077	7,914		(030,034)
Net loss	\$	(744,757)	\$ (574,732)	\$	(9,952,494)
Net loss per share: basic and diluted	\$	(.01)	\$ (.01)		
		` ,			
Weighted average shares outstanding: basic and diluted	1	20,341,445	114,222,270		

The accompanying notes are an integral part of these financial statements.

# <u>Index</u>

# NANOVIRICIDES, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF CASH FLOWS (UNAUDITED)

					For the Cumulative Period From May 12, 2005 (Inception)
	Th	ree Months End	ed Sept	tember 30,	through September 30,
ODED ATING A CTIVITIES.		2008		2007	2008
OPERATING ACTIVITIES:	ф	(744.757)	ф	(574.722)	¢ (0.052.404)
Net loss	\$	(744,757)	\$	(574,732)	\$ (9,952,494)
Adjustments to reconcile net loss to net cash used in					
operating activities: Shares issued for services rendered		26 200		10 400	660 157
		26,200		18,400 14,800	660,157
Warrants granted to scientific advisory board Options issued to officers as compensation		47,500		3,157	354,741 121,424
Depreciation and amortization		1,628		1,282	10,675
Amortization of deferred financing expenses		1,020		1,202	51,175
Non cash interest on convertible debentures		_		<u>-</u>	73,930
Non cash interest expense on beneficial conversion feature		<del>-</del>		_	75,750
of convertible debentures		_		_	713,079
Changes in assets and liabilities:					715,075
Prepaid expenses		(98,191)		21,833	(426,735)
Deferred expenses		(50,151)		21,033	(2,175)
Other current assets		_		_	(102,873)
Accounts payable- trade		123,578		4,972	419,133
Accounts payable –related parties		172,355		(99,080)	546,749
Accrued expenses		(3,130)		(30,247)	93,000
Accrued payroll to officers and related payroll tax expense		(165,676)		35,352	92,756
		( , ,		/	,,,,,,
Net cash used in operating activities		(640,493)		(604,263)	(7,347,458)
INVESTING ACTIVITIES:		10.000			(60,000)
Security deposit		12,000		-	(68,000)
Purchases of property and equipment		(430,200)		-	(572,107)
Purchase of trademarks		(410.200)		-	(7,587)
Net cash used in investing activities		(418,200)		-	(647,694)
FINANCING ACTIVITIES:					
Proceeds from issuance of convertible debentures					1,000,000
Proceeds from issuance of common stock and warrants		-		-	1,000,000
in connection with private placements of common stock –					
net of fees		3,227,554		2,375,000	8,970,379
not of fees		J,441,JJ <del>4</del>		2,373,000	920,000
		_		-	920,000

Edgar Filing: NANOVIRICIDES, INC. - Form 10-Q

Proceeds from exercise of stock warrants attached to			
convertible debentures			
Proceeds from exercise of stock options	-	-	90,000
Stock subscriptions received	-	-	20
Net cash provided by financing activities	3,227,554	2,375,000	10,980,399
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,168,861	1,770,737	2,985,247
CASH AND CASH EQUIVALENTS, BEGINNING OF			
PERIOD	816,386	967,797	-
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 2,985,247	\$ 2,738,534	\$ 2,985,247

The accompanying notes are an integral part of these financial statements.

# <u>Index</u>

# NANOVIRICIDES, INC. (A DEVELOPMENT STAGE COMPANY) STATEMENTS OF CASH FLOWS (CONTINUED) SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITY (UNAUDITED)

During the periods indicated below, the Company had the following non-cash activity:

			Ci Pe	For the umulative riod From
	Three Mor Septem 2008		(I	nception) through otember 30,
Common stock issued for services rendered	\$ 26,200	\$ 18,400	\$	660,157
Stock options issued to the officers as compensation	-	3,157		121,424
Stock warrants granted to scientific advisory board	47,500	14,800		354,741
Stock Warrants granted to Brokers	9,849	-		9,849
Common stock issued for interest on debentures	-	-		73,930
Shares of common stock issued in connection with debenture offering	-	-		49,000
Common stock issued upon conversion of convertible debentures	-	-		1,000,000
Debt discount related to beneficial conversion feature of convertible debt	-	-		713,079
Warrants issued in connection with private placement	827,485	-		2,090,117
Common Stock issued upon conversion of accounts payable	150,000	-		150,000

The accompanying notes are an integral part of these financial statements.

# NANOVIRICIDES, INC (A DEVELOPMENT STAGE COMPANY) NOTES TO FINANCIAL STATEMENTS SEPTEMBER 30, 2008 AND 2007 (Unaudited)

# Note 1. Basis of Presentation

The accompanying unaudited interim financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 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 accounting principles generally accepted in the United States of America for complete financial statements.

In the opinion of Management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation for the interim periods have been included. Operating results for the three month period ended September 30, 2008, are not necessarily indicative of the results that may be expected for the year ending June 30, 2009. 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 year ended June 30, 2008.

# Note 2. Organization and Nature of Business

NanoViricides, Inc. was incorporated under the laws of the State of Colorado on July 25, 2000 as Edot-com.com, Inc., and 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 the Company as a Nevada corporation. On May 12, 2005, the Corporations were merged and Edot-com.com, Inc., a Nevada corporation, (the Company), 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 Transaction. For financial accounting purposes, this acquisition was a reverse acquisition of the Company by NVI, under the purchase method of accounting, and was treated as a recapitalization with NVI as the acquirer. Accordingly, the financial statements have been prepared to give retroactive effect to May 12, 2005 (date of inception), of the reverse acquisition completed on June 1, 2005, and represent the operations of NVI.

On June 28, 2005, NVI was merged into its parent ECMM and the separate corporate existence of NVI ceased. Effective on the same date, EDOT-COM.COM, Inc. changed its name to NanoViricides, Inc. and its stock symbol to "NNVC", respectively. The Company is considered a development stage company at this time.

NanoViricides, Inc. (the "Company"), is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. We are a development stage 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., to which we have the necessary licenses in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza, Rabies, and Asian Bird Flu Virus. TheraCour has granted us the right to include dengue fever among the viruses we are able to treat. However, no written agreement has been entered into with TheraCour and no assurance can be given that a written amendment to the licensing agreement with TheraCour will ever be reached or that, if reached, will be on terms favorable to the Company.

# **Index**

We focus our research and clinical programs on specific anti-viral therapeutics. We are seeking to add to our existing portfolio of products through our internal discovery and clinical development programs and through an in-licensing strategy. To date, the Company has not developed any commercial products.

# Note 3. Substantial Doubt Regarding Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, they do not include any adjustments relating to the realization of the carrying value of assets or the amounts and classification of liabilities that might be necessary should the company be unable to continue as a going concern. The Company's significant operating losses and significant capital requirements, however, raise substantial doubt about the Company's ability to continue as a going concern.

Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted nano viral drugs. The Company has not yet commenced any product commercialization. The Company has incurred significant operating losses since its inception, resulting in a deficit accumulated during the development stage of \$9,952,494 at September 30, 2008. 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. Despite the Company's financings in 2008 and 2007 and a cash and cash equivalent balance of \$2,985,247 at September 30, 2008, substantial additional financing will be required in future periods, as the Company believes it will require in excess of \$3,000,000 to fund its operations during the next twelve months, and will also require up to \$2,000,000 to finance planned capital costs, and additional staffing requirements during the next twelve months. Please see "liquidity and Capital resources"

Based on the results of in-vivo and in-vitro studies which were completed in the first calendar quarter of 2007 and the Company's April 9, 2007 Cooperative Research and Development Agreement, (CRADA), with the Walter Reed Army Institute of Research, we commenced a program to seek substantial additional financing, to meet our planned cash requirements, through private placements of our common stock and/or incurring debt (See also Note 7). No assurances can be given that financing will be available or be sufficient to meet our capital needs. If we are unable to obtain financing to meet our working capital requirements, then we may be required to modify our operations, including curtailing our business significantly or ceasing operations altogether. On August 22, 2008, the Company raised \$3,286,000 from the sale of stock and "Warrants." This private placement of stock included 150,000 shares of Common Stock and 75,000 Warrants subscribed in consideration of \$150,000 worth of scientific testing performed for the Company. Also on August 22, 2008, the Company consummated subscriptions with its Warrants holders, thereby raising an additional \$106,250.

Management's plan to support the Company in operation and to maintain its business strategy is to raise funds through public and private offerings and to rely on officers and directors to perform essential functions with minimal compensation. If the Company does not raise all of the money it needs from its public and private offerings, it will have to find alternative sources, such as a secondary public offering, a private placement of securities, or loans from its officers, directors, or others. If the Company requires additional cash and cannot raise it, it will either have to suspend operations until the cash is raised or cease business entirely.

The accompanying financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classifications of liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 4. Summary of Significant Accounting Policies

For a summary of significant accounting policies (which have not changed from June 30,2008), see the Company's Annual Report on Form 10-K for the year ended June 30,2008.

Note 5. Significant Alliances and Related Parties

TheraCour Pharma, Inc.

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. The Company and TheraCour have agreed, in principle, to an amendment to the existing Licensing Agreement to include additional virus types among the virus types the Company is permitted to manufacture, use, and offer for sale, and for a payment of a license fee to TheraCour. TheraCour has permitted the Company to use its nanomaterials to develop a treatment for dengue fever until such time as the Company and TheraCour can complete an amendment to the Licensing Agreement to include dengue fever viruses, West Niles Virus, Japanese Encephalitis Virus, and others among the virus types we are permitted to manufacture, use and offer for sale. In consideration for obtaining this exclusive license, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed. (2) to pay \$25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour, (3) we will pay \$2,000 or actual costs, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf (4) make royalty payments (calculated as a percentage of net sales of the licensed drugs) of 15% to TheraCour Pharma, Inc. (5) agreed that TheraCour Pharma, Inc. retains the exclusive right to develop and manufacture the licensed drugs. TheraCour Pharma, Inc. agreed that it will manufacture the licensed drugs exclusively for NanoViricides, and unless such license is terminated, will not manufacture such product for its own sake or for others, (6) TheraCour may request and NanoViricides, Inc. will pay an advance payment (refundable) equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses.

As to the license fee, there can be no assurance that the license fee will be paid or that the amendment will be become effective, in which case TheraCour may revoke our permissive use of its materials, which may adversely impact our operations and cause the termination of our Cooperative Research and Development Agreement (CRADA) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), and The Walter Reed Army Institute of Research (WRAIR), and the United States Armed Forces Institute of Pathology (USAFIP).

TheraCour may terminate the license upon a material breach by us as specified in the agreement. However, we may avoid such termination if within 90 days of receipt of such termination notice we cure the breach.

Development costs charged by TheraCour Pharma, Inc. for the three months ended September 30, 2008 and 2007 were \$220,749 and \$143,653 respectively, and \$2,307,728 since inception. As of September 30, 2008, pursuant to its license agreement the company has paid a security advance of \$351,878 to and held by TheraCour Pharma, Inc. which is reflected in Prepaid Expenses

No royalties are due TheraCour from the Company's inception through September 30, 2008.

On February 27, 2007, NanoViricides, Inc. entered into a sublease to occupy 5,000 square feet of space in Woodbridge, Connecticut. Performance of the Registrant's obligations was guaranteed by TheraCour Pharma, Inc., a principal shareholder of the Registrant and provider of the materials the Registrant uses in its operations.

TheraCour Pharma, Inc., is affiliated with the Company through the common control of it and our Company by Anil Diwan, President, who is a director of each corporation, and owns approximately 70% of the capital stock of TheraCour Pharma, Inc., which itself owns approximately 30% of the capital stock of the Company.

TheraCour Pharma, Inc. owns 35,370,000 shares of the Company's outstanding common stock as of September 30, 2008

The FASB has issued Interpretation No. 46 (FIN-46R) (Revised December 2003), Consolidation of Variable Interest Entities. FIN-46R clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. It separates entities into two groups: (1) those for which voting interests are used to determine consolidation and (2) those for which variable interests are used to determine consolidation (the subject of FIN-46R). FIN-46R clarifies how to identify a variable interest entity and how to determine when a business enterprise should include the assets, liabilities, non-controlling interests, and results of activities of a variable interest entity in its consolidated financial statements.

FIN-46R requires that a variable interest entity to be consolidated by its "Primary Beneficiary." The Primary Beneficiary is the entity, if any, that stands to absorb a majority of the variable interest entity's expected losses, or in the event that no entity stands to absorb a majority of the expected losses, then the entity that stands to receive a majority of the variable interest entity's expected residual returns. If it is reasonably possible that an enterprise will consolidate or disclose information about a variable interest entity when FIN- 46R becomes effective, the enterprise is required to disclose in all financial statements initially issued after December 31, 2003, the nature, purpose, size, and activities of the variable interest entity and the enterprise's maximum exposure to loss as a result of its involvement with the variable interest entity. For all periods presented in the financial statements, the Company evaluated its relationship with TheraCour Pharma, Inc. for purposes of FIN-46R, and concluded that it is not a variable interest entity that is subject to consolidation in the Company's financial statements under FIN-46R.

# KARD Scientific, Inc.

In June 2005, the Company engaged KARD Scientific to conduct pre clinical animal studies and provide the Company with a full history of the study and final report with the data collected. Dr. Krishna Menon, the Company's Chief Regulatory Officer, is also an officer and principal owner of KARD Scientific. Lab fees charged by KARD Scientific for services for the three months ended September 30, 2008 and 2007 were \$ 0 and \$ 0, respectively, and \$554,235 since inception. The Company has paid KARD a \$50,000 advance payment (refundable) towards future fees

# Note 6. Prepaid Expenses

Prepaid expenses are summarized as follows:

	Sept	September 30, 2008		June 30, 2008
TheraCour Pharma, Inc. *	\$	351,878	\$	236,186
Kard Scientific, Inc. *		50,000		50,000
Prepaid other **		24,857		42,358
_	\$	426,735	\$	328,544

<sup>(\*</sup> See Note 5. Significant Alliances and Related Parties)

# Note 7. Equity Transactions

In August 2008, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$1.56 per share. These warrants, if not exercised, will expire in August 2012. The fair value of these warrants in the amount of \$47,500 was recorded as consulting expense.

The fair value of the Company's option-based awards granted were estimated using the Black-Scholes option-pricing model with the following assumptions.

	4
Expected life in years	years
Risk free interest rate	2.90
Expected volatility	104%
Dividend yield	0%

<sup>(\*\*</sup> See Note 10, Commitments and Contingencies)

# **Index**

For the three months ended September 30, 2008, the Company's Board of Directors authorized the issuance of 10,153 shares of its common stock with a restrictive legend, for consulting services. The Company recorded an expense of \$11,200.

For the three months ended September 30, 2008, the Company's Board of Directors authorized the issuance of additional 13,131 shares of its common stock with a restrictive legend, for legal services. The Company recorded an expense of \$15,000.

On August 22, 2008, the Company consummated subscriptions with certain investors whereby the Company sold 3,286,000 shares (the "Shares") of its common stock, par value\$0.001 per share (the "Common Stock") and ("Warrants") to purchase 1,643,000 shares of Common Stock at an exercise price of \$2.00 per share for an aggregate purchase price of \$3,286,000. The 3,286,000 share private placement of stock included 150,000 shares of Common Stock and 75,000 warrants subscribed in consideration of \$150,000 of scientific testing and other laboratory work performed for the Company. The Warrants may be exercised at any time and expire on September 17, 2011. The Company allocated a relative fair value of \$827,485 to these warrants, by using the Black-Scholes option pricing model.

Also on August 22, 2008, the Company consummated subscriptions with certain of its Warrant holders whereby the Company offered all the holders of its \$2.50 Warrants the option of exercising the Warrants at \$1.00 per share of Common Stock, of which warrants to purchase 50,000 shares of Common Stock for an aggregate price of \$50,000 were exercised. Concurrently, the Company consummated subscriptions with certain other of its Warrant holders whereby the Company offered all the holders of its \$1.00 Warrants the option of exercising the Warrants at \$0.75 per share of Common Stock, of which warrants to purchase 75,000 shares of Common Stock for an aggregate price of \$56,250 were exercised.

# <u>Index</u>

Note 8. Stock Options And Warrants

# **Stock Options**

The following table presents the combined activity of stock options issued for the three months ended September 30, 2008 as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding at June 30, 2008	1,875,000	\$ 0.10	7.25	\$ 2,437,500
Granted	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding at September 30,				
2008	1,875,000	\$ 0.10	6.98	\$ 1,406,250
Exercisable at September 30, 2008	1,875,000	\$ 0.10	6.98	\$ 1,406,250

As of September 30, 2008, there was \$ -0- of unrecognized compensation cost, related to non-vested options granted under employment contracts.

# Stock Warrants

The following table presents the combined activity of stock warrants issued for the three months ended September 30, 2007 as follows:

			Weighted
		Weighted	Average
		Average	Remaining
		Exercise	Contractual
	Number of	Price per	Term
Stock Warrants	Shares	share (\$)	(years)
Outstanding at			
June 30, 2008	4,375,000	\$ 1.58	1.46
Granted	1,707,700	1.99	2.94
Exercised	(125,000)	0.85	-
Expired	-	-	-
Canceled	-	-	-
Outstanding at			
September 30,			
2008	5,957,700	\$ 1.70	1.74

Exercisable at September 30,

2008 5,957,700 \$ 1.70 1.74

Of the above warrants, 2,250,000 expire in fiscal year ending June 30, 2009; 160,000 expire in fiscal year ending June 30, 2010; and 1,660,000 expire in fiscal year ended June 30, 2011 and 1,837,700 expire in fiscal year ended June 30, 2012 and 50,000 expire in fiscal year ended June 30, 2013.

#### Note 9. Income Taxes

Deferred taxes arise from the temporary differences between financial statements and income tax recognition of net operating losses. The net operating loss carryforwards will begin to expire in the year 2017 if not utilized. Utilization of the Company's net operating loss carryforwards are limited based on changes in ownership as defined in Internal Revenue Code Section 382. As of September 30, 2008 the Company accumulated a tax loss of \$9,001,237 resulting in a deferred tax benefit of approximately \$4,510,600 which has been offset by a 100% valuation allowance.

During the three months ended September 30, 2008, the valuation allowance increased by \$333,200 over the June 30, 2008 balance.

The Company's deferred tax assets is summarized as follows:

	September 30,		
		2008	June 30, 2008
Net operating loss carryforwards	\$	3,148,900	2,901,100
Research and development credit		850,100	773,100
Other		511,600	503,200
Gross deferred tax assets		4,510,600	4,177,400
Valuation allowances		(4,510,600)	(4,177,400)
Deferred tax assets	\$	-	\$ -

During the year ended June 30, 2008, the Company recognized a refundable Research and Development tax credit of \$200,190, and has received, to date, \$110,318 of this refundable credit. The remaining credit receivable is included under "Other Current Assets" on the Company's Balance Sheet.

The Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, "Accounting for Uncertainty in Income Taxes ("FIN 48"), on July 1, 2007. As required by Interpretation 48, which clarifies SFAS No. 109, Accounting for Income Taxes, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would make more likely than not sustain the position following an audit. For tax positions meeting this standard, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, the Company applied FIN 48 to all tax positions for which the statute of limitations remained open. The adoption of FIN 48 did not have a material impact on the financial statements.

#### Note 10. Commitments and Contingencies

The Company is dependent upon its license agreement with TheraCour Pharma, Inc. (See Note 5). If it loses 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.

While no legal actions are currently pending, the Company may be party to certain claims brought against it arising in the ordinary course of business. It is not possible to estimate the ultimate liability, if any, in these matters. In Management's opinion, the ultimate resolution of such claims is not expected to have a material adverse effect on the financial position of the Company.

# **Operating Lease**

The Company's principal executive offices are located at 135 Wood Street, West Haven, Connecticut, and include approximately 4,100 square feet of office and laboratory space at a base monthly rent of \$4,692 Commencing September 1, 2008 the Company rented additional storage space and the base monthly rent increased to \$7,192. The term of lease expires in February 28, 2011, and may be extended, at the option of the Company, for an additional two years. The lease can be cancelled by the Company upon providing six months written notice.

# **Index**

On February 27, 2007, NanoViricides, Inc. entered into a sublease to occupy 5,000 square feet of space at 4 Research Drive, in Woodbridge, Connecticut. The term of the occupancy is until January 30, 2009 at a monthly rent of \$11,667, plus an additional \$500 per month for utilities.

Total rent expense amounts to \$51,577 and \$40,628 for the three months ended September 30, 2008 and 2007 respectively, and \$296,754 for the period from inception.

# ITEM 2. DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis should be read in conjunction with our unaudited financial statements and related notes included in this report. This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The statements contained in this report that are not historic in nature, particularly those that utilize terminology such as "may," "will," "should," "expects," "anticipates," "estimates," "believes," or "plans" or comparable terminology are forward-looking statements based on current expectations and assumptions.

Various risks and uncertainties could cause actual results to differ materially from those expressed in forward-looking statements. All forward-looking statements in this document are based on information currently available to us as of the date of this report, and we assume no obligation to update any forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements.

# **OUR CORPORATE HISTORY**

NanoViricides, Inc. was incorporated under the laws of the State of Colorado on July 25, 2000 as Edot-com.com, Inc. and 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 the Company as a Nevada corporation, Edot-com.com (Nevada). On April 15, 2005, Edot-com.com (Colorado) and Edot-com.com (Nevada) were merged and Edot-com.com, Inc., (ECMM) a Nevada corporation, became the surviving entity. On April 15, 2005, the authorized shares of common stock was increased to 300,000,000 shares at \$.001 par value and the Company effected a 3.2 - 1 forward stock split effective May 12, 2005.

On June 1, 2005, Edot-com.com, Inc. acquired NanoViricide, Inc., a privately owned Florida corporation ("NVI"), pursuant to an Agreement and Plan of Share Exchange (the "Exchange"). NVI was incorporated under the laws of the State of Florida on May 12, 2005 and its sole asset was comprised of a licensing agreement with TheraCour Pharma, Inc., ("TheraCour)," an approximately 30% shareholder of NVI) for rights to develop and commercialize novel and specifically targeted drugs based on TheraCour's targeting technologies, against a number of human viral diseases. (For financial accounting purposes, the acquisition was a reverse acquisition of the Company by NVI, under the purchase method of accounting, and was treated as a recapitalization with NVI as the acquirer). Upon consummation of the Exchange, ECMM adopted the business plan of NVI.

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. As a result of the Exchange, NVI 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.

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., Inc. changed its name to NanoViricides, Inc. and its stock symbol on the Pink Sheets to "NNVC", respectively. The Company submitted a Form-10SB to the SEC to become a reporting company on November 14, 2006. The Company's filing status became effective in March, 2007. On June 28, 2007, the company became quotable on The OTC Bulletin Board under the symbol NNVC.OB.

The Company is considered a development stage company at this time.

# Management's Plan of Operation

NanoViricides, Inc. (the "Company"), is an early developmental stage nano-biopharmaceutical company engaged in the discovery, development and commercialization of anti-viral therapeutics. The Company has no customers, products or revenues to date, and may never achieve revenues or profitable operations. Our drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc., one of the Company's principal shareholders, from which we have licensed, in perpetuity, the right to develop drug candidates 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), Rabies, Influenza and Asian Bird Flu Virus. We focus our laboratory research and pre-clinical programs on specific anti-viral solutions. Additionally, TheraCour has permitted the Company to use its nanomaterials to develop a treatment against Dengue Fever viruses, Ebola/Marburg viruses, and viruses causing certain eye diseases. The Company anticipates negotiating with TheraCour an amendment to the Licensing Agreement to include those of these additional viruses that the Company determines it wants to follow for further development. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy.

The Company has incurred significant operating losses since its inception resulting in an accumulated deficit of \$9,952,494 at September 30, 2008. For the three months ended September 30, 2008 the Company had a net loss of \$744,757. 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.

To date, we have engaged in organizational activities; sourcing compounds and materials; developing novel compounds and nanomaterials, and experimentation with studies on cell cultures and animals. We have generated funding through the issuances of debt and private placement of common stock. We have not generated any revenues and we do not expect to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or that we will become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations. The Company currently has no long term debt.

# NanoViricides Technologies, Products in Development, and Collaborations

Pharmaceutical drug development is an expensive and long duration proposition. The Management's plan is to develop each of our nanoviricides to the necessary stage(s) and then engage into co-development relationships with other pharmaceutical companies. Such co-development relationships usually may entail upfront payments, milestones payments, cost-sharing, and eventual revenue-sharing, including royalty on sales. There is no guarantee that we will be able to negotiate agreements that are financially beneficial to the Company at the present stage. The Management plans to continue to raise additional funds as needed for our continuing drug development efforts on public markets.

The Company currently has several drug development programs. Our development model is to employ collaborations with academic labs, government labs, as well as external service providers in order to minimize our capital requirements. We currently have collaborations with the Center for Disease Control and Prevention (CDC) and the National (Central) Institute of Hygiene and Epidemiology (NIHE) (Vietnam) for Rabies, with the Armed Forces Institute of Pathology (AFIP) and NIHE for High-Path or Highly Pathogenic Avian Influenzas (which in addition to H5N1, several H9N as well as H7N influenza virus subtypes are highly pathogenic and have cause or have the potential to cause severe influenza epidemics), and the Walter Reed Army Institute of Research (WRAIR) for Dengue family viruses, United States Army Medical Institute of Infectious Diseases (USAMRIID) for Ebola/Marburg family of hemorrhagic viruses, and the Long Island Jewish Medical System, Feinstein Institute of Medical Research (LIJMS) for viral EKC. In addition, our HIV and common influenza studies were subcontracted to KARD Scientific, Inc.,

USA. We have additional collaborations in formalization process for work on Dengue viruses, HIV, and other viruses.

# **Index**

We have developed lead drug candidates against a number of diseases. Proof-of-principle efficacy studies in animals have been conducted successfully in many of these.

Nanoviricides are designed to work by binding to and eliminating virus particles from the blood-stream, just as antibodies do, only potentially much better. This results in reduction in viremia. A nanoviricide is constructed by chemically attaching a ligand designed to bind to virus particle, to a polymeric material that forms a flexible nanomicelle by self-assembly. If antibodies are known to affect a viral disease, it is possible to construct a nanoviricide against it, and there can be a general expectation of some success, depending upon the ligand chosen.

Our RabiCide<sup>TM</sup> program has resulted in candidates that have enabled survival of 20% to 30% of infected animals after disease has set in, using a particular animal model. Further testing is in progress in a different experimental model. We believe that if this testing succeeds, it may be the first ever therapeutic against rabies. Currently, rabies is a uniformly lethal disease with only prophylactic medications available, which comprise of human antibodies, monoclonal antibody mixtures, and rabies vaccine virus strains. The potential market size for a rabies drug worldwide has been estimated at \$300M to \$500M.

Our FluCide<sup>TM</sup> program has a lead drug candidate that has shown efficacies in animals that far exceed the known drugs such as oseltamivir (Tamiflu®, Roche). Our FluCide-HP<sup>TM</sup>, has demonstrated efficacies superior to FluCide against both Clade 1 and Clade 2 H5N1 strains, and is expected to be effective against all High Path influenzas, based on theoretical expectations. With its high efficacies and spectrum of all potentially epidemic influenza causing viruses, we have been able to stop the development of H5N1-specific AviFluCide in laboratory models.

We have obtained significant positive results against Ebola, although additional development was expected to be required even as we engaged into this program, because Ebola virus produces a soluble glycoprotein decoy that may be capable of fooling certain of our virus-binding ligands.

We are currently working on developing anti-Dengue therapeutics.

We recently developed a nanoviricide against adenoviral Epidemic Kerato-Conjunctivits (EKC). EKC is a severe disease of the eye which in some people causes long term or permanent blurred vision. In an animal study, our EKCCide<sup>TM</sup> lead candidate was shown to rapidly resolve the clinical signs of the disease, when treatment was started after infection had set in. The clinical success included demonstration that no SEI's (immunoprecipitates) were formed in treated animals, as opposed to control group. SEI's are known to be the cause of blurred vision. There are currently no approved drugs available against EKC, and it is an active field of drug development research. The Company is not aware of any other animal studies of anti-EKC drug candidates that have demonstrated resolution of clinical disease. There are about 2.5 million cases of EKC annually in the USA alone. The EKC market size worldwide is estimated variously between \$300M and \$1,000M.

1. Our very first animal studies in SCID-hu mice against HIV-I have resulted in a demonstration that our primaryt nanoviricide drug candidate and as well as several other nanoviricide drug candidates in the HIVCide<sup>TM</sup> program were found to be superior to the three-drug oral cocktail (HAART) given according to standard protocol. Resistance to HAART eventually leads to AIDS. It is possible that HIVCide can be used in addition to HAART to obtain even stronger beneficial effects, which may result in a "functional cure" of HIV as defined by Dr. Fauci of NIAID (we believe that the term Functional Cure of HIV may be defined as: The HIV genome integrates into certain human cells that go into hiding or dormancy for several years. While in hiding, they do not produce HIV to any significant extent and are thought to remain unaffected by current anti-HIV drugs. The standard treatment results in very low levels of HIV viremia, but the immune cells (CD4+ T cells) do not increase in count, and may in fact be decreasing at a slow rate. A more effective therapy could result in complete loss of HIV from the blood stream, allowing immune system function to return to normal, and thereby allowing the patient to enjoy normal life without further daily treatment, until an

episode occurs which mobilizes the "sleeping" cells containing HIV genome. Such a therapy would be called a "functional cure" against HIV. A total cure of HIV would require elimination of the dormant cell pool containing the HIV genome. Nanoviricides act by a different mechanism than standard anti-HIV therapy. The Company believes, therefore, that by combining a nanoviricide with current therapy, a functional cure of HIV may be achieved. However, there is no way to predict whether such a treatment would be successful at providing a functional cure of HIV at present). Nevertheless, we believe that HIVCide is a significant anti-HIV candidate, based on current preliminary data, and we intend to develop it further.

We believe that our technologies and capabilities at attacking different viruses are fairly well demonstrated. Our nanoviricides against specific viruses are discussed earlier. In addition, we have developed "Accurate-Drug-In-Field<sup>TM</sup>" or ADIF<sup>TM</sup> technologies that may show efficacy in treating epidemics like H5N1, SARS or Ebola at source by preventing their spread using a therapeutic developed directly in the field. ADIF technologies are applicable to novel, or engineered viruses, or emerging infections whether natural or man-made. This technology may have significant applications in Biodefense area. Between these two spectrums of specific antiviral developed during peace-time effort, and specific antivirals developed as a "war-like" effort (ADIF), we have demonstrated the capability of developing broad-spectrum nanoviricides. Broad-spectrum nanoviricides are based on the notion that a large number of virus families employ the same cell surface receptor. Thus, if we constructed a nanoviricide that "looks like" a cell to the virus, by carrying the portion of such broad-spectrum receptor on the nanomicelle surface, the virus would "try to infect" such a cell biomimetic, and could in the process get entrapped or dismantled. A nanoviricide is designed as a cell biomimetic, and this has made our broad-spectrum nanoviricides approach possible. Such broad-spectrum nanoviricides could be stockpiled to enable treatment of many infectious agents with very few drugs, and thus would be valuable to worldwide disease programs, and Strategic National Stockpiling efforts.

We believe therefore that the Company has a strong, wide and deep pipeline of drugs several years into the future. However, with relatively meager financial resources, the Company continues to juggle prioritization of the various programs, and program achievements. We are also working on bolstering our infrastructure with the objective of enabling us to file pre-IND applications or some of our drug candidates to the FDA. The Company has received significant interest from major pharmaceutical companies in its EKCCide and HIVCide programs to date, and we expect interest to pick up in other programs as well. There is no guarantee that this interest would result in any financially lucrative co-development agreements.

All of our programs are currently at the pre-clinical stage. We have established preliminary proof of efficacy in conducted preliminary safety studies and have obtained indications that all of our nanoviricides are safe to the animal models, and continue to work on further experiments necessary for development as drugs.

All of these drugs candidates are being developed as injectables, except EKCCide which is an ophthalmic formulation or eye drops solution.

# Plan of Operations

The Company's drug development business model was formed in May 2005 with a license to the patents and intellectual property held by TheraCour Pharma, Inc. that enabled creation of drugs engineered specifically to combat viral diseases in humans. This exclusive license from TheraCour Pharma Inc. serves as a foundation for our intellectual property. The Company was granted 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. Additionally, TheraCour has permitted the Company to use its nanomaterials to develop a treatment against Dengue Fever viruses, Ebola/Marburg viruses, and viruses causing certain eye diseases. The Company anticipates negotiating with TheraCour an amendment to the Licensing Agreement to include those of these additional viruses that the Company determines it wants to follow for further development. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy.

The Company intends to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour Pharma, Inc., the exclusive source for these nanomaterials. With sourcing of materials from TheraCour Pharma, Inc., the Company prefers to manufacture these drugs in our own facility. However, the Company may manufacture these drugs 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. The Company has received significant interest from certain major Pharmaceutical companies for potential licensing or co-development of some of our drug candidates. However, none of these distributor or co-development agreements is in place at the current time.

# **Index**

To date, we have engaged in organizational activities; developing and sourcing compounds and preparing nano-materials; and experimentation involving preclinical studies using cell cultures and animals. We have generated funding through the issuances of debt and private placement of common stock (see Item 5 Recent Sales of Unregistered Securities). We have not generated any revenues and we do not expect 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.

Liquidity and Capital Resources

Requirement for Additional Capital

We currently do not have sufficient cash reserves to achieve all of our budgeted plans for the next twelve months and we may not be able to obtain the necessary financing.

As of September 30, 2008 we had a cash and cash equivalent balance of \$2,985,247, which can support operations through June 30, 2009, at our current rate of spending.

However, in addition to current funds allocated to capital costs and staffing, and in accordance with our business plan, we have also budgeted for additional capital costs and staffing costs of approximately \$2 million dollars for the upcoming twelve months. If we are unable to obtain this additional financing, our business plan will be delayed.

Assuming that we are successful in raising this additional financing, we anticipate that we will incur the following expenses over the next twelve months:

- Research and Development of \$1,500,000: Includes planned costs of \$1,200,000 for multiple drug variations and in-vivo and in-vitro studies for FluCide-1<sup>TM</sup>, FluCide HP<sup>TM</sup>, RabiCide, EKCCide, HIVCide, and Dengue and Ebola/Marburg programs, planned for the year ending June 30, 2009. The Company has allocated the planned costs of \$1,200,000 evenly over the seven drug candidates.
- 2 Corporate overhead of \$750,000: This amount includes budgeted office salaries, legal, accounting and other costs expected to be incurred by being a public reporting company.
- Capital costs of \$1,250,000: This is the estimated cost for equipment and laboratory improvements expected during the year ending June 30, 2009.
- Staffing costs of \$1,500,000: This is the estimated cost of hiring additional scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, as required for development of necessary data for filing an Investigational New Drug Application (IND) with the United States Food and Drug Administration.

The Company will be unable to proceed with its planned drug development progress, meet its administrative expense requirements, capital costs, and staffing costs after June 30, 2009 without obtaining additional financing of approximately \$3,000,000 to \$5,000,000. If we are unable to obtain additional financing, our business plan will be significantly delayed or curtailed. The Company will re-prioritize its objectives and delay certain drug development programs until we can raise sufficient funding that enables further development of the drugs with the goal of filing an Investigational New Drug application (IND) to the FDA.

# **Index**

The Company does not have any arrangements, at this time, for equity or other financing for these further needs of \$3-5M beyond minimum operations. If we are unable to obtain additional financing, our business plan will be significantly delayed.

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

We believe that this coming year's work-plan will lead us to obtain certain information about the safety and efficacy of some of the drugs under development in animal models. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further studies in animal models to obtain necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles of our drug candidates. We believe these data will then enable us to file an Investigational New Drug (IND) 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 will be of relatively short durations. Our business plan is based on these assumptions. If we find that we have underestimated the time duration of our studies, or we have to undertake additional studies, due to various reasons within or outside of our control, this will grossly and adversely impact both our timelines and our financing requirements.

Management intends to use capital and debt financing, as required, to fund the Company's operations. There can be no assurance that the Company will be able to obtain the additional capital resources necessary to fund its anticipated obligations for the next twelve months.

The Company is considered to be a development stage company and will continue in the development stage until it generates revenues from the sales of its products or services.

# Going Concern

The Companying financial statements have been prepared assuming the Company will continue as a going concern. The Company incurred cumulative losses of \$9,952,494 through September 30, 2008. In addition, the Company has not generated any revenues and no revenues are anticipated and has significant capital requirements. These conditions raise substantial doubt about the Company's ability as a going concern. Management recognizes that in order to meet the Company's capital requirements and continue to operate, additional financing will be necessary.

Management's plan to support the Company in operation and to maintain its business strategy is to raise funds through public and private offerings and to rely on officers and directors to perform essential functions with minimal compensation. If the Company does not raise all of the money it needs from its Public and private offerings, it will have to find alternative sources, such as a secondary public offering a private placement of securities, or loans from its officers, directors, or others. If the Company requires additional cash and cannot raise it, it will either have to suspend operations until the cash is raised or cease business entirely. The financial statements do not include any adjustment that might result from the outcome of this uncertainty.

The accompanying financial statements do not include any adjustments related to recoverability and classification of assets or the amounts and classifications of liabilities that might be necessary should the Company be unable to continue as a going concern.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

The Company is not exposed to market risk related to interest rates or foreign currencies.

# ITEM 4. CONTROLS AND PROCEDURES

#### EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Based upon an evaluation of the effectiveness of disclosure controls and procedures, our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") have concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were not effective as of September 30, 2008 because of the material weaknesses discussed below. Notwithstanding the material weaknesses discussed below, our Management has concluded that the financial statements included in this Quarterly Report on Form 10-Q fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles.

- 1. Timeliness of Financial Reporting: Our Chief Executive Officer and Interim Chief Financial Officer concluded that the Company's controls were not effective as of September 30, 2008 due to inherent weaknesses present in the preparation of financial statements as a result of the departure of its Chief Financial Officer on May 16, 2007.
- 2. Segregation of Duties: We did not maintain adequate segregation of duties related to job responsibilities for initiating, authorizing, and recording of certain transactions. Due to this material weakness, there is a reasonable possibility that a material misstatement in the financial statements would not be prevented or detected on a timely basis.

The Company is taking steps for remediation of these weaknesses including the active search for a controller and chief financial officer.

Changes in Internal Control Over Financial Reporting

As reported herein and in our Annual Report on Form 10-K for the year ended June 30, 2008, Management is aware that there is a significant deficiency in our internal control over financial reporting. Other than as described above, there were no material changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

None.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

In August, 2008, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$1.56 per share. These warrants, if not exercised, will expire in August, 2012.

For the three months ended September 30, 2008, the Company's Board of Directors authorized the issuance of 10,153 shares of its common stock with a restrictive legend, for consulting services. The Company recorded an expense of \$11,200.

For the three months ended September 30, 2008, the Company's Board of Directors authorized the issuance of additional 13,131 shares of its common stock with a restrictive legend, for legal services. The Company recorded an expense of \$15,000.

On August 22, 2008, the Company consummated subscriptions with certain investors whereby the Company sold 3,286,000 shares (the "Shares") of its common stock, par value\$0.001 per share (the "Common Stock") and ("Warrants") to purchase 1,643,000 shares of Common Stock at an exercise price of \$2.00 per share for an aggregate purchase price of \$3,286,000. The 3,286,000 share private placement of stock included 150,000 shares of Common Stock and 75,000 warrants subscribed in consideration of \$150,000 of scientific testing and other laboratory work performed for the Company. The Warrants may be exercised at any time and expire on September 17, 2011

Also on August 22, 2008, the Company consummated subscriptions with certain of its Warrant holders whereby the Company offered all the holders of its \$2.50 Warrants the option of exercising the Warrants at \$1.00 per share of Common Stock, of which warrants to purchase 50,000 shares of Common Stock for an aggregate price of \$50,000 were exercised. Concurrently, the Company consummated subscriptions with certain other of its Warrant holders whereby the Company offered all the holders of its \$1.00 Warrants the option of exercising the Warrants at \$0.75 per share of Common Stock, of which warrants to purchase 75,000 shares of Common Stock for an aggregate price of \$56,250 were exercised.

All of the securities set forth above were issued by the Company pursuant to Section 4(2) of the Securities Act of 1933, as amended, or the provisions of Rule 504 of Regulation D promulgated under the Securities Act. All such shares issued contained a restrictive legend and the holders confirmed that they were acquiring the shares for investment and without intent to distribute the shares. All of the purchasers were friends or business associates of the Company's Management and all were experienced in making speculative investments, understood the risks associated with investments, and could afford a loss of the entire investment. The Company has never utilized an underwriter for an offering of its securities.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

# ITEM 5. OTHER INFORMATION

None

**Index** 

# ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibit index

Exhibit

- 31.1 Certification of Chief Executive and Interim Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of Chief Executive Officer and Interim Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (b) Reports on Form 8-K. During the fiscal quarter ended September 30, 2008, the Company filed the following Current Reports on Form 8-K:

On August 29, 2008 the Company filed a Current Report disclosing the Company's sale of 3,286,000 shares of common stock and warrants to purchase 1,643,000 shares of common stock to certain investors. On September 9, 2008 and September 30, 2008, the Company filed a Current Report disclosing under Regulation FD transcripts of interviews given by its Chief Financial Officer on September 3, 2008 and September 26, 2008, respectively

# <u>Index</u>

# **SIGNATURES**

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

Dated: November 18, 2008

NANOVIRICIDES, INC.

/s/ Eugene Seymour, MD Eugene Seymour, M.D. Chief Executive Officer and Interim Chief Financial Officer and Director

/s/ Anil Diwan Anil Diwan, President and Chairman of the Board of Directors