

NANOIRICIDES, INC.  
Form 10-K  
September 14, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED JUNE 30, 2015

**NANOIRICIDES, INC.**

(Name of Business Issuer in Its Charter)

NEVADA  
(State or other jurisdiction of incorporation or organization)

76-0674577  
(I.R.S. Employer Identification No.)

1 CONTROLS DRIVE, SHELTON, CONNECTICUT, 06484

(Address of principal executive offices)

203-937-6137

(Issuer's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

COMMON STOCK, PAR VALUE \$0.001 PER SHARE NYSE MKT

(Title of Class)

(Name of exchange on which registered)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months ( or for such shorter period that the registrant was required to submit and post such files.

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

Edgar Filing: NANOIRICIDES, INC. - Form 10-K

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer", or "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

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

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

Yes " No  x

As of September 14, 2015, there were approximately 57,240,000 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on December 31, 2014 by non-affiliates of the registrant was approximately \$112,046,000 based on the closing price of \$2.71 per share, as reported on the NYSE MKT on December 31, 2014, the last business day of the registrant's most recently completed fiscal second quarter (calculated by excluding all shares held by executive officers, directors and holders known to the registrant of five percent or more of the voting power of the registrant's common stock, without conceding that such persons are "affiliates" of the registrant for purposes of the federal securities laws).

**TABLE OF CONTENTS**

**PART I**

Item 1.	<u>Business</u>	3
Item 1A	<u>Risk Factors</u>	77
Item 1B	<u>Unresolved Staff Comments</u>	96
Item 2.	<u>Properties</u>	96
Item 3.	<u>Legal Proceedings</u>	96
Item 4.	<u>Mine Safety Disclosures</u>	96

**PART II**

Item 5.	<u>Market for the Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	97
Item 6.	<u>Selected Financial Data</u>	103
Item 7.	<u>Management’s Discussion and Analysis of Plan of Operation and Results of Operations</u>	104
Item 7A	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	122
Item 8.	<u>Financial Statements and Supplementary Data</u>	122
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	122
Item 9A	<u>Controls and Procedures</u>	122
Item 9B.	<u>Other Information</u>	124

**PART III**

Item 10.	<u>Directors, Executive Officers, Promoters and Corporate Governance.</u>	124
Item 11.	<u>Executive Compensation</u>	127
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	128
Item 13.	<u>Certain Relationships and Related Transactions and Director Independence</u>	131
Item 14.	<u>Principal Accountant Fees and Services</u>	132

**PART IV**

Item 15.	<u>Exhibits, Financial Statement Schedules</u>	133
----------	--	-----

	<u>SIGNATURES</u>	134
--	-------------------	-----

## **PART I**

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

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

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

## **ITEM I: BUSINESS**

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

#### **The 2014-2015 Financial Year in Review**

NanoViricides, Inc. is a leading company in the application of nanomedicine technologies to the complex issues of viral diseases. The nanoviricide® technology enables direct attacks at multiple points on a virus particle. It is believed that such attacks would lead to the virus particle becoming ineffective at infecting cells. Antibodies in contrast attack a

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

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

During the financial year ending June 30, 2015, we have continued to make significant progress in advancing our drug pipeline, improving our resources, as well as improving our corporate governance and executive capabilities. Significantly, in December 2014, NanoViricides completed purchase of the modern c-GMP-capable production and R&D facilities at 1 Controls Drive, Shelton, CT, from Inno-Haven, LLC, at cost (for details, see below). NanoViricides as well as our affiliates have added significant strength in our staffing, with the R&D staff more than doubling to over 20 persons this year. Our new campus in Shelton has enabled this substantial expansion of our capabilities. This expansion is necessary to accomplish the substantial amount of scientific investigations, process engineering, quality engineering, large scale production and document preparation that goes towards filing investigational new drug applications (IND’s) to the US Food and Drug Administration (“FDA”), and equivalent applications to regulatory agencies across the globe. This expansion has also enabled us to strengthen our novel platform technologies, and engage into further novel, application-oriented R&D work directed to the goal of eradication of viral diseases.

In addition to our anti-influenza drug for hospitalized, severely ill patients in the FluCide™ program, our HerpeCide™ program has now advanced into a late pre-clinical stage, wherein optimization for various disease indications related to different herpesvirus infections is now being undertaken, 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).

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

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

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

We focused our drug development work plans primarily on our lead Influenza drug candidate, and our anti-Herpes-virus programs during the reporting financial year.

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 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. 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.



The next phase of the toxicology package studies for injectable FluCide will involve larger animals, and are estimated to require much larger quantities of the anti-influenza drug candidate. In order to accomplish this, we have continued to scale up our production processes for both the backbone polymer and the ligands at our new Shelton facility. We believe that we will be able to make as much as a few kilograms in a single batch in the new cGMP-capable facility. We have continued to work successfully towards large-scale production of this anti-Influenza drug candidate. The Scale-Up Laboratory in our new Shelton campus now has the necessary equipment for this scale up. During and after each step is completed at the large scale, we must maintain certain process controls, obtain relevant data, and thereafter characterize the resulting products by various methods. This is a tedious, laborious, and time-consuming process.

In addition, in August 2014, we restarted our anti-Ebola drug development program in response to the then raging Ebola epidemic in Africa. Our materials testing agreement with US Army Medical Research in Infectious Diseases (USAMRIID) unfortunately took substantial amount of time to restart. We executed a CRADA (Collaborative Research and Development Agreement for Material Transfer) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) at the end of October, 2014. We were able to send a first panel of novel agents to USAMRIID at the end of January, 2015. We received initial test results in early March, 2015. The nanoviricides approach was found to be very promising in these cell culture studies. We mutually decided with USAMRIID scientists that we should perform another round of improvement of the drug candidates. However, around this time, in early April 2015, the epidemic had begun to be brought under control by the international public health agencies with heroic efforts - despite the lack of treatments or vaccines - and the urgency of our Ebola program, which we engaged into because of the potential global epidemic threat, was no longer apparent. In addition, several drug candidates by other companies had been fortuitously advanced into various modified protocols of clinical trials by that time. With these changes in the global Ebola scenario, NanoViricides determined around May 2015 that we should re-focus our efforts on our commercially important priorities.

We restarted the Ebola program based on our evaluation and belief that an optimized nanoviricide anti-Ebola drug candidate would have been the only viable option, had the epidemic continued to evolve into a global threat. Our belief is now supported by evidence. All of the anti-Ebola drug candidates that were advanced into clinical trials during the epidemic have been either rescinded by the sponsors or have not met statistically significant effectiveness end-points. These candidates include the siRNA therapeutics by Tekmira, antibody cocktail therapeutics by zMAPP, brincidofovir by Chimerix, and favipravir (T-705) by Takeda. In addition, Sarepta and BioCryst did not advance their anti-Ebola drug candidates into efficacy clinical trials.

This year, we also continued our work in our HerpeCide program, encouraged by results in animal studies. We are happy to report that our HerpeCide™ program is now maturing towards selection of final development candidates against several different indications.

In April 2015, we reported dramatic improvement in clinical symptoms associated with a herpes simplex virus dermal infection in recently completed studies 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. Recently in August, we reported that these results were reproduced at a different laboratory, with 100% survival being observed.

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) aka 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.

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

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

The Nanoviricides® technology continues to receive substantial attention and recognition in the scientific world. The NanoViricides Executive Team is also receiving recognition for the Company's achievements.

Our "Injectable FluCide™" drug candidate for severe influenza was chosen as one of the "Top Ten Infectious Diseases Projects to Watch" by a panel of industry experts assembled by Informa and the publishers of In Vivo, Startup and The Pink Sheet. As a result of this selection, Anil R. Diwan, PhD, President and Chairman of the Company, gave a company presentation at the Therapeutic Area Partnerships Meeting on November 20, 2014.

In addition, NanoViricides was selected as one of the top 20 finalists in the "technologies of Tomorrow" segment of the "Buzz of BIO" spot for the BIO2015 conference in Philadelphia, PA. While NanoViricides did not win the top spot in the final voting, the selection itself speaks to recognition of the Company in the prestigious pharmaceutical industry community.

NanoViricides continues to make strides in improving our corporate governance. To this end, we have engaged EisnerAmper LLP as our new public auditors, switching from the smaller firm of Li & Company. EisnerAmper LLP found that in the previous year, we had not accounted for the derivative effect of certain warrants and debentures issued last year according to the required rules. While this does not affect our core financial position, we have corrected this defect and this has resulted in amended and restated filings of previous annual report and two quarterly reports. In addition, we have recently added a new Accounting Manager to our finance department to strengthen the processes and to provide additional oversight.

We continue to improve our balance sheet. In the process of uplisting to the NYSE MKT in September 2013 through June 2014, we raised approximately \$36M in various financing rounds.

In addition, during the reporting financial year, we raised approximately \$6,700,000. On July 2, 2014, we accepted a subscription in the amount of \$5,000,000 for a 10% Series C Convertible Debenture from Dr. Milton Boniuk, a member of the Company's Board of Directors. Additionally, on September 5, 2014, we accepted exercises of certain old warrants for the purchase of an aggregate of 1,926,656 shares of the Company's \$0.001 par value Common Stock for an exercise price of \$3.50 per share for aggregate proceeds of \$6,743,297.

As of June 30, 2015, we have \$31,467,748 in hand, and additional assets of \$214,425 in the form of prepaid expenses. Property, plant and equipment now stand at \$11,962,648 (net of accumulated depreciation of \$1,534,203) with the acquisition of the 1 Controls Drive facility at cost from Inno-Haven, and with additional equipment purchases. Long term Liabilities were at \$11,800,327 and the Shareholder Equity stood at \$31,785,867 as of June 30, 2015. In comparison, as of June 30, 2014, we had cash in hand of approximately \$36,700,000 and additional assets of approximately \$1,300,000 in the form of prepaid expenses, other assets and security deposits. As of June 30, 2014, Long term Liabilities were at \$19,972,953 and the Shareholder Equity stood at \$23,369,303.

During the reporting period we spent \$6,212,332 in cash toward operating activities and approximately \$5,760,109 in capital investment. In contrast, we spent \$6,333,625 in cash toward operating activities and approximately \$5,231,094 in capital investment during the previous year. 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 two years. In addition, in order to conserve cash expenditures, we also pay compensation in stock and stock instruments to various parties.

Thus, the Company has ended the year on a strong financial footing. We have not engaged in any additional raises after the old warrant conversion that closed in September 2014. We believe that we will not need to raise additional capital in the near future. We project, based on various estimates that we have obtained, that our current available financing is sufficient for accomplishing the goal of filing one or possibly two IND or equivalent regulatory applications, and initial human clinical trials in at least one of our drug programs. Two of our drug programs, namely Injectable FluCide, and HerpeCide skin cream, are now in the late pre-clinical or IND-enabling studies stage. We anticipate that these drug candidates will move forward into IND or equivalent regulatory filings, and ensuing human clinical trials. As these drug candidates are advancing into the clinic, we believe that our additional drug candidates will also move forward into IND-enabling studies. We are thus poised for strong growth with a number of drug candidates in a number of disease indications.

## **Overview**

Recently, our anti-Herpes nanoviricide drug candidates have shown excellent effectiveness in topical application in a lethal dermal infection animal model. Importantly, this model employed a highly aggressive and neurotropic herpesvirus strain, namely HSV-1 H129c, that caused lethal zosteriform disease in the mice. We are now performing the studies necessary for selection of IND candidates for several indications related to herpes viruses under our HerpeCide™ program. These indications include ocular herpes keratitis, oral herpes (“cold sores”), genital herpes, and shingles.

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 are also developing a highly effective injectable anti-influenza drug, NV-INF-1, in this program. The Company is developing this injectable drug (NV-INF-1) for hospitalized patients with severe influenza, including immuno-compromised patients. The Company believes that this drug may also be usable as a single-dose injection in a medical office for less severe cases of influenza. Both of these anti-influenza therapeutic candidates are “broad-spectrum”, i.e. they are expected to be effective against most if not all types of influenzas including 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 approval 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 these 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 the anti-herpes drug candidates and the injectable FluCide for severely ill patients towards IND applications in parallel. We have engaged Biologics Consulting Group, a well-known group of regulatory consultants, to advise us on the regulatory pathways, and the studies required for the IND applications for the various indications.

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

The Company is also developing an anti-HIV drug. The drug candidates in this HIVCide™ program were found to have effectiveness equal to that of a triple drug HAART cocktail therapy in the standard humanized SCID-hu Thy/Liv mouse model. Moreover, the nanoviricides were long acting. Viral load suppression continued to hold for more than four weeks after stopping HIVCide treatment. The Company believes that this strong effect and sustained effect together indicate that HIVCide can be developed as a single agent that would provide “Functional Cure” from HIV/AIDS. The Company believes that substantially all HIV virus can be cleared upon HIVCide treatment, except the integrated viral genome in latent cells. This would enable discontinuation of treatment until HIV reemerges from the latent reservoir, which may be several months without any drugs. Moreover, the Company believes that this therapy would also minimize the chances of HIV transmission. The Company is currently optimizing the anti-HIV drug candidates. These drug candidates are effective against both the R5 and X4 subtypes of HIV-1 in cell cultures. The Company believes that these drug candidates are “broad-spectrum”, i.e. they are expected to be effective against most strains and mutants of HIV, and therefore escape of mutants from our drugs is expected to be minimal. Further, the Company is developing a broad-spectrum drug against Dengue viruses that is expected to be useful for the treatment of any of the four major serotypes of dengue viruses, including in severe cases of dengue (DSS) and dengue hemorrhagic fever (DHF). It is thought that DSS and DHF caused by prior antibodies against dengue that a patient’s body creates to fight a second unrelated dengue infection, and the second virus uses these antibodies effectively to hitch a ride into human cells, thereby causing a more severe infection than in naive patients. The Company recently received an “Orphan Drug Designation” for our DengueCide™ drug from the USFDA as well as the European Medicines Agency (EMA). This orphan drug designation carries significant economic benefits for the Company.

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

Our strategy is to minimize capital expenditure. We therefore rely on third party collaborations for the testing of our drug candidates. We continue to engage with our previous collaborators. In addition, we have engaged with TransPharm preclinical services for herpesvirus animal models. We have engaged Biologics Consulting Group, Inc., to help us with the FDA regulatory submissions. We are also engaged with Australian Biologics Pty, Ltd to help us with clinical trials and regulatory approvals in Australia. We believe that cGMP-like manufactured product is acceptable for entering human clinical trials in Australia.

The 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.

We have continued to achieve significant milestones in our drug development activities.

Our FluCide program is moving towards the Investigational New Drug (“IND”) filing stage, with strong showing of safety in multiple animal models. We have previously found that the FluCide drug candidate has shown very high effectiveness against multiple completely unrelated Influenza A viruses in small animal studies.

In addition, this year, our HerpeCide program has matured towards the goal of identifying an IND candidate. The HerpeCide program is expected to result in a franchise of drug candidates for the multitude of indications that involve infection with one of the many types of herpesviruses. We believe that our other programs should also progress successfully towards the regulatory submissions goal.



We have substantially expanded our staff and skillset to accommodate the substantial workload associated with performing all of the studies for moving our advanced drug candidates towards IND filings. We have doubled our internal scientific staff, including the staff of our affiliates, during the reporting year. New staff also must undergo training in new techniques, methods, instrumentation, as well as our own internal processes. We have implemented strong project management processes in order to manage the multitude of our internal projects and sub-projects.

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.

We have been aggressively expanding our portfolio of virus targets and drug candidates every year since our inception in May 2005. We began with drug candidates against Influenza. We then shortly added a drug candidate against Rabies, one of the most difficult diseases to tackle. We started working on Ebola/Marburg viruses (filoviruses) and developed drug candidates worthy of further drug development. Shortly thereafter, we developed a drug candidate against Adenoviral Epidemic Kerato-conjunctivitis (EKC). In 2008, we added anti-HIV drug candidates to our growing portfolio. In 2009, we improved upon our EKC drug candidates to develop new drug candidates that may be effective potentially against most known viral diseases of the external eye. Most of these viral diseases are caused by a wide variety of adenoviruses and herpes simplex viruses. We also developed new drug candidates against the herpes viruses (HSV-1 and HSV-2), for the treatment of recurrent HSV skin infections, such as cold sores and genital warts in 2008-2009. In 2010, we added drug candidates effective against Dengue viruses to our pipeline. In 2011, we began focusing on activities needed for taking our anti-influenza drug into human clinical trials. In 2012, we developed an oral version of our anti-influenza drug candidate in the Flucide program. In 2015, we announced excellent effectiveness of our topical treatment using anti-herpes drug candidates in a lethal dermal infection model, paving the way to developing drug candidates for IND against several different diseases caused by herpesvirus infections. Thus, we have developed a very broad pipeline of drug candidates over the last ten years. We believe that we will have clinically relevant drug candidates in many, if not all, of these disease areas.

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

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 in the background at different priorities.

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

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

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

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

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

We are now optimizing the 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.

Because of the high level of safety observed in our animal studies of our FluCide drug candidate, our Safety and Toxicology studies (“Tox Package” studies) have been estimated to require relatively large quantities of materials. This has necessitated that the Company enable scaled-up production and qualify the production processes at a much larger scale than what is needed for small animal studies. Tox Package does not require cGMP materials. Therefore, we engaged in initial scale up to about 200g batch at our previous facilities rather than waiting for the cGMP facilities to be completed. We have completed the initial studies to verify that the scaled up production of our Injectable and Oral

anti-Influenza drug candidates can be performed successfully.

We are currently implementing the 200g production scale at our new c-GMP capable facilities in Shelton, CT, and performing appropriate process optimization and process control studies as described above.

We believe that the 200g production scale would be sufficient for the “Tox Package” studies for an anti-herpes topical treatment drug candidate in any of the topical indications that we are currently evaluating, whether ocular or dermal. In addition, this scale should be sufficient for the clinical studies product needs for the herpeicide drug candidates. We are therefore accelerating our HerpeCide program for each of several indications. We recently announced that our nanoviricide drug candidates showed excellent clinical effectiveness in a lethal dermal infection animal model in two different laboratories.

In addition, we continue to perform step-wise scale up of production to enable multi-kg batches of our injectable anti-Influenza drug candidate for IND-enabling “Tox Package” studies. These studies are estimated to require up to 2.5 kg of the drug substance. We plan on scaling up from the 200g scale to 500g scale and then to 1kg scale. We may be able to combine several batches at either the 500g scale or at the 1 kg scale, provided that they are sufficiently equivalent in the characterization studies, in order to prepare a single master batch for further Tox Package studies. In the meantime, we have already performed preliminary safety/toxicology studies in rats using 200g material produced in our older R&D facilities in West Haven, CT. These studies have demonstrated excellent safety of FluCide. Previously, we have performed preliminary safety studies in mice as well. Those studies demonstrated excellent safety of FluCide. This led to the calculation of a very large quantity for our ensuing “Tox Package” studies for this drug candidate.

## **Financing**

On July 2, 2014, the Company reported that, Milton Boniuk, MD, the Caroline F. Elles Chair Professor of Ophthalmology at Baylor College of Medicine, and a Director of the Company, invested \$5M in the Company in the form of a convertible debenture (the “Debenture”). The Debenture is convertible into the Company’s common stock at \$5.25 per share upon maturity or earlier at the investor’s option. Until conversion, the debenture carries an interest at the rate of 10% per annum, payable in cash, with the first year’s interest deferred and divided evenly into the remaining three years. In addition, the Company issued 187,000 shares of its restricted Series A Preferred stock to Dr. Boniuk, as initial interest. The Series A stock is not convertible into common stock, is not tradable, and does not carry any dividend rights, or any other financial effects, except in certain limited circumstances.

In addition, on September 5, 2014, we accepted the exercise of warrants for the purchase of an aggregate of 1,926,656 shares of the Company’s common stock for an exercise price of \$3.50 per share for aggregate proceeds of \$6,743,297.

As of June 30, 2015, the end of the reporting period, we have \$31,467,748 in cash and cash equivalents, pre-paid expenses, of \$214,425 and \$11,962,648 of Property and Equipment net of depreciation. Our short term liabilities were at \$600,895 and long term liabilities were \$11,800,327. The shareholder equity stood at \$31,785,867.

With our successful financing efforts, and our continued low rate of expenditure, the Company estimates that it continues to have cash in hand sufficient for more than two years of further R&D and operating expenses. In addition, the Company has successfully achieved the goal of acquiring a state of the art c-GMP capable manufacturing and R&D Lab facility with very limited capital expenditures. We thus ended the financial year in a strong financial position, enabling us to continue to move our drug development programs forward towards IND filings.

## **Corporate Governance**

In addition to technological progress for moving our drugs into the Clinic, we also strive to improve our Corporate Governance and Executive capabilities towards the goal of building a highly successful pharmaceutical company. To this end, we have engaged EisnerAmper LLP as our new public auditors, switching from the smaller firm of Li & Company. EisnerAmper LLP found that in the previous year, we had inadvertently missed accounting for the derivative effect of certain warrants and debentures issued last year according to the required rules. While this does not affect our core financial position, we have corrected this defect and this has resulted in amended and restated filings of previous annual report and two quarterly reports. In addition, we have recently added a new Accounting Manager to our finance department to strengthen the processes and to provide additional oversight.

## Patents and Intellectual Property

We have previously announced certain important issuances of patents on the TheraCour® technology underlying our nanoviricides® drugs. A fundamental patent on the polymeric micelles composition, structure and uses was issued in the USA with substantially broad claims. This validates the novelty of our approach as well as our leadership position in the nanomedicines based on polymeric micelle technologies. This patent application has so far been issued, granted, and/or validated, with substantially similar broad claims as 52 different patents in different countries and multi-country intellectual property organizations. The Company announced in May 2012 that a fundamental patent, on which the nanoviricides® technology is based, is due to be issued in the USA on May 8, 2012. The US Patent (No. 8,173,764) is granted for “Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers.” It was issued on May 8, 2012. The patent term is expected to last through October 1, 2028, including anticipated extensions in compensation for time spent in clinical trials. This US Patent has been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The disclosed structures enable self-assembling, biomimetic nanomedicines. NanoViricides, Inc. holds exclusive, perpetual, worldwide licenses to these technologies for a broad range of antiviral applications and diseases. The other national and regional counterparts of the international Patent Cooperation Treaty (“PCT”) application number PCT/US06/01820, which was filed in 2006, have issued as a Singapore National Patent Publication, a South African patent, and also as an ARIPO regional patent, an OAPI regional patent (covering Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo). It has also issued as a granted patent in New Zealand, China, Mexico, Japan, Australia, Canada, several countries in Europe, Hong Kong, Indonesia, Israel, Korea, Malaysia, Philippines, Pakistan, and Vietnam among others. Estimated expiry dates range nominally from 2026 to 2027 prior to accounting for various extensions available in different regions and countries. Additional issuances are continuing in Europe, and in several other countries around the world.

Another fundamental patent application on the antivirals developed using the polymeric micelles has so far been issued, granted, and/or validated, with substantially broad claims as well, as 9 different patents. The counterparts of the international PCT application PCT/US2007/001607 have issued as a granted patent in ARIPO, Australia, China, Japan, Mexico, New Zealand, OAPI, South Africa, and Korea to date. Additional issuances are expected in Europe, USA, and in several other countries around the world. This patent application teaches antivirals based on the TheraCour polymeric micelle technologies, their broad structures and compositions of matter, pharmaceutical compositions, methods of making the same, and their uses. The nominal expiry dates are expected to range from 2027 to 2029. Further patent prosecution in several other regions and countries is continuing.

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

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

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

### **cGMP Production Capability**

Even more important than the financing initiatives is the realization this year of a cGMP-capable production facility that can make sufficient quantities of our drug candidates for clinical trials and also for initial sales, should the drugs pass regulatory hurdles.

We have been scrutinizing and evaluating various options to make this cGMP clinical product manufacture possible ever since the company was founded. Eventually, we reached the conclusion that given the industry-leading nature of our technologies, the proprietary know-how that we have developed, and the fact that available cGMP contract manufacturing facilities did not possess adequate expertise in the manufacture of defined amphiphilic polymeric products such as our drug candidates, it would be most prudent, expedient, and cost-effective to develop our own manufacturing capabilities. We began looking for sites that could be used as is or renovated to this end as early as 2007. However, the 2008 financial slowdown caused us to temporarily halt the search.



We declared our first pre-IND clinical drug candidate, NV-INF-1, otherwise known as Injectable FluCide™, in September, 2011, and held a pre-IND consultation with the US FDA in March, 2012. The need for cGMP production of clinical quantities of our state of the art nanomedicine drug candidates became urgent thereafter. However, the Company's finances at that time could not support such a capital-intensive project. In order to keep our business plan on track, therefore, Anil R. Diwan, PhD, our co-founder, President and Chairman, took an extreme financial risk and decided to finance a drug manufacturing facility project with funds from his friends and family and borrowings from financiers. He formed Inno-Haven, LLC, a private venture ("Inno-Haven") to develop a customizable multi-drug manufacturing facility that could service several pharma clients. Inno-Haven raised funds from Dr. Diwan, his affiliates, friends and other financiers to initiate the project, and eventually selected and purchased the site at 1 Controls Drive, Shelton CT, with an 18,000 square foot building on 4.2 acres in a scenic area. Inno-Haven formed a business plan for this facility that was independent and separate from NanoViricides, in order to make a business case for the endeavor for the investors that Dr. Diwan brought to the venture. Inno-Haven business plan was to renovate the building into a cGMP Contract Manufacturing Operation (CMO) that would service pre-clinical and clinical needs of several clients. It was estimated that most clients would be small start-up pharmaceutical companies, that lack a manufacturing facility of their own, or the so-called "virtual pharma" drug development companies. Inno-Haven continued development under this assumption, to build a highly customizable, multipurpose, state of the art, cGMP manufacturing facility. In September 2011, we announced the acquisition by Inno-Haven, LLC of an 18,000 square foot building on 4 acres with possibility of expansion in Shelton, CT. Financing for the acquisition by Inno-Haven was provided by certain private investors that included Anil R. Diwan, PhD. Dr. Diwan is President and Chairman of the Company and Managing Member of Inno-Haven. Dr. Diwan's part of the financing came from his personal savings, personal borrowings, and a sale of some of his shares of NanoViricides, Inc. received as a founder. In October 2012, Dr. Diwan completed the programmed sale of the NanoViricides stock that he had obtained as a founder. The Company had agreed to this stock sale. Additionally, Dr. Diwan also provided personal guarantees, as needed, for certain additional contemplated financing initiatives for this project.

Later, in February 2013, NanoViricides signed a Memorandum of Understanding ("MoU") with Inno-Haven. With this MoU, NanoViricides committed to support the security needs of certain financiers of Inno-Haven, and also committed to lease the facility upon meeting certain milestones, at rates to be determined with expert consultations. In addition, Inno-Haven was required to conduct the project as per the requirements to be specified by NanoViricides. No lease was signed and no payments were made to Inno-Haven by NanoViricides.

Because of the constraints posed by the existing building, the very special requirements of an injectable drug producing cGMP facility, and limited available financing, the project required extremely skilled and experienced team. In March 2013, NanoViricides retained Mr. Andrew Hahn, a highly experienced and skilled consultant for facility plan and design, and later also brought in Mr. Phil Mader, of MPH Engineering for Engineering and Design specifications, and Ms. Kathy Cowles of ID3A Architects. We have a strong team engaged on the total renovation project for building cGMP facility and associated R&D laboratories in the Shelton campus. Mr. Andrew Hahn, retired Director of Facilities (Global) for Bristol-Myers-Squibb is our lead designer and overall steward for this project. Mr. Phil Mader, previously the Senior Capital Project Manager at Bristol-Myers Squibb Company in Wallingford, CT ("BMS"), is our Project Manager. Mr. Mader's firm, MPH Engineering is engaged for engineering design. In addition, Ms. Kathy Cowles, founder of ID3A Architects serves as the lead architect. With the help of additional external and internal consultants, this team produced a highly optimized laboratory and manufacturing facility plan and specification that also met the financial constraints. As a result, Inno-Haven retained Mr. Mader's firm, MPH

Engineering, as overall Project Coordinator and Construction Manager, and began construction in or about June, 2013. The construction was completed in June, 2014, while managing customized equipment delivery schedules and some weather-related delays.

The facility was inaugurated on July 21, 2014, by Honorable Congressman Jim Himes as the Chief Guest, with delegates from the offices of Honorable Senators Chris Murphy and Richard Blumenthal, with a felicitation from Honorable Governor Dannel Malloy, and local officials in attendance. In addition, Senator Blumenthal visited the facility in person on December 22, 2014.

The Board of Directors unanimously agreed that it was in the best interests of our shareholders and the Company to purchase the facility from Inno-Haven, LLC on or around July, 2014. Dr. Diwan abstained from the discussions and voting on this matter. NanoViricides completed this purchase in December, 2014, by reimbursing Inno-Haven only for the costs incurred. The due diligence process took significant amount of time.

Thereafter, we continued working on special equipment fit-out modifications, and preparing for facility validation. We have contracted facility validation to a third party. The validation is being conducted in a phased manner.

We started working in the new facility around September/October 2014. Additional special equipment fit-out modifications for the c-GMP portion of the facility were completed in May, 2015. We have now moved all of our in-house work in a phased manner to the new facility. This phased approach enabled us to continue our work on current projects without incurring any significant delays that a shut-down and move process would have caused.

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

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

The Company will be able to produce “cGMP-like” material in the new facility once the facility is validated, all of the protocols are finalized, standardized, and the standard protocols are documented in the manner needed for cGMP operation. A “cGMP-like” drug substance can be loosely defined as drug substance made using the same processes as c-GMP material but prior to undergoing the FDA registration process for the c-GMP facility. Such c-GMP-like product can be used for clinical batches for human clinical studies in several most countries around the world. The Company is currently investigating all such options in order to expedite the timeline to entering human clinical trials. The Company intends to contract out clinical batch fulfillments to outside contract manufacturers.

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

## **Presentations and Conferences**

The Nanoviricides® technology continues to receive substantial attention and recognition in the scientific world. The NanoViricides Executive Team is also receiving recognition for the Company’s achievements.

Our “Injectable FluCide™” drug candidate for severe influenza was chosen as one of the “Top Ten Infectious Diseases Projects to Watch” by a panel of industry experts assembled by Informa and the publishers of In Vivo, Startup and The Pink Sheet. As a result of this selection, Anil R. Diwan, PhD, President and Chairman of the Company, gave a company presentation at the Therapeutic Area Partnerships Meeting on November 20, 2014.

On September 16, 2014, our CEO, Eugene Seymour, MD, MPH was interviewed as a guest on “The Independents”, a show on the Fox Business Channel. Dr. Seymour discussed the current Ebola outbreak and the Company’s progress in developing an anti-Ebola drug for the treatment of patients infected with the Ebola virus.

Our President, Dr. Anil Diwan, was invited to participate in the prestigious 30th Annual Chief Executive of the Year Gala Reception & Dinner held at the New York Stock Exchange on Thursday, July 27, 2015. In addition, he was also invited to participate in the CEO Roundtable Discussion, on the topic of “Understanding and Thwarting Cyber-threats”, which was held prior to the Reception. Further, Ms. Meeta Vyas, our CFO was invited to participate in the roundtable discussion on the topic of “The Data-Enabled CEO: Unlocking Key Insights to Accelerate Business Performance” at this same event. Our President, Dr. Anil Diwan, was also invited last year to participate in the 29th Annual Chief Executive of the Year Gala Reception & Dinner held at the New York Stock Exchange on Thursday, July 17, 2014. In addition, he was also invited to participate in the CEO Roundtable Discussion, on the topic of “Enhancing CEO Effectiveness by Redefining the Role of the CFO”, which was held prior to the Reception.

On July 11, 2014, our President, Dr. Anil Diwan, was invited to present the FluCide™ data at the 3rd Annual Influenza Research and Development Conference. The Conference ran from July 9-11 at the Hyatt Regency in Boston, MA, and was held by GTC Bio.

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

On June 1, 2015, the Company's CEO Eugene Seymour, MD, MPH presented an overview of the Company at the LDMicro conference at the Luxe Hotel in Los Angeles.

On May 29 2015, the Company's CEO Eugene Seymour, MD, MPH presented an overview of the Company at the BIO CEO Investor conference in New York City.

On February 10 2015, the Company's CEO Eugene Seymour, MD, MPH presented an overview of the Company at the Marcum Healthcare conference in New York City.

On January 27, 2015, the Company's CEO Eugene Seymour, MD, MPH presented an overview of the Company at the Stanford University Personalized Medicine World Conference in Mountain View, California.

On January 13, 2015, the Company's CEO Eugene Seymour, MD, MPH presented an overview of the Company at the BioTech Showcase conference in San Francisco.

On December 3, 2014, the Company's CEO Eugene Seymour, MD, MPH presented an overview of the Company at the LDMicro conference at the Luxe Hotel in Los Angeles.

On September 8, 2014, the Company's CEO Eugene Seymour, MD, MPH presented an overview of the Company at the Rodman and Renshaw Healthcare conference in New York City

## **Recognition and Awards**

Our “Injectable FluCide™” drug candidate for severe influenza was chosen as one of the “Top Ten Infectious Diseases Projects to Watch” by a panel of industry experts assembled by Informa and the publishers of In Vivo, Startup and The Pink Sheet. As a result of this selection, Anil R. Diwan, PhD, President and Chairman of the Company, gave a company presentation at the Therapeutic Area Partnerships Meeting on November 20, 2014.

In addition, NanoViricides was selected as one of the top 20 finalists in the “technologies of Tomorrow” segment of the “Buzz of BIO” spot for the BIO2015 conference in Philadelphia, PA. While NanoViricides did not win the top spot in the final voting, the selection itself speaks to recognition of the Company in the prestigious pharmaceutical industry community.

On Wednesday, August 13, 2014, the NanoViricides Executive Team was invited to ring The Opening Bell® at the New York Stock Exchange (NYSE). NanoViricides began trading on the NYSE MKT as of September 25, 2013.

Last year, Anil R. Diwan, Ph.D., President, Chairman, and Co-Founder of the Company was recognized as the “2014 Researcher of the Year” by BusinessNewHaven, a business journal, and the New Haven magazine, that serve the state of Connecticut. The article was published in the February 2014 issue of BusinessNewHaven, and is reproduced on the Company’s website with permission ([www.nanoviricides.com/index.html#bnh-recognition](http://www.nanoviricides.com/index.html#bnh-recognition)). BusinessNewHaven recognizes “Healthcare Heroes” in the state of Connecticut every year. The heroes are chosen from all walks of life in various categories. The magazine seeks to recognize individuals particularly for their persistence, perseverance, novel approaches, and potential for impact on the society. The magazines together have a combined circulation of over 40,000 in Connecticut.

Also last year, NanoViricides, Inc. (NYSE MKT: NNVC) (the “Company”) won the prestigious “IAIR Award” as the “Best North American Company for Leadership in the Nanomedicine Sector”. The invitation-only award ceremony and gala dinner for the “IAIR Awards - North America” was held at the Yale Club in New York City on Tuesday, April 15th, 2014. IAIR (International Alternative Investment Review) is a publication of EDITRICE LE FONTI® SRL, Milan, Italy. They conduct an online survey through their 50,000+ readers to provide to their judging panel which is composed of the editorial staff of IAIR - Excellence in Global Economy and Sustainability and International Family Office Magazine to make the selection of the final award winners. EDITRICE LEFONTI® SRL (IAIR® GROUP / IAIR AWARDS®) is a research institute and a global independent publishing house headquartered in Milan with more than 10 years of experience in the publishing field.

This year, Midtown Partners, Inc., (“Midtown”) published a research report on NanoViricides on February 11, 2014, according to Midtown’s website. The report can be found on their website at <http://www.midtownpartners.com> under the “Research” tab. Midtown initiated research coverage with a “Strong Buy” rating on NanoViricides with this report. The Company did not pay Midtown any fees or commissions for this research report. Previously, the banking arm of Midtown Partners has helped raise financing for NanoViricides in various investment banking engagements, wherein Midtown earned and was paid commissions and/or fees according to the appropriate engagement agreements in force, most recently in January 2014. Chardan Capital Markets, LLC, acted as lead placement agent and Midtown Partners was the co-placement agent in connection with this January 2014 registered direct offering. Midtown’s research analysts interviewed NanoViricides’ executives for this report. Midtown research analysts also performed substantial additional independent research. The Company does not comment on, and does neither endorse nor dispute any such third party research.

## **Drug Development Programs**

We focused our drug development work plans primarily on our lead Influenza drug candidate, and our anti-Herpes-virus programs during the reporting financial year.

### **HerpeCide™**

This year, we also continued our work in our HerpeCide program, encouraged by results in animal studies. We are happy to report that our HerpeCide™ program is now maturing towards selection of a final development candidate. We have now established an agreement with TransPharm Preclinical Solutions (“TransPharm”), a pre-clinical research services organization (CRO) in Jackson, MI. TransPharm will perform the topical dermal efficacy studies for our anti-HSV drug candidates. In addition, we are also seeking CROs and other Institutes of merit where we can perform anti-HSV efficacy studies for other indications including ocular herpes keratitis, shingles, and genital herpes infections in small animal models, to broaden our anti-HSV franchise. Because the topical anti-herpes drug development may be significantly faster than the influenza injectable drug development, we are also beginning

conversations with clinical sites. We recently reported that we have discussed the anti-HSV drug development pathways for various indications with our FDA regulatory consultants at the Biologics Consulting Group (BCG). BCG is advising us on selecting the optimal indications to go after, based on various parameters, including unmet medical need, the pre-clinical and clinical studies needed for approval, and the ease of performing such studies.

In April 2015, we reported dramatic improvement in clinical symptoms associated with a herpes simplex virus dermal infection in recently completed studies in mice. These studies were performed in the laboratory of Dr. Ken S. Rosenthal at Northeast Ohio Medical University (“NEOMED”). These studies utilized the HSV-1 H129c strain which is a highly aggressive and neurotropic strain and is phylogenetically close to a clinical patient isolate.

Two of our anti-Herpes nanoviricides® reduced the extent of disease (morbidity) and mortality of the HSV-1 infected animals that were treated, in this study. These nanoviricides were also shown to significantly reduce virus production in cell culture.

The nanoviricides prevented the development of scabbing of the herpes virus infected lesions in the animal model. For untreated and sham treated animals, the HSV infection progressed from initial redness at the site of infection to lesions that progressed on the skin along the nerve and internally to ultimately kill the mouse. Topical dermal treatment with these two nanoviricide formulations significantly delayed the onset of the clinical symptoms, and prevented the progression of the lesions.



The nanoviricides appeared to block the progression of the HSV-1 virus infection as observed by a reduction in the progression of the spreading of lesions. The observed delay in initiation of disease signs and the survival of the mice would be consistent with a reduction of at least 90% in the production of virus in the animals, possibly during the initial period of replication

Importantly, this improvement resulted in survival of almost all of the nanoviricides-treated mice (>85%), while 100% of untreated mice died of the disease. Further, these nanoviricides were superior to topical treatment with an acyclovir formulation employed as a positive control.

In the past, our anti-Herpes drug candidates had exhibited greater than 99.9% viral load reduction in cell cultures. Certain improvements were necessitated because of the constraints of the dermal application in animal model, so that the applied drops would stay on the skin to exhibit effect of the drug instead of running off.

In August, 2015, we reported that the dramatic clinical effectiveness results demonstrated by these anti-herpes drug candidates were reproduced in a different laboratory. These studies were performed by TransPharm.

In this second study, all of the nanoviricides® tested improved clinical scores dramatically, with clinical presentation being arrested at redness or simply raised local lesions, and a complete absence of zosteriform spreading. All of the nanoviricides treated animals survived the lethal HSV-1 infection challenge while untreated animals died towards the end of the study.

Some of the nanoviricides found effective in the previous study were tested in this study for the confirmation of efficacy in a dermal animal model in a different type of mouse, infected with the same highly aggressive and neurotropic HSV-1 strain H129c, which was used previously.

Dr. Rosenthal is now Professor at the Roseman University of Health Sciences College of Medicine, NV. He continues as Professor Emeritus at Northeast Ohio Medical University (NEOMED), after retiring in December 2014. He is a leading researcher in the field of herpes viruses, antiviral drugs and vaccines. His research interests encompass several aspects of how herpes simplex virus (HSV) interacts with the host to cause disease. His research has addressed how HSV infects skin cells and examined viral properties that facilitate its virulence and ability to cause encephalitis. He is also researching how the human host immune response works against HSV for the development of protective and therapeutic vaccines.

Professor Rosenthal consulted with NanoViricides and TransPharm for the establishment of the animal model for dermal HSV-1 infection using the HSV-1 strain H129c at the TransPharm laboratories.

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) aka 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.

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

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

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

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

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

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

The Company has engaged with Transpharm Preclinical Solutions to perform the topical animal studies as well as cell culture studies for the herpesvirus topical treatments. Transpharm is a pre-clinical contract research services organization (CRO) that offers numerous types of studies for testing antimicrobials, antivirals, antifungals, antiparasitics, along with newer therapies using antibodies. TransPharm’s scientists’ skill set covers a broad range of Research and Development, enabling numerous services at the request of a client.

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

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

In just four cycles of initial candidate improvements, the Company has now reached its goal of substantially complete survival in the highly lethal animal model of dermal herpesvirus infection with the aggressive HSV-1 H129c strain, wherein no current drugs have shown substantial survival effect. Our anti-Herpes program began in 2009, and soon thereafter, the Company demonstrated strong anti-herpes efficacy in cell cultures against two different HSV-1 strains at two different sites. Since then the Company has been optimizing the drug candidates to achieve strong effectiveness in a highly lethal animal model. In the past, due to resource constraints, the Company was able to perform these studies only sporadically. Since up-listing in late 2013 and raising significant amounts of financing, the Company has been able to make significant progress against Herpes rapidly, that has resulted in the recent achievements.

### **FluCide™ - Oral and Injectable**

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 study was conducted at BASi (Bioanalytical Systems, Inc., NASDAQ: BASI) in Evansville, Indiana. The study was performed in a cGLP-like fashion, compliant with BASi Evansville standard operating procedures. BASi has over 40 years of experience providing contract research services and niche instrumentation to the life sciences, primarily drug research and development.

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

This study was developed in collaboration with BASi and conducted by BASi in a c-GLP-like fashion in order to understand the safety parameters of FluCide intravenous dosing.

We have been actively studying different chemical processes and routes of synthesis of the backbone polymer, the ligand, and the nanoviricide drug itself, which is a chemical conjugate of the two. The objective of these studies is to develop pathways that will allow industrial manufacturing scale production of a well-defined drug substance, so that multiple batches will produce consistent product. Our studies also involve the development of methods of chemical and physical characterization of the materials at various stages in the entire production process. These studies also include performing the syntheses at different scales, and at least sufficiently characterizing the products at different stages to enable decision-making regarding different possible process variations. We are also continuing to develop

additional tests that are needed for analyses of samples from animals that will be generated during the safety/toxicology studies, and later in the human clinical trials. Such tests are needed for estimating a drug's distribution pattern in the body as well as the time profile of the distribution. Such tests are also needed to decipher the metabolic fate of the drug. Since a nanoviricide drug is not a simple small chemical or an antibody, development of these tests is relatively complex, and is taking a significant amount of time.

The next phase of the toxicology package studies for our injectable influenza drug candidate will involve larger animals, and will require much larger quantities of the anti-influenza drug candidate. In order to accomplish this, we have continued to scale up our production processes for both the backbone polymer and the ligands at our new Shelton facility. We believe that we will be able to make as much as a few kilograms in a single batch in the new cGMP-capable facility. We have continued to work successfully towards large-scale production of this anti-Influenza drug candidate. The Scale-Up Laboratory in our new Shelton campus now has the necessary equipment for this scale up. Initial process engineering and in-process control schemes have been designed, and in-process control equipment required for this has been identified. Appropriate equipment has been ordered to test the suitability of the control procedures we have designed. Some of this equipment is being tested in practice now. Initial batches for each synthesis step are being committed. We have been able to make up to 200g batches of this drug candidate in our old facility. Scaling up to much larger quantities requires different and larger equipment, and re-optimization of each step. During and after each step is completed at the large scale, we must maintain certain process controls, obtain relevant data, and thereafter characterize the resulting products by various methods.

We have substantially expanded our staff and skillset to accommodate the substantial workload associated with performing all of the studies for moving our advanced drug candidates towards IND filings. We have doubled our internal scientific staff, including the staff of our affiliates, during the reporting year. New staff also must undergo training in new techniques, methods, instrumentation, as well as our own internal processes. We have implemented strong project management processes in order to manage the multitude of our internal projects and sub-projects. In the case of FluCide™, we have completed these optimization studies resulting in two separate FluCide drugs, namely the injectable FluCide, and the oral FluCide. The injectable FluCide is further advanced in its development cycle and is anticipated to be our first drug candidate going towards and IND filing and human clinical studies in the near future as we complete its pre-clinical development and c-GMP manufacturing process development. The oral FluCide is anticipated to follow the injectable FluCide into human trials.

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

In September 2012, we announced that the oral version of FluCide was also highly effective against a different sub-type of influenza A, namely H3N2, in addition to the influenza strain of H1N1 that we had been using for development, in the same lethal animal challenge model. This is an important indication that our drug candidates against influenza are indeed broad-spectrum, i.e. capable of combating most if not all influenza viruses.

In April 2013, we announced, that our two anti-Influenza drug candidates are also expected to be effective against the novel H7N9 strain of Influenza A that has killed 35 people in China this year. Our expectation is based on the analysis of publicly available characteristics of the H7N9 virus.

Since then, we have performed preliminary safety studies in mice that showed excellent safety, leading to estimation of the need for multi-kg quantities of the drug for the full safety and toxicology needed for an IND application, i.e. the “Tox Package” study. We performed another safety study in rats in order to define parameters for the Tox Package study. This rat study also indicated an excellent safety profile for our anti-influenza injectable drug candidate.

We have been working on scaling up single batch production of the injectable anti-influenza drug candidate. The construction of our new cGMP-capable manufacturing facility was delayed by factors outside our control, including several months with severe weather conditions. This has caused our timelines for the production of the tox package

batches to be significantly extended.

We will need to perform animal studies against a few additional strains of influenza viruses in order to substantiate that these drugs are indeed broad-spectrum drug candidates. Additional studies in cell cultures against different strains of influenza are also planned. All of these studies are necessary for filing an IND application.

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



In September 2011, we announced that we have selected a clinical candidate, now designated NV-INF-1, for FDA submission in our highly successful FluCide™ anti-influenza therapeutics program. The Company is now developing certain additional information on NV-INF-1, and is progressing this drug candidate towards an IND for use with hospitalized patients with influenza.

In July 2011, we retained the Biologics Consulting Group to help us with our regulatory filings. Thereafter we sent in a pre-IND meeting request to the US FDA in December, 2011, and held a pre-IND meeting with the US FDA in March, 2012. In July 2012, we retained Australian Biologics Pty. Ltd., a regulatory affairs consulting firm, to coordinate the regulatory review and approval to conduct the first human trials in Australia for Flucide™, the Company's broad-spectrum anti-influenza drug. Australian Biologics will also facilitate clinical trial site(s) selection and development of the clinical trials agreements. Dr. Jim Ackland, the Manager of Australian Biologics Pty, Ltd, has extensive experience in this field. Prior to becoming managing director of this company, he was Vice-President, West Coast and Asia Pacific operations for the Biologics Consulting Group, the Company's US FDA regulatory affairs consulting group. In the 1990's, he was the Head of Regulatory Affairs, Vaccines, for the CSL Group in Australia. The CSL Group is a global, specialty biopharmaceutical company that researches, develops, manufactures and markets products to treat and prevent serious human medical conditions.

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

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

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

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

These data clearly demonstrated that both oral and IV treatment with nanoviricide drug candidates protected the lungs of the mice infected with influenza virus equally well. It is also clear that this lung protection was the result of the substantial decrease in the lung viral load. In addition, they show that FluCide drug candidates when given orally had substantial efficacy, almost matching the effectiveness of the injectable form given at 0.3X of the oral dosage level.

In addition to the antiviral effects, the oral FluCide drug candidates also led to generation of a strong antiviral antibody response. Two different anti-influenza drug candidates were tested in Oral vs. IV comparison. One of the FluCide drug candidates, when administered orally, resulted in  $1866\pm90$  micro-g/ml-plasma of anti-influenza antibody, and  $1258\pm59$  when administered as IV injections. Another FluCide candidate, when given orally, resulted in  $1491\pm37$  ug/ml plasma of anti-influenza antibody, and  $1151\pm53$  when administered as IV injections. The untreated infected animals had  $190\pm22$  ug/ml antibody response, which was the weakest of all, as expected. Of significance, oseltamivir (Tamiflu) resulted in only  $950\pm64$  ug/ml level of antibody response, which was far less than the two oral FluCide groups (p-value  $<0.0003$ ), and also substantially less than the two IV FluCide groups (p-value  $<0.04$ ). These p-values were determined for a comparison of FluCide groups against the oseltamivir group using the most stringent parameters, viz. two-tailed, paired, t-test. A smaller p-value indicates a greater confidence that the difference in observations cannot be a result of pure chance. These data also indicated that the antibody response was stronger when FluCide was given orally rather than as IV injection.

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

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

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

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

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

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

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

In November 2010, the Company reported that its FluCide™ drug candidates demonstrated dramatically improved survival in animals administered a lethal dose of influenza virus. Animals treated with all of the different influenza nanoviricide drug candidates survived for dramatically longer periods as compared to Tamiflu® treated animals. Animals treated with the best of the optimized FluCide nanoviricide drug candidates survived greater than twice as long (18.1 days) as opposed to the animals treated with Tamiflu (only 7.8 days). In a previous study, the Company had reported that animals treated with the then best anti-influenza nanoviricides survived for as long as 13.9 days in the same animal model. These drug candidates also resulted in a dramatic reduction in viral load within the lungs of animals infected with a lethal dose of H1N1 influenza virus. The most effective FluCide candidate demonstrated a fifteen-fold (15X) greater viral load reduction as compared to Tamiflu, and a thirty-fold (30X) greater viral load reduction as compared to untreated animals. Tamiflu demonstrated a viral load reduction of only twofold (2X) compared to the untreated animals in this high infection, lethality study. We then engaged in chemistry optimization studies to help us with the FDA regulatory requirements.

In March through May 2011, the Company reported that further chemistry optimization led to dramatically improved antiviral efficacy with its optimized FluCide™ drug candidates in its most recent animal study. In the influenza mouse lethal infection model, animals treated with one of the optimized FluCide™ nanoviricide drug candidates survived beyond the stated full duration of study (21 days), and those treated with two additional drug candidates survived almost the full duration of the study. Animals in these three groups survived significantly longer (20.2 to 22.2 days) as compared to the animals treated with Oseltamivir (Tamiflu®) only 8.3 days. In addition, the post-infection treatment with these optimized FluCide™ drug candidates resulted in dramatic reduction in the number of lung lesions that are caused by a lethal influenza virus infection. Four days post virus infection, animals treated with three of the optimized FluCide™ nanoviricide drug candidates exhibited greater than 95% reduction in the number of lung lesions as compared to the infected yet untreated control animals (p-values < 0.001). In contrast, animals treated with Oseltamivir (Tamiflu®, Roche) showed only a 50% reduction. In another significant finding, no increase in the number or size of the lung lesions was observed over the entire duration of the study in the FluCide™-treated animals. This was not the case for the Oseltamivir-treated animals. This demonstrated that treatment with FluCide drug candidates provided clear and strong protection against lung damage caused by the severe influenza infection. In addition, in this study, these optimized FluCide™ drug candidates achieved 1,000-fold reduction in the levels of infectious virus in the lungs of animals with a lethal level of influenza virus infection. The amount of infectious virus in the lungs of the infected animals treated with three of the optimized FluCide™ nanoviricide drug candidates was reduced by greater than 1000-fold as compared to the infected untreated control animals (p-values < 0.001), four days after virus infection. In contrast, animals treated with Oseltamivir (Tamiflu®, Roche) showed less than a 2-fold reduction in lung viral load at the same time point. This indicated a 500-fold greater reduction in viral load by FluCide drug candidates over Oseltamivir. Of great clinical significance is the fact that 2 of the optimized FluCide™ drug candidates maintained this greatly reduced lung viral load at 7, 13 and 19 days after virus infection in this 21 day study. Thus, treatment with the optimized FluCide drug candidates appeared to protect against the complete cycle of infection, virus expansion and spread of infection in the lungs that follows the initial virus infection. This was not the case for the Oseltamivir-treated animals. Animals treated with Oseltamivir (Tamiflu®, Roche) showed less than a 2-fold reduction in lung viral load at 4 days and the viral load was increased at 7 days to the same level as that found in the infected, untreated control animals shortly before their death.

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

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

reported from time to time.

## **Ebola**

In August 2014, we restarted our anti-Ebola drug development program in response to the then raging Ebola epidemic in Africa. Our materials testing agreement with US Army Medical Research in Infectious Diseases (USAMRIID) unfortunately took substantial amount of time to restart. We executed a CRADA (Collaborative Research and Development Agreement for Material Transfer) with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) at the end of October, 2014. This agreement enabled that certain novel anti-Ebola nanomedicine drug candidates recently developed by the Company will be evaluated by USAMRIID scientists in their BSL-4 facilities for activity against the deadly Ebola virus under this agreement. In absence of a testing agreement in place, we had not begun syntheses of these candidates. We were able to send a first panel of novel agents to USAMRIID at the end of January 2015. We received initial test results in early March 2015. The nanoviricides approach was found to be very promising in these cell culture studies. Typically, we conduct at least one more cell culture study by improving on the initial candidates using experience from the first testing. We mutually decided with USAMRIID scientists that we should perform another round of improvement of the drug candidates.

This event in early April 2015, coincided with the epidemic beginning to be brought under control by the international public health agencies with heroic efforts - despite the lack of treatments or vaccines - and the urgency of our Ebola program, which was engaged into because of the potential global epidemic threat, was no longer apparent. In addition, several other drug candidates had been fortuitously advanced into various modified protocols of clinical trials by then. With these changes in the global Ebola scenario, NanoViricides determined around May 2015 that we should re-focus our efforts on our commercially important priorities.

We believe that an optimized nanoviricide anti-Ebola drug candidate would have been the only viable option, had the epidemic continued to evolve into a global threat. Our belief is now supported by evidence. All of the anti-Ebola drug candidates that were advanced into clinical trials during the epidemic have been either rescinded by the sponsors or have not met statistically significant effectiveness end-points. These candidates include the siRNA therapeutics by Tekmira, antibody cocktail therapeutics by zMAPP, brincidofovir by Chimerix, and favipravir (T-705) by Takeda. In addition, Sarepta and BioCryst did not advance their anti-Ebola drug candidates into efficacy clinical trials.

The tested anti-Ebola nanoviricides drug candidates were designed to be broad-spectrum. They are based on binding to the Ebola virus glycoprotein at points where this glycoprotein binds to the human cellular receptors. Ebolavirus uses multiple cellular receptors in a complex scheme of entry into the cell. No matter how much the ebola virus mutates, its binding to these cellular receptors is conserved. Thus, the nanoviricide approach has the best possible chance against rapidly mutating viruses such as Ebola, as compared to other current antiviral approaches.

In contrast, the well-known limitations of siRNA cocktail (Tekmira), antibody cocktail (zMAPP), and antisense oligos (Sarepta) approaches were rediscovered in clinical testing against Ebola virus during this epidemic. Drugs in these classes are highly specific to the virus strain(s) that they are developed against, and are very likely to fail against a novel strain of the same virus in the field. The broad-spectrum antivirals favipravir, brincidofovir and BCX-4430 must work intracellularly and when used against Ebolavirus infection in the field, it is likely that the dosages needed to achieve antiviral effectiveness, if any, could not be achieved due to the various limitations of these drugs including potential toxicities at the required dosage levels.

A positive light in this dark Ebola epidemic scenario is that a new Merck anti-Ebola vaccine was recently found to provide protection from Ebolavirus infection. Rapidly mutating viruses such as Influenza and HIV are known to mutate readily to make vaccines ineffective - in the case of HIV, an effective vaccine is yet to appear despite significant R&D work. It remains to be seen if Ebolavirus, which is known to mutate rapidly, would mutate to make this new vaccine ineffective, possibly in a few years of evolution.

We believe that if a similar Ebolavirus epidemic recurs, we are now in a strong position to develop an effective anti-Ebola nanoviricide drug. In contrast to all of the other companies in the field, NanoViricides's work on Ebola virus is not supported by non-dilutive funding such as government grants or charitable foundations. We therefore can

afford to devote only extremely limited resources to such a project, and we must attempt to do so with a dual-purpose mindset.

Significant amount of the research work we performed for Ebola virus was, by design, part of our core efforts. Thus we were able to minimize the impact of undertaking the Ebola program on our other drug development programs.



## Dengue

In June 2013, we submitted an application to the US FDA to designate our anti-dengue drug candidate as an “orphan drug” under the Orphan Drug Act. Subsequently we also submitted a similar orphan drug designation application at the European Medical Agency for this same drug. Dengue, a viral disease, is considered an orphan disease in United States as well as Europe. We retained Coté Orphan Consulting (COC), headed by Dr. Tim Coté, to help us with these submissions. In 2013 we were awarded Orphan Drug Status by the USFDA and the European Medicines Agency(EMA).

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

## HIVCide™

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

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

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

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

In September 2013, the Company reported that it has successfully improved upon its previous lead anti-HIV drug candidate, based on cell culture studies. An improved broad-spectrum anti-HIV nanoviricide that inhibited two distinctly different types of HIV-1 viruses equally well has been identified. This drug candidate also exhibited a very large therapeutic index. The Company had previously reported that it is optimizing the anti-HIV drug candidate. These cell culture studies were conducted by Southern Research Institute, Frederick, MD. The Company reported that it has identified an improved broad-spectrum anti-HIV ligand, based on the previous best ligand from the 2011 study (see above). Also, both of these broad-spectrum ligands, namely (a) the best one from this 2013 cell culture study and (b) the previous best from the 2011 animal study, when connected to a different backbone polymer than in the 2011 study, demonstrated substantially improved inhibition of two different types of HIV-1 virus in a standard cell culture study of virus neutralization and inhibition. The HIV-1 Ba-L, a CCR5-using strain, as well as the HIV-1 IIB, a CXCR4-using strain, were both inhibited equally well by these two different nanoviricide drug candidates in the standard MAGI HIV Antiviral Assay. The MAGI-R5 cells used in the current study express CD4 and both CXCR4 and CCR5 co-receptors. Different HIV-1 strains are known to use CD4 as a required receptor and, additionally, at least one of the CCR5 or CXCR4 (or both) as a co-receptor. The CCR5+ HIV strains generally transmit from human to human, whereas in the patient's body, over time, the CXCR4+ HIV strains dominate. Thus it is important to develop a drug that is effective against both of these types of HIV-1 viruses.

The present cell culture data also showed that the two nanoviricides under study were safe to cells at far greater levels than the level needed for therapeutic effects.

We completed our second anti-HIV in vivo study in the HIVCide program in August 2011 at KARD Scientific. This study was conducted using the standard humanized mouse model. In this model, the immune system of the mouse is replaced by human immune system. Then HIV infection is given. HIV infects the human immune system. The antivirals are then given and tested for their effect on the interaction of HIV with the implanted human immune system. In the previous anti-HIV study, we had found that three different unoptimized anti-HIV nanoviricides exhibited extremely strong effectiveness that was equal to or better than a three drug HAART cocktail (highly effective antiretroviral treatment) in this animal model. We have since developed better optimized ligands to attack the HIV virus particle. In order to find the best ligand, we reduced the amount of ligand attached to the polymer chain in this new study. We were able to select the best nanoviricide anti-HIV ligand in the new study, which appears to be better than all the ligands tested in the previous study. This nanoviricide's effect was still equal to or better than the same 3-drug HAART cocktail, although we had expected a substantially reduced effect.

What is more, the new anti-HIV nanoviricide drug candidate continued to maintain HIV-1 viral load suppression for at least 28 days after last drug dosing in this recent study. So we believe that an intermittent therapy against HIV/AIDS is feasible with nanoviricides. We believe that such a therapy would allow patients to achieve nominally HIV-free status, and have a normal life, for long periods, without drugs. We are now further optimizing the HIVCide drug candidates. In effect, we believe that HIVCide would enable a "functional cure" for HIV, although much work needs to be done as this program matures into a clinical candidate.

Subsequently, we have conducted a cell culture-based study of a set of anti-HIV drug candidates designed using information from this study as well as molecular modeling against known HIV-1 gp120 –human CD4 binding site structures to identify better anti-HIV ligands. This study was performed at Southern Research Institute in Frederick, MD. The Company reported in September 2013 that it has identified an improved broad-spectrum anti-HIV ligand in this study, based on the previous best ligand from the 2011 study. Also, both of these broad-spectrum ligands, when connected to a different backbone polymer than in the 2011 study, have shown substantially improved inhibition of two different types of HIV-1 virus in a standard cell culture study of virus neutralization and inhibition. HIV-1 Ba-L, a CCR5-using strain as well as HIV-1 IIIB, a CXCR4-using strain, were both inhibited equally well by these two different nanoviricide drug candidates in the standard MAGI HIV Antiviral Assay. The present cell culture data also showed that the two nanoviricides under study were safe to cells at far greater levels than the level needed for therapeutic effects.

The Company has designed these anti-HIV ligands using reported gp120 protein structures of several HIV-1 strains in order to achieve broad-spectrum effectiveness. The HIV-1 gp120 protein binds to the human cell surface receptors CD4 and CCR5 or CXCR4 thereby enabling entry of the virus into the cell. The MAGI-R5 cells used in this study express CD4 and both CXCR4 and CCR5 co-receptors. Different HIV-1 strains are known to use CD4 as a required receptor and, additionally, at least one of the CCR5 or CXCR4 (or both) as a co-receptor. The CCR5+ HIV strains generally transmit from human to human, whereas in the patient's body, over time, the CXCR4+ HIV strains dominate. Thus it is important to develop a drug that is effective against both of these types of HIV-1 viruses.

The Company believes that its strategy of mimicking the CD4 binding to HIV-1 should allow the development of broad-spectrum anti-HIV drugs. The site on CD4 at which HIV-1 binds remains the same in spite of the large number of mutations that the HIV virus undergoes. The Company's nanoviricide® technology enables creation of a nanomicelle that looks like the surface of the human cell to the virus, attracting the virus to bind and thereupon neutralizing the virus.

In June 2010, we also reported that our anti-HIV drug candidates demonstrated efficacy in the recently completed cell culture studies using two distinctly different HIV-1 isolates. These studies were performed in the laboratory of Carol Lackman-Smith at the Southern Research Institute, Frederick, Maryland. These results corroborated our previous findings in animal studies. The Company had reported that its best nanoviricide drug candidate against HIV was more than 25 times superior to a three drug combo anti-HIV cocktail based on biomarker test response in all parameters tested. The parameters included improvement in human T cell populations in the animal model and reduction in HIV viral load. The Company has since performed additional studies to optimize the HIV binding ligand and has found ligands that are superior to the one that yielded these strong results. In September 2013, we announced successful anti-HIV drug development studies performed in this same laboratory. Anti-HIV studies are extremely expensive. As such, the Company's HIVCide program has been slowed down.

### **NanoViricides Technology**

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

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

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

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

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

A skin cream appears to be the right formulation for the treatment of oral and genital warts caused by HSV-1 and HSV-2. Last year we had already observed that our drug candidates, in the solution form, were effective in cell cultures against at least two different strains of HSV-1 in two different laboratories. We needed to make skin creams for conducting animal studies and selected different building blocks for our backbone polymer, and built new drugs against HSV. Subsequently, we have also developed the anti-HSV drug candidates in the form of skin lotions.

The skin cream drug candidates against HSV were developed within a matter of weeks. Similarly, development of the skin lotion form of the HSV candidates also took only a few weeks. In both cases, the formulation development itself took only a few days. In contrast, many drug development companies spend years in formulations development.

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

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

We have limited our expenditures on socially conscious projects such as “Neglected Tropical Diseases” (NTD’s), and “Bio-defense” projects to the extent that participatory funding from third parties is available. To this end, we attempt to obtain grants and contracts financing from government and non-government sources. We will continue to work on these programs as time and resources permit. In addition, we continue to develop novel technologies such as ADIF™ (“Accurate-Drug-In-Field™”), which may possibly represent one of the best scientific approaches against manmade and natural novel disease agents. Outbreaks of natural novel viral diseases, such as MERS-CoV (Middle East Respiratory Coronavirus infection, a deadly disease that is seen in the middle east and European areas at present), SARS, Influenza, Ebola/Marburg and other presently unknown diseases will continue to occur. A novel SARS virus called h-CoV-EMC aka MERS-CoV has emerged very recently in the Middle East. This virus does not share the same receptor as the previous 2002-2003 outbreak SARS virus (now called SARS-CoV). At present, there is no feasible therapeutic intervention for outbreaks of novel viruses, such as these new coronavirus outbreaks.

We now have six commercially significant active drug development programs: (1) Oral FluCide™, against all Influenzas, (2) a Piggy-back (injectable or infusible) version of Flucide for hospitalized patients, (3) nanoviricide eye drops against adenoviral EKC and herpes keratitis, (4) HIVCide™-I against HIV/AIDS, (5) HerpeCide™-I skin cream formulation for herpes cold sores and genital warts, and (6) 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). We continue to achieve very strong performance in the testing of these drug candidates.

In our extensive animal studies we have observed that our drug materials were well tolerated in mice, humanized mice, and rabbits, and did not produce any adverse events. These studies involved different viral targets, different nanoviricides, with different ligands attached, and differing polymeric micelle backbones, indicating that our technology and design of nanoviricides appears to be resulting in substantially safe drug substances. We believe that the TheraCour® polymer chemistry inherently endows safety by its design to the nanoviricides drug candidates. The polymer backbone comprises PEG (polyethylene glycol), which is known to minimize antigenicity of the drugs that it is attached to. PEG is extensively employed in drug design, especially for biologics, to minimize immune reactions caused by the native antibodies or proteins as drugs. Particularly well known in this regard is the “PEGylation” technology. We believe that the other parts of the nanoviricide’s polymer backbone are readily metabolizable, and much of it serves as “food” to cells. It is of course possible that toxicity can occur due to a specific ligand. We believe that we have made an effort at designing relatively safe anti-viral ligands. In addition, because our nanoviricides target the virus particle and not the host systems, we believe that our nanoviricide approach itself has inherent safety advantages over traditional antiviral drugs that must penetrate cells, accumulate inside and thereby may result in toxicities by interfering with, or being subject to, cellular processes.

After declaring the injectable FluCide drug candidate in February 2012, we have been focused on taking our technology from the small scale syntheses needed for small animal studies to the large scale syntheses for making large batches of our nanoviricides as would be needed for Safety and Toxicology (“Tox Package” studies) and later for human clinical trials. Because of the significant safety observed during the several animal studies designed to test the effectiveness of FluCide drug candidates in small animals, the scale required for the tox package studies was estimated at kilograms. Originally we had intended to perform kg-scale syntheses only after the new lab and facilities

designed for such scale up was available. However, the facility program was significantly behind due to challenges related to resources availability as well as significant challenges posed by the need for designing complex functionality in a limited space while performing renovation of an existing space. We therefore decided to perform the synthesis of FluCide for tox package in our existing small-scale laboratory. We have been optimizing the processes and translating laboratory operations to appropriate chemical process unit operations in the subsequent time frame. This is a very significant undertaking, given the constraints of our current small-scale facility. After we have completed these process optimizations, we will still need to produce at least three to five batches of the injectable FluCide, analyze the product for comparability, and combine these batches to produce a master batch sufficient to perform the tox package studies with. These activities are currently in progress.

During the reporting year, we have also been focused on the construction, development, and partial phased validation, of the cGMP-capable clinical batch production facility and associated R&D laboratories at the Shelton campus, and moving our current operations there in a phased manner in order to minimize impact on the on-going work. We have commissioned the R&D labs and the Scale-up production lab into operation successfully during this year in the Shelton campus.



Our nanoviricide® technology is based on two separate parts that are chemically connected together to make the nanoviricide drug candidate: (a) a linear polymer made from a monomer of PEG connected to a linker containing fatty acid chains, and (b) virus-binding ligands attached to the connector of this polymer. We design the ligands as mimics of the cell surface receptor(s) to which the virus particle binds, using molecular modeling and other techniques. In the nanoviricide, we believe that the polymer backbone forms a globular micelle with the fatty acid chains floating in the interior of the micelle, thereby resembling a structure similar to the cell surface. When appropriate ligands are attached to the polymer, the resulting polymer would “look like” a cell surface with a very high density of virus binding points. We believe that this would cause the virus to bind to the nanoviricide in preference over binding to host cells, and the virus would “enter” into the nanoviricide micelle, and possibly uncoat itself thinking that it has entered a cell. The nanoviricide is thus designed to act like a “Venus fly-trap” for the virus. To make such a sophisticated nanomachine work, it requires a significant degree of optimization. The tailorable, building-block based design of the TheraCour® polymeric micelle technology on which our nanoviricide® technology is based enables such optimization.

We design several ligands and then attach them to a single polymer backbone and test them in cell culture and animal studies to obtain the best possible ligand. We look to optimize the potency while retaining broad-spectrum effectiveness when we test for the ligands. We optimize the polymer backbone separately. By choosing various building blocks appropriately, and by choosing appropriate chemical processes, it is possible to design polymer backbones that (a) provide the appropriate length of time of residence in the body; (b) provide a formulation optimal for a specific route of administration such as injectable, skin cream, skin lotion, ophthalmic lotion, and even oral as we have been able to do in the case of FluCide™; (c) provide an optimal density of ligands to maximize the ability to attract the virus, bind to it, and potentially dismantle the vulnerable viruses.

This year we have continued to improve our laboratory infrastructure, adding several new instruments and further chemistry capabilities. We have purchased substantial amounts of laboratory equipment for the characterization of our nanomaterials. We are acquiring the capabilities for synthesis, small scale-up, and production of our drug candidates. These are needed for the ensuing development work towards the goal of filing an IND application.

## **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 to 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 24.9% 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., 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 quoted on the OTC Bulletin Board under the symbol NNVC. The Company is considered a development stage company at this time.

On September 10, 2013, the Company adopted a uniform reverse split of its securities in a 3.5 to 1 ratio, reducing its authorized common stock to 85,714,287 shares at \$0.001 par value, in order to satisfy the share price listing requirements of US National exchanges. On Wednesday, September 25, 2013, the Company's common stock began trading on the New York Stock Exchange MKT (NYSE MKT) under the same symbol, namely "NNVC".

NanoViricides, Inc. (the "Company"), is a nano-biopharmaceutical (nanomedicine) 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. The Company's drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. ("TheraCour®"), to which the Company has exclusive licenses in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Influenza including Asian Bird Flu Virus (INF), Herpes Simplex Virus (HSV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), and Rabies. On February 15, 2010, the Company 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 (DENV), Japanese Encephalitis (JEV), West Nile Virus (WNV), viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses.

The Company focuses its research and clinical programs on specific anti-viral therapeutics and is seeking to add to its existing portfolio of products through its internal discovery and clinical development programs and through an in-licensing strategy. To date, the Company has not commercialized any product.

The Company has incurred significant operating losses since its inception resulting in an accumulated deficit of \$54,099,572 at June 30, 2015. For the year ended June 30, 2015, the Company had a net loss of \$2,198,172. 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, private placement of common stock, and sale of registered 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 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 other than the Series B Convertible Debentures and the Series C Convertible Debentures.

## Glossary of Terms

Nano - When used as a prefix for something other than a unit of measure, as in “nanoscience,” nano means relating to nanotechnology, or on a scale of nanometers (one billionth of a meter or greater).

Viricide - An agent which reliably deactivates or destroys a virus.

Nanoviricide ® – An agent which is made by attaching ligands against a certain virus or family of viruses to a nanomicelle based on the Company’s patent-pending and proprietary technologies.

Ligand - A short peptide or chemical molecule fragment that has been designed to specifically recognize one particular type of virus.

Micelle - an aggregate of molecules in a solution, such as those formed by detergents.

Nanomicelle - Micelles on the scale of nanometers.

Pendant polymeric micelles- A polymeric micelle forms from a polymer whose chemical constitution is such that even a single chain of the polymer forms a micelle. A pendant polymer is a polymer that has certain units in its backbone that extend short chains branched away from the backbone. Pendant Polymeric Micelles therefore are polymeric micelle materials that are a class of pendant polymers, and naturally form exceptionally well-defined, self-assembling, globular micelles with a core-shell architecture.

Mutations - The ability (of a virus) to change its genetic structure to avoid the body's natural defenses. Mutants are viruses created from a parent virus strain through a process of natural selection under pressure as it replicates in a host.

P-Value- In statistical hypothesis testing, the p-value is the probability of obtaining a result at least as extreme as that obtained, assuming that the null hypothesis is true; wherein the truth of the null hypothesis states that the finding was the result of chance alone. The fact that p-values are based on this assumption is crucial to their correct interpretation. The smaller the p-value, the greater is the probability that the observed study results and the comparison control are distinct, and therefore that the study results are not a result of chance alone.

More technically, the p-value of an observed value observed of some random variable T used as a test statistic is the probability that, given that the null hypothesis is true, T will assume a value as or more unfavorable to the null hypothesis as the observed value observed. "More unfavorable to the null hypothesis" can in some cases mean greater than, in some cases less than and in some cases further away from a specified center value.

Investigational New Drug Application (Investigational New Drug ("IND"))-The process of licensure of a new drug in the US goes through several steps. A simplified explanation of these steps is as follows. Initially a Company may file a pre-IND application to seek meetings with the FDA for guidance on work needed for filing an IND application. The Company obtains data on the safety and effectiveness of the drug substance in various laboratory studies including cell cultures and animal models. The Company also obtains data on chemical manufacturing of the drug substance. These and certain additional data are used to create an IND which the Company files with the FDA. After the FDA approves an IND application, the Company may conduct human clinical studies. A Phase I human clinical trial is designed typically to evaluate safety of the drug and maximum permissible dosage level. A Phase II human clinical trial that follows is designed to evaluate effectiveness of the drug against the disease in a small cohort of patients. A Phase III human clinical trial thereafter is designed to evaluate effectiveness and safety in larger groups of patients, often at multiple sites. The Company may then submit an NDA (New Drug Application) with the data collected in the clinical trials. The FDA may approve the NDA. Once the NDA is approved, the Company can sell the drug in the USA. European countries have similar processes under the European Medicines Agency (EMA). Other countries have similar processes.

SAR: Structure-Activity-Relationship study. When an initial lead drug compound is found that has activity, further studies on drug compounds obtained by suitably modifying it are performed with the goal of improving efficacy, safety, or both. Such studies are called SAR studies.

## **NanoViricides Technologies, Products in Development, and Collaborations**

Pharmaceutical drug development is an expensive and long duration proposition. Management's plan is to develop each of our nanoviricides to the necessary stage(s) and then engage into licensing or co-development relationships with other pharmaceutical companies. Such licensing or 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. 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 drug development programs with large commercial interest include (1) an injectable drug for hospitalized patients with Influenza, (2) an oral drug for outpatients with Influenza (3) HIV, (4) Topical Eye Drops for viral diseases of the external eye, (5) Herpes "cold sores" and genital Herpes, and (6) Dengue viruses. In addition, the Company believes that, as the holder of potentially paradigm-shifting antiviral drug development technologies, it has a social responsibility to develop drugs against diseases affecting large segments of worldwide populations. In our Social Responsibility programs, we are developing drugs against Neglected Tropical Diseases (NTDs) caused by viruses such as Dengue viruses and Rabies. The Company also has BioSecurity programs that include drug development against hemorrhagic fever viruses such as Ebola/Marburg, and a unique technology that we call "ADIF<sup>TM</sup>" to combat natural or bioterrorism attacks by novel viruses as happened with SARS and may happen with engineered viruses. The Company plans to perform its NTD and BioSecurity R&D and drug development in collaboration with Institutes of renown and with public funding, in order to minimize the strain on our resources. The Company believes that this work provides direct benefits to our commercially important programs. The Company will continue its efforts to obtain federal financing for development of these technologies. However, the Company may not be successful in obtaining such financing. The Company has limited resources and its ability to work on such projects that are deemed of low commercial value is very limited.

Our Collaborations and Service Contracts in Brief

Our development model is to employ collaborations and service contract relationships with renowned academic labs, government labs, as well as service contracts with external service providers in order to minimize our capital requirements. KARD Scientific, Inc., our principal collaborator for animal efficacy testing for Influenza and HIV, has recently closed their animal testing services business, as the principal, Dr. Krishna Menon, intends to reduce his responsibilities due to health reasons. We have established new relationships to enable continuation of our work. Our current relationships include:

For Influenza Viruses:

1. Integrated Biotherapeutics, Inc., MD.
2. Public Health England, UK
3. Southern Research Institute, AL.
4. TheVac, LLC, LA
- 5 National (Central) Institute of Hygiene and Epidemiology (NIHE) (Vietnam), for H5N1 avian flu.

For HIV:

1. Southern Research Institute, Frederick, MD.
- 2 University of California at San Francisco CA.

For Viral Diseases of the Eye (Adenoviruses, Herpesviruses - Epidemic Kerato-conjunctivitis (EKC), Herpes Keratitis):

1. The Long Island Jewish Medical System, Feinstein Institute of Medical Research (LIJMS), NY.
2. TheVac, LLC.

For Herpes Virus Infections:

1. TheVac, LLC
2. Northeastern Ohio Medical University (NEOMED), previously NEOUCOM, Prof. Ken Rosenthal(Retired) Lab.

3. TransPharm Preclinical Solutions, MI

For Dengue Hemorrhagic Fever Viruses:

1. University of California at Berkeley, Prof. Eva Harris Lab.

For Ebola/Marburg Viruses:

1. United States Army Medical Institute of Infectious Diseases (USAMRIID), Dr. Pamela Glass Lab.
2. Public Health England, UK

For Rabies Virus:

1. Center for Disease Control and Prevention (CDC), Dr. Charles Rupprecht Lab.
2. National (Central) Institute of Hygiene and Epidemiology (NIHE), Vietnam.



In addition, we have signed an agreement with the Biologics Consulting Group (BCG), Alexandria, Virginia, to help us with the US FDA applications processes, and with the development of applications as well as drug development programs, as needed. We have also signed an agreement with Australian Biologics Pty, Ltd. to help us with the regulatory processes in Australia.

We have also signed a Master Services Agreement with BASi to perform cGLP and GLP-like safety and toxicological studies that are necessary for filing an IND for each of our drugs.

In April 2014, we finalized a Master Services Agreement (MSA) with Public Health England (PHE), UK, the British government's equivalent of the U.S. Centers for Disease Control, This agreement allows for animal efficacy evaluation of various nanoviricides drug candidates against viruses of mutual interest at the BSL2, BSL3 or BSL4 facilities at PHE-UK as the case may be. Previously, we signed a Non-Disclosure Agreement with Public Health England (PHE) in July 2013. The MSA will allow the scientists at Public Health England to develop a specific proposal for the testing of different nanoviricides, such as FluCide™, against viruses of "mutual interest" to both organizations. More specifically, the first two viruses of mutual interest are H7N9, the influenza virus now circulating in China as well as the latest version of the coronavirus, now circulating in the Middle East. It is now referred to as the MERS virus. This virus is similar to the SARS virus that infected 8000 people and killed approximately 800 people 10 years ago. Both H7N9 and the MERS CoV (coronavirus) have extremely high case fatality rates. We expect to test the nanoviricide antiviral drug candidates in a BSL3/4 facility at PHE. BSL3/4 facilities are designed to contain and enable the safe handling of organisms that can pose a significant threat to health. The BSL3/4 laboratories at PHE-UK, as elsewhere in the world, are currently extremely stressed with the public health challenges of responding to the current Ebola virus epidemic. We anticipate that this agreement will further evolve into a collaborative agreement.

We have also recently signed a Master Services Agreement with Integrated Biotherapeutics, Inc. ("IBT"), Gaithersberg, MD, a provider of pre-clinical anti-viral evaluation services. We intend to perform certain influenza drug candidate studies at IBT.

We have additional collaborations in the process of formalization. We have also signed a Non-Disclosure Agreement with the Lovelace Respiratory Research Institute, Albuquerque, NM.

We typically employ more than one external laboratory to perform testing for a particular disease agent in order to limit possible laboratory level bias. We previously had a collaborative research agreement with the Walter Reed Army Institute of Research (WRAIR), Dr. Putnak Lab, for work on dengue viruses. This agreement has since lapsed, but we believe it can be reactivated at an opportune time.

We have developed lead drug candidates against a number of viral diseases. Proof-of-principle efficacy studies in animals have been conducted successfully in many of these. We have declared a clinical candidate for influenza, the injectable NV-INF-1, We have also developed an orally active form of this anti-influenza drug candidate.

### **The Nanoviricides Concept and Antiviral Strategy**

Nanoviricides are designed to work by binding to and eliminating virus particles from the blood-stream, just as antibodies do, only potentially much better. Treating a patient that has a viral infection with a nanoviricide against that virus is expected to result in reduction in viremia. Reduction in viremia is an important goal in diseases caused by all viral infections.

A nanoviricide is constructed by chemically attaching a ligand designed to bind to a 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. We can choose a ligand from any of a number of chemical classes, including small chemicals, peptides, or antibody fragments or even whole antibodies.

The Company owns an exclusive worldwide license in perpetuity to technology that enables the creation of nanoviricides. A “nanoviricide®” is a flexible nano-scale material approximately a few billionths of a meter in size, comparable to the size of a virus particle, which is chemically programmed by a “ligand” to specifically target and attack a particular type of virus.

In addition, a nanoviricide is also capable of simultaneously delivering a devastating payload of active pharmaceutical ingredients (API) into the virus particle, to destroy its genome (RNA/DNA). We plan to implement this strategy against viruses which cannot be cured without an encapsulated API. In our current drug programs, we have not employed any antiviral API payload.

A nanoviricide is designed to “look like” the portion of a cell membrane to which a virus particle binds, in a sense. This biomimetic approach is expected to fool the virus into binding to the nanoviricide, and in an attempt to “enter” this structure, it is thought that the virus particle may get destroyed. This is because viruses have developed ways of un-coating themselves once they enter a cell, in order to expose the viral genomic material so that the virus can hijack the cellular machinery to make its own copies. We call this the “passive view” of how a nanoviricide may work.

A nanoviricide is designed as a flexible material, that self-assembles, at about the same size scale as a typical virus particle. The flexible material we use is one type of a special polymeric material called TheraCour®, invented by the Company’s founders. It assembles in solution into a flexible ball, somewhat like a ball of hair. We call this a nanoviricide micelle, or “nanomicelle” for short. On first contact with a virus particle, a nanoviricide micelle may bind to a virus particle because of specific interaction between a ligand attached to the nanoviricide and the glycoproteins on the virus surface. This may cause the flexible nanoviricide to reach very close to the virus surface, leading to additional ligands binding to additional viral coat proteins, in a mode called “cooperative binding”. Cooperative binding is a well-known natural process that forms the basis of biological recognition such as antibody-antigen binding, DNA hybridization, and protein assembly, among others. Eventually it is thought that the interior of the nanomicelle, which is lipidic (oil-like) in nature, would fuse with the exterior lipidic coat of the virus particle. This lipidic fusion is also a well-known natural process. Such fusion may lead to the flexible nanomicelle spreading onto the virus surface much like an oil-slick covering a golf ball. In the process, the coat proteins that the virus uses for binding to cells may be expected to become unavailable, and are also likely to even get stripped off completely. The virus particle would then be rendered incapable of binding to a cell, and thus no longer infectious or capable of causing disease or of making copies of itself. We call this the “active view” of how a nanoviricide may work.

One may allegorically say that a nanoviricide has many “arms” and “legs”. The “arms” are the virus binding ligands, that grab the virus surface glycoproteins. Then the “legs”, the lipid chains in the interior of the nanomicelle, “kick” into and crush the lipid envelop of the virus. This may cause the virus particle to fall apart.

Nanoviricides thus are designed to employ the “Bind-Encapsulate-Destroy” strategy, which is akin to the “Find-Encircle-Destroy” war strategy that has been successfully employed historically in many wars.

Antibodies are a major defense of humans and animals against viruses. After a person is infected by a particular virus, he/she develops antibodies against the virus. The infection is fully controlled after a strong antibody response develops. Subsequent exposure to the same virus does not cause disease, because the appropriate memory cells are

activated into producing the correct antibody. However, antibodies by themselves do not destroy a virus particle. After a few antibodies bind to a virus particle, several processes must take place that eventually lead to destruction of the virus particle. Many viruses have developed ways of dysregulating this complex immune response cascade.

Nanoviricides, on the other hand, are designed as “programmed nanomachines” capable of executing the entire strategy of “Bind- Encapsulate-Destroy” without any dependence on or assistance from the human immune system.

Antibodies also may be too specific to a particular virus strain, and thus viruses evade antibodies by changing their external surface. Vaccines create antibodies in the recipient, in order to protect the person. Vaccines are thus limited by the nature of antibodies, and tend to be very specific to the particular strains or groups of strains of a virus. This is why a new seasonal vaccine must be formulated for influenza every year. This is also why a novel influenza strain such as bird flu (H5N1) or the 2009 “Swine flu” virus cannot be defended against by existing vaccines.

It is well known that every virus retains its ability to bind to the same features on the cell surface at the same site on the cellular receptor, despite all evolutionary/spontaneous changes that it constantly undergoes such as mutations, re-assortments, recombinations, etc.,. In designing a nanoviricide, we pay particular attention to the design and selection of a ligand. We generally choose a ligand that mimics the cell surface features to which all virus strains of a particular virus are known to bind. We therefore believe that a resistant viral strain against a nanoviricide would be far less likely to occur than resistance development against any other antiviral agent strategy. If, however, such resistance does occur, a new nanoviricide can be developed by changing the ligand appropriately.

### **The NanoViricides Technology and Approach**

Nanoviricide drugs, which are presently in a preclinical stage of development, are designed to lead to reduction in viremia (virus in the bloodstream) by a set of novel, multiple, concerted, mechanisms:

Each nanoviricide drug is designed as a specifically targeted antiviral agent for a particular type of virus or group of viruses. Often side effects of a drug may be correlated with non-specific interactions with the host cells, tissues, and organs. Most existing anti-viral agents are known to have non-specific effects against both host cells and viral machinery at the same time. Most existing anti-viral agents act inside human cells. It is believed that this intracellular mechanism leads to significant opportunities for non-specific effects against host cells. Nanoviricides, on the other hand, are designed to work directly against virus particles in bodily fluids. The Company believes that this approach may make nanoviricides inherently safer than existing approaches.

A nanoviricide is designed to seek and attach to a specific virus particle, engulfing the virus particle in the process, thereby rendering it incapable of infecting new cells, and disabling it completely. This suggested mechanism of action comprises much more than what the current entry and fusion inhibitors are expected to do. The fusion and entry inhibitors do not completely cover the virus particle and likely block only a few sites on the virus particle, which means the virus particle may still be capable of infecting cells using its unblocked attachment sites. In contrast, a nanoviricide is expected to engulf the virus particle completely, because of its larger size and flexible nature, thus disabling the virus particle completely. The action of a nanoviricide, if it works as designed, in this regard may be expected to be superior to antibody agents that attack viruses. Antibodies, being large, are expected to block relatively greater portions of the virus particle surface compared to small molecule entry inhibitors. However, antibodies depend upon the human immune system responses for clearing up the virus particle. In contrast, nanoviricides are thought to be capable of acting as completely programmed chemical robots that finish their task of destroying the virus particle on their own.

A nanoviricide is designed to be capable of encapsulating an active pharmaceutical ingredient (API) in its core, or “belly”. This is expected to reduce toxic effects of the API. Such encapsulating methods are currently being used in anti-cancer therapy and have shown reduced toxicity as well as increased efficacy (see <http://nihroadmap.nih.gov/nanomedicine/>).

4. A nanoviricide is designed to deliver any encapsulated API directly into the core of the virus particle. This is proposed to result in maximal effect against the anti-viral targets, such as the viral genomic materials. Our goal for this specifically targeted delivery of the API is to minimize toxic effects and also improve efficacy of the API. (see <http://www.nci.nih.gov> ).

5. With this concerted targeted set of mechanisms, our objective is for the nanoviricide to be programmed to (a) prevent the virus particle from being able to infect new cells, (b) dismantle the virus particle, and (c) destroy the genetic material of the virus particle, thereby completely destroying the target. Our complete systems engineered approach to anti-viral therapy is in stark contrast with the current piece-meal approaches. Current drug therapies often have extensive toxicities, limited efficacies, and generation of mutants (mutated viruses) through selective incomplete pressure applied by the therapeutic regime onto the virus.

We designed the nanoviricides to act by completely novel and distinctly different mechanisms compared to most existing anti-viral agents. The self-assembling nanoviricide “Trojan horses” would be expected to course through the blood stream, seek their target, i.e. a specific virus particle, attach themselves to the virus particle target and fuse with the virus particle. This chain of events, if it in fact occurs, is designed to destroy the virus particle’s ability to infect host cells. In addition, if the nanoviricide may contain an encapsulated API, such API may be deployed into the virus particle and might lead to destruction of the virus genetic material (such as viral DNA, viral RNA, etc.), and/or key viral components that the virus carries inside its “belly” (such as the reverse transcriptase, the protease, and the integrase carried by HIV particles), based on the capabilities of the API. This concept needs to be extensively tested in future experiments. The concept of targeted delivery of an API is well known in the cancer therapeutics arena as this quote from the National Cancer Institute website above makes clear: “Nanoscale devices have the potential to radically change cancer therapy for the better and to dramatically increase the number of highly effective therapeutic agents. Nanoscale constructs can serve as customizable, targeted drug delivery vehicles capable of ferrying large doses of chemotherapeutic agents or therapeutic genes into malignant cells while sparing healthy cells, greatly reducing or eliminating the often unpalatable side effects that accompany many current cancer therapies.”

[http://nano.cancer.gov/resource\\_center/nano\\_critical.asp](http://nano.cancer.gov/resource_center/nano_critical.asp) - cancer.

We designed the nanoviricides to act by a novel set of multiple, concerted, mechanisms. However, being so novel, our drugs are not directly comparable to existing anti-viral therapies. Thus, the safety and efficacy of the nanoviricides needs to be established by experimentation, and cannot be anticipated on the basis of any similar information regarding existing drugs. See, Preclinical Safety And Efficacy Studies.

It is important to realize that the flexible nanoviricides nanomedicines show substantial advantages over hard sphere nanoparticles in this antiviral drug application. Hard sphere nanomaterials such as dendritic materials (dendrimers), nanogold shells, silica, gold or titanium nanospheres, polymeric particles, etc., were never designed to be capable of completely enveloping and neutralizing the virus particle.

The Company does not claim to be creating a cure for viral diseases. The Company’s objectives are to create the best possible anti-viral nanoviricides and then subject these compounds to rigorous laboratory and animal testing towards US FDA and international regulatory approvals. Our long-term research efforts are aimed at augmenting the nanoviricides that we currently have in development with additional therapeutic agents to produce further improved anti-viral agents in the future. We believe that many viral infections that are at present untreatable or incurable would be curable using such an advanced approach.

The Company plans to develop several drugs through the preclinical studies and clinical trial phases with the goal of eventually obtaining approval from the United States Food and Drug Administration (“FDA”) and International regulatory agencies for these drugs. The Company plans, when appropriate, to seek regulatory approvals in several international markets, including developed markets such as Europe, Japan, Canada, Australia, and Emerging Regions such as Southeast Asia, India, China, Central and South America, as well as the African subcontinent. The seeking of these regulatory approvals would only come when and if one or more of our drugs, now in early stage of pre-clinical

development, has significantly advanced through the US FDA and international regulatory process. If and as these advances occur, the Company may attempt to partner with more established pharmaceutical companies to advance the various drugs through the approval process.

There can be no assurance that the Company will be able to develop effective nanoviricides, or if developed, that we will have sufficient resources to be able to successfully manufacture and market these products to commence revenue-generating operations.

There can be no assurance that other developments in the field would not impact our business plan adversely. For example, successful creation and availability of an effective vaccine may reduce the potential market size for a particular viral disease.

Our goal, which we can give no assurance that we will achieve, is for NanoViricides, Inc. to become the premier company developing nanomedicines for anti-viral therapy.

### **Our Product Focus and Technologies**

The Company plans to develop several different nanoviricide drugs against a number of human viral diseases. The Company initially obtained an exclusive license in perpetuity to develop drugs based on technologies originally created by TheraCour Pharma, Inc., (TheraCour) against the following human viral diseases: H5N1 (Avian Flu), Human Influenza, Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), and Rabies, including all known strains of these viruses. 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.



We currently have, in early, active development, products against Epidemic Influenzas including the current novel H1N1/2009 “Swine flu” virus, H5N1 and other Highly Pathogenic Avian Influenzas (H5N, H7N, H9N HPAI, Bird Flu), common seasonal human Influenzas ((1) and injectable drug for hospitalized patients, and (2) an oral drug for the rest of the patients), (3) HIV (4) Eye drops against viral diseases of the eye such as conjunctivitis and keratitis, (5) Herpes virus cold sores and genital Herpes, and (6) Dengue viruses. In addition, we have research programs against the novel MERS CoV virus, Rabies virus, Ebola/Marburg family of viruses, as well as other viral hemorrhagic fevers. We also have a research program called ADIF<sup>(TM)</sup> “Accurate-Drug-In-Field”, that we believe is the only way to combat a novel viral threat right in the field before it becomes an epidemic like SARS, bird flu H5N1, Ebola, or other viral outbreak. Adenoviral Epidemic Kerato-Conjunctivitis (EKC) is a severe pink eye disease that may lead to blurry vision in certain patients after recovery. Herpes simplex viral infections cause keratitis of the eye, and severe cases of infection may sometimes necessitate corneal transplants. The Company’s ability to achieve progress in the drugs in development is dependent upon available financing and upon the Company’s ability to raise capital. The Company will negotiate with TheraCour to obtain licenses for additional viral diseases as necessary. However, there can be no assurance that TheraCour will agree to license these materials to the Company, or to do so on terms that are favorable to the Company.

The total market size of drugs for the programs in which we already have lead drug candidates are estimated to be over \$40B in 2013. If we are successful in developing an oral anti-influenza drug that has a significant effectiveness in combatting influenza in humans, we believe that this market size will be substantially greater. It is well known in the medical field that when an effective drug is introduced against a disease, the total market size related to that disease expands significantly, usually into billions of dollars to tens of billions, depending upon the prevalence of the disease and other factors.

Our product development programs can be roughly divided into three sectors: (1) Commercially Important Diseases, (2) Neglected Tropical Diseases (NTD’s) and Biosecurity/Biodefense, and (3) Advanced Technologies.

The commercially important diseases tend to have large market sizes, and are, therefore, attractive targets for collaborations with smaller pharmaceutical companies such as NanoViricides, Inc.

We are also pursuing licensing opportunities for our commercial drug programs. Historically, major pharmaceutical companies have licensed highly innovative drugs only after human clinical studies have established the value of the drug. In recent years, major pharmaceutical companies have entered into very early stage agreements, as early as screening and discovery level, with other pharmaceutical companies. We cannot, however, predict to what extent major pharmaceutical companies will be interested in engaging in early stage collaborations with us to develop our nanoviricide drugs.

We have initiated a Biosecurity/Biodefense program based on the US Government's commitment to Biosecurity. We are performing these developments strictly in various government and institutional collaborations to minimize development costs to us. In addition, we are pursuing grant and contract opportunities in this area to finance the drug development activities. The US Government is virtually the only source of revenue for our Biosecurity/Biodefense programs. Although we believe that we have demonstrated significant successes in this area, we do not intend to develop drugs in this area without continued government funding and assistance.

Our NTD programs were initiated because of the Company's commitment to social responsibility. As a Company led by medical professionals and committed scientists, we believe that these programs could make a substantial impact on the quality of worldwide healthcare. The Company believes its nanoviricide technology enables development of highly effective drug candidates against various diseases, at less effort and expense than traditional drug development. We have taken advantage of various government and institutional collaborations to perform drug development activities in the NTD area at a minimal cost. In addition, our R&D on NTD's also indirectly benefits our drug development for the commercially important diseases.

The NTD's have very high incidence rates worldwide. Most of the NTD infections occur in underdeveloped countries. As such, NTD's have traditionally been assigned low market sizes by market analysts. With the economic prosperity of India, China, Brazil, Russia, and other emerging world economies (the BRIC block), the economic situation relative to healthcare is also changing dramatically. Further, there are significant US government programs designed to promote the development of drugs against various NTD's, including the "priority voucher" program of the US FDA, which may have commercial value. In addition, there are several charitable foundations that are deeply involved in the NTD area in various roles, although primarily in improving access to healthcare.

### **Commercially High Priority Drug Development Programs**

To date, the Company has developed drug candidates against five virus types/disease areas with strong commercial prospects. These include Influenza, HIV, viral diseases of the external eye, Herpes Cold Sores and Genital Herpes, and Dengue viruses. The market size for HIV is estimated to be \$21 billion in 2013. The market for influenza drugs is estimated at about \$7 billion. The eye drops topical viricide market size is estimated to be in the billions of dollars. In addition, the herpes cold sores and genital herpes market size is in several billion dollars. The market for Dengue is also estimated to be in the billions of dollars because of the large extent of population exposed worldwide to the possibility of severe dengue disease.

### **One Influenza Drug Against All Influenzas: "H1N1 Swine Flu", Common Influenzas, High Path Avian Influenzas, Bird Flu, Epidemic and Pandemic Influenzas**

Our FluCide<sup>TM</sup> program lead drug candidates, both the Injectable FluCide, and the Oral FluCide, have shown efficacies in animals that far exceed that of known drugs such as Oseltamivir (Tamiflu®, Roche) against common influenza in an animal model. Previously, we had planned on developing different drugs for different types of influenza infections based on severity. However, we have now consolidated our strategy to develop broadly active, yet highly effective, pan-influenza FluCide drugs. This became feasible because of the significant improvements in efficacy that we were able to achieve in optimizing our FluCide drug candidates. Both our Injectable and Oral FluCide are expected to be highly active against substantially all influenza, including highly pathogenic strains such as H5N1, the novel H1N1/2009 Mexico/California "Swine Flu" epidemic strain, H3N2, H7N, and H9N among others. We are currently developing a single drug for all influenza, whether pandemic, epidemic, seasonal, novel, emerging, human, swine, or avian. We are developing an orally available form of FluCide for out-patients. In addition, we are developing a sterile concentrated solution that is suitable for "piggy-back" infusion for the treatment of hospitalized patients with influenza or influenza-like-illness. We have declared a clinical candidate for influenza.

Recently, with additional SAR (structure-activity-relationship) studies, we have been able to develop influenza virus binding ligands that are expected to be superior to the ones we employed previously. The new ligands are designed to be closer mimics of the sialic acid receptors (than the previously employed ones), yet capable of binding to influenza

virus hemagglutinin (and neuraminidase) proteins that use either the “avian” or the “human” types of sialic acid receptors. Pigs are known to be a “mixing vessel” species, exhibiting both avian and human types of sialic acid receptors, and thereby re-assortment (mixing) of genetic material from influenza strains, subtypes, or types, with different host specificities can occur readily in pigs. We are actively seeking partnerships, collaborations and government funding for our anti-influenza drug program.

In September 2012, we demonstrated oral efficacy of our anti-Influenza drug candidates against two different viruses namely H1N1 and H3N2. With these developments, the Company now intends to develop an oral influenza drug for out-patients. Optimization of oral drugs requires substantially greater research and development work than the optimization of injectable drugs.

The Company intends to continue its injectable FluCide drug development as “piggy-back” infusion solution for hospitalized patients. It is likely that we may pursue approval of this drug candidate as a single injection therapy of out-patients with influenza as well. Recently, peramivir (BioCryst) was approved as a single injection in out-patients. However, its effectiveness in out-patients was limited, and comparable to existing neuraminidase inhibitors such as Tamiflu (Roche; oral). Moreover, it was not found to be effective in hospitalized patients with severe influenza.

#### **Viral Diseases of the Eye: Viral Conjunctivitis, Viral Keratitis – Eye Drops**

We are developing a nanoviricide against adenoviral Epidemic Kerato-Conjunctivitis (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™ 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. There are about 2.5 million cases of EKC annually in the USA alone.

The Company is not aware of any animal studies of anti-EKC drug candidates that have demonstrated resolution of clinical disease. Based on these successful results, we expanded our program to develop a single broad-spectrum nanoviricide treatment effective against most of the viruses causing external eye diseases, including viral conjunctivitis and viral keratitis. A large majority of external eye viral infections are caused by adenoviruses or herpes simplex viruses (mainly HSV-1).

We have now successfully developed drug candidates that are effective against both adenoviruses and against HSV-1, viruses that cause most of the viral diseases of the external eye. We expect to commission additional animal testing against HSV-1 infection of the eye in the coming year.

HSV and some adenoviruses cause most of the cases of keratitis, a serious infection of the cornea (approximately 250,000 US cases/year). Importantly, HSV infection can lead to corneal scarring that may necessitate corneal transplantation. In addition, some adenoviruses cause a majority of conjunctivitis cases ("Pink eye"). The remaining cases of conjunctivitis are caused by bacteria and are treatable with topical antibiotics. Currently there are no effective treatments for viral diseases of the exterior portion of the eye.

The nanoviricide eye drug candidate is formulated as simple eye drops.

The total market for viral conjunctivitis and keratitis is estimated to be in the billions of dollars. The incidence of severe herpes keratitis is estimated to be 250,000 cases per year in the USA. In Japan, where EKC is a reportable disease, it is estimated that there are at least one million cases per year. The number of cases of non-specific conjunctivitis (pink eye) is considered to be far greater, possibly into the tens of millions in the US and hundreds of millions worldwide.

### **Herpes Cold Sores and Genital Herpes**

As a result of the expansion to include HSV for our eye drug candidate, we also undertook a drug development program for a nanoviricide against the herpes simplex viruses, HSV-1 and HSV-2. These viruses cause herpes cold sores or oral lesions and skin lesions, and genital herpes sores. Drugs such as acyclovir are available for HSV. However, the virus, once infection takes place, travels into the closest neural ganglia and "hides" there, causing recurrent outbreaks.

We are currently developing an anti-HSV nanoviricide skin cream formulation for direct application to the lesions. We believe that the distinctly different mechanism of nanoviricide action should result in a complimentary effect with the existing drugs. We believe that direct attack on the HSV particle by the nanoviricide would result in less reinfection of human cells, and may possibly lead to a reduction in the amount of hidden virus. This may lead to reduced rates of recurrence.

We have previously successfully tested certain anti-HSV drug candidates in a cell culture model for effectiveness against Herpes Simplex Virus (HSV-1) infection. This testing was conducted by TheVac, LLC laboratories at the Louisiana Emerging Technology Center located within the Louisiana State University (LSU) campus in collaboration with the LSU School of Veterinary Medicine. Four different nanoviricides showed greater than 10,000-fold (>99.99% or 4-logs) reduction in virus quantity compared to untreated controls in a cell culture assay employing the LSU proprietary green-fluorescent-protein-tagged (GFP) modified HSV-1 McKrae strain.

These nanoviricide drug candidates are designed to act against all herpes simplex virus strains, including HSV-1 and HSV-2. The Company has commissioned additional in vitro studies to confirm the results. Animal studies have also been scheduled.

On May 13, 2010, the Company announced that it had entered into a Research and Development Agreement with Professor Ken Rosenthal Lab at NEOUCOM (now NEOMED). Professor Rosenthal has developed in vitro or cell culture based tests for identifying the effectiveness of antiviral agents against HSV. He has also developed a skin lesion mouse model for HSV infection. Dr. Rosenthal has been involved in the evaluation of HSV vaccines as well as anti-HSV drugs. His laboratory has developed an improved mouse model of skin-infection with HSV to follow the disease progression. This model has been shown to provide highly uniform and reproducible results. A uniform disease pattern including onset of lesions and further progression to zosteriform lesions is observed in all animals in this model. This uniformity makes it an ideal model for comparative testing of various drug candidates. Dr. Rosenthal is a professor of microbiology, immunology and biochemistry at Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM). He is a leading researcher in the field of herpes viruses. His research interests encompass several aspects of how herpes simplex virus (HSV) interacts with the host to cause disease. His research has addressed how HSV infects skin cells and examined viral properties that facilitate its virulence and ability to cause encephalitis. In addition, Dr. Rosenthal has also been studying a viral protein that makes the HSV more virulent by helping the virus to take over the cellular machinery to make copies of its various parts, assemble these parts together into virus particles and release the virus to infect other cells. He is also researching how the human host immune response works against HSV for the development of protective and therapeutic vaccines.

On August 16, 2010, the Company reported that its anti-Herpes drug candidates demonstrated significant efficacy in the recently completed cell culture studies in Dr. Rosenthal Lab at NEOUCOM (now NEOMED). Several of the anti-Herpes nanoviricides® demonstrated a dose-dependent maximal inhibition of Herpes virus infectivity in a cell culture model. Almost complete inhibition of the virus production was observed at clinically usable concentrations. These studies employed the H129 strain of herpes simplex virus type 1 (HSV-1). H129 is an encephalitic strain that closely resembles a clinical isolate; it is known to be more virulent than classic HSV-1 laboratory strains. The H129 strain will be used in subsequent animal testing of nanoviricides.

In April 2015, the Company reported that its anti-HSV drug candidates were highly effective in an animal model of lethal dermal infection of a highly aggressive strain, namely, HSV-1 H129c. These studies were conducted by Professor Ken Rosenthal at NEOMED. Subsequently, in August, 2015, we reported that these results were reproduced with 100% of the nanoviricide-treated animals surviving, at a different laboratory, namely, TransPharm Pre-clinical Services.

We now have evidence that our anti-HSV drug candidates were highly effective against two different strains of HSV-1. We believe that these drug candidates should be effective against most if not all of HSV-1 strains. We also plan to test these drug candidates for effectiveness against HSV-2, as well as HHV-3 (aka VZV, the virus that causes shingles).

Herpes simplex virus (HSV) causes “cold sores” or “fever blisters”, the incidence of which is second only to the common cold (100 million recurrences annually in the US alone). In addition, genital herpes prevalence is 67 million infected individuals in the US alone. This represents 20% of the US population infected with symptomatic, recurrent disease. It is also believed that a large fraction of infected individuals remain asymptomatic. Seroprevalence (people with antibodies) in general French population is about 67% for HSV-1 and 17% for HSV-2. It is estimated that worldwide incidence and infection rates are very similar to these high proportions of infection prevalence.

Existing therapies for herpes virus infections include acyclovir and drugs chemically related to it (e.g. gancyclovir, valcyclovir, others). These drugs, nucleoside analogs, act by inhibiting viral DNA synthesis. However, there is known drug toxicity due to interference with human metabolism. Currently, there is no cure for herpes infection.

Nanoviricides are designed to act by a novel and distinctly different mechanism compared to existing drugs. Nanoviricides are designed to mimic the human cell surface to which the virus binds. Our results suggest that a nanoviricide could become a highly sought after drug against HSV.

Additionally, it is likely that our anti-herpes nanoviricides may be active against shingles as well. Shingles is caused by a herpesvirus called varicella-zoster-virus. Shingles is caused by reactivation of the chickenpox virus when the immune surveillance against this virus is compromised due to age or other factors. Although acyclovir and related drugs may be prescribed for shingles, their effectiveness is limited at best. There is a shingles vaccine, that must be used several weeks prior to a shingles episode. However, its usage is limited. Thus a topical treatment for shingles is currently an unmet medical need.

Our HerpeCide program may thus lead to drugs against multiple indications. A skin formulation for use against cold sores, a skin formulation for use against genital herpes, a skin formulation against shingles, and an eye-drops or gel formulation for use against herpes keratitis are some of the possibilities. The Company is currently evaluating prioritization of the indications to optimize the drug candidates for within the HerpeCide program.

The total market size for herpesvirus drugs is in excess of \$2B at present. We believe that if an effective therapy superior to the current nucleotide analogues can be developed, the market size will increase substantially, given the penetration of various herpesviruses in the human population.

## **HIV**

Our very first animal studies in the standard SCID-hu mice against HIV-I have demonstrated that our primary nanoviricide drug candidate, HIVCide, as well as several other nanoviricide drug candidates were found to be superior to the three-drug oral cocktail (HAART) that is the current standard of care.

We have executed a Master Service Agreement (MSA) with Southern Research Institute, Infectious Diseases Division, Frederick, MD (SRI-F) to conduct these studies. SRI-F is a well-established Contract Research Organization (CRO) that has developed, conducted, and published in scientific journals on standardized study protocols for various mechanisms of anti-HIV action, including microbicides, antibodies, and small chemical therapeutics. We are also planning additional animal studies of these drug candidates. We are also planning additional animal model studies of the HIVCide<sup>TM</sup> lead drug candidate.

We reported that a subset of the anti-HIV nanoviricides tested in cell culture models at Southern Research had very similar activity against two distinctly different isolates of HIV-1, viz. Ba-L and IIIB. HIV-1 Ba-L is CCR5-tropic (uses CD4 and CCR5) whereas HIV-1 IIIB is CXCR4-tropic (uses CD4 and CXCR4 on host cells). The Company had designed the ligands using the known structures of interaction of gp120 of several HIV-1 strains with the CD4 human cell receptor for HIV.



We designed the anti-HIV nanoviricides using rational drug design principles. The ligands we have designed in the case of HIV-1 are thought to be broadly neutralizing. In-silico modeling indicates that our ligands dock to the conserved CD4 binding site of gp120 of HIV-1. We have even observed successful docking of some of our ligands with gp120 of the HIV-1 JRFL strain which is thought to be resistant to HAART.

We have designed additional novel ligands to attack the HIV gp120 at its CD4 binding sites. In order to discriminate the comparative effectiveness of different nanoviricides in the humanized mouse model, we synthesized nanoviricides with reduced ligand density than in our previous study. A new study revealed that one of these nanoviricides was as effective as the three drug HAART cocktail (AZT, 3TC and Efavirenz) in the humanized mouse model. What is more, this drug kept the viral load at a sustained low level until at least 28 days after last drug dose. This sustained drug effect is a very important benefit especially for HIV/AIDS patients. We believe that we may have a “functional cure” for HIV/AIDS.

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, resulting in a “functional cure” of HIV.

The HIV genome integrates into certain human cells that go into hiding or dormancy for several years.

While dormant, the HIV genome does not produce HIV virus particles or HIV proteins to any significant extent and are thought to remain unaffected by current anti-HIV drugs. The current standard treatment results in very low levels of HIV viremia, but the immune cells (CD4+ T cells and CD8+T cells) count eventually begins decreasing at a slow rate. The HAART therapy must be continued for the life of the patient. A more effective therapy could result in complete loss of HIV from the blood stream. This may eliminate the slow loss of healthy immune cell populations, and allow immune system function to return to normal. Patients may then enjoy a normal life without further daily treatment, until an episode occurs which mobilizes the “sleeping” cells containing the 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. Research in the field of reactivating the dormant pool of HIV infected cells is encouraging. If these cells can be reactivated, and simultaneously the HIV viremia controlled, researchers have proposed that this could lead to reduction in the dormant infected cell pool. If their hypotheses are correct, HIVCide could lead to an eventual cure, possibly in combination with other drugs.

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 already achievable. However, there is no way to predict whether such a treatment would be successful at providing a functional cure of HIV at present.

HIVCide is expected to be a significant anti-HIV candidate, acting by a novel mechanism of action and a first-in-class therapeutic, based on current preliminary data. We intend to develop it further.

## Dengue

We are currently working on developing anti-Dengue therapeutics. Dengue is an important NTD. According to the Centers for Disease Control and Prevention in Atlanta (CDC), dengue fever risk is about 1 illness per 1,000 US travelers, and it is the most common cause of fever in returned travelers from the Caribbean, Central America, and South Central Asia. The CDC has also noted “dengue is the most important mosquito-borne viral disease affecting humans. Each year, tens of millions of cases of DF occur and, depending on the year, up to hundreds of thousands of cases of Dengue hemorrhagic fever (DHF).” Dengue fever is also called “break-bone fever”. The first or primary dengue infection has very low fatality rates associated with it. However, when a person is infected with a different type of dengue virus afterwards, the person is at risk of developing Dengue Hemorrhagic Fever (DHF), or Severe Dengue fever. The fatality rate associated with DHF/Severe Dengue may be as high as 10%. There is currently no vaccine or cure for dengue, which causes high fever, muscular pain, headaches, vomiting, and in some cases skin rash. WHO estimates that 2.5 billion people are at risk of dengue fever or of DHF out of a total world population of 6.6 billion. Dengue viruses are carried by *Aedes aegypti* mosquito, which is gaining ground northwards as the global climate warms up. There have been several cases of Dengue in the southern regions of the USA.

We have reported successful cell culture studies against dengue virus type 2 with nanoviricides made using unoptimized ligands. The Company also reported that its anti-Dengue drug candidates demonstrated significant protection in the initial animal survival studies of Dengue virus infection, in an animal study protocol modeled to simulate the ADE syndrome. The best nanoviricide drug candidates demonstrated 50% animal survival in this uniformly lethal mouse model.

These studies were conducted at the Prof. Eva Harris lab at the UC Berkeley.

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

We are now in the process of developing ligands better optimized against the dengue envelope proteins.

#### **Neglected Tropical Diseases and Biosecurity/Biodefense Programs: Ebola, Marburg, Rabies, other viruses**

##### Ebola, Marburg

We have obtained significant positive results against Ebola, although the Ebola virus produces a soluble glycoprotein decoy that may be capable of avoiding certain of our virus-binding ligands. We restarted our anti-Ebola drug development program in light of the recent raging Ebola epidemic in West Africa that has evolved into a major global public health threat.

The Company continues its efforts at obtaining federal funding for this program. In the absence of public funding, the Company's ability to develop these drugs is very limited.

##### Rabies

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 are comprised 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. In absence of public funding, the Company's ability to develop these drugs is very limited.

### **Advanced Technologies : ADIF<sup>(TM)</sup> Technologies**

We believe that our technologies and capabilities at attacking different viruses are fairly well demonstrated. 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 by developing a targeted therapeutic in the field to prevent the spread of the disease.

ADIF technology does not require any knowledge of the molecular biology of the virus, or even its specific identification. An accurate drug, specifically targeted at the virus, can be developed in the field, from nanomicelles stockpiled beforehand. This enables a rapid response timeframe of as short as 3 weeks for initial drug doses, and potentially less than 3 months for sufficient doses to curb the spread of the virus outside the affected area. Thus ADIF technologies are applicable to novel, or engineered viruses, or emerging infections whether natural or man-made. This technology may have significant applications in the Biodefense area. We believe that this is the only technology that can enable humans to combat novel viruses before they spread disease.

We have already demonstrated the ADIF technology capabilities successfully.

### **The Strength of Our Drug Pipeline**

Between the two ends of the spectrum of specific antivirals developed during peace-time effort, and the specific antivirals developed as a "war-like" effort (ADIF), we have also demonstrated the capability of developing broad-spectrum nanoviricides. Broad-spectrum nanoviricides are based on the validated scientific fact that a large number of virus families employ the same cell surface receptor.

Our nanoviricides are designed as “cell biomimetics,” meaning that the nanoviricides “look like” a cell to the virus. The nanoviricide carries a portion of the broad-spectrum receptor on the nanomicelle surface that the virus attaches to and is then entrapped or dismantled by the nanoviricide. 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 that the Company has a strong and wide pipeline of antiviral drugs. However, with relatively meager financial resources, the Company continues to juggle prioritization of the various programs, and program achievements.

We are currently focused on advancing our Injectable FluCide as a pan-Influenza drug for hospitalized patients towards an IND filing and then into human clinical trials. We believe that we have sufficient cash in hand, with the September 2013 financing, to complete Phase I and Phase II human clinical trials for this drug candidate, based on cost estimates we have obtained from certain contract laboratories that perform the necessary studies.

We believe that the Oral FluCide IND development will follow the Injectable FluCide.

In the USA, Emergency Use Authorization for a particular drug can occur under circumstances such as an Epidemic or Pandemic of Influenza under certain conditions after an IND has been filed, prior to a full FDA approval. We are not at the stage of submitting the necessary applications to the FDA as yet.

In addition, with the designation as an Orphan Drug against Dengue by the US FDA, we are now giving high priority to the DengueCide drug development program. This orphan drug designation qualifies NanoViricides for certain tax credits and marketing incentives under the Orphan Drug Act. In addition, the Company will qualify for the waiver of certain FDA fees when it files the New Drug Application (NDA) for DengueCide with the FDA. Further, the Company will also be eligible for a “Priority Review Voucher” (PRV) from the US FDA when the Company files a NDA for DengueCide. If the Company receives a Priority Review Voucher, it can be applied to accelerate the review of another one of our own drugs or it can be sold to another pharmaceutical company for a consideration. Priority review means that the FDA aims to render a decision on the NDA in 6 months. In contrast, the FDA aims to complete a standard review in about 10 months, and it often takes even longer. The estimated economic value of a PRV depends upon the drug class, and could be as high as a few hundred million dollars, according to Duke economists (Ridley et al. 2006; Grabowski et al. 2009). (<https://faculty.fuqua.duke.edu/~dbr1/voucher/>). The Company has already filed a letter of intent as required for filing of an orphan drug designation application for DengueCide with the European Medicines Agency (EMA). A committee has already been established by the EMA to perform the evaluation. The criteria employed for orphan drug designation at the EMA are somewhat different from those employed by the US FDA. The benefits of an EMA orphan drug designation are different from those of the US FDA orphan designation. There is no guarantee that the Company will receive an orphan designation for DengueCide under the EMA. The

Company engaged the consulting firm Coté Orphan Consulting (COC), headed by Dr. Tim Coté, to assist with our DengueCide orphan drug applications to both the US FDA and the EMA.

Our HerpeCide drug development program is progressing satisfactorily. We are currently optimizing the anti-viral ligands against Herpes family of viruses.

Our development against the viral diseases of the eye is also progressing well. We decided to develop an ultra-broad-spectrum nanoviricide that would work against most viral diseases of the eye. Almost all of the viral diseases of the eye are caused primarily by certain adenoviruses and certain herpesviruses (including cytomegalovirus). If successful, such a nanoviricide would eliminate the need for testing which class of virus is responsible for the disease. This would allow doctors to treat the patient with the nanoviricide drug at an earlier time point. Early treatment is known to be very important for antiviral approaches.

Our HIVCide program is our most expensive drug development program. We continue to make progress in small steps in this program, with our limited resources. We believe that we will be able to accelerate our HIVCide development when we obtain appropriate levels of funding for this project, possibly through licensing arrangements.

The Company has received significant interest from pharmaceutical companies in its Viral Eye Diseases drug candidate, and HIVCide and FluCide programs to date, and we expect interest to increase in other programs as well. There is no guarantee that this interest would result in any financially lucrative licensing or co-development agreements.

All of our programs are currently at the pre-clinical stage. We have established preliminary proof of efficacy in cell culture and animal models, and we have conducted preliminary safety studies that have indicated that all of our nanoviricides are safe in the animal models as tested. We continue to work on further experiments necessary for development of our various drug candidates as FDA approvable drugs.

We are developing nanoviricides for different routes of administration, choosing the best option based on a viral disease pathology. Thus, we are developing eye drop formulation for the viral diseases of the external eye. We are developing skin cream and gel formulations for topical application of nanoviricides against oral and genital herpes. All other drugs candidates including FluCide and HIVCide are currently being developed as injectables. We are developing an oral form of FluCide as well. We believe that it will be possible in the future to develop aerosols for influenza and nasal sprays for common colds and similar diseases. This is possible because nanoviricides have been designed so that they can be formulated in many different ways.

### **Drug Development Studies**

The discussions in this section and throughout this Form 10-K describe the tests that have been conducted and the results obtained. These results do not provide sufficient evidence regarding efficacy or safety to support an Investigational New Drug (IND) application with the FDA. Additional studies will need to be conducted. It must be noted that subsequent results may or may not corroborate earlier results.

### **Preclinical Safety And Efficacy Studies**

#### **Preliminary Safety Studies In Vitro**

We have conducted limited initial animal safety studies on one of the core TheraCour® nanomaterials (patent pending). TheraCour technology covers a large range of nanomaterials in a class known as pendant polymeric micelles. These materials are self-assembling, flexible, non-particulate, and stable at room temperature.

We rely upon TheraCour nanomaterial to form the backbone of our nanoviricide antiviral drugs. One of the TheraCour polymers was tested at a 100mg/kgBW (body-weight) dose level in mice in a preliminary experiment. In studies involving gross tissue examination, microscopic histology studies, and blood pathology, no ill-effects or toxic effects were found. These studies showed that the tested core nanomaterial did not cause any organic damage in mice at the amounts tested. All results were within safe limits.

Several additional animal studies have been conducted in which the effect of a nanoviricide in the context of a disease was evaluated using histopathological techniques. Mice infected with influenza virus (H1N1) in a lethality type of study were treated with nanoviricides. The histological effects observed to date have been mild and explained by the disease state and there do not appear to be any deleterious effects of any significance that related to the nanoviricides drugs. Systematic studies for evaluating the safety or toxicity threshold will be performed in the future.

Higher dosage levels and studies on additional materials are planned in order to determine the safety thresholds in laboratory animals. The only purpose of these studies was to give our scientists direction in designing the next set of studies. These have no impact on the regulatory (FDA) process.



### Proof-of Principle

We have conducted studies which demonstrated that when a small chemical molecule (ligand) is attached to our nanomicelles covalently, the resulting nanoviricide has such a high activity that as little as 1/50th of the attached molecule is needed for comparable activity [i.e. a 20mg/kgBW injection of free molecule and a 0.04 mg/kgBW injection of the molecule attached to the polymer showed equivalent efficacy]. These results suggest to us that the observed antiviral activity of the nanoviricide is due to the proposed mechanism of action of the nanoviricide and not to either component of the drug, the ligand or the nanomicelle. This is considered “proof of principle” in that our original theoretical assumptions about the functionality of the nanoviricide have scientifically been validated.

We have also performed studies in vitro in which a murine cytomegalovirus (CMV) preparation was subjected to dilute solutions of two different nanoviricides and the resulting solutions were studied by electron microscopy to evaluate morphological changes in the virus. The nanoviricide treatments led to complete loss of the virus’s lipid coat, resulting in the virion capsids spilling out. The virion capsids of CMV lack the coat proteins required for attachment to cells and are non-infectious. Electron micrographs depicting this can be found on our web site at [http://www.nanoviricides.com/action\\_small.html](http://www.nanoviricides.com/action_small.html).

### **Efficacy Studies - Influenza**

Our original plan was to introduce as many as three different drugs against influenza because of the perceived differences between certain different influenza virus types. For example, bird flu H5N1 Influenza A virus has been simmering in the South Asia region and has been moving all across the world, a little westward every year. This virus and its variants (Clades) cause extremely severe infection that has a rapid onset and a very high fatality rate, as much as 50-80%. We decided to develop an antibody-based nanoviricide to attack this variant (AviFluCide™), as it was expected to have very high effectiveness and rather fast development time if appropriate resources became available. Given the global alerts for H5N1 in 2004-2006, we believed that this was the best course of action to make an accurate drug against H5N1 rapidly available. Another set of avian influenza viruses, H7N, H9N for example, cause very severe disease and also epidemics, but are not as fatal as H5N1. The influenza A viruses that cause severe disease in humans were found to have a common “signature region” in their hemagglutinin protein (HA), called the “polybasic site”. The presence of the polybasic site in HA is known to be associated with increased virulence. We therefore also embarked upon a program to develop a nanoviricide that would recognize a polybasic site motif. This would be FluCide-HP™ (for highly pathogenic viruses). In addition, we embarked on development of a nanoviricide that attacks the sialic acid recognition site on both HA and NA (neuraminidase) proteins on the virus surface. This is called “FluCide™”. Since then, with further optimization of the ligands, we have achieved extremely high effectiveness levels with our FluCide nanoviricide drug candidate. This has allowed us to combine all three anti-influenza programs into a single FluCide program. FluCide is expected to be highly effective against all influenzas, from the most severe forms of influenza including bird flu H5N1 variants, highly pathogenic avian influenza viruses (HPAI), novel epidemic influenzas such as the recent H1N1 A/2009/“Swine Flu”, to the less severe seasonal and common influenzas. We believe that dosage modification is all that would be necessary to combat different types of influenzas. Given that we have not

seen dose-limiting toxicities yet, we believe it is possible to develop a single, highly effective, nanoviricide drug against all influenzas.

Preliminary Cell Culture Studies against H5N1 Avian Influenza, Clade 1 and Clade 2

In vitro (laboratory) evaluation of 14 substances, including controls, was performed to evaluate protection of mammalian cells against infection by the H5N1 subtype. These assays were conducted in Vietnam under the auspices of the National Institute of Hygiene and Epidemiology, Hanoi (NIHE) under the Vietnam Ministry of Health. We identified four different nanoviricides as being highly effective against H5N1 using two different assays, both involving cell culture, one using the plaque reduction method and the other involving microscopic examination, to determine the extent of cytopathic events (CPE) reduction. All of these nanoviricides were effective at extremely low concentrations and many of them are considered by us to be drug candidates.

Four different nanoviricides were selected on the basis of the statistical test called the p-value, (explained below). The p-values for these four compounds were  $p < .003$  which meant that there was a high statistical probability that these results were due to the effect of the test nanoviricides and not due to chance. Thus the “null hypothesis” is rejected and the results can be considered statistically significant.

The most successful of our assays was a nanoviricide based on an antibody fragment as the targeting ligand, which led to substantial suppression of CPE at an extraordinarily low concentration level. This is being developed as AviFluCide-ITM, a drug highly specific to H5N1 that is being developed against the Vietnam strain. We currently believe that it is very likely to work against the Indonesian strain although further studies will be required to determine its efficacy against various highly pathogenic stains of influenza. If it fails to work against the Indonesian 2006 strain, further development may become necessary.

Another nanoviricide which is based on a ligand that we designed in-house, using rational drug design strategy, to be specific to the group of all or a majority of highly pathogenic avian influenza (HPAI) viruses, also showed a very high efficacy. This is being developed as “FluCide-HP<sup>TM</sup>”, a drug designed to be group-specific against emergent and existing highly pathogenic influenza viruses (including H5N1, H7N, H9N and others). Non-H5N1 HPAI (non-pathogenic avian influenza) strains could become a pandemic threat when their occurrences increase, as can all influenza A viruses since they all have the ability to mutate. It is well known that influenza strains drift constantly due to mutation, re-assortment or recombination events leading to failure of vaccines.

A third nanoviricide is based on a ligand that we designed for attacking all influenza A viruses (type-level specificity). This has shown strong efficacy against H5N1 as well, as expected. This is being developed as “FluCide-I<sup>TM</sup>”, a drug designed primarily for use against serious cases of human influenza.

Preliminary analysis of the H5N1 preclinical in vitro studies performed in Vietnam showed that many nanoviricide candidates were effective at as low as 5-nanomolar concentration levels in cell culture experiments. Typically, an early developmental drug that proves effective at concentrations less than 500 nanomolars is considered a strong candidate for FDA approval as an IND applicant.

All of the above studies have been repeated with the same, as well as, additional test methodologies (for example, evaluation of CPE quantitatively by a cell viability soluble dye assay) producing confirmatory results against this rgH5N1 Vietnam strain (based on the Vietnam 2004/2005 H5N1 strain).

Additional cell culture studies against the wild-type clade 2 H5N1 strain isolated in Vietnam in late 2006 showed that FluCide-HP caused a 90% reduction in CPE as measured by the dye assay, whereas FluCide-I gave a 70% reduction in CPE, indicating that both of these broad-spectrum drugs are highly effective even against different strains and different clades of H5N1.

The Indonesia 2006 H5N1 strain also belongs to the clade 2 subgroup within H5N1 subtype.

Both of these drug candidates were also highly effective in vivo against the influenza A H1N1 strain (see below). These studies provide a preliminary indication that the various influenza viruses may have limited ability to escape these nanoviricides drugs via mutations and other changes. The choice of ligands we have performed in such a fashion that the potential for a virus strain to mutate and escape the nanoviricide drug and still remain a serious cause of disease, is minimized. Further studies are planned.

### **In Vivo Efficacy Studies - Influenza**

The preclinical animal testing, performed to study the efficacy (effectiveness) of the test nanoviricide (anti-human influenza, H1N1) substances, revealed potential for development as drugs for the reasons delineated below. Several separate and distinct sets of experiments were performed to address different questions regarding efficacy.

Certain sets of experiments were conducted to determine the destruction/protection of the animal organs. There were ten animals per group and positive and negative controls were employed. Lethal infectious challenges of H1N1 influenza virus were administered, followed by treatment with nanoviricides after a significant delay. The active substances appeared to have protected the organs so that there were no histological (microscopic tissue) changes to the internal organs of the treated animals. Highly significant tissue damage was found in the internal organs of the unprotected (no nanoviricide treatment) groups.

Another set of experiments was performed, again on five separate groups each containing ten animals where the viral load was determined in the animals. The findings revealed that the viral load (number of viral particles per cubic millimeter) in the treated animals was significantly lower than that found in the control animals.

These initial animal findings suggested that the test nanoviricide compound was an effective treatment for human influenza in mice and that the concept of using a nanoviricide as a treatment for certain viral illnesses was a valid one and was deserving of further study. In more scientific terms, the statistical test was met for validity of the findings and these findings could be considered statistically significant. Thus, in statistical terms, one could say that the null hypothesis, that is the statistical likelihood that the observed result was due to chance and not the effect of the drug, was rejected.

**In Vivo Efficacy Studies - Influenza - Optimized Drug Candidates Led to 100% of Mice Treated with Nanoviricides Survival for Full Study Duration, and a Viral Load Reduction of 1,000-times greater than with Oseltamivir**

All but the antibody-based anti-influenza nanoviricides have been tested in mice in an aggressive study involving extremely high levels of infection with a common influenza strain called H1N1. This study was conducted by Dr. Krishna Menon, KARD Scientific, Inc. The results indicate that most of the nanoviricide nanotechnology-based drug candidates were substantially more efficacious than Oseltamivir (Tamiflu®). Initial unpublished data suggest that this earliest nanoviricide anti-influenza drug candidate may be as much as 8 to 10 times (800% to 1,000%) superior to Tamiflu in common influenza.

Additional studies have been performed in the same highly lethal mouse model with H1N1 infection wherein all the mice treated with Oseltamivir died within  $151.4 \pm 1.0$  hours, at which point 100% of the mice treated with a nanoviricide using an improved sialic-acid-based ligand as well as 100% of the mice treated with a nanoviricide made using a ligand designed against the high path site of highly pathogenic influenzas including H5N1 were still surviving. Mice treated with H5N1-based nanoviricide survived until  $186.0 \pm 1.4$  hours, whereas those treated with sialic-acid-based drug candidate survived until  $190.0 \pm 3.7$  hours in this test. The control, untreated mice died within  $119.0 \pm 0.6$  hrs. Oseltamivir is the active ingredient of Tamiflu®. It is estimated that the Tamiflu dose would need to be increased by much more than ten times (i.e. much more than 1,000%) to match the efficacy of this sialic-acid-based nanoviricide drug candidate. These estimates are very preliminary in nature. From this unpublished data, we have concluded that the results are statistically significant with a  $p < 0.003$ .

Virus Load in lungs of lethally infected animals was reduced significantly as well. The virus load in lungs of infected animals was reduced to  $92 \pm 21$  pfu/ml by the H5N1-based candidate and  $119 \pm 18$  pfu/ml by the sialic-acid-based candidate in this study. These are very low levels of virus load. The control untreated mice had a viral load of  $946 \pm 115$  pfu/ml at this sampling point. Thus, the reduction in viral load was approximately 1 log units for both of these candidates. Virus load reduction estimates depends upon various factors. Improvement in dosing regimen may be expected to provide a further reduction in viral load.

We further improved the chemical nature of the ligand using information from rational drug design in silico studies and developed new ligands. Nanoviricides based on these new ligands were tested in the same totally lethal animal model study as above. We reported some of the results from this study in late November, 2009.

All of the mice treated with the new anti-influenza nanoviricides were surviving even when all of the mice from the Oseltamivir treated group had died. The new version of FluCide drug candidate extended the lifespan of lethally infected mice to  $334 \pm 11$  hrs. (or 14 days) on average. In contrast, mice treated with an extended Oseltamivir protocol (twice daily until death) survived for  $193 \pm 3$  hrs. (or 8 days) on average. Control infected mice survived for only

121±2 hrs. (or 5 days). FluCide was given as an IV injection, on alternate days, for five treatments. Oseltamivir was given as oral, twice daily, each at 20mg/kg through life (or 14 treatments). Increased length of Oseltamivir treatment led to an increase in survival of this group compared to our previous study. Viral load at 120h was reduced in the Oseltamivir treated group to only about half of (0.51x) that in untreated control. In contrast, viral load reduction at this time point in the nanoviricide treated group was approximately 0.13x that of untreated control, an improvement in viral load reduction by nearly a factor of four.

We performed another drug candidate optimization study in August 2010. In this study, all of the mice treated with the new anti-influenza nanoviricides continued to survive long after all of the mice from the Oseltamivir treated group had died. The best of these drug candidates extended the lifespan of lethally infected mice to 435± 5 hrs. (or 18 days) on average. In contrast, mice treated with an extended Oseltamivir protocol (twice daily until death) survived for 188±1 hrs. (or 7.8 days) on average. Control infected mice survived for only 121±1 hrs. (or 5 days). FluCide was given as an IV injection, on alternate days, for nine treatments. Oseltamivir was given as oral, twice daily, each at 20mg/kg through life (or 14 treatments). Viral load at 108h was reduced in the Oseltamivir treated group to only about half of (0.51x) that in untreated control. In contrast, viral load reduction at this time point in the best nanoviricide treated group was approximately 0.03x that of untreated control, an improvement in viral load reduction by nearly a factor of 30, or 1.5 logs of viral load reduction.

Of great significance is the fact that the viral load was not only brought down by a factor of greater than 1,000-fold, but also that this reduced viral load was maintained by the nanoviricide treatment throughout the observed period of 19.5 days.

We were able to declare a clinical candidate in this drug program following the next drug candidate optimization study. In this study, three of the nanoviricides drug candidates enabled the lethally influenza-infected mice to survive for the near total duration of the study (21 days). One group survived beyond study duration, for 22 days. In contrast, Oseltamivir treated animals died in 8.1 days, and untreated animals died in 5.2 days.

Viral load at 108 h was reduced from untreated control in the Oseltamivir group to only a factor of 0.7, whereas the three nanoviricide groups showed at least 1,000-fold to 2,000-fold (greater than 3 logs) viral load reduction compared to untreated control. At 180h, viral load in the three best nanoviricide treated groups was reduced at least 1,800-fold (greater than 3.2 logs) compared to that in the Oseltamivir group. Viral load in nanoviricide treated groups continued to hold at the low levels even at 19.5 days post-infection.

Lung plaque count at 108h in these nanoviricide treated groups was nearly zero, as compared to a relative count of  $40 \pm 2$  in untreated animals, and  $19 \pm 3$  in Oseltamivir treated animals. The lung plaque count in nanoviricide treated animals continued to remain at a near zero value ( $1.5 \pm 1$ , or less than 2 in a sum of three fields) even at 19.5 days post-infection. Lung plaque area trended the same way. The plaques are caused by viral infection resulting in death of lung cells. Similarly, the lung weight remained at normal throughout the course in the three groups of nanoviricide-treated animals, whereas it more than doubled in the case of untreated animals (at 108h) and Oseltamivir treated animals (at 180h). Exudate filling the lungs and local swelling is expected to lead to an increase in lung weight when infected.

Four days post-virus infection, animals treated with three of the optimized FluCide™ nanoviricide drug candidates exhibited a substantial reduction in both eosinophils and overall leukocytes in lung tissue as compared to untreated infected control animals. Further, this reduction of damaging immune system cells in lung tissue was found to persist over the entire duration of study. In contrast, animals treated with Oseltamivir (Tamiflu®, Roche) initially showed reduced eosinophil and leukocyte counts that rapidly rose to the level of untreated infected animals. Eosinophil expansion occurs in response to a viral infection, and can be indicative of a viral infection.

Various types of leukocytes also increase in response to a viral infection. These phenomena are part of the normal immune response to the infection. In severe influenza cases, it is thought that patients can go into a stage called “cytokine storm syndrome”. This may be thought of as an all-out attack by an expanded army of white blood cells in response to an uncontrolled viral infection. In an attempt to control the viral infection, the immune system attacks the infected cells and damages nearby normal cells, possibly leading to severe lung damage that may be potentially fatal.

Thus, treatment with the optimized FluCide drug candidates appeared to protect against the complete cycle of influenza virus infection, virus expansion and spread of infection in the lungs that follows the initial virus infection. In addition, possibly as an effect of keeping the viral infection controlled, treatment with nanoviricide drug candidates also appeared to protect against the damaging effects of overactivation of the immune system, including leukocyte penetration, eosinophil expansion, and lung damage. Thus, the nanoviricide drug candidates appear to control the viral load infection strongly thereby protecting the patient from the potentially fatal “cytokine storm” syndrome.

These results led us to declare one of the three best nanoviricide candidates as a clinical candidate.

This study clearly indicated that our clinical candidate under the FluCide program, NV-INF-1, should be highly effective in the treatment of very severe forms of influenza. We anticipate that it will be effective against all strains of influenza viruses, given the broad-spectrum, sialic-acid-mimetic nature of the ligand. We have therefore been able to consolidate our anti-Influenza drug programs into a single drug program against all influenzas, be it common or seasonal influenza, epidemic severe influenza such as H1N1/2009/“Swine Flu”, highly lethal bird flu H5N1, or other influenza virus type/strain. We believe that the same drug would be effective by adjusting the dosage parameters against most if not all forms of influenzas.



A single dose treatment of out-patient influenza with FluCide appears very likely, based on the results of these studies. When a person present with the first signs of influenza, the medical professional can give a single injection. In most cases no follow on treatment would be needed. This has several great advantages. Patient compliance, a major issue in antiviral therapy, becomes a non-issue. In addition, during a pandemic, the patient load on medical services is very high. Single treatment becomes a very attractive option.

For hospitalized patients, we plan on developing a solution that gets incorporated in a “piggy-back” fashion into the fluid infusion setup that is already in use. This simplifies hospital procedures and ensures that the intended dose of drug is fully administered.

Considering that the preclinical data for Oseltamivir and for peramivir are similar in terms of effect on survival or time course, it is clear that our nanoviricides may be expected to be far superior to peramivir as well.

### **Preliminary Efficacy Studies In Vivo – Viral EKC**

Viral EKC, or Viral Epidemic Kerato-Conjunctivitis is a severe pink eye disease that lasts for several days with painful discharge causing sticky eyes. In addition, a few percentage of the recovered patients experience permanent blurred vision or partial loss of vision due to the presence of “immuno-precipitates” that occur as a result of the body’s immune response to the virus. Approximately 50% of all EKC cases are viral; the remaining being caused by bacteria. Bacterial EKC is treatable with antibiotics. There are no current treatments against Viral EKC (“EKC”).

In a preliminary rabbit eye animal study, we tested two different nanoviricides against EKC caused by infection with Adenovirus 5, a well-known causative agent. The virus was supplied by the CDC. Controls of uninfected, untreated eyes, of infected, untreated eyes, and of infected eyes treated with the standard eye wash formulating solution, were also part of the experiment. Treatment with eye drops of nanoviricides was started 15 hours post-infection, well after the disease had set in, and was continued twice a day for ten days. On the third day, eyes treated with nanoviricide B were completely cleared up with no redness, stickiness, exudate, or furry eyebrows. The other nanoviricide was slightly less effective. The eyes in control groups in contrast showed all classic signs of infection throughout the due course of disease. Further examination has indicated that treatment with nanoviricide B resulted in all eyes being completely free of sub- epithelial filtrate and immuno-precipitate formation, whereas eyes in the control groups exhibited SEI and immuno-precipitates as expected.

The study concluded that both nanoviricide B and nanoviricide C were highly effective against adenoviral EKC and of these, nanoviricide B was substantially superior. Further studies are scheduled.

In addition to adenoviruses, herpesviruses form another important cause of viral EKC as well as additional related diseases of the eye. We plan to extend our studies to herpesviral eye infections in the near future.

### **Preliminary Efficacy Studies In Vivo – HIV**

In a preliminary animal study against HIV in a well established animal model, SCID-hu-Thy/Liv mice, we have previously tested a number of nanoviricides against a positive control (that is known effective drug) that comprised the clinically employed well established HAART therapy of oral three drug combo (AZT+3TC (lamivudine) + Efavirenz (a non-nucleoside reverse transcriptase inhibitor (NNRTI)). Several additional parameters were tested and indicate significant benefit of nanoviricide therapy.

Treatment with HAART and anti-HIV nanoviricides resulted in a significant reduction in viral load in the Thy/Liv implant as determined by qPCR and viral particle counts in aspirated implant lymphocytes by EM. qPCR analysis showed that HAART and nanoviricide treatment reduced the implant viral load equally well, with nanoviricide results showing slight superiority. The aspirated lymphocytes showed substantially lower viral particle burden in nanoviricide treated groups, as compared to HAART-treated groups. The EM data are considered preliminary and we do not draw any conclusions rather than they support the viral load reduction studied by qPCR.

Similar to the reduction in viral load, both HAART and nanoviricide treatment had positive long term effects on reducing thymocyte depletion as shown by the proportion of CD4+CD8+ thymocytes (double-positive, or “DP”) in the 5th week post-infection. Implants in the HAART and nanoviricide treatment groups exhibited 80-85% CD4+,CD8+ DP cells while the vehicle control groups had only approximately 30% CD4+CD8+ thymocytes.

The equal treatment effect was produced by administering only 150 mg/kg nanoviricide, as opposed to a total of 4,200 mg/kg of HAART drug load. Thus, nanoviricides were more than 25X (2,500%) superior to the HAART cocktail on a dosage level basis. In addition, the nanoviricide therapy was given only during the first week whereas HAART therapy was continued for 42 days. Thus, there is a significant possibility that extending nanoviricide treatment further could have far more significant benefits than observed in this study.

No adverse events were observed with nanoviricide therapy. The physical appearance of the animals was much better in the nanoviricide treated animals than in the HAART treated animals. These preliminary findings suggest that nanoviricide therapy was safe, well tolerated, and did not result in any adverse events. HAART therapy in humans is known to be associated with significant adverse events including nausea, weight loss, and lipid redistribution, among other factors. The very large dosages of drugs in HAART therapy are thought to lead to various adverse events.

In summary, treatment of SCID-Hu mice with nanoviricides following HIV-1 Ba-L infection of hu-Thy/Liv implants resulted in significantly reduced viral load and significantly improved double positive, CD4+,CD8+ thymocyte proportion. These effects appear to have resulted in improved survival and reduced body weight loss. Importantly, comparison with mice treated with the HAART cocktail for the duration of the study revealed that the nanoviricide anti-viral agents were comparable or slightly superior to HAART treatment for all parameters evaluated. It is important to note that nanoviricides were single administrations only at 24, 48 and 72 hours post- infection while the HAART cocktail was administered daily for the duration of the study. The nanoviricide total drug load was only 150 mg/kg as opposed to a total HAART drug load of 4200 mg/kg, thus equivalent effects were observed with nanoviricide drug candidates at ~1/25th of the HAART drug load. It would be important to determine if extended nanoviricide administration shows significantly greater efficacy. Additionally, we are not aware of any anti-HIV drug candidate that is equivalent or superior by itself alone to the HAART cocktail.

The HAART cocktail we used consisted of AZT+3TC+Efavirenz, at 40 + 20 + 40 mg/kg, respectively, administered p.o. 1x daily for the duration of the study, beginning 24 hrs. after virus inoculation, for a total drug load of 4,200mg/kg. In contrast, the nanoviricide treatments were given only during the first week, at days 1, 3, and 5 post-infection, at 50 mg/kg (tail vein injection), for a total drug load of 150 mg/kg. We intend to increase the extent of nanoviricide drug treatment in the future studies.

Because of the high effectiveness of the three different nanoviricides, we were not able to select the best candidate in this study. We therefore devised a new study. In this study, some of the anti-HIV ligands from the previous study, and some newly designed anti-HIV ligands were attached to the nanomicelle. However, the density of ligands attached was kept low, anticipating that this would allow discrimination between the efficacy of these ligands.

In this study, we found that the effectiveness of one of the nanoviricides we tested was substantially comparable to the three-drug HAART cocktail. Both HAART and nanoviricide treatment had positive long term effects on reducing

thymocyte depletion as shown by the proportion of CD4+CD8+ thymocytes (double-positive, or “DP”) at 48 days post-infection. Implants in the HAART and nanoviricide treatment groups exhibited 75-85% CD4+,CD8+ DP cells while the vehicle control groups had only approximately 30% CD4+CD8+ thymocytes. Similarly, viral load in the nanoviricide treated group was reduced by >0.7 logs, slightly less than that with the HAART cocktail.

Most significantly, the nanoviricide treatment was given on alternate days through day 20 only, and then stopped. HAART treatment continued daily for the 48 days of study duration. In spite of this, the viral load in the nanoviricide treated groups did not increase at 48 days as compared to that at 24 days. This indicates a strong and sustained viral load reduction with the nanoviricide treatment. We had observed a similar effect in the earlier study as well.

No adverse events were observed with the nanoviricide therapy, in contrast to the HAART therapy.

This nanoviricide was based on a new ligand that we have designed. We design ligands based on mimicking the fashion in which the CD4 protein binds to HIV gp120 using molecular modeling. We believe that our biomimetic approach is based on conserved features of this binding interaction. We therefore believe that productive HIV mutations are less likely against our nanoviricides as compared to other approaches. We are now working on improving this new nanoviricide drug candidate further, to increase its potency.

Intermittent treatment protocols, such as once per month or once per week become feasible when sustained drug effect is maintained. Sustained drug effect is a holy grail for the treatment of long lasting diseases. Sustained drug delivery and controlled drug delivery are well established fields. We had always believed that we should expect sustained drug effects, because of the polymeric nature of the TheraCour® material that forms the base of our nanoviricides. We are now seeing clear indications of this in various studies.

Patient compliance is a major issue in HIV/AIDS treatment. This is because of the large numbers of drugs that must be taken in large quantities, and several times a day. Complicating this is the fact that these drug treatments cause nausea, gastrointestinal side effects, and other adverse effects. Thus, intermittent treatment is a very important goal in developing novel HIV/AIDS therapeutics.

We believe that HIVCide would be a highly effective anti-HIV drug, given our results. We have used the standard humanized mouse model for testing. In this model, the immune system of the mouse is replaced by human immune system. Then HIV infection is given. HIV infects the human immune system. The antivirals are then given and tested for their effect on the interaction of HIV with the implanted human immune system. This model is known to be a good predictor for anti-HIV drugs that work in humans.

HIVCide works by a very different mechanism than the current HAART drugs in the drug cocktail, NRTI, NNRTI, Protease Inhibitors, and now, Integrase Inhibitors. Thus, HIVCide is expected to give much stronger effects in combination with such drugs. In addition, for patients who have failed current drug therapy, HIVCide would be an attractive option.

We believe that HIVCide would enable a “Functional Cure” of HIV/AIDS. Current combination therapy is capable of bringing the HIV viral load in patients to extremely low levels. However, mutational resistance emerges and the therapy eventually fails. This can be rescued to some extent by drug substitution, until this strategy also fails. We believe that HIVCide is based on a drug strategy that potentially minimizes such failures, since HIV mutations that result in the mutant not being attacked by HIVCide would also be deficient in binding to the CD4 receptor on T cells. Thus, such mutants would not be capable of causing a productive re-infection cycle. Thus, HIVCide treatment, either as a single agent or in combination with other drugs, would lead to significantly reduced viral load and reinfection within the body. The patient would then be able to lead a normal life, and possibly not even have sufficient viral load to be capable of passing on the infection to others. In addition, the sustained effect of HIVCide after stopping therapy by itself indicates long durations of treatment free life would be feasible in this scenario.

#### **Preliminary Efficacy Studies In Vitro (Cell Cultures) – HIV**

We reported in June 2010, that our anti-HIV drug candidates demonstrated efficacy in the recently completed cell culture studies using two distinctly different HIV-1 isolates. The studies were performed in the laboratory of Carol Lackman-Smith at the Southern Research Institute, Frederick, Maryland.

This in vitro or cell culture study validated the in vivo anti-HIV activity of the nanoviricides® as determined in a SCID/Hu Thy/Liv mouse model by KARD Scientific, a contract research organization, and previously reported by the Company.

Significantly, a subset of the anti-HIV nanoviricides tested in cell culture models at Southern Research had very similar activity against two distinctly different isolates of HIV-1, viz. Ba-L and IIB. The Company had designed the ligands using reported gp120 structures of several HIV-1 strains.

The HIV-1 isolate Ba-L was the same as that employed in the Company's previously reported animal model studies. This virus binds and infects cells expressing the human receptor CCR5 in addition to the well-known receptor CD4. In contrast, HIV-1 IIB is a CXCR4-tropic virus that infects cells expressing the human receptor CXCR4 in addition to the receptor CD4. The same viral gp120 or SU glycoprotein is involved in binding to both co-receptors, viz. CD4 and either CCR5 or CXCR4. HIV that binds to CD4 and to at least one other co-receptor, such as CXCR4 or CCR5, results in productive infection leading to disease, and eventually AIDS.

It has been a formidable challenge for researchers in the field to develop an anti-HIV drug that works against all subtypes and strains. Several anti-HIV drugs and drug candidates have demonstrated significant activity against only one of these various HIV-1 subtypes. In addition, HIV mutates, changing its genome and protein structure during an active infection. Mutants resistant to the patients' treatment drugs can develop and proliferate, leading to failure of therapy, including the HAART regimen.

The Company believes that its strategy of designing ligands that are close mimics of the invariant binding site on CD4 has resulted in nanoviricides that are active against multiple HIV-1 subtypes. These results suggest that mutations in HIV-1 may be unlikely to result in significant resistance to an anti-HIV nanoviricide.

Based on these anti-HIV studies, the Company believes that it has a strong lead drug candidate against HIV. If the preliminary results are substantiated in further studies, and later in human clinical trials, it would be the first time ever that a new drug in development would have been found to be superior to the entire cocktail of three drugs called HAART.

At present, there are several drugs against HIV. These have led to HIV becoming a chronic, treatable, disease that can be controlled through the lifespan of an infected individual until an episode occurs. An episode is usually characterized by development of resistance against the therapy given. Drugs in the cocktail are then substituted or additional drugs added to provide additional benefit.

To the initially developed three drug classes, NRTI, NNRTI, and PI, recently three new classes have been added. These are EFI (Entry/Fusion Inhibitors) such as Fuzeon™ (Roche), II (Integrase Inhibitors) such as Isentress™ (Merck), elvitegravir (Gilead), and most recently, CCR5-blockers, maraviroc (Pfizer). Of these, NRTI, NNRTI, PI, and II act intracellularly, blocking different steps in the virus replication. EFI block the early step of virus entry and fusion with a human cell. CCR-5 blockers inhibit viral entry by blocking one of the receptors on the human cells used by the virus. However, HIV can also use CXCR4 in addition to or instead of CCR5, and viruses that do so cannot be affected by CCR5-blockers. Current standard of care is a three-drug combination called HAART. This leads to significant viral load control until resistance emerges. A recent clinical trial has established the validity of an approach that combines an II as a fourth drug into the original three drug combination cocktail. Fuzeon showed significant toxicity, potentially due to its action against human cells, and has not gained much acceptance, with a substantial number of patients falling off therapy due to side effects.

None of these drug classes alone cause benefits equivalent to the combination of the three drugs of the HAART cocktail. Nanoviricides are expected to act by a completely novel mechanism that is expected to result in complete dismantling of the extracellular virus load, rather than simply inhibition of entry of a small fraction of the extracellular virus load. Thus, nanoviricides mechanism is distinct from and superior to that of EFI and CCR5-blockers, as well as antibody cocktails. In addition, nanoviricides can be combined for significant geometric increase in benefit with

agents that act intracellularly such as the NRTI, NNRTI, PI and II class of drugs. Thus we believe that nanoviricides will become a significant tool in the arsenal against HIV.

If the viral load reduction seen in the preliminary animal study by a nanoviricide in comparison with HAART therapy proves to be predictive of benefit, then we can estimate that the anti-HIV nanoviricide alone or perhaps in combination with one or more components of the existing arsenal of drugs may provide what has been called a “functional cure” against HIV. A total cure is a state in which all virus, including copies of its genome integrated into human cells, is eliminated from the body, so that the virus infection does not exist and cannot recur. A functional cure can be paraphrased as a drug treatment which practically eliminates substantially all circulating virus, so that therapy can be stopped until a new recurrence happens after a significantly prolonged time interval. Thus, patients can live worry-free lives for years before requiring treatment again.

### **Preliminary Efficacy Studies In Cell Cultures – HSV-1**

We have successfully tested certain nanoviricide drug candidates in a cell culture model of HSV-1 infection. The study was designed as a virus neutralization study. This testing was conducted by TheVac, LLC laboratories at the Louisiana Emerging Technology Center located within the Louisiana State University (LSU) campus in collaboration with the LSU School of Veterinary Medicine.



Four different nanoviricides showed greater than 10,000-fold (>99.99% or 4-logs) reduction in virus quantity compared to untreated controls in a cell culture assay employing the LSU proprietary green-fluorescent-protein-tagged (GFP) modified HSV-1 McKrae strain. Virus quantity was determined in terms of pfu or plaque forming units, as is customary.

In August 2010, we reported on additional cell culture studies on our HSV-1 and HSV-2 nanoviricide drug candidates performed in Professor Ken Rosenthal's Lab at the NEOUCOM. These studies confirmed the results obtained in testing at TheVac, LLC previously.

The Rosenthal Lab studies demonstrated almost complete inhibition of the HSV-1 H129 strain. The extent of inhibition was also found to be dose-level dependent. The H129 strain is an encephalitic strain that closely resembles a clinical isolate; it is known to be more virulent than classic HSV-1 laboratory strains.

These nanoviricide drug candidates are designed to act against all herpes simplex virus strains, including HSV-1 and HSV-2. The Company has scheduled additional in vitro studies. Animal studies have also been scheduled.

#### **Preliminary Efficacy Studies In Cell Cultures – Dengue**

In June, 2010 the Company reported that its anti-Dengue drug candidates demonstrated significant efficacy in preliminary cell culture studies. The studies were performed in the laboratory of Dr. Eva Harris, Professor of Infectious Diseases at the University of California, Berkeley (UC Berkeley).

Several of the anti-Dengue nanoviricides® demonstrated a dose-dependent inhibition of Dengue virus infectivity in two distinctly different cell culture models of dengue virus infection. These studies employed the serotype dengue virus 2. The Company believes that these nanoviricide drug candidates mimic a common natural host cell receptor by which the four different dengue virus serotypes bind to the body's host cells, thus causing disease. The virus is "fooled" into thinking it has attached to its target cell and instead enters a nanoviricide nanomicelle, it is believed. A nanoviricide would thus stop the spread of the viral infection to new uninfected cells.

#### **Preliminary Efficacy Studies In Vivo – Dengue**

In late June 2010, the Company reported that its anti-Dengue drug candidates demonstrated significant protection in the initial animal survival studies of Dengue virus infection. The studies were performed in the laboratory of Dr. Eva Harris, Professor of Infectious Diseases at the University of California, Berkeley (UC Berkeley).

Treatment with one of the anti-Dengue nanoviricides® led to survival of 50% of the animals for the duration of study in the ADE model (see below). In addition, animals treated with several anti-Dengue nanoviricides survived longer than the control animals treated with vehicle alone. This ADE model of infection is uniformly fatal in 100% of the infected animals within 5 days after infection.

Dr. Harris is a leading researcher in the field of dengue viruses. Her group has developed a unique animal model for the most severe and potentially fatal form of Dengue virus infection in humans, Dengue Hemorrhagic Fever/Dengue Shock Syndrome (DHF/DSS). The model emulates the “Antibody-Dependent Enhancement (ADE)” of Dengue virus infection in humans that is believed to lead to DHF/DSS.

The Company has developed a library of chemical ligands that are expected to bind to the dengue virus envelope proteins of several different subtypes of dengue viruses. These ligands were developed using the results of sophisticated, well established, molecular modeling software. A number of candidate nanoviricides that are capable of attacking the dengue virus were created using these ligands. A “nanoviricide” is a chemical substance made by covalently attaching a number of copies of a virus-binding ligand to a specifically designed, patented (and patent pending) polymeric micelle structure. It is believed that when a nanoviricide binds to a virus particle, the interaction would extend to the binding of a large number of ligands to the virus surface, and the flexible nanomicelle would then engulf the virus, rendering it incapable of infecting a cell.

Dengue virus is a member of the Flaviviridae family of viruses, some of which are often spread by ticks and mosquitoes. Other important viruses in this family include Yellow Fever virus, West Nile virus and Hepatitis C virus. The market for novel treatments for Hepatitis C is estimated to be in the billions of dollars in the US alone.

When a person is exposed to dengue for the first time, the disease usually is not severe. When the same person is later infected by a different dengue serotype, the body produces antibodies against the previous dengue serotype. The new dengue virus uses these antibodies to infect more cells, thus leading to severe dengue disease. Such a secondary infection may lead to dengue hemorrhagic fever or dengue shock syndrome with high fatality rates. The ADE phenomenon has made development of vaccines and antibody therapeutics against Dengue a tremendous challenge. A vaccine works by creating antibodies against the included serotypes.

Currently there are no approved vaccines for the prevention of dengue, nor drugs for treatment of dengue virus infection. The worldwide market size for an effective anti-dengue treatment may be as large as that for Hepatitis C virus treatment, reaching billions of dollars, based on current population exposure data. Dengue, dengue hemorrhagic fever and dengue shock syndrome are emerging as serious global health problems. Dengue is endemic throughout much of the world and now threatens over 3 billion people world-wide or 40% of the world's population. Because of its world-wide distribution, dengue is considered an emerging threat in the United States. Dengue is officially considered a "neglected tropical disease" by the World Health Organization. Between 100-400 million people are infected by dengue virus every year. Recently, the government of Cali, Columbia declared a dengue emergency because of the number of dengue infections and deaths. Globalization and climate change along with changes in the ecology of the virus-carrying mosquito are accelerating the spread of the virus. Without proper treatment, DHF fatality rates can exceed 20%. (Source: WHO Dengue and dengue hemorrhagic fever Fact Sheet No. 117, March 2009; <http://www.who.int/mediacentre/factsheets/fs117/en/> ).

Based on these studies, the Company believes that a broad-spectrum nanoviricide that is highly effective against all four dengue serotypes is now feasible, based on the current data. Such a drug would circumvent the problems caused by a phenomenon called "Antibody-Dependent-Enhancement" or "ADE". ADE is thought to result in severe dengue disease syndromes such as dengue shock syndrome (DSS) and dengue hemorrhagic fever (DHF).

### **Preliminary Efficacy Studies In Vivo – Rabies**

As part of our agreement with Vietnam that enabled us to perform studies on various H5N1 strains and gave us access to anti-H5N1 antibodies from multiple host species, we have undertaken the development of anti-rabies drug candidates.

We performed two separate animal studies using a lethal mouse model in which mice were infected intracerebrally with 1,000LD50 of rabies challenge standard virus strain. Each group had 10 animals and there were 36 groups all together. In both studies, three different nanoviricides led to significant indefinite survival of mice. In the intracerebral virus-neutralization mechanism study, two of the tested nanoviricides led to 30% of the mice surviving indefinitely, and one led to 20% of the mice surviving indefinitely. In the intraperitoneal nanoviricide administration route study, two of these nanoviricides led to 20% of the mice surviving indefinitely. A 20% or greater population survival is considered statistically significant in this study. BayRab®, a commercial antibody used for post-exposure prophylaxis of rabies, gave 0% population survival rate in both studies. A nanoviricide made using antibody-based ligand followed the same course as the antibody itself, and gave a 0% population survival rate.

These studies appear to be the first ever in which a non-vaccine agent led to a significant population survival extent in rabies-infected mice in any high lethality infection protocol. Two of the three nanoviricides that led to high population survival rates in these studies are being further developed under the RabiCide-I™ project. Further studies are planned.

On July 3, 2008, the Company signed an agreement with the Centers for Disease Control and Prevention (CDC, Atlanta, Georgia) for further animal studies. If these studies meet the goals and expectations of the CDC Rabies scientists, it is anticipated that the Company will be able to develop an anti-rabies nanoviricide drug. The Company anticipates that such a drug could be used for post-exposure prophylaxis, replacing costly antibody therapies. The Company also anticipates that additionally, a post-infection rabies treatment drug may also be possible, if the testing results so indicate.

An estimated 10 million people receive post-exposure treatments each year after being exposed to rabies-suspect animals. About 30,000 people in the United States receive both pre-and post-exposure prophylaxis every year, at a cost of over \$1,000 per treatment course. The annual number of deaths worldwide caused by rabies is estimated to be 55,000, mostly in rural areas of Africa and Asia, according to a recent World Health Organization report. The market size for post-exposure prophylaxis for rabies has been estimated at \$300 million to \$500 million annually.

Rabies, a uniformly fatal disease found primarily in Africa and Southeast Asia, had never before been successfully treated with drugs. There are currently no FDA-approved treatment options for rabies once symptoms develop. In addition, the Company believes that significantly increased survival rate of these lethally infected animals is possible in the dose-ranging studies to follow.

### **Preliminary Efficacy Studies In Vitro and In Vivo – Ebola/Marburg**

In July 2010, our collaborators at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) presented the data on evaluation of anti-Ebola/Marburg nanoviricides. Significant efficacy was reported to have been achieved in cell culture studies. Animal studies indicated improvement in lifetime in the uniformly lethal mouse model. Further improvement in chemistry and dosage levels may be expected to lead to significant survival.

The Company plans to improve the drug candidates further. Ebola is a very “smart” virus. In order to evade the antibody response, it creates portions of its glycoprotein that is on the virus surface in copious quantities and exudes them. The soluble glycoprotein serves as a decoy reducing the effectiveness of neutralizing agents such as antibodies. The success of nanoviricides in cell cultures as well as the limited success achieved in the very first animal study is in spite of these effects. We therefore are confident that a Broad-Spectrum anti-Ebola effective nanoviricide that works against all Ebola and Marburg virus types, as well as possibly several other hemorrhagic viruses that bind to cells through similar mechanisms is quite feasible.

Considering that Ebola is not a commercially viable drug development target, we continue to actively pursue federal funding opportunities for this project.

### **A Note on Our Studies to Date**

Current pharmaceutical industry work in antiviral therapy generally results in small efficacy improvements. Thus, in the case of influenza, peramivir<sup>(TM)</sup>, (BioCryst) was reported as having approximately equal efficacy to Oseltamivir

(Tamiflu, Roche), in the most recent studies reported. In these clinical studies, peramivir was administered as an IV infusion at about 300mg or 600mg. IV infusion is a cumbersome process requiring hospital based administration. Previously, it was suggested that peramivir may have a superior safety profile and thus may enable use of large doses (compared to Tamiflu). Peramivir previously failed its Phase II clinical trials, and BioCryst stated that this may have been due to the use of needles of insufficient length in the Phase II study. Peramivir has since been approved in Japan. It was approved by the US FDA as an injectable for patients with uncomplicated influenza, to be administered within 48 hours, in December 2014 under the trade name Rapivab. Its clinical studies indicated its effectiveness was similar to other agents in its class, and that it had no effectiveness in severely ill patients hospitalized with influenza.

We believe our data clearly indicate that our Flucide™ drug candidates are substantially superior to Tamiflu (Oseltamivir). It is reasonable to assume that FluCide would be substantially superior to zanamivir and peramivir as well, given that these drugs are known to have efficacies similar to oseltamivir.

However, it should be noted that all of our studies to date were preliminary. Thus, the evidence we have developed is indicative, but not considered confirmative, of the capabilities of the nanoviricides technology's potential. These results merely lead us to the next step in the development process. They have limited relevance when it comes to the FDA regulatory process. Despite such excellent early results, there is a risk that the nanoviricides may not result in drugs suitable for commercial production.

It must be stressed that the results discussed above were very preliminary and similar results may not be found on retesting. However, further repeat studies will be necessary to substantiate and many validate these results.

In statistics, a result is called significant if it is unlikely to have occurred by chance. “A statistically significant difference” simply means there is statistical evidence that there is a difference; it does not mean the difference is necessarily large, important or significant in the usual sense of the word. For a detailed discussion of the significance of the p-value, please see <http://en.wikipedia.org/wiki/P-value> ..

In traditional frequentist statistical hypothesis testing, the significance level of a test is the maximum probability, assuming the null hypothesis, that the statistic would be observed. Hence, the significance level is the probability that the null hypothesis will be rejected in error when it is true (a decision known as a Type I error). The significance of a result is also called its p-value; the smaller the p-value, the more significant the result is said to be. Significance is represented by the Greek symbol,  $\alpha$  (alpha). Popular levels of significance are 5%, 1% and 0.1%. If a test of significance gives a p-value lower than the  $\alpha$ -level, the null hypothesis is rejected. Such results are informally referred to as ‘statistically significant’. For example, if someone argues that “there’s only one chance in a thousand this could have happened by coincidence,” they are implying a 0.1% level of statistical significance. The lower the significance level, the stronger is the evidence.

A very small  $\alpha$ -level (e.g. 1%) is less likely to be more extreme than the critical value and so is more significant than high  $\alpha$ -level values (e.g. 5%). However, smaller  $\alpha$ -levels run greater risks of failing to reject a false null hypothesis (a Type II error), and so have less statistical power. The selection of an  $\alpha$ -level inevitably involves a compromise between significance and power, and consequently between the Type I error and the Type II error.

Our experiments have constantly resulted in the p-value less than 0.003, which makes the tests very accurate, that there are no errors statistically for such an experiment, and all the values obtained from these experiments are of significance.

### **Mechanism of Nanoviricides Action**

It should be noted that while the nanomaterials and nanomedicines we are developing are designed with the set of ground rules stated earlier as our design goals, it is generally not possible to establish whether each of these mechanisms is actually active or whether it is truly responsible for the efficacy observed.

We believe that mechanisms are guidelines rather than endpoints. Our study endpoints and development programs are defined for establishing efficacy, safety, and chemical manufacturing controls, rather than establishing mechanisms of action.

### **Escape Mutants**

Escape mutants are a known risk and challenge to any given anti-viral drug. Our plan is to develop new drugs with modified ligands that attack the new attachment sites of the escape mutants. The rationale for this is based on the concept that a nanoviricide drug is constructed from several building blocks. One of these building blocks is the ligand that attaches specifically to the virus. Identifying or creating a new ligand that binds to an escape mutant enables creating a new drug, simply by replacing the ligand part of a drug already known to be reasonably safe and efficacious. The Company's scientists have developed strategies for identifying and designing such ligands.

### **Ligand Tuning™**

A very broad-spectrum nanoviricide can be made by using a ligand that binds to a very large number of types and strains of a given virus. Usually, but not always, it is possible to identify a ligand that will provide such a broad specificity against a particular virus, or a group of viruses.

Usually, the broader the spectrum of a ligand, the lower is its efficacy level by itself. Thus, it is always beneficial to develop highly efficacious narrow spectrum drugs against potentially deadly diseases. Both high efficacy and low efficacy ligands can be combined on the same nanomicelle for "tuning" the spectrum of activity of the nanoviricide drug.



### **A Note on US FDA Priority Review Vouchers**

The Food and Drug Administration Amendments Act of September 2007 authorizes the FDA to award a priority review voucher to any company that the FDA has determined is eligible for priority approval process for a treatment for a neglected tropical disease. The priority review voucher can be traded to another company in a manner similar to carbon (emissions) credit vouchers. The recipient company can save as much as six months on their drug review process, and it is anticipated that they would be willing to trade in vouchers with cash benefits to the company developing drugs against neglected tropical diseases. The regulation became effective as of September 30, 2008.

Economists at Duke University, who proposed the voucher concept in 2006, have calculated that reduction of the FDA approval time from 18 to six months could be worth more than \$300 million to a company with a top-selling drug with a net present value close to \$3 billion. At this level, the voucher would be expected to offset the substantial investment and risk required for discovery and development of a new treatment for a neglected tropical disease. (David B. Ridley, Henry G. Grabowski and Jeffrey L. Moe, "Developing Drugs For Developing Countries", Health Affairs, 25, no. 2 (2006): 313-324; doi: 10.1377/hlthaff.25.2.313; © 2006 by Project Hope. and ( [http://blogs.cgdev.org/globalhealth/2007/10/fda\\_priority\\_review.php](http://blogs.cgdev.org/globalhealth/2007/10/fda_priority_review.php) ).

While there is no indication whether NanoViricides, Inc. can obtain priority review for its drugs against neglected tropical diseases, the high efficacies of our drug candidates lead us to believe that this may be possible. FDA awards priority review status on the basis of several criteria. NanoViricides, Inc. is currently working on several neglected tropical diseases, including Dengue fever viruses, rabies, Ebola/Marburg viruses, among others. Of these, Dengue viruses are explicitly included in the list under this Public Law, and the remaining viruses are eligible for similar treatment according to the language in the Public Law, at the discretion of the Secretary of Health (Food and Drug Administration Amendments Act of 2007, P.L. 110-85, Sept. 27, 2007, <http://www.fda.gov/oc/initiatives/fdaaa/PL110-85.pdf> ).

### **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: Human Immunodeficiency Virus (HIV/AIDS), Influenza including Asian Bird Flu Virus, Herpes Simplex Virus (HSV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), 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.

In consideration for obtaining these exclusive licenses, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of certain 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) TheraCour Pharma, Inc. retains the exclusive right to develop and manufacture the licensed drugs. TheraCour Pharma, Inc. 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; and (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. 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 year ended June 30, 2015, 2014 and 2013 were \$2,403,126, \$2,611,754 and \$1,988,046 respectively. As of June 30, 2015, pursuant to its license agreement, the Company has paid a security advance of \$0 to and held by TheraCour Pharma, Inc., which is reflected in prepaid expenses.

No royalties are due TheraCour from the Company's inception through June 30, 2015.

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 16.8% of the Common Stock of the Company.

TheraCour Pharma, Inc. owns 9,619,170 shares of the Company's outstanding Common Stock and 2,000,000 shares of the Company's Series A Preferred Stock. The Company anticipates the need to procure large quantities of the nanoviricides drug candidates for the upcoming studies. In order to support this production scale, TheraCour Pharma, Inc., the Company's largest shareholder and licensor of the TheraCour® technology that the Company uses in its anti-viral drug development, has initiated a program to expand its laboratory facilities and staffing.

### **Collaborations and Subcontract Arrangements**

All of our agreements provide for the evaluation of Nanoviricides® substances created and provided by the Company to the Laboratory. In general, the Laboratory is compensated for certain material and personnel costs for these evaluations. The evaluations involve in vitro and in vivo scientific studies at the Laboratory using their established protocols. In some cases, the Company provides scientific input regarding certain modifications to their protocols as may be needed. The Laboratory returns the results and data to the Company. The Laboratory is allowed to publish the results after allowing time for the Company to protect intellectual property (IP) as needed. The Company sends nanoviricides as well as positive control (i.e. known therapeutics) and negative control (i.e. known not to work) compounds as needed in a fully formulated, ready to use form, to the Laboratory. All IP related to the nanoviricide materials, their formulations and reformulations, and their usage, rests with the Company. Any IP developed by the Laboratory regarding their own know-how, such as laboratory tests, their modifications, etc. rests with the Laboratory. Joint inventions are treated as per applicable US Laws.

The Company tries to choose the scientific laboratories with the most appropriate facilities and know-how relating to a particular field for the evaluation of an antiviral agent developed by the Company. The Company also tries to work with more than one laboratory for the evaluation of an antiviral agent developed by the Company. The Company also tries to work with more than one laboratory for a given group of viruses whenever possible. We seek to improve

confidence by obtaining independent datasets for corroboration of the efficacy and safety of the nanoviricides we develop. In addition, the Company is not dependent on a particular Laboratory for the development of any specific drug candidate in our product pipeline.

To date, the Company has engaged in non-GLP Efficacy and Safety evaluations in both in vitro (cell culture models) and in vivo (animal models) of our different Nanoviricides® at different laboratories.

#### Collaboration with the Health Ministry of the Government of Vietnam

On December 23, 2005, the Company signed a Memorandum of Understanding with the National Institute of Hygiene and Epidemiology in Hanoi (NIHE), a unit of the Vietnamese Government's Ministry of Health. This Memorandum of Understanding calls for cooperation in the development and testing of certain nanoviricides. The parties agreed that the initial target would be the development of drugs against H5N1 (avian influenza). NIHE thereafter requested that we develop a drug for rabies, a request to which we agreed. The initial phase of this agreement called first for laboratory testing, followed by animal testing of several drug candidates developed by the Company. Preliminary laboratory testing of FluCide<sup>(TM)</sup>-I, AviFluCide<sup>(TM)</sup>-I and FluCide-HP<sup>(TM)</sup> against various H5N1 strains in cell culture were successfully performed at the laboratories of the National Institute of Hygiene and Epidemiology in Hanoi (NIHE). In addition, animal studies of RabiCide drug candidates were also performed at the NIHE BSL2 facilities. The next stage of the project, animal testing of the Influenza and H5N1 candidates, has been delayed until the BSL3+ animal facility in Hanoi is ready. The H5N1 testing will utilize the NIHE's BSL3 (biological safety laboratory level 3) laboratory. Rabies testing can safely be done at their BSL2 facility.

## Other Collaborations

The Nanoviricides approach depends upon significant scientific input as well as scientific experimentation during various stages of developments. The Company currently does not have the facilities to conduct most of the anti-viral studies. The Company's strategy is to minimize capital outlays as well as operating costs by engaging external expert teams for our anti-viral testing work. The Company has been successful in building the necessary relationships to date to effect this strategy. The Company has thereby made and will need to continue to develop additional collaborations in order to minimize capital outlays.

To date, we have entered into the following collaborations.

Cooperative Research and Development Agreement for Material Transfer, dated October 15, 2007, between NanoViricides, Inc. and United States Army Medical Research Institute of Infectious Disease ("Laboratory").

The term of the agreement was for one year initially and extended for an additional year. It has been extended again, based on positive results. The Company shall invent, develop, and provide to the laboratory, Nanoviricides® that are expected to be capable of attacking a multiplicity of different Ebola and Marburg viruses. The Laboratory shall assess in vitro and in vivo activity of the anti-Ebola Nanoviricides® provided against the virus.

Cooperative Research and Development Agreement for Material Transfer, dated October, 2014, between NanoViricides, Inc. and United States Army Medical Research Institute of Infectious Disease ("Laboratory"). The term of the agreement is for one year. The Company shall invent, develop, and provide to the laboratory, nanoviricides® that are expected to be capable of attacking a multiplicity of different Ebola and Marburg viruses. The Laboratory shall assess in vitro and in vivo activity of the anti-Ebola Nanoviricides® provided against the virus.

There is no payment by the Company to the Laboratory, nor from the Laboratory to the Company. USAMRIID has federal funding to support their part of the work.

Clinical Study Agreement, dated May 6, 2009, between NanoViricides, Inc. and TheVac, LLC. ("Laboratory").

From May 1, 2009 through October 31, 2009, the Laboratory performed pre-clinical studies on various antiviral activities of up to eleven different formulations and assessed the potential of six nanoviricides manufactured by the Company. The Company paid the Laboratory the amount of \$55,000 for the studies.

Master Services Agreement, dated August 31, 2009, by and between Southern Research Institute (“Southern”) and NanoViricides, Inc.

The term of this agreement was three years from its execution. The Company agrees to supply necessary quantities of its products in order for Southern to complete specific studies as to the efficacy and safety of the Company’s compounds. The Company shall pay charges associated with each task order and provide payment in the amount and as indicated therein. It is anticipated the Company will pay approximately \$9,530 for such services. SRI is a general contract research organization (CRO). As per the first Task Order, SRI is evaluating the in vitro activity of a set of Nanoviricides® against HIV. These nanoviricides were created, produced, formulated and sent to Southern in a ready to use form by the Company. Under this agreement, Southern will estimate the work load and invoices for additional task orders, subject to the Company’s agreement on costs.

Technical Testing Agreement, dated December 15, 2007, between The Feinstein Institute for Medical Research (“Feinstein”) and NanoViricides, Inc.

The term of this agreement ran from December 17, 2007 through December 31, 2010. Feinstein performed animal studies testing services on epidemic kerato-conjunctivitis and related viral diseases of the cornea and conjunctiva. All test results and inventions resulting from the tests remained property of the Company. Inventions resulting from the testing services would be determined by an independent patent counsel with the Company retaining a commercial license on such inventions. The Company paid Feinstein an amount equal to \$40,090.19 for the costs associated with the research.

Materials Cooperative Research and Development Agreement between NanoViricides, Inc. and Centers for Disease Control and Prevention.

The CRADA provided that the CDC would test the efficacy of the Company's drug candidates against rabies. The nanoviricides provided by the Company remained its proprietary information. The CDC retains rights to certain inventions that may be conceived during testing. The Company paid the CDC an amount equal to approximately \$10,000 for the costs associated with the research.

Research and Development Agreement with Professor Ken Rosenthal's laboratory at the Northeastern Ohio Medical University (NEOMED, formerly called NEOUCOM)

On May 13, 2010, the Company announced that it had signed a research and development agreement with Professor Ken Rosenthal's laboratory at the Northeastern Ohio Medical University (NEOMED). Pursuant to the terms of this Agreement, Professor Rosenthal and NEOMED will evaluate the effectiveness of nanoviricides drug candidates against Herpes Simplex Viruses, HSV-1 and HSV-2, in both cell culture and animal models. The focus of this evaluation will be the development of drug candidates against herpes skin infections (oral and genital herpes). Dr. Ken Rosenthal is a professor of microbiology, immunology and biochemistry at NEOMED. He is a leading researcher in the field of herpes viruses. His laboratory has developed an improved mouse model of skin-infection with HSV to follow the disease progression. This model has been shown to provide highly uniform and reproducible results. A uniform disease pattern including onset of lesions and further progression to zosteriform lesions is observed in all animals in this model. This uniformity makes it an ideal model for comparative testing of various drug candidates which, the Company believes, can be expected to lead to a broad-spectrum anti-HSV antiviral treatment capable of attacking both HSV-1 and HSV-2.

Professor Rosenthal retired in December 2014, continued his laboratory and our R&D through April 2015, and has closed the lab thereafter. He is now Professor at Roseman University of Health Sciences College of Medicine, NV. He continues as Professor Emeritus at Northeast Ohio Medical University (NEOMED).

Research and Development Agreement with the University of California, Berkeley (UC Berkeley)

On February 16, 2010, the Company announced that it had signed a research and development agreement with Dr. Eva Harris's laboratory at the University of California, Berkeley (UC Berkeley). Under this agreement, Dr. Harris and coworkers will evaluate the effectiveness of nanoviricides® drug candidates against various dengue viruses. Cell culture models as well as in vivo animal studies will be employed for testing the drug candidates. Dr. Eva Harris is a Professor of Infectious Diseases at UC Berkeley. She is a leading researcher in the field of dengue. Her group has

developed a unique animal model for dengue virus infection and disease that effectively emulates the pathology seen in humans. In particular, the critical problem of dengue virus infection, called “Antibody-Dependent Enhancement” (ADE), is reproduced in this animal model. When a person who was previously infected with one serotype of dengue virus is later infected by a different serotype, the antibodies produced by the immune system can lead to increased severity of the second dengue infection, instead of controlling it. ADE thus can lead to severe dengue disease or dengue hemorrhagic fever (DHF). This agreement was extended in 2014.

Pre-Clinical Services Agreement with TransPharm

In January 2015, we commenced a master pre-clinical studies agreement with Transpharm Preclinical Solutions (“TransPharm”), a pre-clinical research services organization (CRO) in Jackson, MI. TransPharm has and will perform the topical dermal efficacy studies for our anti-HSV drug candidates. The agreement can also be extended to other indications for which TransPharm may already have an animal model or may be able to establish an animal model.



### Safety/Toxicology Studies Agreement with BASi

In September 2014, we signed an agreement with BASi. BASi is a pre-clinical contract services organization that specializes in cGLP and GLP-like safety and toxicological testing of drug candidates and preparation of the “Tox Package” section of an IND application. BASi performed a GLP-like preliminary safety and toxicology study in which there were no significant compound related adverse events found. Our safety and toxicology studies for FluCide are being conducted by BASi for submission with an IND application. BASi will also perform the safety toxicology studies for the anti-herpes nanoviricide drug candidates in our HerpeCide program.

### Other Agreements and Contracts

The Company continues to receive or obtain and evaluate various research and drug development collaborations with a number of parties that include government institutions, academic labs, contract service organizations, pharmaceutical companies, and other potential business collaborators or partners in the normal course of business. We have also received requests for material for testing under Material Testing Agreements (MTAs) from certain agencies. However, there can be no assurance that a final agreement may be forthcoming.

Further, the Company has had preliminary negotiations and discussions with other pharma and non-pharma commercial enterprises regarding commercial projects based on the Company’s technologies.

### **Background: Bio-Defense - Emergency Preparedness NanoViricides Technology May be Well Suited for Bio-Terrorism and Emerging Disease Threat Response**

In our early stages of development, we have designed a building-block based approach of nanoviricides drug development which may have potential use against bio-terrorism, accidental release of infectious agents, or natural outbreaks. This building block approach is expected to have the potential to allow us to expeditiously develop a new drug to fight new and emerging threats. The Company has made several presentations to various agencies within the U. S. Department of Defense regarding this technology.

### **Background: Bio-Defense “Rapid Threat Response”**

One of the long-term goals of the Company is to develop the ability to assist in the response of governments to viral bio-threats, whether due to bio-terrorism or natural events. Such a response scenario may in fact be possible because of the building-block nature of the nanoviricides platform technology. In this scenario, a base nanoviricide would be stockpiled under strategic national and international stockpiling programs, and a new drug could be developed against a threat even prior to identifying the actual pathogen that is the cause of the public health crisis event. This capability is seen as extremely valuable because it is anticipated that bioterrorism agents of the future as well as natural outbreaks may be of novel pathogens and therefore identification and diagnosis of the same may take large amounts of time, a time period in which an epidemic may threaten to become a pandemic. Such was the case with SARS, and other smaller outbreaks. Two years ago, a Cocksackie virus outbreak in Northern India resulted in several child fatalities during the pathogen identification time frame itself, despite being caused by a previously known pathogen. Last year, there were many cases of an unidentified infection in children in Northern India that resulted in several deaths.

### **Background: Anti-HIV Drugs - Importance of Reduction in Viremia**

In the field of HIV treatment, it is well established that keeping the viremia to a minimum level has significant clinical benefits. Thus, in one clinical study, only 8% of HIV infected patients with a viral load of less than 4350 copies of viral mRNA/uL progressed to full-blown AIDS in 5 years. By contrast, 62% of patients with a viral load of greater than 36,270 copies of mRNA/uL had developed AIDS in the same period (ref 145 from PATH p254). Viremia is significantly controlled with the current state of the art highly active antiretroviral therapies (HAART) against HIV, to the extent of almost undetectable viral load (i.e. less than 50-75 copies of HIV RNA per ml) in many patients. However, this is a dynamic condition, in which the rate of creation of new virus particles is balanced by the rate of their destruction, primarily by the body's innate defenses. In addition, once an escape mutation occurs, the HAART therapy loses its effectiveness and viral load rises sharply. Similarly, other precipitative events such as a secondary infection can cause progress to the AIDS stage. The AIDS stage is characterized by rapidly rising HIV viral loads (viremia) and, concomitantly, rapidly declining CD4+ T cells (an important component of human immune system). Eventually, the patient dies of complications related to the debilitation of immune response, often by a variety of secondary infections or even neoplasms (cancers) that grow unchecked.

In the very first stage of HIV infection, i.e. immediately after infection, there is a rapid rise in HIV viremia in the first few weeks, called the Acute HIV Syndrome (or Disease). If the body's immune system then brings the viremia under control, into a dynamic state, it is called "Asymptomatic HIV Disease". This stage lasts for a median 10 years, and a precipitative event, such as usually a secondary infection, leads to the clinical manifestations of AIDS. During the asymptomatic stage, it is known that the level of the steady state viremia correlates with the future progression of the disease and the life span of the patient.

While HAART therapy, when successful, leads to "undetectable" levels of viremia, the virus levels may still be at about 50 copies per ml, or about 1.5 million circulating virions in the blood and probably many magnitudes more virions inside cells and other tissues. This is still a very large load of virus. Thus, control of viremia is important even in the asymptomatic stage of "latent" HIV infection, even with HAART therapy.

Based on our early stage in-vitro and in-vivo results on our anti-viral influenza nanoviricides, we now have a scientific basis to expect that once we identify and attach a suitable ligand to develop an anti-HIV nanoviricide, it may well be possible to control viremia in all three stages of the HIV disease; viz. the early acute HIV infection syndrome, the later clinically latent HIV infection, and the late stage of full-blown AIDS. This "system" still needs to be extensively tested in the laboratory and in animals before any definitive statements can be made about its effectiveness.

### **The Company's Plan of Attacking HIV/AIDS**

As previously anticipated, we began pre-clinical studies of our first generation anti-HIV nanoviricide drug, HIVCide(tm)-I in the later part of our 2007-2008 fiscal year. The early studies have been extremely successful, and in these preliminary studies we have found at least one lead drug candidate that provided results superior to the three-drug oral cocktail that is currently in human clinical use as HAART therapy. Additional cell culture studies against two distinctly different strains of HIV-1 were conducted this year. These studies confirmed the efficacy of the nanoviricides against both HIV-I strains. We plan on continuing these studies towards the preparation of a Tox Package for filing an IND in the near future. These planned studies are elaborate, intensive, time-consuming, resource-intensive, and expensive. Our ability to conduct these studies depends upon adequate financing for the staff as well as for the materials required for the various experiments. We plan on continuing to rely upon external providers and collaborators for various services as before, wherever possible, in order to minimize capital expenses. The Company will strategically evaluate any outsourcing of the production of certain key intellectual property sensitive materials very carefully.

As the studies progress, we may find it necessary to accelerate the development of a second anti-HIV drug, HIVCide-II, in order to cover the various types, strains, quasi-species and mutants of the HIV viruses as completely as possible. Our objective is to develop anti- HIV drugs that together respond to the needs of combating the rapidly changing HIV viruses in the most complete fashion possible. The Company expects that these two anti-HIV drugs

together should encompass the currently known array of HIV types and subtypes in the world. These first nanoviricides drugs have been designed to engulf the virus particles, and dismantle them.

Together, these two drugs in combination with one or more of the existing therapies may result in a “functional cure” for HIV infection. To obtain a complete cure, it will be necessary to eliminate the HIV virus and its genome completely from the body. Eliminating the HIV virus completely would require eliminating it from the “memory cells” - dormant cells inside which the HIV genome remains hidden, and springs to life in a later episode. The current two nanoviricides are not designed to accomplish this task. The Company is currently researching various approaches for impacting the HIV-hiding memory cell population in our march towards a true cure for HIV.

## **Background: Influenza**

### Seasonal Influenza

Seasonal influenza, commonly known as the common flu, is a viral infection characterized by symptoms including fever, cough, sore throat, fatigue, headache, and/or chills. According to the U.S. Centers for Disease Control and Prevention (“CDC”), ([www.cdc.gov](http://www.cdc.gov)), an estimated 5% to 20% of the American population suffers from influenza annually, more than 200,000 people are hospitalized from flu complications, and approximately 36,000 people die from the flu in the US. The worldwide death toll is estimated at upwards of 200,000 per year. Influenza is particularly dangerous to the elderly, young children and people with certain chronic health conditions. Outbreaks of seasonal flu tend to follow predictable patterns usually occurring in the winter. New vaccines are developed annually based on known flu strains and are usually available for the annual flu season. There are also antiviral treatments available for the treatment of people infected with the influenza virus.

### Avian Influenza

According to information taken from the CDC website, avian influenza, or bird flu, is an infection caused by viruses which occur naturally among birds. This form of flu is very contagious among birds and can lead to serious illness and sometimes death. There are two main forms of disease that infect domestic poultry, one a low pathogenic form and the other a highly pathogenic form. The latter form can cause disease that affects multiple internal organs and with a mortality rate between 90-100% in these birds within 2 days.

While there are many different subtypes of the influenza A viruses, only three subtypes are known to be currently circulating among humans. Avian influenza A viruses are found chiefly in birds, but there have been confirmed cases of infection in humans, generally as a result of contact with infected birds. These infections have led to symptoms of normal flu to more severe and life threatening conditions. Influenza A (“H5N1”) is a subtype of an influenza virus that is highly contagious among birds and can be very deadly to them. Of the avian influenza viruses that have crossed the species barrier to infect humans, the H5N1 has caused the largest number of detected cases of severe disease and death in humans. In 2006, it is suspected that the Indonesia strain of H5N1 may have mutated to result in limited spreading from one person to another, only in close contact circumstances. It is possible that the substantially high case fatality rate may be keeping the human to human spread in check. But as influenza A viruses constantly change, they could mutate over time to have the ability to spread among humans.

### Pandemic Influenza

Pandemic flu is a global disease outbreak that occurs when a new influenza virus emerges so that people have had no previous exposure. This situation occurs rarely and only occurred three times in the 20th century. Minor pandemic outbreaks and minor epidemics occur relatively frequently.

The lesson from the “swine flu” pandemic outbreak of 2009 is very interesting. The H1N1/2009 outbreak appears to have begun in Mexico and was first identified in California. Thereafter it ravaged through Mexico and rapidly spread through the cities in USA and across the world, causing a global pandemic. While the US Government and various other governments made every effort to bring vaccines to contain the disease into production, the vaccines became available too late in the sequence of events. It has become quite evident that creating a new vaccine, testing it for efficacy, scaling it up through production, manufacturing, supplying to a supply center, and distributing it locally are all steps that have significant natural time limitations. In spite of accelerating the FDA approval processes involved within these steps to the maximum extent possible, vaccines could not reach the population in time.

Nature has once again opened the eyes of the world to the need for developing novel, effective treatments against influenza viruses that keep changing like a chameleon. The “swine flu” caused an epidemic in India in September/October, 2009, and was back in full force again in India in September/October 2010. In addition, the “bird flu” H5N1 epidemic in Southeast Asian countries continues to slowly simmer. The H5N1 virus has recently been found in pigs as well. Pigs serve as a transition species for adaptation of the flu virus originating in birds to become successful in infecting and spreading in human populations.

#### Flu Prevention and Treatment

The development of effective therapeutics has challenged medical researchers due to the seasonal variation in viral strains and the highly infectious nature of influenza. Patients, therefore, have limited treatment options. Amantadine<sup>(TM)</sup> and rimantadine<sup>(TM)</sup> are used for treatment of influenza A but are ineffective against influenza B. In addition, these drugs cause some adverse side effects, and the virus tends to develop resistance to these drugs. For the 2005-2006 flu season, the CDC has recommended against the use of amantadine and rimantadine for the treatment or prophylaxis of influenza in the United States due to signs of resistance to those drugs. Arbidol is in human use for influenza treatment in Russia and China but it has not yet been widely accepted as being effective. Arbidol side effects include allergic reactions and sensitization, particularly in children.

Vaccines are available against the disease but have limitations: people require advance vaccination; vaccines are limited by their specificity to particular strains of the virus; and vaccines offer little protection if the vaccine is inaccurate. In addition, many people decline the required injections because of fear and/or discomfort, as well as side effects such as allergies. The ability of the virus to change its structure to avoid the body's natural defenses is a serious obstacle to developing an effective vaccine against influenza. Different strains can arise when surface antigens on the virus (the portion of the virus that causes an immune reaction in humans) undergo minor genetic mutations each year as the virus replicates. Because of this mutability, the immunity acquired in response to infection by a particular strain of the virus does not provide adequate protection against viruses that subsequently arise. The production of a new vaccine each year is not only complex and expensive, but also an inefficient method of global disease control. The time lag between threat potential assignment and vaccine production implies that a novel influenza mutant can develop in the field and may result in very poor vaccine response.

### Inhibiting Influenza Neuraminidase

Research during the past two decades has seen dramatic advances in understanding the molecular structure and function of the influenza virus. Considerable attention has been focused on the enzyme neuraminidase, which is located on the surface of the virus particle. Neuraminidase assists in the release and spread of the flu virus by breaking the chemical strands that hold the new viruses to the cell surface, allowing the replicated virus to spread and infect other cells. This process progresses until the host's immune response can produce enough antibodies to bring the infection under control. Inhibiting the neuraminidase enzyme keeps new viruses attached to the cell surface, thereby preventing the spread of the virus and the further infection of other cells. The subsequent quantities of virus in the bloodstream are not enough to cause disease but are sufficient to induce the body to mount an immune response.

Roche, in collaboration with Gilead Sciences, and GlaxoSmithKline ("GSK") have currently approved neuraminidase inhibitors on the market. Roche's neuraminidase inhibitor, oseltamivir (Tamiflu™) is a twice-a-day, orally active neuraminidase inhibitor, while GSK's neuraminidase inhibitor, Relenza™ is administered by dry powder inhaler twice a day. Both drugs are approved for marketing in the United States and other countries for treatment of influenza. Roche's neuraminidase inhibitor is also approved for prophylaxis use for prevention of influenza. In addition to these companies with neuraminidase inhibitors, there are other companies working to develop vaccines and other antiviral drugs to be used against various strains of influenza.

BioCryst has developed a neuraminidase inhibitor, peramivir, as an IV infusion, for the treatment of common influenza as well as H5N1. Peramivir previously failed its Phase II human trials, and BioCryst had stated that this may be due to the use of short needles in the Phase II study. In spite of various issues with efficacy and bioavailability, peramivir was approved for influenza treatment in Japan in January, 2010. It was developed with the help of a contract worth \$234.8 million from the US Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services. Peramivir (Rapivab) was approved for intravenous administration in Dec 2014 by the US FDA. Overall, patients who received 600 mg of peramivir as a single injection had symptom relief 21 hours sooner, on average, than those who received the placebo, which is consistent with other drugs in the same class.

In other words, the effect of peramivir was not interpreted to be superior to oseltamivir or zanamivir. In addition, efficacy could not be established in patients with serious flu requiring hospitalization, as announced by the US FDA on December 22, 2014.

Several molecular biology oriented studies have described that there are significant differences between the neuraminidase of the H5N1 strain and those of the other common influenza strains that may be responsible for the poor efficacy of neuraminidase inhibitors as a class against H5N1. The New England Journal of Medicine reported one study which assessed the results of 17 prior studies related to the effectiveness of neuraminidase inhibitors. de Jong, Memo d., Thanh, Tran T., Khanh, Truong H., et. al. "Oseltamivir Resistance during treatment of Influenza A (H5N1) Infection, New England Journal of Medicine, Volume 353:2667-2672, December 22, 2005, November 25.

#### Other Drugs Against Influenza

The broad-spectrum nucleoside analog prodrug T-705 (Toyoma, Japan) is now in clinical trials. Its mechanism of action is stated as a viral polymerase inhibitor, after conversion by two cellular enzymes. Phase III clinical trials started in Japan in late 2009. Phase II clinical trials started in the USA in early 2010.



Fludase<sup>(TM)</sup> (DAS181) (NexBio: now Ansun Biopharma) is an enzyme that removes sialic acids from human cells, thus blocking entry of influenza virus. It was in Phase II clinical trials in the USA.

BCX4430 (BioCryst) is a broad-spectrum adenosine analog that has shown inhibitory activity against many RNA viruses. It received FDA Fast-track designation during the recent Ebola epidemic for development as a drug against Ebolavirus infection.

Some companies are developing viral M2-channel inhibitors, in the same drug class as amantadines. The objective is to develop M2-channel inhibitors with less potential for development of drug resistance or escape mutants.

#### Antibodies Against Influenza

Crucell, NV has recently reported that they are developing monoclonal antibodies as drugs against H5N1 bird flu. We ourselves were developing AviFluCide-I which uses a ligand based on certain anti-H5N1 antibodies. However, escape of virus against antibody drugs has been a major challenge, particularly for the influenzas and for HIV, and many other viral diseases. All of these viruses exhibit a significant antigenic drift, caused usually by small changes in the structure of their coat protein.

#### FluCide Program

Our broad-spectrum nanoviricide, FluCide-I is targeted to bind to the virus at its sialic acid binding sites on both hemagglutinin (HA) and neuraminidase (NA) proteins. The FluCide nanoviricide carries a multiplicity of ligands that are designed to mimic the sialic acid natural ligand. FluCide-I is thus expected to bind to the virus at multiple sites on the virus surface. This targeted surfactant-like attack is expected to destroy the virus particle or render it incapable of infecting a human cell. Influenza viruses are well known to be susceptible to surfactants.

Since both Influenza viral HA and NA continue to bind to sialic acids in spite of all mutations, FluCide-I is expected to be able to attack the virus even when it mutates, and thereby suppress escape significantly. However, this needs to be proven in extensive studies.

- 1 The Writing Committee of the World Health Organization (WHO) Consultation on Human Influenza A/H5. Avian influenza A (H5N1) infection in humans. *N Engl J Med* 2005;353:1374-1385.
- 2 Hien TT, Liem NT, Dung NT, et al. Avian influenza A (H5N1) in 10 patients in Vietnam. *N Engl J Med* 2004;350:1179-1188.
- 3 Chotpitayasunondh T, Ungchusak K, Hanshaoworakul W, et al. Human disease from influenza A (H5N1), Thailand, 2004. *Emerg Infect Dis* 2005;11:201-209.
- 4 Moscona A. Neuraminidase inhibitors for influenza. *N Engl J Med* 2005;353:1363-1373.
- 5 Identification of influenza isolates by hemagglutination inhibition. In: Department of Communicable Disease Surveillance and Response. WHO manual on animal influenza diagnosis and surveillance. Geneva: World Health Organization, 2002:28-36. (WHO/CDS/CSR/NCS/2002.5.)
- 6 de Jong MD, Cam BV, Qui PT, et al. Fatal avian influenza A (H5N1) in a child presenting with diarrhea followed by coma. *N Engl J Med* 2005;352:686-691.
- 7 Boom R, Sol C, Beld M, Weel J, Goudsmit J, Wertheim-van Dillen P. Improved silica-guanidiniumthiocyanate DNA isolation procedure based on selective binding of bovine alpha-casein to silica particles. *J Clin Microbiol* 1999;37:615-619.
- 8 Boom R, Sol CJ, Salimans MM, Jansen CL, Wertheim-van Dillen PM, van der Noordaa J. Rapid and simple method for purification of nucleic acids. *J Clin Microbiol* 1990;28:495-503.
- 9 Chen H, Smith GJ, Zhang SY, et al. Avian flu: H5N1 virus outbreak in migratory waterfowl. *Nature* 2005;436:191-192.
- 10 Gubareva LV, Kaiser L, Matrosovich MN, Soo-Hoo Y, Hayden FG. Selection of influenza virus mutants in experimentally infected volunteers treated with oseltamivir. *J Infect Dis* 2001;183:523-531.
- 11 Le QM, Kiso M, Someya K, et al. Avian flu: isolation of drug-resistant H5N1 virus. *Nature* 2005;437:1108-1108.
- 12 Whitley RJ, Hayden FG, Reisinger KS, et al. Oral oseltamivir treatment of influenza in children. *Pediatr Infect Dis J* 2001;20:127-133. [Erratum, *Pediatr Infect Dis J* 2001;20:421.]

13 Kiso M, Mitamura K, Sakai-Tagawa Y, et al. Resistant influenza A viruses in children treated with oseltamivir: descriptive study. *Lancet* 2004;364:759-765.

14 Ward P, Small I, Smith J, Suter P, Dutkowski R. Oseltamivir (Tamiflu) and its potential for use in the event of an influenza pandemic. *J Antimicrob Chemother* 2005;55: Suppl 1:i5-i21.

15 Yen HL, Monto AS, Webster RG, Govorkova EA. Virulence may determine the necessary duration and dosage of oseltamivir treatment for highly pathogenic A/Vietnam/1203/04 influenza virus in mice. *J Infect Dis* 2005;192:665-672.

16 Maines TR, Lu XH, Erb SM, et al. Avian influenza (H5N1) viruses isolated from humans in Asia in 2004 exhibit increased virulence in mammals. *J Virol* 2005;79:11788-11800.

### **Background: Rabies**

The current protocol for treatment after exposure to Rabies (known as post-exposure prophylaxis or “P.E.P.”) is highly successful in preventing the disease if administered promptly, within fourteen days after infection. The first step is immediately washing the wound with soap and water, which is very effective at reducing the number of viral particles. In the United States, patients receive one dose of immunoglobulin and five doses of rabies vaccine over a twenty-eight day period. One-half the dose of immunoglobulin is injected in the region of the bite, if possible, with the remainder injected intramuscularly away from the bite. The first dose of rabies vaccine is given as soon as possible after exposure, with additional doses on days three, seven, fourteen, and twenty-eight after the first. Patients that have previously received pre-exposure vaccination do not receive the immunoglobulin, only the post-exposure vaccinations.

Because of the significant expense of the rabies treatment, there is limited availability in the rural areas of these underdeveloped countries (The cost in the U.S. is approximately \$1,000 for a course of treatment).

At the request of the Vietnamese Ministry of Health, we initiated development of an anti-rabies drug. Rabies is a serious public health problem in Vietnam, Thailand, India, and many other tropical and subtropical countries.

Our first RabiCide drug candidates were tested at NIHE, Vietnam, in the first quarter of 2007. The Rabies drug, identified as RabiCide™, salvaged 30% of the animals given 1000X the lethal dose of rabies virus directly into the brain. There can be no assurance that our drug candidate (RabiCide), if developed, can successfully be manufactured. There are no guarantees that the drug, even if successfully manufactured, can produce revenue for the Company.

The United States Center for Disease Control has recently declared that the United States is now free of canine rabies, although dogs and humans may still get rabies from other animals such as bats, raccoons, and skunks ( [http://cdc.gov/news/2007/09/canine\\_rabies.html](http://cdc.gov/news/2007/09/canine_rabies.html) ). In addition, the World Health Organization has recently declared that the world will be free of canine rabies by the middle of the next decade. Thus the commercial potential, for the Company, of a rabies drug is uncertain.

### **Background: NanoViricides Company Philosophy**

NanoViricides, Inc. is a for-profit company. We have identified several diseases as large commercially important drug development targets. These include HIV, Hepatitis C, Herpes Simplex Virus, and Influenzas, among others. It is theoretically possible to develop nanoviricide drugs against a large number of infectious disease agents, particularly viruses. In this regard, there is a potential to develop good nanoviricides against these infectious agents, including those that are primarily seen in developed countries and well as those primarily seen in developing and sub-tropical areas.

Significant effort and scientific developments will be necessary in order to develop nanoviricides against drugs that affect the brain, and the central nervous system (CNS). This issue, a result of the blood-brain barrier, which does not allow drugs injected in the bloodstream to go into the CNS fluid, is well known. This is a major barrier for all drug development against CNS diseases. It may not be necessary to overcome this challenge in order to develop good nanoviricides against Dengue fever, West Nile virus, and other diseases that progress only slowly to attack the CNS. There may well be a time window for the nanoviricides to attack the virus in the circulation before it has an opportunity to move into the central nervous system in such diseases. Blood-brain barrier is also compromised in severe disease states. This may help the nanoviricides to be effective against neurotropic viruses even after they have localized in the CNS. Extensive studies will be necessary to resolve blood-brain-barrier issues. Alternatively, it is possible to inject drugs directly into the CNS, although this is a cumbersome and skill-requiring procedure.

It is not possible for any early-stage pharmaceutical company to expeditiously tackle a large number of disease targets without significant assistance and collaborations, both financial and technical. The Company has been successful in building the necessary relationships to date with various civilian and military agencies as well as with various universities and commercial entities regarding various collaborations. The Company has thereby made and will need to continue to develop additional collaborations in order to minimize capital outlays.

## Products

NanoViricides, Inc. currently has no products for sale

The following table summarizes NanoViricides active development projects as of June 30, 2015.

**Table 1. Products in Development**

Project	Virus	Description	Development Stage
1. Injectable FluCide™ for hospitalized patients	Influenza (Common), H5N1 Bird Flu, Highly Pathogenic Influenzas, novel H1N1/2009	Broad-Spectrum Anti-Influenza nanoviricide	Advanced Preclinical; Pre-IND Meeting held with US FDA
2. Oral Flucide™ for outpatients	Influenza (Common), H5N1 Bird Flu, Highly Pathogenic Influenzas, novel H1N1/2009	Broad-Spectrum Anti-Influenza nanoviricide	Advanced Preclinical; Pre-IND Meeting held with US FDA
3. Nanoviricide against Ebola	Ebola, Marburg	Broad-Spectrum nanoviricide against all strains of Ebola and Marburg filoviruses	Early Preclinical; High Priority during recent epidemic. Now background project.
4. HIVCide™	HIV/AIDS	Escape-resistant Anti-HIV nanoviricide	Preclinical
5. Nanoviricide Eye Drops	Adenoviruses, HSV-1	Eye Drops for Viral Diseases of the External Eye	Preclinical
6. HerpeCide™	HSV-1, HSV-2, HHV-3 (VZV)	Herpes “Cold Sores” and Genital Herpes, Shingles, Chicken-pox.	Advanced Preclinical

Topical Cream and Gel  
Formulations

7. DengueCide™	Dengue viruses, all types	Broad-Spectrum nanoviricide against all types of Dengue viruses	Preclinical
8. RabiCide™	Rabies	Anti-Rabies nanoviricide	Preclinical; Background Project
9. HepCCide™	HCV	Anti-HCV nanoviricide	Project on hold

**FluCide**, is currently in preclinical studies against all common influenzas as well as avian influenza H5N1. It is a broad-spectrum anti- influenza nanoviricide. It is based on ligands that we have developed through rational drug design. These ligands are based on a well-known mechanism by which influenza viruses bind to cells. One mechanism involves the hemagglutinin coat protein of influenza virus binding to sialic acids on cell surfaces. Our broad-spectrum ligand used in FluCide is based on the sialic acid expressed by cells. Therefore, it is expected to work well against all of the influenza viruses. Since all influenza viruses, no matter what type (A, B, C), which subtype (e.g. HxNy of Influenza A), or clades, or strains, must bind to one of two varieties of sialic acid, we have designed the ligand such that all of the influenza viruses must bind to our ligand. If an influenza virus escapes FluCide, this mutant virus would be unable to bind to both types of sialic acids, and would be thus unable to infect most animal species, including birds and mammals. We are currently developing an Injectable FluCide drug for hospitalized patients, and an Oral FluCide drug for the rest of the patients.

**HIVCide** , is our first announced drug project against HIV-I. Our first HIV drug to be developed is a targeted nanoviricide against HIV and is engineered with specific recognition ligands that allow multiple-point binding to inactivate HIV virus in the bloodstream.

**Nanoviricide Eye Drops** - We previously undertook a new project and have already designed a ligand, made a nanoviricide drug, and completed successful animal studies that indicate significant preliminary efficacy and safety of a drug candidate against the severe pink eye disease caused by adenoviruses called epidemic kerato-conjunctivitis. We have expanded the indication to include HSV, another cause of viral eye diseases. We designed new broad-spectrum ligands expected to be active against all HSV types and strains, as well as retaining the previously observed activity features against adenoviruses and created new nanoviricide drug candidates. We have already tested these against HSV in cell cultures. Animal model studies against Herpes Keratitis are anticipated after we improve the anti-HSV activity of the drug candidates.

**HerpeCide** - We are currently optimizing the anti-HSV ligands in animal studies for different disease indications. We believe we will be able to successfully advance the optimized drug candidates into an IND and human clinical trials. HerpeCide is being developed as skin cream or gel formulation for the treatment of oral and genital herpes lesions. Please see also Herpes Keratitis drug candidate under “Nanoviricides Eye Drops” above.

**DengueCide** - We obtained an orphan drug designation from the US FDA for our lead drug candidate in this program. We now plan on engaging into full pre-clinical development program for this drug candidate.

**RabiCide** , a nanoviricide against Rabies finished its first set of animal studies in the first quarter of 2007 in Vietnam. The candidate ligands for this nanoviricide were designed by the Company using publicly available information regarding the interaction of the rabies virus with cells. The Company has slowed down its development programs in NTDs and BioDefense areas since the economic crisis in order to conserve resources.

**Nanoviricide against Ebola/Marburg** - Previously our collaboration with USAMRIID for the development of a nanoviricide against Ebola/Marburg has resulted in significantly active drug candidates. We are currently improving these drug candidates. We continue our efforts at obtaining federal funding for this project.

**HCV** - A Hepatitis C nanoviricide is planned for research and development to begin after we have an optimized drug candidate for Dengue Fever. The Company has not yet sourced the materials to target this disease. The cell culture models available for HCV are very limited in nature. In particular, their application to study relative efficacies of virus neutralizing drugs is not well established. The in vivo studies against HCV require specialized animal models. A highly specialized mouse model with a human liver xenograft has become available for HCV studies. However, the

studies take a very long time and also are very expensive. The Company has only begun the early stages of a plan to develop nanoviricides against Hepatitis C. This project continues to be of major commercial interest. However, we plan to tackle it when appropriate levels of funding resources are available to the Company. With the introduction of a spate of new successful anti-HCV drugs recently, the bar for entry in this field is much higher than when we started out. While we believe that the nanoviricides technology can enable a much more effective drug than the existing combination drugs, we do not believe that our resources permit us to undertake development of such a drug candidate at this time.

### **Drug Formulations**

We have successfully formulated nanoviricides as eye drops, as IV injections and as skin creams and gels. We choose the formulation and route of administration that is expected to provide the best outcome for a particular viral disease, based on disease pathology. It is possible to administer nanoviricides drugs using other approaches as well.

Recently, we have been successful in developing nanoviricides against influenza that demonstrated very high effectiveness when given orally. This may be the very first time orally active targeted nanomaterial-based drug candidates have been developed and shown to have efficacy in animal models.



## **Development Stage of Products**

Our Influenza program is the most advanced and we have engaged into advanced pre-clinical development activities after obtaining valuable advice from the US FDA in a pre-IND meeting held in March, 2012. Initial safety and toxicology studies have been conducted in two animal models, namely mice and rats. For a complete safety/toxicology study package, we have estimated the need for production of approximately 2kg of the drug, due to the excellent safety observed in earlier studies. We have at present achieved production of approximately 200g per batch. Further process scale up is being performed at our new cGMP-capable facility at 1 Controls drive, Shelton, CT. We will need cGMP drug product for filing an IND and conducting clinical trials in the future. [cGMP = current Good Manufacturing Practices]. We are aggressively working on developing cGMP capability for our nanoviricides drug product lines.

Our Herpesvirus program has now advanced to a level where a limited amount of further optimization is expected to lead to IND candidates against a number of possible indications. The topical treatments for skin infections of HSV (oral cold sores), and for ocular HSV infection (herpes keratitis) are likely to require substantially less development work as compared to the injectable drug against influenza. As such, the Company has determined that it is in the best interests of shareholders that the Company should pursue development of its anti-herpes drug candidates towards an IND application in parallel to the development of its anti-Influenza drug candidate. It is likely that the treatment amount of the drug for controlling local infection would be much smaller than the amounts needed for systemic drugs such as, say for example, our own anti-influenza drug candidate. If so, our already proven ~200g scale batch production processes should be sufficient to support the safety/toxicology testing requirement as well as human clinical studies requirement for our anti-herpes nanoviricide drug.

All of the other products are in various stages of pre-clinical development. The Company believes that our anti-influenza drug candidates, anti-Dengue drug candidate, anti-HIV drug candidates, anti-viral eye drops drug candidates, as well as anti-HSV drug candidates, have all produced substantial positive results and should be developed further towards the goal of filing appropriate IND applications. All of our developments are subject to availability of appropriate levels of financing.

## **Drug Development Plan**

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. ("TheraCour"), the exclusive source for these nanomaterials. With sourcing of materials from TheraCour, 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 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.

## **Manufacturing**

### Manufacturing of Research Materials

Nanomaterials that form the basis of our nanoviricide drugs are produced for research by TheraCour Pharma, Inc. at our facilities in Shelton, Connecticut, under our licensing agreement with TheraCour.

### Manufacturing of Drugs

We have purchased the state of the art c-GMP capable manufacturing and research and development facility in Shelton, CT from Inno-Haven, LLC, a special purpose company formed for the purpose of real estate acquisition and improvements, which has acquired and renovated a light industrial building in Shelton, CT. Inno-Haven is controlled by Dr. Anil R. Diwan. The financing for the original acquisition of the building in 2011, and its total renovation was raised by Dr. Diwan through his personal funds, borrowings, other private investors, and partially through the sale of NanoViricides stock that he has acquired as a founder of NanoViricides, Inc. in accordance with a 10b5-1 trading plan. Inno-Haven has performed total renovation of the facility to enable modern laboratory space and cGMP facilities for the manufacture of the NanoViricides' drug candidates. Inno-Haven has raised substantial capital financings for this project. The Board of Directors of NanoViricides, Inc. unanimously agreed that the purchase of this facility from Inno-Haven is in the best interests of the Company and its shareholders, with Dr. Diwan abstaining from the discussion and voting. This determination was based on the potential lease costs derived in consultations with experts. Inno-Haven agreed to the sale of the facility to NanoViricides, Inc. NanoViricides purchased the facility from Inno-Haven by paying for the total costs borne by Inno-Haven. The sale and purchase was completed in December, 2014.

The Company intends to manufacture Injectable and Oral FluCide, HIVCide, Nanoviricide Eye Drops, HerpeCide, DengueCide, RabiCide as well as other drugs for pre-clinical animal studies and human clinical studies, in facilities owned by the Company. Our cGMP-capable manufacturing facility in Shelton, CT has sufficient capacity for supply of the pre-clinical and clinical batches needed for all of our drug candidates as and when they are anticipated to be needed. The Company may go to a cGMP third party provider for the final fill-and-finish of the clinical drug products. The current facility is not intended to support the large scale demand for high volume drugs such as oral FluCide. However, the Company believes that the current facility has sufficient production capacity to enable market entry and support rising demand for a couple of years for drugs that are anticipated to require smaller product quantities.

It is not possible to estimate the number of treatments that can be produced at the plant without the knowledge of the amount of drug needed for a treatment. The dose and treatment regimen are usually established as part of a successful Phase II human clinical trial. The Company believes that the production capacity at the Shelton facility could be sufficient to produce tens of millions of dollars in revenues as part of the initial market launch years.

The Company intends to supply the multi-billion-dollar markets for its drugs, when a drug gets licensed, primarily by licensing the manufacture to appropriate third party cGMP contract manufacturing operators (CMOs). Alternatively, the Company may license the drugs outright to another pharmaceutical company or a third party, if appropriate.

Certain FDA regulations enable the use of research products produced in a non-GMP-certified facility for certain human studies, provided the materials and production facility meet certain standards. The Company may be able to

take advantage of these regulatory amendments in order to advance our drugs into IND stage and first-in-human studies more rapidly. Several countries in the world allow “c-GMP-like” materials to be used for early human clinical trials. We believe that Australia is one of them. A “c-GMP-like” material can be loosely defined as material that is produced in a c-GMP compliant facility that has not yet undergone FDA registration as a cGMP drug manufacturing facility.

For our future commercial products, we will need to develop additional manufacturing capabilities and establish additional third party suppliers to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any products that are approved for commercial sale. If we are unable to develop manufacturing capabilities internally or contract for large scale manufacturing with third parties on acceptable terms for our future antiviral products, our ability to conduct large-scale clinical trials and meet customer demand for commercial products would be adversely affected.

We believe that the technology we use to manufacture our products and compounds is proprietary. For our products, we may have to disclose all necessary aspects of this technology to contract manufacturers to enable them to manufacture the products and compounds for us. We plan to have discussions with manufacturers under non-disclosure and non-compete agreements that are intended to restrict them from using or revealing this technology, but we cannot be certain that these manufacturers will comply with these restrictions. In addition, these manufacturers could develop their own technology related to the work they perform for us that we may need to manufacture our products or compounds. We could be required to enter into an agreement with that manufacturer if we wanted to use that technology ourselves or allow another manufacturer to use that technology. The manufacturer could refuse to allow us to use their technology or could demand terms to use their technology that are not acceptable.

We believe that we are in compliance with all material environmental regulations related to the manufacture of our products.

### **Patents, Trademarks, and Proprietary Rights**

The Company has an exclusive license in perpetuity for technologies developed (with materials referenced in Table 1 below) by TheraCour for the following virus types: HIV, Hepatitis C Virus, Herpes, 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.

In consideration for obtaining these exclusive licenses, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus a maximum of 30% of direct costs as a Development Fee payable in periodic installments as billed; (2) we will pay \$25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour; (3) we will pay \$2,000 or actual costs, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf (4) to make royalty payments of fifteen percent (15%) of net sales of the licensed drugs to TheraCour Pharma, Inc.; (5) that TheraCour retain the exclusive right to develop and synthesize nanomicelle(s), a small (approximately twenty nanometers in size) long chain polymer based chemical structure, as component elements of the Licensed Products. TheraCour agreed that it will develop and synthesize such licensed nanomicelles exclusively for NanoViricides, and unless such license is terminated, will not develop or synthesize such licensed nanomicelles for others; and (6) TheraCour may request and NanoViricides, Inc. will pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. TheraCour Pharma, Inc. 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.

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, Injectable FluCide, Oral FluCide, DengueCide, HivCide, Nanoviricide Eye Drops, HerpeCide, 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 Company has licensed key patents, patent applications and rights to proprietary and patent-pending technologies related to our compounds, products and technologies (see Table 2), but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

**Table 2: Intellectual Property, Patents, and Pending Patents Licensed by the Company**

Patent or Application	Date of Issue/ Application	US Expiry Date	International	Owners
<sup>1</sup> US6,521,736 (Certain specific amphiphilic polymers).	Issued: Feb 18, 2003	Feb 18, 2020	N/A	TheraCour Pharma and Univ. of Massachusetts, Lowell. [Nonexclusive license from TheraCour Pharma].
<sup>2</sup> PCT/US06/01820 (SOLUBILIZATION AND TARGETED DELIVERY OF DRUGS WITH SELF-ASSEMBLING AMPHIPHILIC POLYMERS).	Applied: Jan 19, 2006 PCT U.S. Issuance: May 8, 2012.	October, 2028 (estimated)	Applications are in various prosecution stages. Fifty two of these have been issued or validated	TheraCour Pharma, Inc. [Exclusive License].
<sup>3</sup> PCT/US2007/001607 SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTIVIRAL AGENTS	Applied: Jan 22, 2007	Ca. 2027 (estimated)	Applications are in various prosecution stages. Nine of these have been issued or validated	TheraCour Pharma, Inc. [Exclusive License].

A provisional U.S. patent application filed in July 2009 was abandoned, in favor of a broader international (PCT) patent application covering the contents of that application and also more recent inventions in the same technology stream. The priority date afforded by the provisional application would have been available only in the U.S., and therefore a single, uniform, international application covering the technology invented to date will be pursued instead.

The two PCT applications listed above are now in national or regional application stages.

A fundamental patent on the polymeric micelles composition, structure and uses was issued in the USA with substantially broad claims. This validates the novelty of our approach as well as our leadership position in the nanomedicines based on polymeric micelle technologies. The counterparts of this patent application, PCT/US06/01820, have so far been issued or validated with substantially similar broad claims in fifty two regions and countries that include ARIPO, Australia, Canada, China, several countries in Europe, Hong Kong, Indonesia, Israel, Japan, Korea, Mexico, New Zealand, OAPI, Philippines, Pakistan, United States, Vietnam, and South Africa. The OAPI regional patent covers Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo. The US expiry date is estimated at October, 2028. Other expiry dates range nominally from 2026 to 2028.

Another fundamental patent application is on the antivirals developed using the polymeric micelles, PCT/US2007/001607. The counterparts of this application have so far been issued in nine regions and countries with substantially broad claims as well, in ARIPO, Australia, China, Japan, Mexico, New Zealand, OAPI, and South Africa. The nominal expiry dates are expected to range from 2027 to 2029.

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

These patents have nominal expiry dates in 2026 to 2027 without accounting for various extensions available in different countries and regions. The dates can be further extended in several countries and regions for the additional allowances due to the regulatory burden of drug development process. 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 before entering human clinical trials. The estimated expiry date for the FluCide patent, if issued, would be no earlier than 2034.



Of the patents and technologies licensed, the Company believes that the Company will not be using the intellectual property, compositions of matter, or other aspects described and secured under the US Patent No. US 6,521,736. The Company believes that this patent describes an inferior technology compared to the technology in the later patent filings of Dr. Diwan. This patent, the Company believes, discloses prototype materials that served to establish the proof of principles developed by Dr. Anil Diwan, the Company's President and co-founder, whether such materials were possible to create and whether such materials would indeed be capable of encapsulation of pharmaceutically relevant compounds. The Company believes that the new and novel compositions disclosed in the new patent applications, No. PCT/US06/01820, and No. PCT/US2007/001607, and additional proprietary intellectual property provide the necessary features that enable the development of nanoviricides. The Company believes that no other published literature materials or existing patents are capable of providing all of the necessary features for this development, to the best of our knowledge. However, the Company has no knowledge of the extensive active internal developments at a number of companies in the targeted therapeutics area.

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

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

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

## **Trademarks**

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

## **Competition**

Our products in development target a number of diseases and conditions that include several different kinds of viral infections. There are many commercially available products for these diseases and a large number of companies and institutions are spending considerable amounts of money and other resources to develop additional products to treat these diseases. Most of these companies have substantially greater financial and other resources, larger research and development staffs, and extensive marketing and manufacturing organizations. If we are able to successfully develop products, they would compete with existing products based primarily on:

- efficacy;
- safety;
- tolerability;
- acceptance by doctors;
- patient compliance;
- patent protection;
- ease of use;
- price;
- insurance and other reimbursement coverage;
- distribution;
- marketing; and
- adaptability to various modes of dosing.

The current approved drugs for influenza include the neuraminidase inhibitors Tamiflu, Relenza, and Peramivir, anti-influenza drugs that are sold by Roche, Glaxo SmithKline (GSK), and BioCryst partners, respectively. In addition, M2 channel inhibitors, generic drugs include amantadine and rimantadine, both oral tablets that only inhibit the replication of the influenza A virus. There is significant viral resistance to the approved M2 channel inhibitors especially in the US. Several companies are developing anti-influenza drugs at present. Small chemical classes include neuraminidase inhibitors, M2-channel inhibitors, RDRP inhibitors, among others. There are also monoclonal, polyclonal, and mixed antibodies, as well as enzymes as drugs in development.

There are a growing number of anti-HIV drugs being sold or in advanced stages of clinical development. Companies with HCV and HIV products include Gilead, Bristol-Myers Squibb Company (BMS), Roche, Boehringer Ingelheim, Merck & Co., Inc. (Merck), in addition to several other pharmaceutical and biotechnology firms.

There are currently no approved drugs for the treatment of viral diseases of the external eye. A drug in development, called CTC-96, was shown to have little clinical benefit in published animal studies. Another drug in development, an Aganocide(tm) compound from NovaBay Pharma in collaboration with Alcon went through Phase II clinical studies. Alcon (a division of Novartis) discontinued further development of this drug following mixed results in a Phase II clinical trial. NovaBay regained the rights to it and continued further development. Aganocides, by virtue of their chemical structure, are generally not expected to be useful for any applications other than topical.

There are several drugs in the market that effectively control HSV cold sores and genital herpes lesions in most patients. These include the nucleoside analogues idoxuridine, vidarabine, acyclovir, famciclovir, and derivatives. However, their efficacy is limited or toxicities are high. Brincidofovir, based on the toxic drug cidofovir, is in development by Chimerix.

Our HCV drugs are at the earliest stage of development. There are a growing number of anti-HCV drugs being sold or are in advanced stages of clinical development. Companies with HCV licensed products or drugs in development include Valeant, Schering, Gilead, Vertex, Intermune, and Achillion (licensed to Johnson & Johnson), among others. With the introduction of a spate of new successful anti-HCV drugs recently, the bar for entry in this field is much higher than when we started out. While we believe that the nanoviricides technology can enable a much more effective drug than the existing combination drugs, we do not believe that our resources permit us to undertake development of such a drug candidate at this time.

Currently there are two accepted methods of rabies prophylaxis: rabies vaccines and rabies immune globulin, manufactured by many foreign and multinational manufacturers including Aventis Pasteur and Chiron (acquired by Novartis). These accepted methods will be the standard against which our new anti-rabies drug in development will be judged.

In order to compete successfully, we must develop proprietary positions in patented drugs for therapeutic markets. Our products, even if successfully tested and developed, may not be adopted by physicians over other products and may not offer economically feasible alternatives to other therapies.

## **Government Regulation**

Our operations and activities are subject to extensive regulation by numerous government authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation by the United States Food and Drug Administration (“FDA”). The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and the product approval process is very expensive and time consuming.

The FDA must approve a drug before it can be sold in the United States. As of the date of this filing, the FDA has approved other nano- particulate drugs including Emend® by Merck and Rapamune® by Wyeth, as well as others. The general process for FDA approval is as follows:

### Preclinical Testing

Before we can test a drug candidate in humans, we must study the drug in laboratory experiments and in animals to generate data to support the drug’s potential safety and benefits. We submit this data to the FDA in an investigational new drug application IND seeking their approval to test the compound in humans.

### Clinical Trials

If the FDA accepts the investigational new drug application, we study the drug in human clinical trials to determine if the drug is safe and effective. These clinical trials involve three separate phases that often overlap, can take many years to compile and are very expensive. These three phases, which are themselves subject to considerable regulation, are as follows:

Phase I. The drug is given to a small number of healthy human subjects or patients to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.

Phase II. The drug is given to a limited patient population to determine the effect of the drug in treating the disease, the best dose of the drug, and the possible side effects and safety risks of the drug.

Phase III. If a compound appears to be effective and safe in Phase II clinical trials, Phase III clinical trials are commenced to confirm those results. Phase III clinical trials are long-term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug. It is not uncommon for a drug that appears promising in Phase II clinical trials to fail in the more rigorous and reliable Phase III clinical trials.

### **FDA Approval Process**

If we believe that the data from the Phase 3 clinical trials show an adequate level of safety and effectiveness, we will file a new drug application (NDA) with the FDA seeking approval to sell the drug for a particular use. The FDA will review the NDA and often will hold a public hearing where an independent advisory committee of expert advisors asks additional questions regarding the drug. This committee makes a recommendation to the FDA that is not binding on the FDA but is generally followed. If the FDA agrees that the compound has met the required level of safety and effectiveness for a particular use, it will allow us to sell the drug in the United States for that use. It is not unusual, however, for the FDA to reject an application because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted is reliable or conclusive.

At any point in this process, the development of a drug could be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future, will be completed successfully or within any specified time period. We may choose, or the FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

The FDA may also require us to complete additional testing, provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive post-marketing testing and surveillance to monitor the safety or benefits of our product candidates if it determines that our new drug application does not contain adequate evidence of the safety and benefits of the drug. In addition, even if the FDA approves a drug, it could limit the uses of the drug. The FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for any drug we sell, including those of companies who manufacture our drugs for us as well as our own and these facilities are subject to periodic inspections by the FDA. The FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection.

We are also subject to other federal, state and local regulations regarding workplace safety and protection of the environment. We use hazardous materials, chemicals, viruses and various radioactive compounds in our research and development activities and cannot eliminate the risk of accidental contamination or injury from these materials. Any misuse or accidents involving these materials could lead to significant litigation, fines and penalties.

Drugs are also subject to extensive regulation outside of the United States. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries in the European Union (which includes most major countries in Europe). If this procedure is not used, under a decentralized system, an approval in one country of the European Union can be used to obtain approval in another country of the European Union under a simplified application process at present. After approval under the centralized procedure, pricing and reimbursement approvals are also required in most countries. These procedures are undergoing revision and modification at present. We have never received approval for a product in the European Union to date.

### **Employees and Service Providers**

The Company had six full time employees. In addition, most of the business activities of the Company including accounting and legal work and business development are provided by subcontractors and consultants. Further, the Company has subcontracted nanomaterials research and development (“R&D”) to TheraCour under the license agreement with TheraCour. TheraCour currently has a staff of about twenty-five, most of who are scientists with PhD or advanced degrees and experience. The Company has subcontracted its animal studies to various contract research organizations, government institutes, academic labs, and private institutions. Some of the Company’s R&D work was performed by agencies in Vietnam. In the future, the Company anticipates having additional service providers. We believe that we have good relations with our employees and subcontractors.

## Reports to Security Holders

As a result of its filing of Form 10-SB and listing on the FINRA OTC Bulletin Board, the Company became subject to the reporting obligations of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These obligations include filing an annual report under cover of Form 10-K, with audited financial statements, unaudited quarterly reports on Form 10-Q and the requisite proxy statements with regard to annual shareholder meetings. The public may read and copy any materials the Company files with the Securities and Exchange Commission (the “Commission”) at the Commission’s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0030. The Commission maintains an Internet site ( <http://www.sec.gov> ) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the Commission. Information about the Company is also available on its Web site at [www.nanoviricides.com](http://www.nanoviricides.com) . Information included on the Web site is not part of this Form 10-K.

The Company’s common stock was listed on the NYSE MKT (A US national exchange) on September 25, 2013. The NYSE MKT Exchange requires additional corporate governance, financial and reporting requirements.

## Website

Our website address is [www.nanoviricides.com](http://www.nanoviricides.com).



We intend to make available through our website, all of our filings with the Commission and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the EDGAR website containing our reports.

## **Our Information**

Our principal executive offices are currently located at 1 Controls Drive, Shelton, Connecticut 06484 and our telephone number is (203) 937-6137. We can be contacted by email at [info@nanoviricides.com](mailto:info@nanoviricides.com).

## **ITEM 1A. RISK FACTORS**

Our business, financial condition, operating results and prospects are subject to the following risks. Additional risks and uncertainties not presently foreseeable to us may also impair our business operations. If any of the following risks actually occurs, our business, financial condition or operating results could be materially adversely affected. In such case, the trading price of our common stock could decline, and our stockholders may lose all or part of their investment in the shares of our common stock.

This Form 10-K contains forward-looking statements that involve risks and uncertainties. These statements can be identified by the use of forward-looking terminology such as “believes,” “expects,” “intends,” “plans,” “may,” “will,” “should,” “anticipation” or the negative thereof or other variations thereon or comparable terminology. Actual results could differ materially from those discussed in the forward- looking statements as a result of certain factors, including those set forth below and elsewhere in this Form 10-K.

### **Risks Specific to Our Business**

*Our company is a development stage company that has no products approved for commercial sale, never generated any revenues and may never achieve revenues or profitability.*

Our company is a development stage company that has no products approved for commercial sale, never generated any revenues and may never achieve revenues or profitability. We are a development stage biopharmaceutical company. Currently, we have no products approved for commercial sale and, to date, we have not generated any

revenues. Our ability to generate revenue depends heavily on:

- demonstration and proof of principle in pre-clinical trials that a nanoviricide is safe and effective;
- successful development of our first product candidates FluCide, Nanoviricide Eye Drops, HIVCide, HerpeCide or another one of the drug candidates in our pipeline;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- the successful commercialization of our product candidates; and
- market acceptance of our products.

All of our existing product candidates are in early stages of development. It will be several years, if ever, until we have a commercial drug product available for resale. If we do not successfully develop and commercialize these products, we will not achieve revenues or profitability in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our operations.

We are a development stage company with a limited operating history, making it difficult for you to evaluate our business and your investment. We are in the development stage and our operations and the development of our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including but not limited to:

- the absence of an operating history;
- the lack of commercialized products;
- insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- limited experience in dealing with regulatory issues; the lack of manufacturing experience and limited marketing experience;

- an expected reliance on third parties for the development and commercialization of our proposed products;
- a competitive environment characterized by numerous, well-established and well capitalized competitors; and
- reliance on key personnel.

***Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company.***

Our ability to become profitable depends primarily on the following factors:

- our ability to develop drugs, obtain approval for such drugs, and if approved, to successfully commercialize our nanoviricide drug(s);
- our R&D efforts, including the timing and cost of clinical trials; and
- our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, regulatory affairs, sales, marketing and distribution.

***Even if we successfully develop and market our drug candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.***

We have incurred significant operating losses and may not ever be profitable. As of June 30, 2015, we had a cash and cash equivalent balance of \$31,467,748. Also, the Company has incurred significant operating losses since its inception, resulting in an accumulated deficit of \$54,099,572 at June 30, 2015. Such losses are expected to continue for the foreseeable future. As a result of recent financing, the Company estimates that it has sufficient cash to support current operations through the next two years, i.e. through June, 2017.

***We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.***

We currently do not have sufficient resources to complete the development and commercialization of any of our proposed products. As of June 30, 2015, we have a cash and cash equivalent balance of \$31,467,748 which will be sufficient to fund our operations for the next twenty four months at our budgeted rate of expenditures.

In the event that we cannot obtain acceptable financing, or that we are unable to secure additional financing on acceptable terms, we would be unable to complete development of our various drug candidates. This would necessitate implementing staff reductions and operational adjustments that would include reductions in the following business areas:

- research and development programs;
- preclinical studies and clinical trials; material characterization studies, regulatory processes;
- establishment of our own laboratory or a search for third party marketing partners to market our products for us.

The amount of capital we may need will depend on many factors, including the:

- progress, timing and scope of our research and development programs;
- progress, timing and scope of our preclinical studies and clinical trials;
- time and cost necessary to obtain regulatory approvals;
- time and cost necessary to establish our own marketing capabilities or to seek marketing partners;
- time and cost necessary to respond to technological and market developments;
- changes made or new developments in our existing collaborative, licensing and other commercial relationships; and
- new collaborative, licensing and other commercial relationships that we may establish.

Our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future, as we may:

- enter into leases for new facilities and capital equipment;
- enter into additional licenses and collaborative agreements; and

incur additional expenses associated with being a public company.

***We have limited experience in drug development and may not be able to successfully develop any drugs.***

Until the formation of NanoViricide, Inc. (the Company's predecessor prior to the reverse merger in 2005) our management and key personnel had no experience in pharmaceutical drug development and, consequently, may not be able to successfully develop any drugs. Our ability to achieve revenues and profitability in our business will depend, among other things, on our ability to:

- develop products internally or obtain rights to them from others on favorable terms;
- complete laboratory testing and human studies;
- obtain and maintain necessary intellectual property rights to our products;
- successfully complete regulatory review to obtain requisite governmental agency approvals;
  - enter into arrangements with third parties to manufacture our products on our behalf; and
- enter into arrangements with third parties to provide sales and marketing functions.

***Development of pharmaceutical products is a time-consuming process, subject to a number of factors, many of which are outside of our control. Consequently, we can provide no assurance of the successful and timely development of new drugs.***

Our drug candidates are in their developmental stage. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into reliable, commercially competitive drugs on a timely basis. Drugs that we may develop are not likely to be commercially available for a few years. The proposed development schedules for our drug candidates may be affected by a variety of factors, including technological difficulties, proprietary technology of others, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our drug candidates could result either in such drugs being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in "Risk Factors", we may not be able to complete successfully the development or marketing of any drugs.

We may fail to successfully develop and commercialize our drug candidates because they:

- are found to be unsafe or ineffective in clinical trials;
- do not receive necessary approval from the FDA or foreign regulatory agencies;
- fail to conform to a changing standard of care for the diseases they seek to treat; or
- are less effective or more expensive than current or alternative treatment methods.

Drug development failure can occur at any stage of clinical trials and as a result of many factors and there can be no assurance that we or our collaborators will reach our anticipated clinical targets. Even if we or our collaborators complete our clinical trials, we do not know what the long-term effects of exposure to our drug candidates will be. Furthermore, our drug candidates may be used in combination with other treatments and there can be no assurance that such use will not lead to unique safety issues. Failure to complete clinical trials or to prove that our drug candidates are safe and effective would have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

***We must comply with significant and complex government regulations, compliance with which may delay or prevent the commercialization of our drug candidates.***

The R&D, manufacture and marketing of drug candidates are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, R&D activities (including testing in primates and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. Noncompliance with applicable requirements can result in various adverse consequences, including approval delays or refusals to approve drug licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, recalls or seizures of products, injunctions against shipping drugs and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining FDA approval has historically been costly and time consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include: (1) the successful conclusion of pre-clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND application to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a New Drug Application, or NDA, for a drug product or a biological license application, or BLA, for a biological product to allow commercial distribution of the drug or biologic. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our drug candidates through clinical testing and to market.

The FDA reviews the results of the clinical trials and may order the temporary or permanent discontinuation of clinical trials at any time if it believes the drug candidate exposes clinical subjects to an unacceptable health risk. Investigational drugs used in clinical studies must be produced in compliance with current good manufacturing practice, or GMP, rules pursuant to FDA regulations.

Sales outside the United States of products that we develop will also be subject to regulatory requirements governing human clinical trials and marketing for drugs and biological products and devices. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources. In most cases, even if the FDA has not approved a product for sale in the United States, the product may be exported to any country if it complies with the laws of that country and has valid marketing authorization by the appropriate authority. There are specific FDA regulations that govern this process.

We also are subject to the following risks and obligations, related to the approval of our products:

• The FDA or foreign regulators may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them.

• If regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution.

• In addition, many foreign countries control pricing and coverage under their respective national social security systems.

• The FDA or foreign regulators may not approve our manufacturing processes or manufacturing facilities.

• The FDA or foreign regulators may change their approval policies or adopt new regulations.

• Even if regulatory approval for any product is obtained, the marketing license will be subject to continual review, and newly discovered or developed safety or effectiveness data may result in suspension or revocation of the marketing

license.

If regulatory approval of the product candidate is granted, the marketing of that product would be subject to adverse event reporting requirements and a general prohibition against promoting products for unapproved or “off-label” uses.

In some foreign countries, we may be subject to official release requirements that require each batch of the product we produce to be officially released by regulatory authorities prior to its distribution by us.

We will be subject to continual regulatory review and periodic inspection and approval of manufacturing modifications, including compliance with current GMP regulations.

***We can provide no assurance that our drug candidates will obtain regulatory approval or that the results of clinical studies will be favorable.***

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



In accord with our work-plan we filed a pre-IND application with the US FDA, and held a meeting with the US FDA for our anti-influenza drug candidate, NV-INF-1 in March, 2012. Subsequent to that, we have developed an orally available anti-influenza drug candidate based on our nanoviricides technology. This may be the first time ever that a targeted nanomedicine with activity when given orally has been developed and such activity demonstrated in vivo. We are now performing certain preclinical animal studies on this drug candidate. A set of these studies is designed to evaluate the safety and toxicology in animal models. Another set of the studies is designed to evaluate the pharmacokinetics and pharmacodynamics of the drug in animals. In addition, we have begun to perform efficacy studies using multiple different unrelated types and subtypes of influenza viruses in order to assess the broad-spectrum anti-influenza activity of our drug candidates. The efficacy studies are being performed in various in vitro (cell culture) models as well as in vivo (animal) models. In addition, we are performing certain chemical and physical characterizations, chemistry synthesis process optimizations, and quality control and quality assurance studies. Further, we need to scale up the syntheses to a larger scale of about 1kg. These chemistry, characterization, manufacturing, and quality studies will form part of the CMC package (Chemistry, Manufacturing, and Controls). The data will then be used to file an IND application or its overseas equivalent, towards the goal of obtaining regulatory approval for testing the drugs in humans.

On July 23, 2012 the Company announced that it had retained Australian Biologics Pty. Ltd, a regulatory affairs consulting firm, to coordinate the regulatory review and approval to conduct the first human trials in Australia for Flucide™, the Company's broad spectrum anti-influenza drug. Australian Biologics Pty. Ltd will also facilitate clinical trial site selection and development of clinical trial agreements which we intend to pursue. The Company has previously retained the Biologics Consulting Group for helping us formulate our regulatory strategy, design the studies to be performed, and develop the IND application for submission to the US FDA.

The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical and clinical trials may reveal that one or more products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed drug and failure to receive such approvals would have an adverse effect on the drug's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a proposed drug may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such proposed drug from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

***Even if we obtain regulatory approvals, our marketed drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and foreign regulations, we could lose our approvals to market these drugs and our business would be seriously harmed.***

Following any initial regulatory approval of any drugs we may develop, we will also be subject to continuing regulatory review, including the review of adverse experiences and clinical results that are reported after our drug candidates are made commercially available. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. The discovery of any previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug or manufacturer or facility, including withdrawal of the drug from the market. If we are required to withdraw all or more of our drugs from the market, we may be unable to continue revenue generating operations. We do not have, and currently do not intend to develop, the ability to manufacture material for our clinical trials or on a commercial scale. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drugs ourselves, including reliance on the third-party manufacturer for regulatory compliance. Our drug promotion and advertising is also subject to regulatory requirements and continuing FDA review.

***Development of our drug candidates requires a significant investment in R&D. Our R&D expenses in turn, are subject to variation based on a number of factors, many of which are outside of our control. A sudden or significant increase in our R&D expenses could materially and adversely impact our results of operations.***

We have expended \$31,175,063 on research and development from inception through June 30, 2015.

We have estimated a total cash expenditure budget of approximately \$8M for the next 12 months, of which approximately \$6M is expected to go towards research and development for our drug candidates, including IND-enabling studies of two of our lead drug candidates, namely Injectable FluCide, and HerpeCide Skin Cream, and approximately \$2M is budgeted for general and administrative expenses.

In the prior years we have established lead compounds against a number of viral diseases and completed animal studies proof of principle against a number of viral diseases. We now have lead drug compounds against all Influenzas, HIV, Viral diseases of the Eye, Oral and Genital Herpes, Herpes Keratitis, possibly Shingles, and Dengue viruses. We are currently working on identifying and establishing collaborations with pharmaceutical companies as well as government institutions for the purpose of co-development of these products. Notwithstanding these efforts, we will continue the development of these drugs, as well as our other drug development endeavors that include Rabies, Dengue viruses, and Ebola/Marburg viruses.

We currently have sufficient funds on hand to take at least one drug candidate through initial human clinical trials, and at least one or two drug candidates towards regulatory submissions for starting human clinical trials. We believe we will be pursuing Injectable Flucide™ and HerpeCide™ as our first two drug candidates for an IND and initiating human clinical trials. Beyond this development, we estimate that we may need approximately an additional \$10M to \$15M for human development of the Ocular HerpeCide, Oral Flucide and Denguecide drug candidates towards IND filing over the next 36-48 months. The additional funds will also be needed to pay additional personnel, increased subcontract costs related to the expansion and further development of our drug pipeline, and for additional capital and operational expenditures required to file the additional IND applications.

***The Company will be unable to proceed with its business plan beyond approximately June 30, 2017, without obtaining additional financing to support its budgeted Research and Development and other costs.***

Because we expect to expend substantial resources on R&D, our success depends in large part on the results as well as the costs of our R&D. A failure in our R&D efforts or substantial increase in our R&D expenses would adversely affect our results of operations. R&D expenditures are uncertain and subject to much fluctuation. Factors affecting our R&D expenses include, but are not limited to:

• the number and outcome of clinical studies we are planning to conduct; for example, our R&D expenses may increase based on the number of late-stage clinical studies that we may be required to conduct;

the number of drugs entering into pre-clinical development from research; for example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision;

licensing activities, including the timing and amount of related development funding or milestone payments; for example, we may enter into agreements requiring us to pay a significant up-front fee for the purchase of in-process R&D that we may record as R&D expense.

***We have no experience in conducting or supervising clinical trials and must outsource all clinical trials.***

We have no experience in conducting or supervising clinical trials that must be performed to obtain data to submit in concert with applications for approval by the Food and Drug Administration (“FDA”). The regulatory process to obtain approval for drugs for commercial sale involves numerous steps. Drugs are subjected to clinical trials that allow development of case studies to examine safety, efficacy, and other issues to ensure that sale of drugs meets the requirements set forth by various governmental agencies, including the FDA. In the event that our protocols do not meet standards set forth by the FDA, or that our data is not sufficient to allow such trials to validate our drugs in the face of such examination, we might not be able to meet the requirements that allow our drugs to be approved for sale.

Because we have no experience in conducting or supervising clinical trials, we must outsource our clinical trials to third parties. We have no control over their compliance with procedures and protocols used to complete clinical trials in accordance with standards required by the agencies that approve drugs for sale. If these subcontractors fail to meet these standards, the validation of our drugs would be adversely affected, causing a delay in our ability to meet revenue-generating operations.

***We are subject to risks inherent in conducting clinical trials. The risk of non compliance with FDA-approved good clinical practices by clinical investigators, clinical sites, or data management services could delay or prevent us from developing or ever commercializing our drug candidates.***

Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our drug candidates.

We or regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the patients enrolled in our clinical trials. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations will be subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our drug candidates or we may be criminally prosecuted. If we are unable to complete clinical trials and have our products approved due to our failure to comply with regulatory requirements, we will be unable to commence revenue generating operations.

***Efforts of government and third-party payors to contain or reduce the costs of health care may adversely affect our revenues even if we were to develop an FDA approved drug.***

Our ability to earn sufficient returns on our drug candidates may depend in part on the extent to which government health administration authorities, private health coverage insurers and other organizations will provide reimbursement for the costs of such drugs and related treatments. Significant uncertainty exists as to the reimbursement status of

newly approved health care drugs, and we do not know whether adequate third-party coverage will be available for our drug candidates. If our current and proposed drugs are not considered cost-effective, reimbursement to the consumers may not be available or sufficient to allow us to sell drugs on a competitive basis. The failure of the government and third-party payors to provide adequate coverage and reimbursement rates for our drug candidates could adversely affect the market acceptance of our drug candidates, our competitive position and our financial performance.

***If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions.***

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information. Disclosure of our trade secrets or proprietary information could compromise any competitive advantage that we have.

We depend upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of the technology. These measures may not afford us sufficient or complete protection, and may not afford an adequate remedy in the event of an unauthorized disclosure of confidential information. In addition, others may independently develop technology similar to ours, otherwise avoiding the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations.

***We will rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights, and we may be liable for infringing upon the intellectual property rights of others.***

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with which we have entered into licensing agreements. We have exclusively licensed patent applications from TheraCour Pharma, Inc. and expect to file patents of our own in the coming years. There can be no assurance that any of these patent applications will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. Further, we rely on a combination of trade secrets, know-how, technology and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

We do not believe that any of the drug candidates we are currently developing infringe upon the rights of any third parties nor are they infringed upon by third parties; however, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our drug candidates so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from the TheraCour Pharma Inc. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

***Other companies or organizations may assert patent rights that prevent us from developing and commercializing our drug candidates.***

We are in a relatively new scientific field that has generated many different patent applications from organizations and individuals seeking to obtain important patents in the field. Because the field is so new, very few of these patent applications have been fully processed by government patent offices around the world, and there is a great deal of uncertainty about which patents will issue, when, to whom, and with what claims. It is likely that there will be significant litigation and other proceedings, such as interference proceedings in various patent offices, relating to patent rights in the field. Others may attempt to invalidate our patents or other intellectual property rights. Even if our rights are not directly challenged, disputes among third parties could lead to the weakening or invalidation of those intellectual property rights.

Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and drug candidates, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.



***We are dependent upon TheraCour Pharma Inc. for the rights to develop the products we intend to sell.***

Our ability to develop, manufacture and sell the products the Company plans to develop is derived from our “Material Licensing Agreement” with TheraCour Pharma Inc. (“TheraCour”). While we hold the license in perpetuity, the Agreement may be terminated by TheraCour as a result of: the insolvency or bankruptcy proceedings by or against the Company, a general assignment by the Company to its creditors, the dissolution of the Company, cessation by the Company of business operations for ninety (90) days or more or the commencement by the Company or an affiliate to challenge or invalidate the issued patents.

The Company does not hold the rights to any other patents nor does the Company conduct its own research and development to develop other products to manufacture and sell. If the Company’s Agreement with TheraCour is terminated, it is unlikely we will be able to commence revenue-generating operations or that the Company could continue operating at all.

***We lack suitable facilities for clinical testing; reliance on third parties.***

The Company does not have facilities that could be used to conduct clinical testing. We expect to contract with third parties to conduct all clinical testing required to obtain approvals for any drugs that we might develop. We currently outsource all clinical testing to a number of third parties in various collaborations and service contracts. In addition, KARD Scientific is not under contract to perform studies for us, and studies are commissioned with KARD on an as needed basis. Any of our collaborators or service providers may discontinue the service contract or collaboration. We will then be required to modify our priorities and goals, obtain other collaborators or service providers to replace the ones we lose, or we may even be forced to abandon certain drug development programs. In addition, any failures by third parties to adequately perform their responsibilities may delay the submission of our proposed products for regulatory approval, impair our ability to deliver our products on a timely basis or otherwise impair our competitive position.

***We have limited manufacturing experience.***

The Company has never manufactured products in the highly regulated environment of pharmaceutical manufacturing. There are numerous regulations and requirements that must be maintained to obtain licensure and the permits required to commence manufacturing, as well as additional requirements to continue manufacturing pharmaceutical products. We do not own or lease facilities currently that could be used to manufacture any products that might be developed by the Company, nor do we have the resources at this time to acquire or lease suitable facilities.

*We have no sales and marketing personnel.*

We are an early stage development Company with limited resources. We do not currently have any products available for sale, so have not secured sales and marketing staff at this early stage of operations. We cannot generate sales without sales or marketing staff and must rely on officers to provide any sales or marketing services until such staff are secured, if ever. Even if we were to successfully develop approvable drugs, we will not be able to sell these drugs if we or our third party manufacturers fail to comply with manufacturing regulations.

If we were to successfully develop approvable drugs, before we can begin selling these drugs, we must obtain regulatory approval of our manufacturing facility and process or the manufacturing facility and process of the third party or parties with whom we may outsource our manufacturing activities. In addition, the manufacture of our products must comply with the FDA's current Good Manufacturing Practices regulations, commonly known as GMP regulations. The GMP regulations govern quality control and documentation policies and procedures. Our manufacturing facilities, if any in the future and the manufacturing facilities of our third party manufacturers will be continually subject to inspection by the FDA and other state, local and foreign regulatory authorities, before and after product approval. We cannot guarantee that we, or any potential third party manufacturer of our products, will be able to comply with the GMP regulations or other applicable manufacturing regulations.

As of the date of this filing, we have three employees and several consultants and independent contractors. The only consultant/contractor that we consider critical to the Company is TheraCour, discussed in the next risk factor. KARD Scientific, another consultant/contractor (See ITEM 1. Background: Collaborations and Subcontract Arrangements) is considered by the Company important but not critical as they are replaceable with moderate difficulty. All other consultant/contractors would be more readily replaceable. While the Company's current operations cause it to be unlikely that we will need to grow and hire additional consultants, contractors or employees, if future preclinical studies of our nanoviricide drugs and technology show significant improvements in efficacy over existing drugs, we intend to expand our operations and staff materially. At that time our new employees may include a number of key managerial, technical, financial, R&D and operations personnel who will not have been fully integrated into our operations. We would expect the expansion of our business to place a significant strain on our limited managerial, operational and financial resources. We have no experience in integrating multiple employees. Therefore, there is a substantial risk that we will not be able to integrate new employees into our operations which would have a material adverse effect on our business, prospects, financial condition and results of operations.

***We license our core technology from TheraCour Pharma Inc. and we are dependent upon them as they have exclusive development rights. If we lose the right to utilize any of the proprietary information that is the subject of this license agreement, we may incur substantial delays and costs in development of our drug candidates .***

The Company has entered into a Material License Agreement with TheraCour Pharma, Inc. ("TheraCour") (a approximately 16.8% shareholder of the Company's common stock) whereby TheraCour has exclusive rights to develop exclusively for us, the materials that comprise the core drugs of our planned business. TheraCour is a development stage company with limited financial resources and needs the Company's progress payments to further the development of the nanoviricides. 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. No royalties are due to TheraCour from the Company's inception through June 30, 2015.

We depend on TheraCour and other third parties to perform manufacturing activities effectively and on a timely basis. If these third parties fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval, and these events could harm our competitive position and adversely affect our ability to commence revenue generating operations. The manufacturing process for pharmaceutical products is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We and our manufacturers are subject to the FDA's current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record-keeping and quality standards and similar regulations are in effect in other countries. In addition, our manufacturing operations are subject to routine inspections by regulatory agencies.

***Our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.***

We anticipate substantial reliance upon strategic collaborations for marketing and the commercialization of our drug candidates and we may rely even more on strategic collaborations for R&D of our other drug candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering our drug candidates for non-medical applications to government agencies does not require us to develop new sales, marketing or distribution capabilities beyond those already existing in the company. Selling antiviral drugs, however, does require such development. We plan to sell antiviral drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaborations with third parties capable of providing these services. In addition, we have not yet marketed or sold any of our drug candidates or entered into successful collaborations for these services in order to ultimately commercialize our drug candidates.

If we determine to enter into R&D collaborations during the early phases of drug development, our success will in part depend on the performance of our research collaborators. We will not directly control the amount or timing of resources devoted by our research collaborators to activities related to our drug candidates. Our research collaborators may not commit sufficient resources to our programs. If any research collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

Manufacturers producing our drug candidates must follow current GMP regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the current GMP regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates and cause us to fall behind on our business objectives.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our drug candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and R&D programs with the marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

***We employ the use of certain chemical and biological agents and compounds that may be deemed hazardous and we are therefore subject to various environmental laws and regulations. Compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable.***

We use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we safely store these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs complying with environmental laws and regulations adopted in the future.

***If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages.***

Our R&D and manufacturing activities will involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We carry \$1,000,000 casualty and general liability insurance policies. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources and insurance coverage, and our clinical trials or regulatory approvals could be suspended.

***We may not be able to attract and retain highly skilled personnel.***

Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other pharmaceutical companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than us. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations will be materially and adversely affected.

***We depend upon our senior management and their loss or unavailability could put us at a competitive disadvantage.***

We currently depend upon the efforts and abilities of our management team. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of key-person life insurance for all of our key personnel.

The Company believes that its two executive officers, Eugene Seymour, Chief Executive Officer and Chief Financial Officer and Anil Diwan, President and Chairman of Board, are critical to the success of the Company. The Company is a limited beneficiary of a certain amount of key man insurance for these two executive officers that the Company maintains. However there can be no assurances that the amount of the key man insurance coverage would be sufficient to provide replacement of these key officers for continuing the Company's operations in a timely manner, should such an event arise.

The Company also maintains a limited amount of Directors and Officers Liability insurance coverage to protect all of its directors and executive officers taken together. There can be no assurance that this D&O coverage will be sufficient to cover the costs of the events that may lead to its invocation, in which case, there could be a substantial impact on the Company's ability to continue operations, should such an unforeseen event occur.

On March 3, 2010, the Company entered into employment agreements with its two executive officers, Eugene Seymour, Chief Executive Officer and Chief Financial Officer and Anil Diwan, President and Chairman of Board. Both agreements provide a minimum annual base salary of \$250,000 for a term of four years. In addition, Dr. Seymour and Dr. Diwan were eligible for an increase in base salary to \$275,000 once the Company consummated a financing with gross proceeds of at least \$5,000,000. Also, the base salary is eligible to be increased to \$300,000 for Dr. Seymour and \$300,000 for Dr. Diwan since the Company has been listed on a national stock exchange. As additional compensation under the employment agreements, the Company issued 71,429 (as adjusted) shares of the Company's Series A Preferred Stock and shall issue an additional 71,429 (as adjusted) shares of Series A Preferred Stock on each anniversary of the respective employment agreements. The prior employment agreements expired as of February 29, 2014 and Drs. Diwan and Seymour continued to work on the basis of such expired agreements at a salary of \$300,000 per annum.

On July 21, 2015, the Company entered into new employment agreements with Dr. Diwan and Dr. Seymour, effective July 1, 2015. The terms of the agreements, as more fully set forth below, were determined by the Registrant's independent Compensation Committee of the Board of Directors based upon comparative compensation reports prepared by an independent third-party research firm. The Compensation Committee determined that the proposed compensation for Drs. Diwan and Seymour were in line with similar publicly-traded pharmaceutical companies. Both agreements provide Drs. Diwan and Seymour would receive compensation of \$350,000 for the first year of employment, \$375,000 for the second year and \$400,000 for the final year. Additionally, both executives were awarded a grant of 225,000 shares of the Registrant's Series A Preferred Stock that vest equally over the term of the employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of the executive. The employment agreements also provides incentive bonuses of \$75,000 per

year payable on or before July 31, 2015, 2016 and 2017. The agreements provide for customary benefits including health and life insurance coverage, and vacation days. The agreements also provide customary terms regarding confidentiality, restrictive covenants, non-solicitation and non-disclosure.

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 (as adjusted) shares of Series A Preferred Stock and 35,715 (as adjusted) shares of common stock, and will issue an additional 26,786 (as adjusted) shares of Series A Preferred Stock and 35,715 (as adjusted) shares of common stock on each anniversary date of the agreement.

On March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provides for a term of four years with a base salary of \$150,000. In addition, the Company issued 35,715 (as adjusted) shares of common stock, and will issue an additional 35,715 (as adjusted) shares of common stock on each anniversary date of the agreement.

In July 2014, the Compensation Committee of the Board of Directors unanimously agreed that these employment agreements shall continue in effect until new employment agreements become effective.



*There are conflicts of interest among our officers, directors and stockholders.*

The Company has a majority independent Board of Directors, a fully independent Compensation Committee, and a fully independent Audit Committee.

Certain of our executive officers and directors and their affiliates are engaged in other activities and have interests in other entities on their own behalf or on behalf of other persons. Neither we nor our stockholders will have any rights in these ventures or their income or profits. Specifically, Anil Diwan owns approximately 70% of the capital stock of TheraCour Pharma, Inc. which owns 16.8% of our Common Stock, and 2,000,000 shares of the Company's Series A Preferred stock, provides the Company the nanomaterials with which it intends to develop its products and is the holder of the intellectual property rights the Company uses to conduct its operations. While the Company is not aware of any conflict that has arisen or any transaction that has not been conducted on an arm's length basis to date, Dr. Diwan may have conflicting fiduciary duties between the Company and TheraCour.

In addition, one of our independent directors, Dr. Milton Boniuk has dispositive power over 2,276,819 shares of common stock, and 187,000 shares of Series A preferred shares. In addition, Dr. Boniuk is the holder, or has dispositive power over \$4,000,000 of the Company's Series B Convertible Debentures and \$5,000,000 of the Company's Series C Convertible Debentures. The Company believes that as a significant investor himself, he represents the interests of the shareholders at large.

Currently, the Company does not allow a conflicting Shareholder, Director, or Executive Officer to vote on matters wherein a conflict may be perceived. The conflicting entity is not allowed to nominate alternate person to vote for them either. Other than this safeguard, the Company currently does not have any policy in place to deal with such should such a conflict arise

In particular:

Our executive officers or directors or their affiliates may have an economic interest in, or other business relationship with, partner companies that invest in us.

Our executive officers or directors or their affiliates have interests in entities that provide products or services to us.

In any of these cases:

Our executive officers or directors may have a conflict between our current interests and their personal financial and other interests in another business venture.

Our executive officers or directors may have conflicting fiduciary duties to us and the other entity.

The terms of transactions with the other entity may not be subject to arm's length negotiations and therefore may be on terms less favorable to us than those that could be procured through arm's length negotiations.

***We anticipate entering into contracts with various U.S. government agencies. In contracting with government agencies, we will be subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy.***

We may enter into contracts with various U.S. government agencies which have special contracting requirements that give the government agency various rights or impose on the other party various obligations that can make the contracts less favorable to the non- government party. Consequently, if a large portion of our revenue is attributable to these contracts, our business may be adversely affected should the governmental parties exercise any of these additional rights or impose any of these additional obligations.

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

• suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;

• terminate our existing contracts;

• reduce the scope and value of our existing contracts;

• audit and object to our contract-related costs and fees, including allocated indirect costs;

• control and potentially prohibit the export of our drug candidates; and

• change certain terms and conditions in our contracts.

The U.S. government may terminate any of its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination for default provisions do not permit these recoveries and make us liable for excess costs incurred by the U.S. government in procuring undelivered items from another source.

As a U.S. government contractor, we may become subject to periodic audits and reviews. Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, including allocated indirect costs. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, compensation and/or management information systems. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R&D costs and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities to which purely private sector companies are not.

***We may fail to obtain contracts to supply the U.S. government, and we may be unable to commercialize our drug candidates.***

The U.S. government has undertaken commitments to help secure improved countermeasures against bio-terrorism. The process of obtaining government contracts is lengthy and uncertain, and we must compete for each contract. Moreover, the award of one government contract does not necessarily secure the award of future contracts covering the same drug. If the U.S. government makes significant future contract awards for the supply of its emergency

stockpile to our competitors, our business will be harmed and it is unlikely that we will be able to ultimately commercialize our competitive drug candidate.

In addition, the determination of when and whether a drug is ready for large scale purchase and potential use will be made by the government through consultation with a number of government agencies, including the FDA, the NIH, the CDC and the Department of Homeland Security. Congress has approved measures to accelerate the development of bio-defense drugs through NIH funding, the review process by the FDA and the final government procurement contracting authority. While this may help speed the approval of our drug candidates, it may also encourage competitors to develop their own drug candidates.

The market for government stockpiling of H5N1 medicines and other antiviral drugs in the Strategic National Stockpile is fairly new and uncertain.

At the present many governments have already stockpiled influenza medicines for H5N1. We cannot predict with certainty the size of the market, if any for all of the antiviral drugs that the governments may want to stockpile. Consequently, we cannot predict whether sales, if any, to governments will be sufficient to fund our business plan and commence revenue-generating operations.

***If the U.S. government fails to continue funding bio-defense drug candidate development efforts or fails to purchase sufficient quantities of any future bio-defense drug candidate, we may be unable to generate sufficient revenues to continue operations.***

We hope to receive funding from the U.S. government for the development of our bio-defense drug candidates. Changes in government budgets and agendas, however, may result in future funding being decreased and de-prioritized, and government contracts typically contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding, and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U.S. government fails to continue to adequately fund R&D programs, we may be unable to generate sufficient revenues to continue operations. Similarly, if we develop a drug candidate that is approved by the FDA, but the U.S. government does not place sufficient orders for this drug, our future business may be harmed.

#### Risks Related to the Biotechnology/Biopharmaceutical Industry

***The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with enterprises equipped with more substantial resources than us.***

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition based primarily on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain government approval for testing, manufacturing and marketing.

Our anti-influenza drug in development, Flucide, would compete with neuraminidase inhibitors Tamiflu and Relenza, anti-influenza drugs that are sold by Roche and Glaxo SmithKline (GSK), respectively. Generic competitors include amantadine and rimantadine, both oral tablets that only inhibit the replication of the influenza A virus. BioCryst Pharmaceuticals, Inc. is developing IV Infusions formulations of peramivir, an influenza neuraminidase inhibitor, for the treatment of influenza. Peramivir is approved in Japan and had obtained emergency use authorization in the US. Several H5N1 bird flu, and influenza novelH1N1/2009 vaccines are also in development worldwide. Several companies are developing anti-influenza drugs and vaccines.

We have recently completed preliminary animal studies against HIV that have resulted in the finding that certain of our drug candidates were superior to the oral HAART cocktail in SCID-hu Thy/Liv humanized mice lethally infected with HIV-I. We thus believe that we have a very strong lead drug identified against HIV. There are several companies with anti-HIV drugs in the market. A new drug, maraviroc from Pfizer has recently been approved, which falls in a new class called CCR5-blockers. Prior to this, two new drugs in a new class called Integrase Inhibitors have been approved. A drug in the class called Entry & Fusion Inhibitors, enfuvirtide, (Fuzeon™, Roche) has also been available. Additionally, the classical drugs, NRTI's, NNRTI's and PI's (protease inhibitors) are used in various combinations. A three drug combo has been approved. A four-drug combo is expected to be approved soon. The HIVCide-I nanoviricide is expected to act by a very different kind of mechanism, defining a new class of drugs, that is

complementary to the existing classes of anti-HIV drugs.

Our nanoviricide eye drops for viral diseases of the eye are currently under development. We have shown significant clinical efficacy in an animal model of EKC (adenoviral epidemic kerato-conjunctivitis). We have also shown very strong in vitro efficacy in HSV-1 reduction in cell cultures. We believe that this drug has a very good efficacy and safety profile, based on current data. There are no approved drugs against all viral diseases of the eye, or adenoviral EKC in particular. Several drugs are available for the treatment of herpes keratitis. Idoxuridine, vidarabine, acyclovir and its derivatives, are among the leading ones. Aganocide is under development. We believe that the nanoviricide eye drops should have a significant advantage in terms of reduced frequency of application needed and simple application procedure.

Our HCV drugs are at the earliest stage of development. There are a growing number of anti-HCV drugs being sold or in advanced stages of clinical development. Two new protease inhibitors have been approved. Companies with anti-HIV and HCV products include Bristol-Myers Squibb Company (BMS), Roche, Boehringer Ingelheim, Merck & Co., Inc. (Merck), Abbott Laboratories, and Schering Plough, in addition to several other pharmaceutical and biotechnology firms.

We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, government agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of numerous products under development or manufactured by competitors that are used for the prevention or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that potentially directly compete with our drug candidates even though their approach to such treatment is different.

We expect that our drug candidates under development and in clinical trials will address major markets within the anti-viral sector. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of the market introduction of some of our potential drugs or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop drugs, complete pre-clinical testing, clinical trials, approval processes and supply commercial quantities to market are important competitive factors. We expect that competition among drugs approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent protection.

***The successful development of biopharmaceuticals is highly uncertain. A variety of factors including, pre-clinical study results or regulatory approvals, could cause us to abandon development of our drug candidates.***

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including:

- pre-clinical study results that may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or a IND and later NDA, preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economical; and

the proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

Success in pre-clinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict.

#### Risks Related to the Securities Markets and Investments in Our Common Stock

***If we do not meet the continued listing standards of the NYSE MKT our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.***

As of September 25, 2013, our common stock was listed on the NYSE MKT, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If, however, we fail to satisfy the continued listing standards, such as, for example, the requirement that our shares not trade "for a substantial period of time at a low price per share" or that we not dispose of our principal operating assets or discontinue a substantial portion of our operations, among other requirements, the NYSE MKT may issue another non-compliance letter or initiate delisting proceedings.



If our securities are delisted from trading on the NYSE MKT and we are not able to list our securities on another exchange or to have them quoted on NASDAQ, our securities could be quoted on the OTC Bulletin Board or on the “pink sheets.” As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

***Our Company is subject to the periodic reporting requirements of the Securities Exchange Act of 1934 (the “Exchange Act”), which will require us to incur audit fees and legal fees in connection with the preparation of such reports. These additional costs will reduce or might eliminate our profitability.***

Our Company is required to file periodic reports with the Commission pursuant to the Exchange Act and the rules and regulations promulgated thereunder. To comply with these requirements, our independent registered auditors will have to review our quarterly financial statements and audit our annual financial statements. Moreover, our legal counsel will have to review and assist in the preparation of such reports. The costs charged by these professionals for such services cannot be accurately predicted at this time, because factors such as the number and type of transactions that we engage in and the complexity of our reports cannot be determined at this time and will have a major effect on the amount of time to be spent by our auditors and attorneys. However, the incurrence of such costs will obviously be an expense to our operations and thus have a negative effect on our ability to meet our overhead requirements and earn a profit. We may be exposed to potential risks resulting from new requirements under Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, the trading price of our Common Stock, if a market ever develops, could drop significantly, or we could become subject to Commission enforcement proceedings.

As currently required under Section 404 of the Sarbanes-Oxley Act of 2002, we are required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. The Company conducted an evaluation of the effectiveness of its internal control over financial reporting as of June 30, 2015. Based on its evaluation, the Company concluded that its internal controls over financial reporting were not effective to provide reasonable assurance that information required to be disclosed is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the Commission. The material weakness in the reporting process was due to the insufficient complement of personnel with the appropriate level of knowledge to identify and account for non-routine transactions such as derivative instruments. The report of our independent registered public accounting firm for the period ending June 30, 2015 indicated that our internal control over financial reporting was not effective as of June 30, 2015. We expect to continue to incur additional expenses and diversion of management’s time as a result

of performing the system and process evaluation, testing, and remediation required to comply with the management certification and auditor attestation requirements.

If we continue to fail to achieve and maintain the adequacy of our internal controls, as such standards are modified, supplemented, or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results would be harmed, investors could lose confidence in our reported financial information, the trading price of our Common Stock, if a market ever develops, could drop significantly, or we could become subject to the Commission's enforcement proceedings.

***Our Common Stock may be considered a “penny stock” and may be difficult to sell.***

The Commission has adopted regulations which generally define “penny stock” to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. Historically, the price of our Common Stock has fluctuated greatly. If, the market price of the Common Stock is less than \$5.00 per share it therefore may be designated as a “penny stock” according to Commission rules. The “penny stock” rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 together with their spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser’s written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the Commission relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common shares, and may result in decreased liquidity for our common shares and increased transaction costs for sales and purchases of our common shares as compared to other securities.

***Our stock price may be volatile and your investment in our common stock could suffer a decline in value.***

The price of our common stock, as quoted on the NYSE MKT may fluctuate significantly in response to a number of factors, many of which are beyond our control. These factors include:

- progress of our products through the regulatory process;
- results of preclinical studies and clinical trials;
- announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our products or our competitors’ products in both the United States and foreign countries;
- developments or disputes concerning patent or proprietary rights;
- general market conditions for emerging growth and pharmaceutical companies;
- economic conditions in the United States or abroad;
- actual or anticipated fluctuations in our operating results;
- broad market fluctuations; and
- changes in financial estimates by securities analysts.

***There is a risk of market fraud.***

Shareholders should be aware that, according to SEC Release No. 34-29093, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include (1) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (2) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (3) boiler room practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (4) excessive and undisclosed bid-ask differential and markups by selling broker-dealers; and (5) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses. We are aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities. The occurrence of these patterns or practices could increase the volatility of our share price.

As of September 25, 2013, our common stock was listed on the NYSE MKT national exchange. However, shareholders should be aware that the occurrence of the above-mentioned patterns and practices cannot be entirely precluded and that the occurrence of these patterns or practices could increase the volatility of our share price.

*A registration of a significant amount of our outstanding restricted stock may have a negative effect on the trading price of our stock.*

At June 30, 2015, shareholders of the Company had 15,688,161 shares (as adjusted) of restricted stock, or approximately 33% of the outstanding common stock. If we were to file a registration statement including all of these shares, and the registration is allowed by the SEC, these shares would be freely tradable upon the effectiveness of the planned registration statement. If investors holding a significant number of freely tradable shares decide to sell them in a short period of time following the effectiveness of a registration statement, such sales could contribute to significant downward pressure on the price of our stock.

***We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our capital stock must come from increases in the fair market value and trading price of the capital stock.***

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements, which we may enter into with institutional lenders, may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements and any other factors that the board of directors decides is relevant. Therefore, any return on your investment in our capital stock must come from increases in the fair market value and trading price of the capital stock.

***We may issue additional equity shares to fund the Company's operational requirements, which would dilute share ownership.***

The Company's continued viability depends on its ability to raise capital. Changes in economic, regulatory or competitive conditions may lead to cost increases. Management may also determine that it is in the best interest of the Company to develop new services or products. In any such case additional financing is required for the Company to meet its operational requirements. There can be no assurances that the Company will be able to obtain such financing on terms acceptable to the Company and at times required by the Company, if at all. In such event, the Company may be required to materially alter its business plan or curtail all or a part of its operational plans as detailed further in Management's Discussion and Analysis in this Form 10-K. While the Company currently has no offers to sell its securities to obtain financing, sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. In the event that the Company is unable to raise or borrow additional funds, the Company may be required to curtail significantly its operational plans as further detailed in Requirements for Additional Capital in the Management Discussion and Analysis of this Form 10-K.

The Company is authorized to issue up to 150,000,000 total shares of Common Stock on a post-split basis without additional approval by shareholders. As of June 30, 2015, we had 57,242,070 shares of common stock outstanding, warrants and options convertible to 6,512,390 shares of common stock and 3,583,445 shares of Series A Preferred

Stock convertible into 12,542,058 shares of Common Stock only in the event of a change in control.

As of September 25, 2013, our common stock is listed on the NYSE MKT national exchange.

***Large amounts of our common stock will be eligible for resale under Rule 144.***

As of June 30, 2015, 15,688,161 of 57,242,070 issued and outstanding shares (as adjusted) of the Company's common stock were restricted securities as defined under Rule 144 of the Securities Act of 1933, as amended (the "Act") and under certain circumstances may be resold without registration pursuant to Rule 144. In addition the 3,583,445 shares of Series A Preferred Stock are restricted and convertible into 12,542,058 shares of Common Stock only in the event of a Change of Control of the Company.

Approximately 2,285,033 shares of our restricted shares of common stock (as adjusted) are held by non-affiliates who may avail themselves of the public information requirements and sell their shares in accordance with Rule 144. As a result, some or all of these shares may be sold in accordance with Rule 144 potentially causing the price of the Company's shares to decline.

In general, under Rule 144, a person (or persons whose shares are aggregated) who has satisfied a six month holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by a person who is not an Affiliate, as such term is defined in Rule 144(a)(1), of the Company and who has satisfied a one-year holding period. Any substantial sale of the Company's common stock pursuant to Rule 144 may have an adverse effect on the market price of the Company's shares. This filing will satisfy certain public information requirements necessary for such shares to be sold under Rule 144.

*The requirements of complying with the Sarbanes-Oxley act may strain our resources and distract management.*

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Sarbanes-Oxley Act of 2002. The costs associated with these requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Historically, as a private company we have maintained a small accounting staff, but in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant additional resources and management oversight will be required. This includes, among other things, retaining independent public accountants. This effort may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we may need to hire additional accounting and financial persons with appropriate public company experience and technical accounting knowledge, and we cannot assure you that we will be able to do so in a timely fashion.

*Sales of additional equity securities may adversely affect the market price of our common stock and your rights in the Company may be reduced.*

We expect to continue to incur drug development and selling, general and administrative costs, and in order to satisfy our funding requirements, we may need to sell additional equity securities. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, any new securities issued may have greater rights, preferences or privileges than our existing common stock that may adversely affect the market price of our common stock and our stock price may decline substantially.

**ITEM 1B: UNRESOLVED STAFF COMMENTS.**

None.

## **ITEM 2: PROPERTIES**

### Description of Property

The Company's principal executive offices are located at 1 Controls Drive, Shelton, CT, and include approximately 18,000 square feet of office, laboratory, and cGMP-capable drug manufacturing space. These facilities are fully owned by the Company. There is no mortgage on these facilities.

We subcontract the laboratory research and development work to TheraCour Pharma, Inc., under the License Agreement with TheraCour. Management believes that the space is sufficient for the Company to monitor the developmental progress at its subcontractors.

## **ITEM 3: LEGAL PROCEEDINGS.**

From time to time, we are a party to legal proceedings arising in the ordinary course of business. We are not currently a party to any other legal proceedings that we believe could have a material adverse effect on financial condition or results of operations.

## **ITEM 4: MINE SAFETY DISCLOSURES.**

Not applicable.



**PART II****ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our Common Stock commenced trading on the NYSE MKT on September 25, 2013 under the symbol "NNVC". The Company's Common Stock, after the Company became a publicly traded company in May 2005, was initially traded on the Pink Sheets under the symbol NNVC and from June 29, 2007, through September 24, 2013, the Company's Common Stock has been quoted on the Over The Counter Bulletin Board. The table below sets forth the high and low prices for the Company's Common Stock for the quarters included within the past two fiscal years adjusted for the Company's 3.5 for reverse split which was effective on September 10, 2013. Quotations reflect inter-dealer prices, without retail mark-up, mark-down commission, and may not represent actual transactions. Since the Company's common stock trades sporadically, there is not an established active public market for its common stock. No assurance can be given that an active market will exist for the Company's common stock and the Company does not expect to declare dividends in the foreseeable future since the Company intends to utilize its earnings, if any, to finance its future growth, including possible acquisitions.

Quarter ended	Low price	High price
June 30, 2015	\$1.44	\$2.37
March 31, 2015	\$2.13	\$3.15
December 31, 2014	\$2.58	\$3.99
September 30, 2014	\$3.06	\$4.73
June 30, 2014	\$3.04	\$4.77
March 31, 2014	\$2.67	\$6.65
December 31, 2013	\$4.52	\$5.72
September 30, 2013	\$2.38	\$7.59
June 30, 2013	\$1.89	\$5.20
March 31, 2013	\$1.12	\$2.38
December 31, 2012	\$1.58	\$2.38
September 30, 2012	\$1.58	\$2.80

**Number of Shareholders.**

As of June 30, 2015, a total of 57,242,070 shares of the Company's common stock are outstanding and held by approximately 181 shareholders of record of our common stock. This number of shareholders does not reflect the persons or entities that hold their stock in nominee or street name through various brokerage firms. Of this amount,

41,554,097 shares are unrestricted, of which, 2,243,487 shares are held by affiliates. Approximately 2,285,023 shares are restricted securities held by non-affiliates, and the remaining 13,402,940 shares are restricted securities held by affiliates. These shares may only be sold in accordance with Rule 144. As of June 30, 2015, there were 5,976,675 warrants and 535,715 stock options to purchase the Company's Common Stock outstanding.

Dividends.

The Company has not paid any cash dividends since its inception. The Company currently intends to retain any earnings for use in its business, and therefore does not anticipate paying dividends in the foreseeable future.

Long-Term Incentive Plans Awards in Last Fiscal Year

None.

On September 3, 2013, effective September 10, 2013, NanoViricides, Inc. filed a Certificate of Change to its Articles of Incorporation pursuant to Section 78.209 of the Nevada Revised Statutes (the "Amendment"). The Amendment effectuated a reverse stock split of the Company's common stock, par value \$0.001 per share (the "Common Stock") by simultaneously decreasing the number of the Company's authorized and outstanding capital stock on a basis of 1 for 3.5 shares (the "Split"). All share amounts and per share amounts have been retroactively restated to reflect this reverse stock split.

Fiscal Year Ending June 30, 2013 Transactions

For the year ended June 30, 2013, the Board of Directors authorized the issuance of 571,429 shares of its \$.001 par value common stock with a restrictive legend for the payment of additional interest payable to the holders of the Company's Series B Convertible Debentures and recognized a charge for interest expense of \$665,497.

For the year ended June 30, 2013, the Board of Directors authorized the issuance of 71,428 shares of its \$.001 par value common stock with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$60,000.

For the year ended June 30, 2013, the Board of Directors authorized the issuance of 169,643 shares of its Series A Preferred stock \$.001 par value with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$445,044.

For the year ended June 30, 2013, the Scientific Advisory Board (SAB) was granted warrants to purchase 68,572 shares of common stock. The warrants expire during the fiscal year ending June 30, 2017. The Company recorded a consulting expense of \$141,600.

For the year ended June 30, 2013, the Company's Board of Directors authorized the issuance of 42,977 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$84,956.

For the year ended June 30, 2013, the Company's Board of Directors authorized the issuance of 8,521 shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of \$18,750.

Fiscal Year Ending June 30, 2014 Transactions

On September 9, 2013, the Company entered into a Securities Purchase Agreement (the "Agreement") with certain purchasers (the "Purchasers"), relating to the offering and sale (the "Offering") of units ("Units") at the aggregate purchase price of \$3.50 ("Purchase Price") per Unit, consisting of one share of the Company's common stock, par value \$0.001 per share (the "Common Stock") and a warrant to purchase one share of Common Stock ("Warrant"), issuable upon exercise of the Warrant at the exercise price of \$5.25 per share (the "Warrant Shares", collectively with the Units,

Common Stock and Warrant, the “Securities”) The Warrants are exercisable immediately and expire five years after issuance.

On September 12, 2013, post reverse split the Company and the Purchasers consummated the purchase and sale of the Securities (the “Closing”), and the Company raised gross proceeds of \$10,308,996 before expenses of the Offering of approximately \$618,540, which includes placement agent and attorneys’ fees. The Company issued 2,945,428 Units. On September 25, 2013 certain of these Unit Holders exercised 35,357 Warrants to purchase 35,357 shares of the Company’s common stock, par value \$0.001 per share, for gross proceeds of \$185,624. On January 21, 2014 and February 6, 2014 certain of these Unit Holders exercised 75,000 and 25,000 Warrants to respectively purchase 75,000 and 25,000 shares of the Company’s common stock, par value \$0.001 per share, for gross proceeds of \$393,750 and \$131,750 respectively.

The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the Securities and Exchange Commission on December 21, 2012. The Company, pursuant to Rule 424(b) under the Securities Act of 1933, has filed with the Securities and Exchange Commission a prospectus supplement relating to the Offering.

In connection with the Offering, pursuant to a Placement Agency Agreement dated September 9, 2013 among Midtown Partners & Co., LLC and Chardan Capital Markets, LLC (collectively, the “Placement Agents”), the Company paid the Placement Agents an aggregate cash fee representing 6% (3% each) of the gross Purchase Price paid by the Purchasers and warrants to purchase an aggregate of 2% (1% each) of the number of shares of Common Stock sold in the Offering (the “Compensation Warrants”) and substantially similar to the Warrants, at an exercise price equal to \$5.25 per share. The Compensation Warrants will otherwise comply with FINRA Rule 5110(g)(1) in that for a period of nine months after the issuance date of the Compensation Warrants, neither the Compensation Warrants nor any warrant shares issued upon exercise of the compensation warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the Closing. Upon issuance of the Compensation Warrants, the Company recognized Costs associated with the sale of securities ( a capital item ) of \$113,696 and a corresponding increase in additional paid in capital of \$113,696.

On September 25, 2013, the Company’s Common Stock began trading on the NYSE MKT exchange under the symbol NNVC.

On January 21, 2014, the Company entered into a Securities Purchase Agreement (the “Agreement”) with certain purchasers (the “Purchasers”), relating to the offering and sale (the “Offering”) of units (“Units”) at the aggregate purchase price of \$5.25 (“Purchase Price”) per Unit. The price per Unit was equal to a four percent (4%) discount to the 20-day VWAP of the Company’s stock price on Friday, January 17, 2014. The exercise price of the Warrant was equal to the closing price of the Company’s stock on Friday, January 17, 2014. Each Unit consisted of one share of the Company’s common stock, par value \$0.001 per share (the “Common Stock”) and Sixty-Five Hundredths (65/100) of a warrant to purchase one share of Common Stock (“Warrant”), issuable upon exercise of the Warrant at the exercise price of \$6.05 per share (the “Warrant Shares”, collectively with the Units, Common Stock and Warrant, the “Securities”). The Warrants are exercisable immediately and expire five years after issuance.

On January 24, 2014, the Company and the Purchasers consummated the purchase and sale of the Securities (the “Closing”) of 3,815,285 shares of Common Stock and 2,479,935 Warrants, and the Company raised gross proceeds of \$20,030,207 before expenses of the Offering of approximately \$1,200,000, which includes placement agent fees but does not include attorneys’ fees and other expenses. The Company intends to use the proceeds for general business purposes and expects that it will be able to accelerate the development of its drug candidate pipeline with this additional funding.

The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the Securities and Exchange Commission on December 21, 2012 and Form S-3MEF (File No. 333-193439).

In connection with the Offering, pursuant to a Placement Agency Agreement dated January 20, 2014 among Midtown Partners & Co., LLC and Chardan Capital Markets, LLC (collectively, the “Placement Agents”), the Company paid the Placement Agents an aggregate cash fee representing 6% of the gross Purchase Price paid by the Purchasers and warrants to purchase an aggregate of 2% of the number of shares of Common Stock sold in the Offering (the “Compensation Warrants”) representing two percent of the Shares and substantially similar to the Warrants, at an exercise price equal to \$6.05 per share. The Compensation Warrants will otherwise comply with FINRA Rule 5110(g)(1) in that for a period of six months after the issuance date of the Compensation Warrants, neither the Compensation Warrants nor any warrant shares issued upon exercise of the compensation warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the Closing.

Unregistered Securities

In December 2013, the Company issued 7,143 shares of Common Stock with a restrictive legend at \$3.50 per share upon the exercise of Warrants.

For the year ended June 30, 2014, the Board of Directors authorized the issuance of 571,429 shares of its \$.001 par value common stock with a restrictive legend for the payment of additional interest payable to the holders of the Company's Series B Convertible Debentures and recognized a charge for interest expense of \$2,605,716.

For the year ended June 30, 2014, the Company's Board of Directors authorized the issuance of 29,662 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$102,001.

For the year ended June 30, 2014, the Company's Board of Directors authorized the issuance of 13,146 shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of \$45,000.

For the year ended June 30, 2014 the Board of Directors authorized the issuance of 203,079 shares of its Series A Preferred stock \$.001 par value with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$2,123,014.

For the year ended June 30, 2014, the Company authorized the issuance of 71,430 shares of its \$.001 par value common stock with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$287,860.

For the year ended June 30, 2014 the Scientific Advisory Board (SAB) was granted warrants to purchase 72,439 shares of common stock. The warrants expire during the fiscal year ending June 30, 2018. The Company recorded a consulting expense of \$199,849.

The estimated fair value of the preferred shares issued to Company employees as a whole for the fiscal year ended June 30, 2014 was calculated to be \$2,123,014. There are no assurances that such estimated fair value represents a market value between a willing buyer and seller.

Fiscal Year Ending June 30, 2015 Transactions

On July 17, 2014 the Company filed a registration statement on Form S-3 (the "Form S-3") registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009, ("Old Warrants") as described more fully in the Form S-3 (the "Registered Warrants"). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. Holders of the Old Warrants were required to submit Notice of Exercise by August 15, 2014, or their warrants would expire. The Company received Notices to Exercise Warrants and the exercise price to purchase an aggregate of 1,926,656 shares of the Company's common stock at the exercise price of \$3.50 per share for an aggregate purchase price of \$6,743,297.

On February 1, 2015 the Company's Board of Directors authorized the issuance of 571,433 shares of the Company's \$0.001 par value common stock as annual interest payable to holders of the Company's Series B Debentures. The Company recorded interest expense of \$1,502,870 for the year ended June 30, 2015 calculated using the fair market value of the Company's common stock on the date issued.

Unregistered Securities

On July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debentures, the Company issued 187,000 Shares of its Series A Convertible Preferred stock to Dr. Milton Boniuk, pursuant to the terms of the Debenture. The Company allocated the proceeds received between the Debenture and the Preferred Stock on a relative fair value basis. The amount allocated to the Preferred stock was \$1,152,297.

For the year ended June 30, 2015, the Scientific Advisory Board was granted fully vested warrants to purchase 68,592 shares of common stock at exercise prices between \$2.00- \$5.02 per share expiring in the fiscal year ending June 30, 2019. These warrants were valued at \$59,675 and recorded as consulting expense.



For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 200,508 fully vested shares of its Series A Convertible Preferred stock for employee compensation. The Company recorded an expense of \$852,760.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 2,858 shares of its Series A Convertible Preferred Stock which are fully vested for consulting services. The Company recorded an expense of \$24,474.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 35,154 shares of its common stock which are fully vested with a restrictive legend for consulting services. The Company recorded an expense of \$109,360 which is the fair value at date of issuance.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 16,408 shares of its common stock which are fully vested with a restrictive legend for Director services. The Company recorded an expense of \$45,000 which is the fair value at date of issuance.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 71,430 shares of its common stock which are fully vested, with a restricted legend, for employee compensation. The Company recorded an expense of \$125,003 which is the fair value at the date of issuance.

**USE OF PROCEEDS FROM SALES OF REGISTERED SECURITIES**

Thus far, the Company has used a portion of the net proceeds of the past offering, and intends to use the balance, for research and development and working capital

**ITEM 6: SELECTED FINANCIAL DATA**

The selected financial data presented below are for each fiscal year in the five-year period ended June 30, 2015. This data is derived from, and qualified by reference to, our audited financial statements and notes thereto appearing elsewhere in this Form 10-K.

**Statements of Operations Data:**

	Years Ended June 30,				
	2015	2014	2013	2012	2011
(in thousands, except per share amounts)					
Operating expenses:					
Research and development	\$3,660,322	\$5,131,523	\$4,292,909	\$4,265,933	\$4,155,846
General and administrative	3,402,778	3,535,849	2,297,470	1,815,816	2,273,609
Total operating expenses	7,063,100	8,667,372	6,590,379	6,081,749	6,429,455
Loss from operations	(7,063,100 )	(8,667,372 )	(6,590,379 )	(6,081,749 )	(6,429,455 )
Other income (expense):					
Interest income	160,859	171,001	55,587	46,787	14,339
Interest expense	(2,649,592 )	(3,092,550 )	(962,535 )		
Discount on convertible debentures	(1,175,344 )	(569,495 )	(129,006 )		
Change in fair value of derivatives	8,529,005	(1,443,200 )	(1,249,335 )	(172,245 )	(62,049 )
Total other income (expense), net	4,864,928	(4,934,244 )	(2,285,289 )	(125,458 )	(47,710 )
Loss before income taxes	(2,198,172 )	(13,601,616)	(8,875,668 )	(6,207,207 )	(6,477,165 )
Income tax provision	-	-	-	-	-
Net loss	\$(2,198,172 )	\$(13,601,616)	\$(8,875,668 )	\$(6,207,207 )	\$(6,477,165 )

NET LOSS PER COMMON SHARE

- Basic	\$ (0.04	) \$ (0.27	) \$ (0.19	) \$ (0.15	) \$ (0.16	)
- Diluted	\$ (0.09	) \$ (0.27	) \$ (0.19	) \$ (0.15	) \$ (0.16	)

Weighted average common shares  
outstanding

- Basic	56,553,848	51,225,622	45,892,549	42,763,481	39,765,976
- Diluted	59,220,515	51,225,622	47,606,835	42,763,481	39,765,976

**Balance Sheets Data:**

	As of June 30,				
(in thousands)	2015	2014	2013	2012	2011
Cash and cash equivalents	\$31,467,748	\$36,696,892	\$13,923,245	\$14,274,985	\$9,224,023
Working capital	31,081,278	36,437,242	13,343,441	12,809,544	89,169,141
Total assets	44,187,089	43,859,995	16,407,554	15,629,808	10,758,067
Long term liabilities	11,800,327	19,972,953	7,219,718	-	-
Accumulated deficit	(54,099,572)	(51,901,400)	(38,299,784)	(29,424,116)	(23,216,909)
Stockholders' equity	31,785,867	23,369,303	8,009,652	13,850,193	10,170,891

**ITEM 7: 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 Company's Annual Report on Form 10-K for the year ended June 30, 2015. Readers should carefully review the risk factors disclosed in this Form 10-K and other documents filed by the Company with the SEC.

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

**PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "NNVC believes," "management believes" and similar language. The forward-looking statements are based on the current expectations of NNVC and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report. Actual results may differ materially from results anticipated in these forward-looking statements. We base the forward-looking statements on information currently available to us, and we assume no obligation to update them.

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

### **Management's Plan of Operation**

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 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. 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. The Company may want to add further virus types to its drug pipeline. The Company would then need to negotiate with TheraCour an amendment to the Licensing Agreement to include those of such additional viruses that the Company determines it wants to follow for further development. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy.

The Company intends to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour Pharma, Inc., the exclusive source for these nanomaterials. The Company may manufacture these drugs itself, or under subcontract arrangements with external manufacturers that carry the appropriate regulatory licenses and have appropriate capabilities. The Company intends to distribute these drugs via subcontracts with distributor companies or in partnership arrangements. The Company plans to market these drugs either on its own or in conjunction with marketing partners. The Company also plans to actively pursue co-development, as well as other licensing agreements with other pharmaceutical companies. Such agreements may entail up-front payments, milestone payments, royalties, and/or cost sharing, profit sharing and many other instruments that may bring early revenues to the Company. Such licensing and/or co-development agreements may shape the manufacturing and development options that the Company may pursue. The Company has received significant interest from certain 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.

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 the sales of securities under our shelf registration and the private placement of common stock (*See*, Item 5). The Company does not currently have any long term debt, other than Series B Convertible Debentures of \$6M and the Series C Convertible Debentures of \$5M presented in the Financial Statements and more fully described herein. 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.

#### Collaborative Agreements and Contracts

(See also “Our Collaborations and Service Contracts in Brief” elsewhere in this report.)

On December 23, 2005, the Company signed a Memorandum of Understanding (MOU) with the National Institute of Hygiene and Epidemiology in Hanoi (NIHE), a unit of the Vietnamese Government’s Ministry of Health. This Memorandum of Understanding calls for cooperation in the development and testing of certain nanoviricides. The parties agreed that NanoViricides will retain all intellectual property rights with respect to any resulting product and that the initial target would be the development of drugs against H5N1 (avian influenza). NIHE thereafter requested that we develop a drug for rabies, a request to which we agreed. The initial phase of this agreement called first for laboratory testing, followed by animal testing of several drug candidates developed by the Company. Preliminary laboratory testing of FluCide™-I, AviFluCide-ITM and AviFluCide-HPTM were successfully performed at the laboratories of the National Institute of Hygiene and Epidemiology in Hanoi (NIHE), against both clade 1 and clade 2 of H5N1 virus isolated in Vietnam. Successful animal testing of RabiCide-ITM, the Company’s rabies drug, was performed in Vietnam during the first half of 2007, and reproducibly repeated in 2008. Rabies testing can safely be done at their BSL2 facility. The H5N1 animal testing requires a BSL3 (biological safety laboratory level 3) laboratory. NIHE has acquired a BSL3 animal testing capacity during 2008.

We have finalized execution of a Materials Cooperative Research and Development Agreement (M-CRADA) with the Centers for Disease Control and Prevention (CDC), Atlanta, GA in July, 2008. This agreement was initiated based on our success against Rabies in the animal studies conducted at NIHE Vietnam. Preliminary animal studies against Rabies were expected to start in the last quarter of calendar year 2009 or first quarter of calendar year 2010. The Company has lowered the priority of this program during the recent economic crisis in order to use our resources most effectively. Subsequent to the agreement execution, the Company has supplied certain materials to CDC for testing. This testing, if successful, is expected to expand to involve potential use of nanoviricides as (1) a post- infection therapeutic drug against rabies, possibly in conjunction with a rabies vaccine, and (2) a post-exposure prophylactic drug against rabies, to replace costly human or monoclonal antibodies, possibly in conjunction with a rabies vaccine. To date, there is no effective post-infection therapeutic against rabies. Post-exposure prophylaxis market has been estimated to be as much \$300M to \$500M worldwide.

We finalized a CRADA with Walter Reed Army Institutes of Research (WRAIR) to develop collaboratively antiviral agents against all four types of dengue viruses in April, 2007. Preliminary work has commenced under this CRADA. This CRADA will need to be renegotiated due to changes in funding requirements at WRAIR. The Company has not renewed this agreement.

We finalized a Materials Transfer Agreement (MTA) with the United States Army Institute of Infectious Diseases (USAMRIID) to develop antiviral agents against Ebola, Marburg and other hemorrhagic viruses in October 2007. Preliminary studies began in February 2008. Certain nanoviricides candidates were found to be highly successful against Ebola virus in pre-clinical cell culture studies. Ebola virus is known to produce, in vivo, a soluble decoy protein that is a portion of its surface glycoprotein. If the nanoviricides that were successful in the in vitro studies bind to the decoy protein portion of the Ebola virus envelope, then we would expect that the nanoviricides would be neutralized in vivo by the decoy protein. We are therefore developing novel ligands that would potentially bind to the Ebola virus glycoprotein portion that is known to be not a part of the decoy protein. The MTA was extended for another year in October, 2009 to continue these studies. The Company has lowered the priority of this program during the recent economic crisis in order to use our resources most effectively.

We finalized an agreement with a Medical Institute to perform animal studies of our eye drop formulation of nanoviricides against viral EKC (viral Epidemic Kerato-conjunctivitis) in March, 2008. The first EKC-Cide<sup>TM</sup>-I animal study was completed in June, 2008. Biochemical testing of the samples is continuing. The study indicated that the best nanoviricide drug candidate showed excellent clearance of clinical signs of the disease, viz. redness of the eye as well as sticky exudates, in a short time after treatment.

On May 6, 2009, the Company entered into a Clinical Study Agreement with THEVAC, LLC, a company affiliated with the Emerging Technology Center of the Louisiana State University. TheVac performed biological testing of certain anti-herpes nanoviricides. TheVac conducted studies on the effect of anti-herpes nanoviricide drug candidates against certain herpes simplex viruses in cell culture models.

On May 13, 2010, the Company announced that it had entered into a Research and Development Agreement with Professor Ken Rosenthal Lab at NEOUCOM (now called NEOMED). Professor Rosenthal has developed in vitro or cell culture based tests for identifying the effectiveness of antiviral agents against HSV. He has also developed a skin lesion mouse model for HSV infection. Dr. Rosenthal has been involved in the evaluation of HSV vaccines as well as anti-HSV drugs. His laboratory has developed an improved mouse model of skin-infection with HSV to follow the disease progression. This model has been shown to provide highly uniform and reproducible results. A uniform disease pattern including onset of lesions and further progression to zosteriform lesions is observed in all animals in this model. This uniformity makes it an ideal model for comparative testing of various drug candidates. Dr. Rosenthal is a professor of microbiology, immunology and biochemistry at Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOMED). He is a leading researcher in the field of herpes viruses. His research interests encompass several aspects of how herpes simplex virus (HSV) interacts with the host to cause disease. His research has addressed how HSV infects skin cells and examined viral properties that facilitate its virulence and ability to cause encephalitis.



In addition, Dr. Rosenthal has also been studying a viral protein that makes the HSV more virulent by helping the virus to take over the cellular machinery to make copies of its various parts, assemble these parts together into virus particles and release the virus to infect other cells. He is also researching how the human host immune response works against HSV for the development of protective and therapeutic vaccines.

On August 16, 2010, the Company reported that its anti-Herpes drug candidates demonstrated significant efficacy in the recently completed cell culture studies in Dr. Rosenthal Lab at NEOMED. Several of the anti-Herpes nanoviricides® demonstrated a dose-dependent maximal inhibition of Herpes virus infectivity in a cell culture model. Almost complete inhibition of the virus production was observed at clinically usable concentrations. These studies employed the H129 strain of herpes simplex virus type 1 (HSV-1). H129 is an encephalitic strain that closely resembles a clinical isolate; it is known to be more virulent than classic HSV-1 laboratory strains. The H129 strain will be used in subsequent animal testing of nanoviricides. Since then the Company was optimizing formulations for use in the dermal HSV-1 H129c infection animal model in the Rosenthal lab. The Company also continued to further optimize the anti-herpes nanoviricides. Our herpes program was run at a lower priority than other programs until recently. In April 2015, after only 4 cycles of SAR (Structure-Activity-Relationship based improvements), our anti-herpes nanoviricides demonstrated strong effectiveness in the lethal HSV-1 H129c dermal infection model in the Rosenthal Lab at NEOMED. Treatment with certain nanoviricides caused significant improvements in the clinical observations, and led to >85% survival of the infected animals, wherein 100% of the untreated animals died within 10 days. In August 2015, the Company reported that these results were reproduced in dermal animal model at Transpharm, with 100% of the nanoviricides treated animals surviving.

The HerpeCide program has thus advanced to the lead identification stage this year. We are now working on this program with a high priority, in parallel with our Injectable FluCide program.

On May 17, 2010, the Company announced that it had signed a research and development agreement with the University of California, San Francisco (UCSF), for the testing of its anti-HIV drug candidates. Most recently, the Company's anti-HIV injectables animal testing was performed by KARD Scientific.

The Company's anti-HIV drug testing in cell cultures is performed at the Southern Research Institute in Frederick, MD.

On February 16, 2010, the Company announced that it had signed a research and development agreement with Dr. Eva Harris's laboratory at the University of California, Berkeley (UC Berkeley). Under this agreement, Dr. Harris and coworkers will evaluate the effectiveness of nanoviricides® drug candidates against various dengue viruses. Cell culture models as well as in vivo animal studies will be employed for testing the drug candidates. Dr. Eva Harris is a Professor of Infectious Diseases at UC Berkeley. She is a leading researcher in the field of dengue. Her group has developed a unique animal model for dengue virus infection and disease that effectively emulates the pathology seen in humans. In particular, the critical problem of dengue virus infection, called "Antibody-Dependent Enhancement" (ADE), is reproduced in this animal model. When a person who was previously infected with one serotype of dengue virus is later infected by a different serotype, the antibodies produced by the immune system can lead to increased severity of the second dengue infection, instead of controlling it. ADE thus can lead to severe dengue disease or dengue hemorrhagic fever (DHF).

The above collaborations, subcontract, or service contract agreements, and our on-going animal studies at KARD scientific were sufficient to perform preliminary evaluations of effectiveness and safety of our drug candidates against a number of diseases.

In July 2011 we signed an agreement with Biologics Consulting Group to help us with our regulatory strategy and filings.

In July 2012 we signed an agreement with Australian Biologics Pty Ltd to help us with our regulatory strategy and filings in Australia, and to help us with potentially developing clinical trials programs in Australia.

As we advanced our drug programs further, we have continued to engage into additional collaborations to help us with the various studies that are needed for developing an Investigational New Drug application (IND) for the US FDA or equivalent regulatory applications for other agencies.

In May 2013, we retained Coté Orphan Consulting (COC), headed by Dr. Tim Coté, to help us with identifying orphan drug indications in our portfolio and to perform the regulatory agency submissions needed for obtaining orphan drug designations for those drugs.

In April 2014, we finalized a Master Services Agreement (MSA) with Public Health England (PHE), UK the British government's equivalent of the U.S. Centers for Disease Control,. This agreement allows for animal efficacy evaluation of various nanoviricides drug candidates against viruses of mutual interest at the BSL2, BSL3 or BSL4 facilities at PHE-UK as the case may be. Previously, we had signed a Non-Disclosure Agreement with PHE in July 2013. The MSA allows the scientists at Public Health England to develop a specific proposal for the testing of different nanoviricides, such as FluCide™, against viruses of “mutual interest” to both organizations.

In May 2014, we executed a Master Services Agreement with Integrated Biotherapeutics, Inc. (“IBT”), Gaithersberg, MD, a provider of pre-clinical anti-viral evaluation services. We intend to perform certain influenza drug candidate studies at IBT.

In September 2014, we signed an agreement with BASi. BASi is a pre-clinical contract services organization that specializes in cGLP and GLP-like safety and toxicological testing of drug candidates and preparation of the “Tox Package” section of an IND application. BASi performed a GLP-like preliminary safety and toxicology study in which there were no significant compound related adverse events found. Our safety and toxicology studies for FluCide are being conducted by BASi for submission with an IND application. BASi will also perform the safety toxicology studies for the anti-herpes nanoviricide drug candidates in our HerpeCide program.

In January 2015, we commenced a master pre-clinical studies agreement with TransPharm Preclinical Solutions (“TransPharm”), a pre-clinical research services organization (CRO) in Jackson, MI. TransPharm has and will perform the topical dermal efficacy studies for our anti-HSV drug candidates. The agreement can also be extended to other indications for which TransPharm may already have an animal model or may be able to establish an animal model.

## Financings

On July 2, 2014, (the “Closing Date”), the Company accepted a subscription in the amount of \$5,000,000 for a 10% Coupon Series C Convertible Debenture (the “Debenture”) from Dr. Milton Boniuk, a member of the Company’s Board of Directors (the “Holder”). The Debenture is due on June 30, 2018 (the “Maturity Date”) and is convertible, at the sole option of the Holder, into restricted shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”) at the conversion price of \$5.25 per share of Common Stock. The Debenture bears interest at the coupon rate of ten percent (10%) per annum, computed on an annual basis of a 365 day year, payable in quarterly installments on March 31, June 30, September 30 and December 31 of each calendar year until the Maturity Date. Interest for the first quarter ending September 30, 2014 shall be calculated on a per diem basis from the Closing Date.

The Company, at its sole option, shall have the right, but not the obligation, to repurchase the Debenture at any time prior to the Maturity Date (the “Redemption”). If the Company intends to repurchase the Debenture, it shall deliver written notice to the Holder (the “Redemption Notice”) of its intent to redeem the Debenture on a date not less than five (5) days after the Redemption Notice (the “Redemption Date”). If the closing bid price of the Common Stock is greater than \$5.25 on the Redemption Date, unless the Holder, on or prior to the Redemption Date, elects to receive the “Redemption Payment”, as that term is defined herein, the Company shall pay to the Holder: (i) 952,381 shares of Common Stock in consideration of the exchange of the principal amount of the Debenture; and (ii) any and all accrued coupon interest. If on or prior to the Redemption Date, the Holder elects to receive the Redemption Payment, or the closing bid price of the Common Stock is less than \$5.25, the Company shall issue to the Holder: (i) the principal amount of the Debenture; (ii) any accrued coupon interest; (iii) additional interest of 7% per annum for the period from the date of issuance of the Debenture to the Redemption Date; and (iv) warrants to purchase 619,048 shares of Common Stock which shall expire in three years from the date of issuance at an exercise price of \$6.05 per share of Common Stock (the “Redemption Warrants”, and collectively with (i) – (iii), the “Redemption Payment”). The Company shall use its best efforts to register the shares underlying the Redemption Warrants under a “shelf” registration statement, provided same is available to the Company, in accordance with the provisions of the Securities Act.

As additional interest on the Debenture, the Company issued 187,000 shares of its restricted Series A Preferred Stock (the “Series A”) to the Holder. Each share of Series A votes at 9 votes per share. In addition, only in the event of a “change of control” of the Company, each Series A preferred share is convertible to 3.5 shares of its new common stock. A “change of control” is defined as an event in which the Company’s shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition. In the absence of a change of control event, the Series A stock is not convertible into Common Stock, and does not carry any dividend rights or any other financial effects.

The Offering was conducted directly by the Company without the use of a placement agent. Accordingly, no placement agent fees or other commissions were paid by the Company in connection with the Offering.

NanoViricides, Inc. (the “Company”) accepted notices to exercise warrants for the purchase of an aggregate of 1,926,656 shares of the Company’s common stock at the exercise price of \$3.50 per share for aggregate proceeds of \$6,743,297. On July 17, 2014, the Company filed a registration statement on Form S-3 (the “Form S-3”) registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009, as described more fully in the Form S-3 (the “Registered Warrants”). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. As of August 15, 2014, any Registered Warrants as specified above and not previously exercised have expired on September 5, 2014.

### **Subsequent Events**

On July 21, 2015 the Company entered into employment agreements with Anil Diwan, PhD, the Company’s founder, President and Chairman, and Eugene Seymour, MD, MPH, the Company’s Chief Executive Officer and Director effective July 1, 2015.

The Company and Dr. Diwan agreed Dr. Diwan would continue to serve as the Company’s President and Chairman of the Board of Directors 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 that vest equally over the term of the employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Diwan. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017.

The Company and Dr. Seymour agreed that Dr. Seymour would continue to serve as the Company's Chief Executive Officer and Director 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 that vest equally over the term of employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Seymour. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017.

### **The Company's Drug Pipeline**

Management believes that it has achieved significant milestones in the development of a number of antiviral nanoviricide drug candidates. We now have six high efficacy lead drug candidates against five commercially important diseases, namely, All Influenza viruses ((1) Injectable FluCide for hospitalized patients, and (2) Oral FluCide for the rest of the patients), (3) HIV (HIVCide-I), (4) Nanoviricide Eye Drops for Viral Infections of the External Eye, (5) HerpeCide™, a nanoviricide against Herpes "Cold Sores", genital herpes, and possibly shingles, and (6) DengueCide™, a designated Orphan Drug against Dengue viruses. Further, the Company has identified highly active nanoviricide drug candidates against Ebola/Marburg, and against Rabies. In addition, the Company has also established the technology feasibility for (a) broad-spectrum nanoviricides, and (b) Just-in-Time ADIF™ technology; both of which are well suited for stockpiling to defend against known as well as novel infectious diseases. Further, the HerpeCide program may result in multiple drug candidates as described below.

Management's beliefs are based on results of pre-clinical cell culture studies and in vivo animal studies using small animals such as various types of specially engineered mice and rabbits, as appropriate.

The Company has not yet performed detailed safety profile studies to be included in a "Tox Package" for submission to the FDA for any of our drug candidates. Our studies regarding safety of the various nanoviricide drug candidates to date have been preliminary and of a limited nature.

Of these, the Company's Injectable FluCide for hospitalized patients is in IND-enabling studies stage. We have performed initial safety and toxicology studies in two different animal models and demonstrated an excellent safety profile. This strong safety profile translated into a requirement of multiple kilograms of the drug substance for the Tox Package studies. The Company has undertaken a significant production scale-up program in order to satisfy this requirement. The older scale of 200g that was achieved at our older facilities in West Haven, CT is being re-implemented at our new scale-up and R&D facility in the Shelton campus. Further scale-up to a 500g scale is also progressing satisfactorily at the new facility. We believe that an additional scale-up to ~1kg per batch scale will be needed in order to produce the multi-kg quantity estimated for the Tox Package studies. We need to repeat each step of the synthesis at each scale at least twice, and characterize the resulting product in order to achieve reproducible

manufacturing. We have to adjust production parameters and perform the synthesis again until we can establish reproducible production process. To this end, we are implementing a number of process control tools and characterization techniques at present. These studies on production of this FluCide drug candidate are designed to enable reproducible production, and to inform the CMC section (“Chemistry, Manufacture, and Control”) of our IND application for the drug.

A majority of the novel work needed in the scale-up and CMC development of this drug candidate relates to the polymer portion of the drug substance. Therefore, we believe that these studies would also inform the production scale-up and CMC development of our other drug candidates.

In addition, subsequent to the reporting period, we reported in August 2015 that several drug candidates in our HerpeCide program have demonstrated excellent effectiveness against an aggressive strain of herpes, namely HSV-1 H129c in a lethal dermal infection model. This program has thus advanced to the lead selection stage. We have already planned the activities for the lead selection process. In consultation with our regulatory consultants, namely Biologics Consulting Group (BCG), we have identified at least four different indications that we could develop drug candidates and file IND applications for based on our broad-spectrum anti-herpes drug candidates. These include, a topical skin cream to treat oral herpes lesions, a topical skin cream for genital herpes treatment, an ocular solution (eye drops or gel) to treat herpes keratitis of the eye, and a topical skin cream to treat shingles. Of these, shingles is caused by VZV, which is a herpesvirus but is not in the same family as the herpes simplex viruses (HSV-1 and HSV-2) that cause the other diseases listed. We believe that the broad-spectrum nature of our anti-herpes nanoviricides would likely allow application against VZV in addition to HSV-1 and HSV-2. We are currently in the process of prioritizing within the HerpeCide program as to the indications to go after. We will continue to optimize the drug candidates and their formulations using the dermal HSV-1 infection model, which we believe would be applicable to the treatment of HSV-1 oral lesions, as well as the treatment of shingles. We are currently seeking additional collaborations or service providers for animal models of HSV-2 genital infection, and for HSV-1 herpes keratitis of the eye. We believe that we will be able to obtain the necessary collaborations soon. In addition, we are also seeking collaborations or service contracts for VZV efficacy evaluations. We are discussing our regulatory study pathways with BCG in order to engage the appropriate collaborations or service contracts.

One of the most important and impactful achievements for us has been our modern, state of the art, nanomedicines R&D, characterization, scale-up, and c-GMP-capable manufacturing facility in Shelton, CT. The history of this project is described elsewhere in this document. This 18,000 sqft facility contains class 100 clean rooms for multi-kilogram-scale synthesis and production of injectable drugs, as well as other nanomedicines. This is a custom manufacturing facility, where all of the equipment is manually assembled for the synthesis program at hand. Thus, we will be able to produce any of our nanoviricides drug candidates at this facility, from the gram scale required during early studies, to kg-scale that may be needed for tox package studies. In addition, once cGMP program for a specific drug substance is implemented, this facility can produce cGMP-like drug substance for human clinical studies. We intend to register the facility as a cGMP manufacturing facility as our drugs move to the clinical stage.

Controlled manufacture of multi-functional polymeric materials is a highly specialized proprietary knowledge-base that we have developed and continue to enhance as our programs go further. We were unable to advance our programs to clinical stage because of the lack of appropriate controlled manufacturing ability in the past. We now have our own facility where we can design, develop, and implement such controlled manufacture of our drug candidates. This has removed a major road-block that we have faced in the past.

We are now a unique company in the field of nanomedicines, in that we now have fully integrated operations from discovery, design, synthesis, to clinical scale production of nanomedicines.



We are happy to report that this new facility is now fully functional, and we have moved all of operations to this facility. This project took almost 18 months longer than was originally estimated, causing significant delays in our ability to advance our drug candidates to the clinical stage. However, we believe that we are now well equipped to advance our drug candidates to the clinical stage.

The Company thus has a strong and growing drug pipeline to take us several years into the future. The Company already has technologies in development that promise to yield even better drugs against various diseases as the drugs we are developing now approach their product end of lifecycle.

It should be noted that all of our studies to date were preliminary. Thus, the evidence we have developed is indicative, but not considered confirmative, of the capabilities of the nanoviricides technology's potential. With the success of these preliminary studies, the Company has decided to perform further pre-clinical studies that validate safety and efficacy of its materials and its various anti-viral drugs. Management intends to use capital and debt financing to enable the completion of these goals.

### **Requirement for Additional Capital**

As of June 30, 2015, we have a cash and cash equivalent balance of \$31,467,748 which will be sufficient to fund our currently budgeted operations for more than the next twenty four months.

We believe we currently have sufficient funds on hand to take at least one drug candidate into initial human clinical trials, and at least one or two additional candidates into regulatory submissions stage. We believe we will be pursuing injectable Flucide™ and one of the Herpeceide indications as our first drug candidates for an IND or equivalent regulatory submission and for initiating human clinical trials. After that, we estimate that we may need approximately an additional \$10M to \$15M for human clinical development of the nanoviricide antiviral eye drops, oral FluCide and DengueCide drug candidates towards IND filing over the next 36-48 months. The additional funds will also be needed to pay additional personnel, increased subcontract costs related to the expansion and further development of our drug pipeline, and for additional capital and operational expenditures required to file the corresponding IND applications.

Further, we anticipate incurring limited additional capital costs in the upcoming eighteen months for further improvements at our 1 Controls Drive, Shelton, Ct. facility, to support an initial new drug application filing with the FDA in accordance with our business plans.

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

1. Planned Research and Development Costs of \$12,000,000: Planned costs for in-vivo and in-vitro studies for pan-influenza Injectable Flucide, Herpeceide, Eye Nanoviricide, Oral FluCide, HIVCide, DengueCide, and Ebola/Marburg and Rabies programs, and planned costs for Phase I and Phase IIa human clinical trials of our injectable Flucide™ and topical Herpeceide drugs. Includes staffing costs of approximately \$3,500,000, for the scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to FDA compliance, as required for development of necessary data for filing an Investigational New Drug with the United States Food and Drug Administration.

2. Corporate overhead of \$4,000,000: This amount includes budgeted office salaries, legal, accounting, investor relations, public relations, and other costs expected to be incurred by being a public reporting company.

3. Capital costs of \$1,000,000: This is the estimated cost for equipment and laboratory improvements.

4. Clinical Trials Costs budgeted at \$7M, and an additional \$5M costs for clinical trials that may extend beyond the 24 month timeframe, as follows:

4a. If and when we initiate human clinical trials for Injectable FluCide, we anticipate approximately \$2 million total costs for the Phase I clinical trials, and approximately \$5 million for the Phase IIa (virus challenge human efficacy study) clinical trials. In a subsequent year, if Phase I and Phase IIa are successful, we anticipate approximately \$10 million for Phase IIb human clinical trials. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional costs. These estimates assume that FluCide is highly effective and therefore would require relatively few patients in each arm of the each trial in order to establish statistically significant results.

4b. If and when we initiate human clinical trials for Topical HerpeCide, we anticipate approximately \$1 million total costs for the Phase I clinical trials, and approximately \$4 million for the Phase II (study in recruited patients presenting with disease) clinical trials. In a subsequent year, if Phase I and Phase II are successful, we anticipate approximately \$10 million for Phase III human clinical trials. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional costs. These estimates assume that Topical HerpeCide is highly effective and therefore would require relatively few patients in each arm of the each trial in order to establish statistically significant results.

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

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

We believe that this coming year's work-plan will lead us to obtain certain information about the safety and efficacy of some of the drugs under development in animal models. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further studies in animal models to obtain necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles of our drug candidates. We believe these data will then enable us to file an Investigational New Drug application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

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

Management intends to use capital and debt financing, as required, to fund the Company's operations. 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.

#### Research and Development Costs

The Company does not maintain separate accounting line items for each project in development. The Company maintains aggregate expense records for all research and development conducted. Because at this time all of the Company's projects share a common core material, the Company allocates expenses across all projects at each period-end for purposes of providing accounting basis for each project. Project costs are allocated based upon labor hours performed for each project.

The Company has signed several cooperative research and development agreements with different agencies and institutions.

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

The following table summarizes the primary components of our research and development expenses as allocated, during the periods presented in this Annual Report on Form 10-K.

Table 3: R&amp;D Cost Allocations

	Year Ended June 30, 2015	Year Ended June 30, 2014	Year Ended June 30, 2013
All Influenzas: FluCide™	\$ 1,629,000	\$ 2,000,000	\$ 1,300,000
EKC-Cide™, other Eye Viral Infections	100,000	100,000	100,000
HIV-Cide™	100,000	414,000	800,000
Herpes infections	670,000	570,000	770,000
Dengue	100,000	600,000	267,000
Other (Ebola, and other projects)	300,000	99,730	100,000
Unallocated stock compensation	761,322	1,347,793	955,909
Total Research and development	\$ 3,660,322	\$ 5,131,523	\$ 4,292,909

**Time Schedules, Milestones and Development Costs**

In the event that funding can be achieved, we shall endeavor to achieve completion of the following events within the next twelve months:

The status of each of our major research and development projects is as follows:

**Table 4: Drug Development Status**

**Project 1                      Injectable FluCide™ against All Influenzas for Hospitalized Patients**

Current status                      We have declared a clinical candidate for influenza, NV-INF-1. This single drug is expected to be effective against most if not all influenza viruses. It is expected to be highly effective against all Influenza A viruses including bird flu H5N1 all clades, Highly Pathogenic Avian Influenzas of all types, subtypes and strains, seasonal Influenzas, H7N9, H3N2, as well as 2009/H1N1 epidemic virus. We are now engaging into advanced pre-clinical drug development, or IND-enabling studies. We are currently performing synthesis scale up studies and the studies required for the Chemistry, Manufacture and Controls section of an IND application. We have performed initial safety/toxicology studies in small animals- mice and rats - intended at helping with the design of the full Safety and Toxicology studies (“Tox Package”). We have prepared and used a first batch of materials for initial tox package studies. We intend to perform full Tox Package Studies when sufficient quantities become available. We also plan to perform additional animal studies as well as cell culture studies for efficacy of this drug candidate against a limited, unrelated influenza virus subtypes and strains. These studies are required for developing an Investigational New Drug (IND) application to the US FDA.

Nature, timing and estimated costs                      The Company had budgeted approximately \$1,500,000 for the material development, production and testing of this drug in 2012 and 2013, an additional \$2M in 2014, and spent approximately \$1.6M in 2015 on this project. These costs were paid from our available cash balances. Management has determined the results to be satisfactory. We now need to perform material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at \$2,500,000. If we are successful with the IND, we could begin Phase I and Phase II human clinical trials. We have estimated costs of approximately \$5,000,000 for the initial human clinical trials and associated expenses of this drug candidate. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies and the initial human clinical trials.

Anticipated completion date                      Preclinical stage workload remaining is approximately 12-18 months. However, because of the complexities of FluCide development including number of Influenza virus strains, etc., the project

speed is limited by our available third party collaborations. We intend to add additional collaborators in order to speed up the project. The Company anticipates filing an IND application after completion of the preclinical IND-enabling studies. Phase I drug testing to begin after the IND filing, and requires availability of cGMP-like manufactured product. The cGMP production capability is expected to be achieved in 9 to 12 months after we begin scale up production in the new facility.

Timing of  
commencement of  
expected material  
net cash inflows

If we complete our preclinical studies in the next 12~18 months, and also are able to produce clinical batches at the end of this period, we can expect Phase I and Phase II human clinical trials to be completed at the earliest by 2017-2018. Revenues may occur as a result of licensing the drug to another pharmaceutical partner at this stage. After Phase III clinical trials completion, revenues are expected to occur after FDA approval and marketing of the drug. Revenues may occur earlier if Flucide is approved for use in other countries or if the BARDA authority determines that FluCide should be stockpiled in the USG CDC stockpile of drugs for defense against pandemic influenza. If we are successful in partnering the drug with another pharmaceutical Company, we may see revenues much earlier than FDA approval. We believe that related to the high priority for our work on Ebola that we started due to the epidemic, our FluCide project plan has been delayed by about 6 to 9 months.

The potential market for Injectable FluCide may be in the range of \$300M to \$3B, depending upon market penetration and other conditions. Our current manufacturing capability at the Shelton plant may be estimated to be capable of supplying approximately \$10M-\$100M of the demand at full-scale operation, depending upon the cost of the drug and the dose required. This production scale is believed to be sufficient for initial market entry and is expected to be able to produce revenues that can fuel a larger manufacturing capacity needed for this drug product. However, the Company intends to license commercial manufacture of this drug to a commercial partner.

**Project 2 Oral FluCide™ against All Influenzas for Out-Patients**

**Current status**  
 We have developed a highly effective anti-influenza drug candidate that is active when given orally. We believe that we will be able to optimize this drug candidate and declare a clinical candidate with a limited amount of structure-activity-relationship (SAR) efficacy studies. This single drug is expected to be effective against most if not all influenza viruses. It is expected to be highly effective against all Influenza A viruses including bird flu H5N1 all clades, Highly Pathogenic Avian Influenzas of all types, subtypes and strains, seasonal Influenzas, H7N9, H3N2, as well as 2009/H1N1 epidemic virus. We are now engaging into advanced pre-clinical drug development, or IND-enabling studies. After completing the SAR studies, we will need to perform synthesis scale up studies and the studies required for the Chemistry, Manufacture and Controls section of an IND application. We believe that these studies will benefit from the studies already performed for the injectable FluCide version, as both the oral and injectable drug candidates employ the same virus-binding ligand. We intend to perform Safety and Toxicology studies (“Tox Package”) when sufficient quantities become available. We also plan to perform additional animal studies as well as cell culture studies for efficacy of this drug candidate against a limited, unrelated influenza virus subtypes and strains. These studies are required for developing an Investigational New Drug (IND) application to the US FDA.

**Nature, timing and estimated costs**  
 The Company had budgeted approximately \$500,000 for the material development, production and testing of this drug in 2012 and 2013. These costs were paid from our available cash balances. Management has determined the results to be satisfactory. We now need to perform SAR, followed by material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at \$2,500,000. The Company intends to undertake these oral influenza drug studies after advancing Injectable Influenza and HerpeCide drug candidates into clinical stage. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies. If we are successful with the IND, we could begin Phase I and Phase II human clinical trials. We have estimated costs of approximately \$10,000,000 for the initial human clinical trials of this drug candidate.

**Anticipated completion date**  
 Preclinical stage is expected to be completed in 9-24 months after filing an IND application for our Injectable FluCide drug candidate, based on our current prioritization, and is dependent on external contractor dependencies. The Company anticipates filing an IND application after completion of the preclinical IND-enabling studies. Phase I drug testing to begin after the IND filing, and requires availability of cGMP-like manufactured product. The cGMP production capability is expected to be achieved in 9 to 12 months following cGMP production of the injectable FluCide drug candidate.



Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely

The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable. The volume of demand at market introduction would be too large to be manufactured in our current facilities. However, we believe as we advance the Injectable FluCide into human clinical trials, we will be able to resolve the large scale manufacturing issues. We intend to license large-scale manufacture to a commercialization partner.

Timing of commencement of expected material net cash inflows

Due to several uncertainties and external dependencies in this project, initial revenues commencement date cannot be projected reliably at present. The potential market for oral FluCide may be in the range of \$1B to \$10B, depending upon market penetration.

**Project 3**

**Nanoviricide Eye Drops for all Viral Infections of the External Eye**

Current status

We have developed new, broad-spectrum. ligands that should be capable of enabling nanoviricide binding to herpes simplex viruses, while retaining the features that were previously successful against adenoviral EKC in clinical studies. The resulting nanoviricides have been tested against HSV-1 in cell cultures against two different strains of HSV-1, and a lead drug candidate has been identified. We are developing nanoviricide eye drop solution that should be capable of resolving the broad range of viruses that can cause infections of the external eye resulting in conjunctivitis or keratitis. The majority of these viruses are adenoviruses or HSV. We have recently found excellent effectiveness of our anti-herpes nanoviricide drug candidates against HSV-1. We believe that the same drug candidate should work well in the external eye application when formulated appropriately.

Nature, timing and estimated costs

The Company has budgeted approximately \$300,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. Should management determine the results to be satisfactory, we will need to obtain additional financing to perform material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at \$1,500,000. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies.

Anticipated completion date

Pre-clinical stage workload is estimated at 18-24 months. The efficacy related studies work plan is dependent upon availability of an external collaborator to perform ocular HSV infection and adenovirus infection studies in appropriate small animal models.

Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely

This project is dependent upon external collaborators and service providers who can perform the appropriate efficacy animal studies in small animals. We are currently working on engaging certain collaborators and service providers for this project. We believe we have relationships with ophthalmological doctors, surgeons, and institutes that would enable us to obtain collaborations for performing appropriate clinical trials for this drug. We believe that our current cGMP-like manufacturing facility has the capacity for the production of clinical quantities as well as for initial market entry. We may need to engage with a commercialization partner for manufacturing of the marketed drug, when ready.

Timing of commencement  
of expected material net  
cash inflows

We have brought this project at a high priority. Much of the drug candidate optimization for this project may be performed in the context of our HerpeCide project, although some special issues related to infection and treatment of the eye and the treatment of adenoviruses will remain and will need to be worked out as part of this project. As an alternative, the Company may advance a separate drug candidate against ocular herpes infections (herpes keratitis, HK), as an outgrowth of the dermal herpeptide program. Such a HK-only drug candidate may be expected to go into IND filing stage about 6-9 months after the IND filing of a dermal herpeptide.

115

The potential market size for an HK-only drug may be in the \$1B range. A single broad-spectrum drug that works against adenoviruses as well herpesvirus infections of the eye is much more desirable from a clinical standpoint. There is no treatment for adenoviral infections of the eye at present, although they are self-limiting.

**Project 4**

**HIVCide™, nanoviricide against HIV/AIDS viruses**

Current status

HIV-Cide is currently in preclinical studies. It is designed to mimic the site at which all HIV gp120 bind to the CD4 receptor. It is therefore expected to work against all HIV-1 subtypes and strains. HIV-Cide has been successfully tested in SCID-huThy/Liv mouse model and was found to have very high efficacy, equal to that of >25X (2,500%) dosage level of the triple drug HAART combination therapy. In vitro studies against two different HIV-1 strains were very successful. The Company is planning additional in-vivo and in-vitro studies at various institutions and subcontractors to further optimize the drug candidate.

Nature, timing and estimated costs

The Company has budgeted approximately \$2,000,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. Should management determine the results to be satisfactory, we will need to obtain additional financing to perform material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at \$7,000,000. We conduct HIVCide development at a slow pace because of the inherent long nature of these studies, and also because we do not have sufficient funds to dedicate to this project.

Anticipated completion date

Not known

Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely

The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable.

Timing of commencement of expected material net cash inflows

It is not known or estimable when net cash inflows from this project will commence if ever, due to the uncertainties associated with the completion of the product, regulatory submissions, approvals and market purchases of this product.

**Project 5**

**HerpeCide™ for Oral and Genital Herpes Cold Sores, “Fever Blisters” and Herpetic Ulcers**

Current status

HerpeCide is currently in preclinical studies against oral and genital herpes virus infections. It is being developed as a skin cream or gel formulation. We have recently found excellent effectiveness of our anti-herpes nanoviricide drug candidates against HSV-1 in animal studies using a highly aggressive, neurotropic, strain, namely H129c. We have accelerated the Topical HerpeCide program with the goal of developing IND candidates for several herpes virus disease indications.



Nature, timing and estimated costs      The Company has budgeted approximately \$600,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies.

Anticipated completion date      The IND-enabling studies workload is expected to be about 18-24 months. We have recently engaged with TransPharm preclinical services to perform animal efficacy studies using the animal model of Professor Ken Rosenthal.

The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable.

Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely      Clinical studies for a topical drug for dermal herpes breakouts are expected to be somewhat complex. While Phase I clinical studies are rather simple due to the topical nature, Phase IIa studies would require recruitment of patients when breakout occurs. We are working on developing relationships with clinical hospitals for this purpose. We believe that our current cGMP-like manufacturing facility has the capacity for the production of clinical quantities as well as for initial market entry. We may need to engage with a commercialization partner for manufacturing of the marketed drug, when ready.

Timing of commencement of expected material net cash inflows      The market size for an effective topical herpicide cream or gel is estimated to be around \$1-10B.

**Project 6      DengueCide™, a nanoviricide against all Dengue viruses**

Current status      Anti-dengue nanoviricide drug candidates are currently in preclinical studies. These candidates are being designed to mimic the human cell binding sites common to all types of dengue viruses. The best nanoviricide resulted in a 50% survival of mice in a uniformly lethal animal protocol simulating the ADE effect. This drug candidate has been designated an Orphan Drug for Dengue by the US FDA. This orphan drug designation carries with it several economic benefits. The Company therefore expects to expedite the development of this drug candidate.

The Company is planning additional in-vivo and in-vitro studies at various institutions and subcontractors during 2014-2014.

Nature, timing and estimated costs      The Company has budgeted approximately \$1,000,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. Should management determine the results to be satisfactory, we will need to obtain additional financing to perform material

Edgar Filing: NANOIRICIDES, INC. - Form 10-K

characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at \$2,000,000. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies.

Anticipated completion date      Not known

Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely

The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable.

Timing of commencement of expected material net cash inflows

It is not known or estimable when net cash inflows from this project will commence if ever, due to the uncertainties associated with the completion of the product, regulatory submissions, approvals and market purchases of this product.

**Project 7                      EbolaCide™: Anti-Ebola nanoviricide**

Current status

We restarted the anti-Ebola nanoviricides project due to the recent raging ebola epidemic in West Africa that appeared to be on course to become a major global public health threat. We tested our first set of novel anti-Ebola nanoviricides at USAMRIID in March 2015. The nanoviricide technology was found to be a good approach and one more cycle of drug optimization to improve efficacy was anticipated. In May 2015, the Company decided to re-focus its activities on FluCide and HerpeCide programs, as the epidemic had been brought under control and the urgency of the Ebola program was therefore no longer apparent. We will continue to develop drug candidates against Ebola as a background project, and we anticipate seeking non-diluting funding when opportunities become available.

We restarted this program based on our evaluation and belief that an optimized nanoviricide anti-Ebola drug candidate would have been the only viable option, had the epidemic continued to evolve into a global threat. Our belief is now supported by evidence. All of the anti-Ebola drug candidates that were advanced into clinical trials during the epidemic have been either rescinded by the sponsors or have not met statistically significant effectiveness end-points. These candidates include the siRNA therapeutics by Tekmira, antibody cocktail therapeutics by zMAPP, brincidofovir by Chimerix, and favipravir (T-705) by Takeda. In addition, Sarepta and BioCryst did not advance their anti-Ebola drug candidates into efficacy clinical trials.

Nature, timing and estimated costs

The Company has budgeted and spent approximately \$300,000 for the internal material development, production and testing of this drug in FY2015. These costs are being paid from our available cash balances.

Anticipated completion date

We do not have a completion date. This is now a background project.

Timing of commencement of expected material net cash inflows

We cannot project the timing of revenues, if any, from this project. We will continue to seek funding from non-dilutive sources for this project.

**Other drug candidates:**

Nanoviricides against Rabies, Hepatitis C Virus (HCV), Middle East Respiratory Syndrome human Coronavirus (MERS-CoV), and several other viral diseases are at various early stages of research and development and involve a substantial amount of uncertainty as to the development of these drug candidates. At this time, very little resources have been allocated to these drugs. However should the early studies of any of these drug candidates provide an indication of high efficacy, the corresponding drug candidate will become a full-fledged drug development project and the Company will endeavor to seek additional funding for the necessary drug development work.

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.

The work-plan we have developed for the next twelve months is expected to enable us to file an investigational new drug application late in our 2015-2016 fiscal year, and we believe we have the funding needed for the same. Our work-plan is extremely dependent on external factors, collaborations, and unanticipated delays can occur. We have experienced unanticipated delays in construction, post-construction modifications, and equipment set-up at our new Shelton facility that cumulatively effectively delayed our work-plan towards IND filing of our first drug candidate by more than 18 months. However, we believe that most of those issues are now overcome.

Enabling the cGMP facility has been the major issue for us in the past in our progress towards regulatory filings. We believe that this issue should be resolved in the ensuing fiscal year, with a kg-scale pilot “cGMP-like” facility coming on line. A non-GMP 200g scale production setup is being worked on at present. This scale is sufficient for all of our anti-herpes drug candidates, and the eye nanoviricide drug candidate. Thus we anticipate that our anti-herpes drug development can be accelerated as this production capacity develops. cGMP-like production for the 200g scale should be enabled in 3-6 months after the 200g scale optimizations are completed.

During the scale up and optimization of our production level operations, we continue to work on a number of different polymer backbones (“nanomicelles”) and several antiviral ligands in order to make sure that different formulation and pharmacokinetic-pharmacodynamic (PK-PD) needs can be met during the PK-PD programs for our various drug candidates. While this loads up our initial activities, it is expected to de-risk the further drug development towards IND or regulatory filings by making available backup drug candidates with different PK-PD profiles.



This work-plan is expected to reduce certain risks 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 needed 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 further, studies on acute viral infectious diseases are expected to 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 needs.

We believe that we have sufficient funding for taking at least one of our drug candidates into initial clinical trials, and at least one or more additional candidates into the regulatory filing stage. We do not anticipate raising additional funds in the near future. When needed, management intends to use equity-based and debt financing, as required, to fund the Company's operations. Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain the additional financial resources necessary to fund its anticipated obligations beyond the next twenty-four months.

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

## Results of Operations

The Company is a biopharmaceutical company and does not have any revenue for the years ended June 30, 2015, 2014 and 2013.

### *Comparison of the Year End June 30, 2015 to the Year Ended June 30, 2014*

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

**Operating Expenses** - General and administrative expenses decreased \$ 133,071 to \$ 3,402,778 for the year ended June 30, 2015, from \$3,535,849 for the year ended June 30, 2014. The decrease in general and administrative expenses is generally attributable to a decrease in the valuation of stock compensation paid to employees. The recent decrease in the Company's share price resulted in a decrease in the compensation costs recognized. These decreases were offset by a reimbursement of litigation costs paid of \$150,000.

Research and development expenses for the year ended June 30, 2015 decreased \$1,471,201 to \$ 3,660,322 from \$5,131,523 for the year ended June 30, 2014. The cost of research and development increased, however, this year to year decrease is generally attributable to a decrease in the valuation of stock compensation paid to research scientists which is calculated based upon the Company's stock price at the date of issuance or, in regards to the Company's Series A Preferred Shares, the estimated fair value as calculated based upon certain assumptions including the Company's share price (See Note 8 to the Financial Statements), and to certain chemical inventories, supplies and other costs paid in the prior fiscal year.

**Other Income (Expenses)** – Interest income was \$160,859 and \$171,001 for the years ended June 30, 2015, and 2014, respectively. Interest income included interest on cash or cash equivalent deposits in interest-bearing account. The Company has incurred interest expense of \$2,649,592 and \$3,092,550 for the years ended June 30, 2015 and June 30, 2014 respectively. The Company amortizes the discount on its Series B and Series C Debentures which were calculated at issuance. The Company recognized an amortization of bond discount expense of \$1,175,344 and \$569,495 for the years ended June 30, 2015 and 2014, respectively. The increase in bond discount expense arises from the Series C Debenture issued on July 2, 2015.

**Income Taxes** – There is no provision for income taxes due to ongoing operating losses. As of June 30, 2015, we had estimated cumulative tax benefits and development tax credits and other deferred tax credits resulting in a deferred tax

asset of approximately \$26,400,000. This amount has been offset by a full valuation allowance.

**Net Loss** - For the year ended June 30, 2015, the Company had a net loss of \$2,198,172, or a basic loss per share of \$0.04 and fully diluted loss per share of \$0.09 compared to a net loss of \$13,601,616, or a basic loss per share of \$0.27 and a fully diluted loss per share of \$0.27 for the year ended June 30, 2014. The reduction in the Company's net loss from the year ended June 30, 2014 to the year ended June 30, 2015 of \$11,403,444 is generally attributable to decreases in non cash expenses and the gain resulting from the change in fair value of derivatives, and interest expenses and compensation paid in the Company's stock or other securities.

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

The Company had cash and cash equivalents of \$31,467,748 and \$36,696,892 at June 30, 2015 and 2014 respectively. On the same dates, accounts payable and accrued liabilities outstanding totaled \$600,895 and \$517,739, respectively.

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 \$54,099,572 and \$51,901,400 at June 30, 2015 and 2014, respectively.

The Company estimates that it can support current budgeted operations through June 30, 2017.

While our cash and cash equivalent balance is sufficient for us to continue our operations through June 30, 2017, it is insufficient to fully execute the Company's business plan. If the Company is unable to obtain debt or equity financing to meet its cash needs it may have to severely limit its business plan by reducing the funds it hopes to expend on pre-clinical studies and trials, and/or research and development projects.

### ***Comparison of the Year End June 30, 2014 to the Year Ended June 30, 2013***

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

**Operating Expenses** - General and administrative expenses increased \$1,238,379 to \$3,535,849 for the year ended June 30, 2014, from \$2,297,470 for the year ended June 30, 2013. The increase resulted from the Company's general increase in non-research and development expenditures associated with development of its various drug candidates, an increase in the valuation of stock compensation paid to employees which is calculated based upon the Company's

stock price at the date of issuance or, in regards to the Company's Series A Preferred Shares, the estimated fair value as calculated based upon certain assumptions including the Company's share price.

Research and development expenses for the year ended June 30, 2014 increased \$838,614 to \$5,131,523 from \$4,292,909 for the year ended June 30, 2013. This increase in the cost of research and development is largely attributable to the development of additional drug candidates and increased research and development payroll costs. The increase cost of research and development is also attributable to a increase in the valuation of stock compensation paid to research scientists.

**Other Income (Expenses)** – Net Interest income was \$171,001 and \$55,587 for the years ended June 30, 2014, and 2013, respectively. Net interest income in 2014 included interest on cash equivalent deposits in an interest-bearing account. The Company has incurred interest expense of \$3,092,550 and \$962,535 for the years ended June 30, 2014 and 2013, respectively. The Company amortizes the discount on its Series B and Series C Debentures which were calculated at issuance. The Company recognized an amortization of bond discount expense of \$569,495 and \$129,006 for the year ended June 30, 2014 and 2013 respectively. The year ending June 30, 2014 was the first full year in which the Company recognized interest on its debenture and bond discount expense and accounts for the increase in these expenses.

**Income Taxes** – There is no provision for income taxes due to ongoing operating losses. As of June 30, 2014, we had estimated cumulative tax benefits resulting from federal net operating loss carry-forwards of approximately \$11,104,134 and deferred research and development tax credits and other deferred tax credits resulting in a deferred tax benefit of approximately \$20,172,664. This amount has been offset by a full valuation allowance.

**Net Loss** - For the year ended June 30, 2014, the Company had a net loss of \$13,601,616, or \$ (\$0.27) per share (as adjusted) compared to a net loss of \$8,875,668, or (\$0.19) per share (as adjusted) for the year ended June 30, 2013. The increase in the Company's net loss from the year ended June 30, 2013 to the year ended June 30, 2014 of \$4,725,948 is generally attributable to an increase in non cash expenses for employee stock compensation, and interest expenses paid on debentures in cash and in the Company's stock.

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

The Company had cash and cash equivalents of \$36,696,892 at June 30, 2014 and 13,923,245 at June 30, 2013. On the same dates, accounts payable and accrued liabilities outstanding totaled \$1,226,960 and \$1,178,183 respectively.

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 \$51,901,400 at June 30, 2014. and \$38,299,783 at June 30, 2013.

*Off Balance Sheet Arrangements*

We have not entered into any off-balance sheet arrangements during the year ended June 30, 2015.

120

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

***Research and Development*** – Research and development expenses consist primarily of costs associated with the preclinical and or clinical trials of drug candidates, compensation and other expenses for research and development, personnel, supplies and development materials, costs for consultants and related contract research and facility costs. Expenditures relating to research and development are expensed as incurred.

***Accounting for Stock Based Compensation*** – The Company follows the provisions of ASC 718 – *Stock Compensation*, which requires the measurement of compensation expense for all shared-based payment awards made to employees and non-employee directors, including employee stock options. Shared-based compensation expense is based on the grant date fair value estimated in accordance with the provisions of ASC 718 and is generally recognized as an expense over the requisite service period, net of forfeitures.

***Accounting for Non-Employee Stock Based Compensation*** – The Company accounts for equity instruments issued to parties other than employees for acquiring goods or services under guidance of section 505-50-30 of the FASB Accounting Standards Codification (“FASB ASC Section 505-50-30”). Pursuant to FASB ASC Section 505-50-30, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the performance is complete or the date on which it is probable that performance will occur.

## RECENT ACCOUNTING PRONOUNCEMENTS

### **Recently Issued Accounting Pronouncements**

In August 2014, the FASB issued ASU No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” (“ASU 2014-15”). ASU 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently evaluating the impact of

the adoption of ASU 2014-15 on the Company's financial statements and disclosures.

In April 2015, the FASB issued ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30), "Simplifying the Presentation of Debt Issuance Costs," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU requires retrospective adoption and will be effective for fiscal years beginning after December 15, 2015 and for interim periods within those fiscal years. We expect the adoption of this guidance will not have a material impact on our financial statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by Item 8 appears after the signature page to this report.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES**

*(a) Dismissal of Independent Registered Public Accounting Firm*

On December 1, 2014, Li and Company, PC (“Li”) was dismissed as the independent registered public accounting firm of NanoViricides, Inc. (the “Company”). The Company’s Board of Directors and audit committee approved the dismissal of Li.

Li’s reports on the Company’s financial statements for the years ended June 30, 2014 and 2013, respectively, did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the years ended June 30, 2014 and 2013, and through December 1, 2014, there were no disagreements with Li on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Li, would have caused it to make reference thereto in connection with its reports on the financial statements for such years. During the years ended June 30, 2014 and 2013, and through December 1, 2014, there were no matters that were either the subject of a disagreement as defined in Item 304(a)(1)(iv) of Regulation S-K or a reportable event as described in Item 304(a)(1)(v) of Regulation S-K..



*(b) New Independent Registered Public Accounting Firm*

On December 2, 2014, the Company's Board of Directors, acting in the capacity of an audit committee, engaged EisnerAmper LLP ("Eisner") as the Company's new independent registered public accounting firm to act as the principal accountant to audit the Company's financial statements. During the Company's fiscal years ended June 30, 2014 and 2013, and through December 2, 2014, neither the Company, nor anyone acting on its behalf, consulted with Eisner regarding the application of accounting principles to a specific completed or proposed transaction or the type of audit opinion that might be rendered on the Company's financial statements, and no written report or oral advice was provided that Eisner concluded was an important factor considered by the Company in reaching a decision as to any such accounting, auditing or financial reporting issue.

**ITEM 9A. CONTROLS AND PROCEDURES**

Evaluation of Disclosure Controls and Procedures

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

As required by Exchange Act Rule 13a-15(b), the Company carried out an evaluation, under the supervision and with the participation of management, including its principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2015.

(a) Based upon an evaluation of the effectiveness of disclosure controls and procedures, our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") have concluded that as of the end of the period covered by this Annual Report on Form 10-K our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were not effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC and is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure due to the material weakness in internal control over financial reporting described below under "Management's Annual Report on Internal Control Over Financial Reporting."

To address the material weakness described below, the Company performed additional analysis and other procedures (as further described below under the subheading “Management’s Remediation Initiatives” to ensure that the Company’s financial statements were prepared in accordance with U.S. GAAP. Accordingly, the Company’s management believes that the financial statements included in this Form 10-K fairly present, in all material respects, the Company’s financial condition, results of operations and cash flows for the periods presented and that this Form 10-K does not contain any misstatement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the periods covered by this report.

(b) Changes in internal control over financial reporting. The Company has established an independent Board of Directors comprising three independent members and two executives who are also elected Directors. Under this Board the Company has established an independent Audit Committee, an independent Compensation Committee, an independent Nomination Committee, and an Executive Committee. The Company has met or exceeded corporate governance standards of the NYSE MKT, a national exchange.

### **Management's Annual Report on Internal Control Over Financial Reporting**

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

Management including Chief Financial Officer and Chief Executive Officer ("Management") conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2015. To evaluate the effectiveness of our internal control over financial reporting, management used the criteria described in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Framework"). Based on its evaluation under the *Internal Control - Evaluation Framework* (1992) management concluded that our internal control over financial reporting was not effective as of June 30, 2015 due to the material weakness described below.

Management concluded that the effectiveness of our internal controls over financial reporting as of June 30, 2015, was not effective because of a material weakness in the reporting process due to the insufficient complement of personnel with the appropriate level of knowledge to identify and account for non-routine transactions such as derivative instruments. The Company disclosed and reported this material weakness in conjunction with its restatement of its annual and interim financial statements for the fiscal year ended June 30, 2014, and for the interim financial statements for the period ended September 30, 2014.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Although management has implemented certain initiatives as described below as of June 30, 2015, and we believe that such initiatives will fully remediate the identified weakness, these initiatives have not been in operation for a sufficient period of time, nor has the Company initiated a new financial transaction containing derivatives, for the Company to obtain evidence of its operating effectiveness. Therefore Management has concluded that as of June 30, 2015, the material weakness in internal control over financial reporting described above has not been remediated for the current fiscal year.

### **Management Changes**

Management has made a number of changes in the finance organization with a focus on increasing the identification and evaluation of financial derivatives knowledge and improving financial reporting processes in the organization. In 2015, the Company appointed a new accounting manager with U.S. GAAP and financial derivative knowledge to supplement the staff charged with compiling and filing its U.S. GAAP results. In addition, the Company has established a financial reporting controls committee comprised of members of senior management. The committee was established to provide oversight to the Company's efforts for ensuring appropriate internal control over financial reporting including, but not limited to, remediation of the aforesaid material weakness and identifying and testing for potential internal control weakness in the financial reporting process to assure reliability and accuracy.

### **Management's Remediation Initiatives**

Since the identification of this material weakness, management has taken steps to strengthen the Company's financial control governance structure by, among other things, implementing a process of enhanced internal review of all financial transactions including engagement of outside specialists to evaluate our financial transactions as they may arise. In addition, we have hired an experienced accountant and certified public accountant as an accounting manager, to provide for additional oversight and controls. The actions that we are taking are subject to ongoing senior management review and Audit Committee oversight. Although management has implemented these initiatives as of June 30, 2015, and we believe that such initiatives will fully remediate the identified weakness, these initiatives have not been in operation for a sufficient period of time, nor has the Company initiated any new non-routine transactions, for the Company to obtain evidence of its operating effectiveness.

Our independent registered public accounting firm, EisnerAmper LLP, has audited our financial statements and the effectiveness of our internal control over financial reporting as of June 30, 2015. Their report is included in this form 10-K.

### **Changes in Internal Control Over Financial Reporting**

In prior years the Company reported the appointment of Milton Boniuk, Mukund Kulkarni and Stanley Glick as independent directors and members of the Audit Committee.

In May 2015, the Company hired an additional accountant and Certified Public Accountant as an Accounting Manager.

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 for the quarter ended June 30, 2015, that have

materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B Other Information**

None.

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CORPORATE GOVERNANCE**

The following table sets forth the names and ages of our current directors and executive officers, their principal offices and positions and the date each such person became a director or executive officer. Executive officers are elected Biannually by our Board of Directors. Each executive officer holds the office until he/she resigns, is removed by the Board or his/her successor is elected and qualified. Directors are elected annually by our stockholders at the annual meeting. Each director holds his/her office until the successor is elected and qualified or his/her earlier resignation or removal.

The following persons are the directors and executive officers of our company:

Name	Age	Title
Anil Diwan, PhD.	56	President; Chairman of the Board
Eugene Seymour, MD, MPH	74	Chief Executive Officer; Director
Stanley Glick, CPA	78	Director, Independent
Mukund S. Kulkarni, MD	67	Director, Independent
Milton Boniuk, MD	82	Director, Independent
Meeta Vyas	56	Chief Financial Officer

The Company's executive officers and directors are elected biannually and serve until their term expires.

**Eugene Seymour, MD, MPH**, age 74, has been Chief Executive Officer (CEO) and a director of the Company since consummation of the merger on June 1, 2005. From 1996 until May 2005 he has been a private investor and has held no corporate positions. During this period he formed a non-profit foundation that funded both testing and training programs for health workers in Asia and Africa. He was a consultant to the UN Global Program on AIDS and was sent to several countries, (Lithuania, Latvia, Estonia and Russia) to interact with local physicians and assist them in setting up testing programs. Dr. Seymour obtained a Master's degree in the Epidemiology of Infectious Diseases at UCLA in addition to his medical degree. He began clinical practice in Internal Medicine and joined the UCLA Medical School faculty. He left UCLA after two years and joined the USC faculty as Associate Professor. Dr.

Seymour served in the Medical Corps of US Army Reserve during the Vietnam era and attained the rank of Major. In 1986, he was requested by the US government to establish a testing laboratory and run a large-scale surveillance program for HIV prevalence in the Hispanic population in Los Angeles. His laboratory ended up testing over 50,000 people. In 1989, he founded StatSure Diagnostic Systems, Inc. (SDS) (formerly Saliva Diagnostic Systems, Inc.), raised capital and developed the rapid HIV antibody blood test (Hema-Strip). He took the company public in 1993 as CEO and President. He left SDS in 1996. Dr. Seymour holds 8 issued patents, and is married with three children, two of whom are physicians. The Company concluded Dr. Seymour's extensive experience in treating infectious disease and viruses, plus his public company experience, make him an ideal candidate to serve in these capacities.

**Anil Diwan, PhD**, age 56, has been President and the Chairman of the Board of Directors of the Company since consummation of the merger on June 1, 2005. Dr. Diwan simultaneously therewith and since its formation, has also served as the Chief Executive Officer and Director of AllExcel, Inc. (from 1995 to the present) and TheraCour Pharma, Inc. (from 2004 to the present) and is the original inventor of the technologies licensed to NanoViricides Inc., as well as the TheraCour polymeric micelle technologies and products based on them. Since 1992, he has researched and developed TheraCour nanomaterials. Dr. Diwan was the first to propose the development of novel pendant polymers for drug delivery that led to an explosion of research in pharmacological applications of polymeric micelles. Anil has won over 12 NIH SBIR grants. Dr. Diwan holds several issued patents, and threePCT international patent applications in various stages of prosecution in a number of countries, and, and has made intellectual property depositions of several additional patentable discoveries with the patent attorney. Dr. Diwan has held several scholastic distinctions, including an All-India 9th rank on the Joint Entrance Examination of all IIT's. He holds a Ph.D. in Biochemical Engineering from Rice University (1986) and B.S. in Chemical Engineering from Indian Institute of Technology (IIT) Bombay (1980). We concluded Dr. Diwan's experience plus his status as creator of the Company's technologies render him uniquely qualified to serve in these capacities.

**Stanley Glick, CPA**, age 78, was appointed as an independent Director and as chair of the Audit Committee of the Company on June 22, 2012. Mr. Glick has over forty years of experience in his long career of providing auditing, accounting, tax, and management advisory services, to clients in various industries. Mr. Glick has been a member of several Boards of Directors for not-for-profit organizations in the Westport, CT area. In particular, he has served as a Director and member of Audit Committee of "A Better Chance" of Westport, CT, from 2000 to 2005. From 1977 until present, Mr. Glick has managed an independent practice as a Certified Public Accountant in Connecticut and New York States. Prior to forming his own CPA firm, Mr. Glick was employed by local and regional CPA firms where he performed and supervised audits and financial reporting. Mr. Glick is a member of the American Institute of Certified Public Accountants, The Connecticut Society of Certified Public Accountants, and the New York State Society of Certified Public Accountants. He holds a Bachelor of Business Administration degree in Accounting from Baruch College of Business (now Baruch College of the City University of New York). Mr. Glick is married and lives in Trumbull, CT. We concluded that Mr. Glick's broad business, accounting and auditing experience meets the criteria of an independent director and an "audit committee Financial Expert. The Company has expanded and enhanced its Board of Directors by the appointment of Stanley Glick CPA, as an independent director. The Company understands that as an SEC-filing company trading on the over-the-counter bulletin-board, the Company is currently not required to appoint independent board members, and is not required to appoint an independent board member financial expert to chair its Audit Committee. However, the Company believes that an independent board member with expertise in financial reporting and management advisory services, chairing the audit committee, would provide additional assurances to the financial community and other users of the Company's financial statements. Mr. Glick's appointment as an independent director and audit committee chairman, significantly improves the Company's financial oversight and management.

**Mukund S. Kulkarni, MBA, PhD**, age 67, has been a Chancellor of Penn State Harrisburg since 2010 where Dr. Kulkarni joined in 1985 as a Professor of Finance in the School of Business Administration. Prior to becoming chancellor, he was senior associate dean for academic affairs from 2006-2010. Prior thereto and from 1996, he served as the director of the School of Business Administration. In addition to his administrative appointment, Dr. Kulkarni holds the rank of professor of finance. Dr. Kulkarni earned his bachelor's degree from Shivaji University located in Kolhapur, India and master's degrees from University of Pune located in Pune, India, and an M.B.A. from Marshall



University. He also earned a Doctorate in Economics from the University of Kentucky. Dr. Kulkarni is widely published in academic journals and has presented papers at several scholarly conferences. Dr. Kulkarni is an invited lecturer and consultant to several academic institutions in the U.S. and abroad, in addition to state government and nonprofit organizations. Dr. Kulkarni is widely engaged in social and civic activities in and around the Harrisburg region. He is member of several boards of civic and nonprofit organizations including the Harrisburg Regional Chamber of Commerce, United Way of the Capital Region, Modern Transit Partnership, and Asian Indian Americans of Central Pennsylvania, among others. He has delivered lectures and provided consultations to other business schools, government agencies, and non-profit organizations, and he has valuable corporate experience in the commercial banking industry. As a result of his valuable experience in the commercial banking industry and his vast academic background in economics and finance, the Company concluded Dr. Kulkarni was qualified to serve as a member of its Board of Directors.

**Milton Boniuk, MD**, age 82, is an astute and highly successful businessman and entrepreneur, in addition to being an accomplished eye surgeon, educator, and administrator. Dr. Boniuk is a renowned eye surgeon in private practice who specializes in Ocular Oncology and Oculoplastics. He is also the Caroline F. Elles Chair of Ophthalmology at the Alkek Eye Center at the Baylor College of Medicine. Dr. Boniuk has been a long term investor and strong supporter of NanoViricides, Inc. Dr. Boniuk is also well known for his philanthropic endeavors. Most recently, he gave \$28.5M to Rice University to establish The Boniuk Institute for the Study and Advancement of Religious Tolerance, following up on a previous \$5M gift for this cause. Dr. Boniuk earned his MD at the Dalhousie University, Halifax, Nova Scotia, Canada, followed by an internship at the Victoria General Hospital, Halifax, Nova Scotia, Canada, and Residency at the Center for Ophthalmology, Jefferson Medical College - Wills Eye Hospital, Philadelphia, PA. In addition, he served a Fellowship in Ophthalmic Pathology at the world-renowned Armed Forces Institute of Pathology, Washington, D.C. Dr. Boniuk has made significant contributions in cataract surgery, glaucoma, corneal dystrophies, retinal diseases and surgery. He is a nationally and internationally recognized expert in the pathology and surgical management of orbital and intra-ocular tumors. His description of the ocular pathology of the congenital rubella syndrome in 1967 was a landmark publication. Of note, Dr. Boniuk has made substantial medical contributions in areas that are of great significance to the Company, such as ocular adenoviral infections, that cause epidemic kerato-conjunctivitis (EKC). The Company has developed a drug candidate for EKC infection that was successfully tested in rabbits. These animals serve as a surrogate for the viral disease in human eyes. We concluded Dr. Boniuk's experience plus business acumen render him qualified to serve as a member of its Board of Directors.

**Meeta Vyas, SB, MBA**, age 56, is known as a strong leader with board level experience and successful achievements as a Senior Executive in a broad range of entities including publicly listed corporations, non-revenue generating entities, and medium to large size companies. Ms. Vyas has over twenty-five years of experience in performance and process improvement of both publicly listed companies and non-revenue producing entities, in areas ranging from Finance and Operations to Strategy and Management. Meeta holds the distinction of being the first Indian woman to be named CEO of a publicly listed U.S. corporation, Signature Brands, Inc., best known for "Mr. Coffee" and "Health-O-Meter" brand products. As CEO, acting COO and Vice Chairman of the Board of Signature Brands, Inc., she was responsible for the development and implementation of a turnaround plan, resulting in Signature's return to profitability and growth. Later, as the CEO of the World-Wide Fund for Nature - India (WWF-India) and then as a Vice President of the National Audubon Society (USA), both non-revenue generating entities, Meeta successfully raised unrestricted funding that significantly exceeded annual requirements and also instituted financial processes to measure a variety of performance metrics. Earlier in her career, she was responsible for designing the strategy and initiating the implementation plan for the highly successful information technology outsourcing program at General Electric ("GE"). Also at GE, Ms. Vyas ran GE Appliances' Range Products business unit having revenues exceeding \$1 Billion where her team doubled operating income in less than two years. Prior to that, as a management consultant with McKinsey and Company, she served publicly listed companies in chemicals, industrial, and technology markets, primarily focusing on growth strategies, valuations, post-merger integrations, and logistics operations. Ms. Vyas is married to Anil Diwan, the Company's President and Chairman and principal shareholder of TheraCour Pharma, Inc. Ms. Vyas holds a MBA in Finance from Columbia University's Graduate School of Business, and a SB in Chemical Engineering from the Massachusetts Institute of Technology.

#### AUDIT COMMITTEE

In June 2012, Stanley Glick, CPA was elected, as an independent member, to the Company's Board of Directors and the Chair of the Company's Audit Committee. Due to his education and extensive experience as a Certified Public Accountant, Mr. Glick meets the criteria of an independent director and an "Audit Committee Financial Expert" as provided in Release 33-8173 and 34-47235. In addition, in June, 2013, Milton Boniuk and Mukund S. Kulkarni were appointed as independent directors and members of the Audit Committee.

## CODE OF ETHICS

We have adopted a code of ethics meeting the requirements of Section 406 of the Sarbanes-Oxley Act of 2002. We believe our code of ethics is reasonably designed to deter wrongdoing and promote honest and ethical conduct; provide full, fair, accurate, timely and understandable disclosure in public reports; comply with applicable laws; ensure prompt internal reporting of violations; and provide accountability for adherence to the provisions of the code of ethic. Our code of ethics is filed as an exhibit to this Form 10-K.

**ITEM 11. EXECUTIVE COMPENSATION**

The following table reflects all forms of compensation for the years ended June 30, 2015, 2014 and 2013:

Name and Principal Position	Year	Salary	Bonus (\$)	Stock Award(s) (\$)	Option Awards(#)	All Other Compensation (\$)	Total (\$)
Eugene Seymour, CEO, Director	2015	\$300,000	\$ —	\$267,859	—	\$ —	\$567,859
	2014	\$291,667	—	\$770,861	—	\$ —	\$1,062,528
	2013	\$275,000	\$ —	\$187,387	—	\$ —	\$462,387
Anil Diwan President, Director	2015	\$300,000	\$ —	\$267,859	—	\$ —	\$567,859
	2014	\$291,667	—	\$770,861	—	\$ —	\$1,062,528
	2013	\$275,000	\$ —	\$187,387	—	\$ —	\$462,387
Meeta Vyas CFO Appointed May 13, 2013	2015	\$118,800	\$ —	\$222,980	—	\$ —	\$341,780
	2014	108,000	—	338,697	—	—	446,697
	2013	12,000	—	9,000	—	—	21,000

The following table sets forth for each named executive officer certain information concerning the outstanding equity awards as of June 30, 2015.

Name and Principal Position	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested	Market Value of Shares or Units of Stock that Have Not Vested	Equity Incentive Plan Awards: Number of Unearned Shares, Other Rights that Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Other Rights that Have Not Vested
-----------------------------	---	---	----------------------------	------------------------	---	---	--	--

Eugene Seymour, CEO and Director	142,857	-	\$ 0.35	September 26, 2015	—	—	—	—
Anil Diwan, President and Director	285,714	-	\$ 0.35	September 26, 2015	—	—	—	—
Milton Boniuk, MD	-	-	\$ -	-	—	—	—	—
Mukund Kulkarni	-	-	\$ -	-	—	—	—	—
Stanley Glick	-	-	\$ -	-	—	—	—	—
Meeta Vyas	-	-	\$ -	-	—	—	—	—

#### COMPENSATION OBJECTIVES

We believe that the compensation programs for the Company's executive officers should reflect the Company's performance and the value created for the Company's stockholders. In addition, the compensation programs should support the short-term and long-term strategic goals and values of the Company, and should reward individual contributions to the Company's success. Our compensation plans are consequently designed to link individual rewards with Company's performance by applying objective, quantitative factors including the Company's own business performance and general economic factors. We also rely upon subjective, qualitative factors such as technical expertise, leadership and management skills, when structuring executive compensation in a manner consistent with our compensation philosophy.

## ELEMENTS OF COMPENSATION

**BASE SALARY.** All full time executives are paid a base salary. Base salaries for our executives are established based on the scope of their responsibilities, professional qualifications, academic background, and the other elements of the executive's compensation, including stock-based compensation. However, at this time current total annual compensation is not in line with comparable companies, because our philosophy was to pay modest salaries with no bonus to conserve capital resources for future company growth. Our intent is to set executives' base salaries near the median of the range of salaries for executives in similar positions with similar responsibilities at comparable companies, in line with our compensation philosophy. Base salaries are reviewed annually, and may be increased to align salaries with market levels after taking into account the subjective evaluation described previously.

**EQUITY INCENTIVE COMPENSATION.** We believe that long-term performance is achieved through an ownership culture participated in by our executive officers through the use of stock-based awards. Currently, we do not maintain any incentive compensation plans based on pre-defined performance criteria. The Board of Directors has the general authority, however, to award equity incentive compensation, i.e. stock options, to our executive officers in such amounts and on such terms as the committee determines in its sole discretion. The Board of Directors does not have a determined formula for determining the number of options available to be granted. The Board of Directors will review each executive's individual performance and his or her contribution to our strategic goals periodically. With the exception of stock options automatically granted in accordance with the terms of the employment agreement with our executive officers, our Board of Directors grants equity incentive compensation at times when we do not have material non-public information to avoid timing issues and the appearance that such awards are made based on any such information. As additional compensation for the year ended June 30, 2015, under the Company's employment agreements, the Company issued 200,508 shares of the Company's Series A Preferred Stock and 71,430 of the Company's restricted Common Stock. The convertible preferred series A shares are subject to restriction on sale. The valuation applied to the shares was based upon an appraisal derived from the application of statistical calculations and based upon assumptions at the time of the appraisal that may not be realized.

## DETERMINATION OF COMPENSATION

The Company's executive compensation program for the named executive officers (NEOs) is administered by the Board of Directors. The Board of Directors makes independent decisions about all aspects of NEO compensation, and takes into account compensation data and benchmarks for comparable positions and companies in different applicable geographical areas. The Compensation Committee of the Board assists the Board in achieving these objectives.

The Company's current executives' compensation program as of the date of this report has been at the same level since 2005. The program is simplistic and is less structured than a more mature corporation. Two of our officers are founders or co-founders of the Company and their ownership in the Company has driven their philosophy to provide

modest salaries. The compensation structure was set to retain capital resources in the Company to further growth.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS, MANAGEMENT, AND RELATED STOCKHOLDERS MATTERS.**

The following table sets forth information relating to the beneficial ownership of the Company's common stock by those persons beneficially holding more than 5% of the Company's common stock, by the Company's directors and executive officers, and by all of the Company's directors and executive officers as a group as of June 30, 2015, on a post-reverse-split adjusted basis.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner (1)	Percent of Class	
TheraCour Pharma, Inc.(2) 135 Wood Street West Haven, CT 06516	9,619,170	16.8	%
Anil Diwan (2) (3) 135 Wood Street West Haven, CT 06516	2,082,310	3.64	%
Eugene Seymour (4) 135 Wood Street West Haven, Connecticut 06516	1,287,286	2.25	%
Milton Boniuk (5) 135 Wood Street West Haven, CT 06516	1,705,391	2.8	%
MuKund Kulkarni 135 Wood Street West Haven, CT 06516	126,184	0.22	%
Stanley Glick 135 Wood Street West Haven, CT 06516	9,805	0.01	%
Meeta Vyas (6) 135 Wood Street West Haven, CT 06516	147,021	0.26	%
All Directors and Executive Officers as a Group (7 persons)	14,877,167	25.98	%

(1) For each shareholder, the calculation of percentage of beneficial ownership is based upon approximately 57,242,070 shares of Common Stock outstanding as of September 15\_\_, 2015, and shares of Common Stock subject to options, warrants and/or conversion rights held by the shareholder that are currently exercisable or exercisable within 60 days, which are deemed to be outstanding and to be beneficially owned by the shareholder holding such options, warrants, or conversion rights. The percentage ownership of any shareholder is determined by assuming that the shareholder has exercised all options, warrants and conversion rights to obtain additional securities and that no other shareholder has exercised such rights.

(2) Anil Diwan, the Company's President and Chairman, also serves as the CEO and Director of TheraCour Pharma Inc. and owns approximately 70% of the outstanding capital stock of TheraCour. Anil Diwan has both



investment and dispositive power over the NanoViricides shares held by TheraCour Pharma, Inc. Does not include 2,000,000 shares of the Company's Series A Preferred Stock (the "Series A"), held by TheracourPharma, Inc. which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.

(3) Anil Diwan, President and Chairman of the Board of Directors. Includes 285,714 shares of common stock issuable upon exercise of options held by Dr. Diwan that are currently exercisable or will become exercisable within 60 days. Does not include 16,531,429 shares owned by TheraCour Pharma, Inc. (after calculating the Series A Convertible Preferred Stock (the "Series A Preferred Stock"), over which Dr. Diwan holds voting and dispositive power. Does not include 571,429 shares of Series A Preferred Stock which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.

(4) Eugene Seymour, Chief Executive Officer and Director. Includes 1,044,429 shares of NanoViricides common stock held by Dr. Seymour and 142,857 shares of NanoViricides common stock issuable upon exercise of options held by Dr. Seymour that are currently exercisable or will become exercisable within 60 days. Does not include 428,571 shares of the Company's Series A Preferred Stock (the "Series A") which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.

(5) Milton Boniuk, Independent Member of the Board of Directors. Includes 1,033,963 shares of common stock and warrants to purchase an additional 542,856 shares of common stock, held by Milton Boniuk and his wife Laurie. Does not include 380,954 shares of common stock held by the Boniuk Charitable Foundation, and 438,097 shares of common stock and warrants to purchase 257,142 shares of common stock currently exercisable held by Boniuk Interests Ltd. Does not include 952,381 shares of common stock issuable upon conversion of a 10% Coupon Series C Convertible Debenture or 187,000 shares of Series A Preferred Stock held by Milton Boniuk IRA. Does not include an indeterminate number of shares of common stock issuable upon conversion of debentures held by Boniuk Charitable Foundation and Boniuk Interests Ltd. Dr. Boniuk holds voting and dispositive power over the Boniuk Charitable Foundation and Boniuk Interests Ltd.

(6) Includes 26,001 shares held by Connect Capital LLC, over which Ms. Vytas holds voting and dispositive power. Does not include 64,299 shares of Series A Preferred Stock.

## EMPLOYMENT AGREEMENTS

On March 3, 2010, the Company entered into employment agreements with its two executive officers, Eugene Seymour, Chief Executive Officer and Chief Financial Officer and Anil Diwan, President and Chairman of Board. Both agreements provided a minimum annual base salary of \$250,000 for a term of four (4) years (see subsequent event footnote.) In addition, Dr. Seymour and Dr. Diwan are eligible for an increase in base salary to \$275,000 if the Company consummates a financing with gross proceeds of at least \$5,000,000. Also, the base salary shall increase to \$300,000 for Dr. Seymour and \$300,000 for Dr. Diwan if the Company becomes listed on a national stock exchange. On September 13, 2013 the Company was listed on the NYSEMKT, a national exchange.

As additional compensation under each of the employment agreements, the Company issued 71,430 shares of the Company's Common Stock on each anniversary of the respective employment agreements.

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 Compensation Committee of the Board of Directors extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements (See subsequent event footnote).

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 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 provides for a base salary of \$9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. On January 1, 2015 her compensation was increased to \$10,800 per month.

Subsequent to the current fiscal year, on July 21, 2015 the Company entered into employment agreements with Anil Diwan, PhD, the Company's founder, President and Chairman, and Eugene Seymour, MD, MPH, the Company's Chief Executive Officer and Director effective July 1, 2015.

The Company and Dr. Diwan agreed Dr. Diwan would continue to serve as the Company's President and Chairman of the Board of Directors 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 that vest equally over the term of the employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Diwan. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017.

The Company and Dr. Seymour agreed that Dr. Seymour would continue to serve as the Company's Chief Executive Officer and Director 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 that vest equally over the term of employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Seymour. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017.

## COMPENSATION OF DIRECTORS

At this time, directors, who are officers of the Company, receive no remuneration for their services as directors of the Company. The Company reimburses directors for expenses incurred in their service to the Board of Directors. The Company paid accrued fees to its independent directors of \$30,000 to each Director, of which half is to be paid in the Company's common stock.

## COMPENSATION OF SCIENTIFIC ADVISORY BOARD

The Company anticipates holding four Scientific Advisory Board meetings per annum. As compensation, each member of the Scientific Advisory Board (SAB) will be granted each quarter 10,000 warrants to purchase the Company's common stock at 120% of the Company's closing stock quote on the day following the meeting. Should the Company not call a quarterly meeting, quarterly warrants will be granted on May 15, August 15, November 15, and February 15. The warrants have a four year expiration date. In addition the Company will reimburse each SAB member for travel and other out-of-pocket expenses incurred in the course of performing their services. For the years ended June 30, 2015, 2014 and 2013 the SAB was granted a total of 68,572 stock warrants each year exercisable into common shares at prices from \$ 1.67 to \$ 4.22 per share, \$3.16 to \$5.47 per share and \$1.58 to \$2.03 per share respectively.

## **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

On June 2, 2012, Stanley Glick, CPA was appointed as an independent member of our Board of Directors. Up until that time we did not have any independent directors on our Board of Directors, and therefore had no formal procedures in effect for reviewing and pre-approving any transactions between us, our directors, officers and other affiliates. We have used and will continue to use our best efforts to insure that all transactions are on terms at least as favorable to the Company as we would negotiate with unrelated third parties.

On February 1, 2013, Dr. Boniuk and entities over which Dr. Boniuk has voting and dispositive power subscribed for \$4,000,000 of the Company's Unsecured 8% Coupon Series B Convertible Debentures. On September 10, 2013, Dr. Boniuk and entities affiliated to him subscribed to \$3,000,000 of the Company's units issued in a registered direct offering. On July 2, 2014 the Company accepted a subscription from Dr. Boniuk to invest \$5,000,000 in the Company's Series C Convertible Debenture.

On May 13, 2013, Meeta Vyas was appointed as the Company's Chief Financial Officer. During the term of Ms. Vyas' service, she will be compensated on the basis of \$9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. Ms. Vyas is married to Anil Diwan, the President and Chairman of the Company. On January 1, 2015 her compensation was increased to \$10,800 per month.

TheraCour Pharma, Inc.

On May 12, 2005, the Company entered into a Material License Agreement, amended as of January 8, 2007 (the "License") with TheraCour Pharma, Inc., ("TheraCour"), our largest shareholder. As of the present, TheraCour granted the Company an exclusive license in perpetuity for technologies developed by TheraCour for six virus types: HIV, HCV, Herpes, Rabies, Asian (bird) flu and Influenza. 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) to pay the greater of \$2,000 or actual costs, for other general and administrative expenses incurred by TheraCour on our behalf; (4) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour; (5) that TheraCour Pharma, Inc. shall retain the exclusive right to develop and synthesize nanomicelle(s), a small (approximately twenty nanometers in size) long chain polymer based chemical structure, as component elements of the Licensed Products. TheraCour agreed that it will develop and synthesize such nanomicelles, to be used for the Licensed Products, exclusively for NanoViricides, and unless such license is terminated, will not develop or synthesize the nanomicelles to be used for the Licensed product for its own sake or for others; and (6) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. TheraCour may terminate the License upon a material breach by us as specified in the agreement. However, the Company has the opportunity to cure the breach within 90 days of receipt of notice to terminate the License. On February 15, 2010, the Company approved an Additional License Agreement with TheraCour Pharma, Inc. ("TheraCour"). Pursuant to the exclusive Additional License Agreement, in consideration for the issuance of 2,000,000 shares of the Company's Series A Preferred Stock, (the "Series A Preferred"), 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.

Development costs charged by and paid to TheraCour Pharma, Inc. were \$2,403,126, \$2,611,754, \$1,988,046, and for the fiscal years ended June 30, 2015, 2014, and 2013, respectively. No royalties are due or have been paid from inception through June 30, 2015.

As of June 30, 2015, TheraCour owns 9,619,170 shares of the Company's outstanding common stock and 2,000,000 shares of Series A Preferred. Anil Diwan, the Company's President and Chairman, also serves as the CEO and Director of TheraCour and owns approximately 70% of the outstanding capital stock of TheraCour.

#### KARD Scientific, Inc.

In June 2005, the Company engaged KARD Scientific to conduct pre clinical human influenza animal (mouse) studies and provide the Company with a full history of the study and final report with the data collected. This project is on-going. NanoViricides has a fee for service arrangement with KARD. We do not have an exclusive arrangement with KARD; we do not have a contract with KARD; all work performed by KARD must have prior approval of the executive officers of NanoViricides; and we retain all intellectual property resulting from the services by KARD. Dr. Krishna Menon, the Company's Chief Regulatory Officer-Consulting, a non-executive officer position, is also an officer and principal owner of KARD Scientific. The Lab fees charged by KARD Scientific for services were \$0, \$314,156, and \$1,035,983 for the fiscal years ended June 30, 2015, 2014 and 2013 respectively,. Dr. Menon has resigned as our Chief Regulatory Officer-Consulting, a non-executive officer position, in 2014 due to personal health reasons. Dr. Randall W. Barton, our Chief Scientific Officer, has taken over the duties of Acting Regulatory Officer.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

#### Audit Fees

The aggregate fees for each of the last two years for professional services rendered by the principal accountant for our audits of our annual financial statements and interim reviews of our financial statements included in our filings with Securities and Exchange Commission on Form 10-K and 10-Qs or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for those years were approximately:

June 30, 2015	\$ 175,000	EisnerAmper LLP.
June 30, 2015	\$ 7,500	Li and Company, P.C.
June 30, 2014	\$ 119,312	Li and Company, P.C.

Audit Related Fees

The aggregate fees in each of the last two years for the assurance and related services provided by the principal accountant that are not reasonably related to the performance of the audit or review of the Company's financial statements and are not reported in paragraph (1) were approximately:

June 30, 2015	\$ 0	EisnerAmper LLP.
June 30, 2015	\$ 2,000	Li and Company, P.C.
June 30, 2014	\$ 1,000	Li and Company, P.C.

The aggregate fees in each of the last two years for the professional services rendered by the principal accountant for tax compliance, tax advice and tax planning were approximately:

June 30, 2015	\$ 0	EisnerAmper LLP.
June 30, 2015	\$ 0	Li and Company, P.C.
June 30, 2014	\$ 0	Li and Company, P.C.

All Other Fees

The aggregate fees in each of the last two years for the products and services provided by the principal accountant, other than the services reported in paragraph (1) were approximately:

June 30, 2015	\$ 0	EisnerAmper LLP.
June 30, 2015	\$ 0	Li and Company, P.C.
June 30, 2014	\$ 0	Li and Company, P.C.

Pre-Approval Policies

The Board of Directors, and the Audit Committee appointed by the Board, currently do not have any pre-approval policies or procedures concerning services performed by Li and Company, P.C. All the services performed by Li and Company, P.C. as described above were pre-approved by the Audit Committee.

**ITEM 15. EXHIBITS**

Exhibit No.	Description
3.1*	Articles of Incorporation, as amended, of the Registrant
3.2*	By-laws of the Registrant
4.1*	Specimen Stock Certificate of the Registrant
4.2*	Series A Convertible Debenture
4.3*	Form of Warrant
10.1*	Share Exchange Agreement between NanoViricide, Inc. and the Registrant
10.2*	Employment Agreement Eugene Seymour
10.3*	Employment agreement Anil Diwan
10.4*	Employment agreement Leo Ehrlich
10.5*	Form of Scientific Advisory Board Agreement
10.6*	Amended License Agreement with TheraCour Pharma, Inc.
10.7*	Lease with landlord
10.8*	Form of First Subscription Agreement
10.9*	Form of Second Subscription Agreement
10.10*	Code of Ethics



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

- 10.11\* Amended Agreement #2 with TheraCour Pharma, Inc.
- 10.12\* Memorandum of Understanding with Vietnam's National Institute of Hygiene and Epidemiology (NIHE) dated December 23, 2005
  
- 31.1 Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
  
- 31.2 Certification of 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 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.
  
- 32.2 Certification of 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.
  
- 101.INS XBRL Instance Document.
- 101.SCH XBRL Schema Document.
- 101.CAL XBRL Calculation Linkbase Document.
- 101.DEF XBRL Definition Linkbase Document.
- 101.LAB XBRL Label Linkbase Document.
- 101.PRE XBRL Presentation Linkbase Document.

\* Incorporated by reference to the Company's registration statement on Form 10-SB, filed with the Securities Commission on November 14, 2006, as amended.

## 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: September 14, 2015

### **NANOIRICIDES, INC.**

*/s/ Eugene Seymour, MD*

Name: Eugene Seymour, M.D.

Title: Chief Executive Officer and Director

(Principal Executive Officer)

*/s/ Meeta Vyas*

Name: Meeta Vyas

Title: Chief Financial Officer

(Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

September 14, 2015

*/s/ Eugene Seymour, MD*

Name: Eugene Seymour, MD

Title: Chief Executive Officer and Director

(Principal Executive Officer)

September 14, 2015 */s/ Anil Diwan*

Name: Anil Diwan

Title: President and Chairman of the Board  
of Directors

September 14, 2015 */s/ Meeta Vyas*

Name: Meeta Vyas

Title: Chief Financial Officer

(Principal Accounting Officer)

September 14, 2015 /s/ *Milton Boniuk*

Name: Milton Boniuk

Title: Director

September 14, 2015 /s/ *Mukund Kulkarni*

Name: Mukund Kulkarni

Title: Director

September 14, 2015 /s/ *Stanley Glick*

Name: Stanley Glick

Title: Director

NanoViricides, Inc.

Index to the Financial Statements

Contents	Page(s)
<u>Reports of Independent Registered Public Accounting Firms</u>	F-2, F-3, F-4
<u>Balance Sheets at June 30, 2015 and 2014</u>	F-5
<u>Statements of Operations for the fiscal years ended June 30, 2015, 2014 and 2013</u>	F-6
<u>Statement of Changes in Stockholders' Equity for the period from July 1, 2012 through June 30, 2015</u>	F-7
<u>Statements of Cash Flows for the fiscal years ended June 30, 2015, 2014 and 2013</u>	F-8
<u>Notes to the Financial Statements</u>	F-9

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

NanoViricides, Inc.

We have audited the accompanying balance sheet of NanoViricides, Inc. (the “Company”) as of June 30, 2015 and the related statements of operations, changes in stockholders’ equity and cash flows for the year then ended. The financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NanoViricides, Inc. as of June 30, 2015, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), NanoViricides, Inc.’s internal control over financial reporting as of June 30, 2015, based on criteria established in the *Internal Control - Integrated Framework* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”), and our report dated September 14, 2015 expressed an adverse opinion on the Company’s internal control over financial reporting.

/s/ EisnerAmper LLP

Iselin, New Jersey

September 14, 2015

F-2

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

NanoViricides, Inc.

We have audited NanoViricides, Inc.'s (the "Company") internal control over financial reporting as of June 30, 2015, based on criteria established in the *Internal Control - Integrated Framework* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. The material weakness in the reporting process was due to the insufficient complement of personnel with the appropriate level of knowledge to identify and account for non-routine transactions such as derivative instruments. This material weakness was considered in determining the nature, timing, and extent of the audit tests applied in our audit of the June 30, 2015 financial statements, and this report does not affect our report dated September 14, 2015, on those financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, NanoViricides, Inc. has not maintained effective internal control over financial reporting as of June 30, 2015, based on criteria established in *Internal Control - Integrated Framework* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet of NanoViricides, Inc. as of June 30, 2015 and the related statements of operations, changes in stockholders' equity, and cash flows for the year then ended and our report dated September 14, 2015 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

Iselin, New Jersey

September 14, 2015

F-3



To the Board of Directors and Stockholders of

NanoViricides, Inc.

West Haven, Connecticut

We have audited the accompanying balance sheets of NanoViricides, Inc. (the “Company”) as of June 30, 2014 and the related statements of operations, stockholders’ equity and cash flows for the fiscal years ended June 30, 2014 and 2013. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2014 and the results of its operations and its cash flows for the fiscal years ended June 30, 2014 and 2013 in conformity with U.S. generally accepted accounting principles.

The Company’s balance sheet as of June 30, 2014 and the related statements of operations, stockholder’s equity and cash flows for the fiscal year ended June 30, 2014 have been restated. The restatements of the financial statements are described in Note 2 to the financial statements included in its amended annual report on Form 10-K/A filed on February 23, 2015.

Skillman, New Jersey

September 29, 2014

Edgar Filing: NANOVIKICIDES, INC. - Form 10-K

(Except for Notes 2 to the financial statements included in its amended annual report on Form 10-K/A filed which are dated February 23, 2015)

F-4

NanoViricides, Inc.

## Balance Sheets

	June 30, 2015	June 30, 2014
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 31,467,748	\$ 36,696,892
Prepaid expenses	214,425	108,089
Other current assets	-	150,000
<b>Total Current Assets</b>	<b>31,682,173</b>	<b>36,954,981</b>
<b>PROPERTY AND EQUIPMENT</b>		
Property and equipment	13,496,851	6,736,742
Accumulated depreciation	(1,534,203 )	(1,239,986 )
<b>Property and equipment, net</b>	<b>11,962,648</b>	<b>5,496,756</b>
<b>TRADEMARK and PATENTS</b>		
Trademark and patents	458,954	458,954
Accumulated amortization	(59,217 )	(50,696 )
<b>Trademark and patents, net</b>	<b>399,737</b>	<b>408,258</b>
<b>OTHER ASSETS</b>		
Security deposits	-	1,000,000
Service agreements	142,531	-
Other Assets	142,531	1,000,000
<b>Total Assets</b>	<b>\$ 44,187,089</b>	<b>\$ 43,859,995</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 89,517	\$ 376,446
Accounts payable – related parties	316,196	49,455
Accrued expenses	28,515	91,838
Deferred interest payable - current portion	166,667	-
<b>Total Current Liabilities</b>	<b>600,895</b>	<b>517,739</b>
<b>LONG TERM LIABILITIES:</b>		
Debenture subscription deposit	-	5,000,000
Debentures payable - Series B, net of discount	4,700,582	4,037,568
Debentures payable - Series C, net of discount	2,480,605	-
Derivative liability - Series B, debentures	366,764	5,699,703

Edgar Filing: NANOIRICIDES, INC. - Form 10-K

Derivative liability - Series C, debentures	476,289	-
Derivative liability - warrants	3,442,754	5,235,682
Deferred interest payable - long term portion	333,333	-
Total Long Term Liabilities	11,800,327	19,972,953
Total Liabilities	12,401,222	20,490,692
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, \$0.001 par value, 10,000,000 and 4,000,000 shares designated, respectively, 3,583,445, and 3,193,079 shares issued and outstanding, respectively	3,584	3,194
Series B Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, none issued and outstanding	-	-
Series C Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, none issued and outstanding	-	-
Common stock, \$0.001 par value; 150,000,000 and 85,714,286 shares authorized, respectively, 57,242,070, and 54,620,993 shares issued and outstanding, respectively	57,242	54,621
Additional paid-in capital	85,824,613	75,212,888
Accumulated deficit	(54,099,572 )	(51,901,400 )
Total Stockholders' Equity	31,785,867	23,369,303
Total Liabilities and Stockholders' Equity	\$44,187,089	\$43,859,995

*See accompanying notes to the financial statements*

NanoViricides, Inc.

## Statements of Operations

	Year Ended June 30,		
	2015	2014	2013
<b>OPERATING EXPENSES</b>			
Research and development	\$3,660,322	\$5,131,523	\$4,292,909
General and administrative	3,402,778	3,535,849	2,297,470
Total operating expenses	7,063,100	8,667,372	6,590,379
<b>LOSS FROM OPERATIONS</b>	(7,063,100 )	(8,667,372 )	(6,590,379 )
<b>OTHER INCOME (EXPENSE):</b>			
Interest income	160,859	171,001	55,587
Interest expense	(2,649,592 )	(3,092,550 )	(962,535 )
Discount on convertible debentures	(1,175,344 )	(569,495 )	(129,006 )
Change in fair value of derivatives	8,529,005	(1,443,200 )	(1,249,335 )
Other income (expense), net	4,864,928	(4,934,244 )	(2,285,289 )
<b>LOSS BEFORE INCOME TAXES</b>	(2,198,172 )	(13,601,616 )	(8,875,668 )
<b>INCOME TAX PROVISION</b>	-	-	-
<b>NET LOSS</b>	\$(2,198,172 )	\$(13,601,616 )	\$(8,875,668 )
<b>NET LOSS PER COMMON SHARE</b>			
- Basic	\$(0.04 )	\$(0.27 )	\$(0.19 )
- Diluted	\$(0.09 )	\$(0.27 )	\$(0.19 )
<b>Weighted average common shares outstanding</b>			
- Basic	56,553,848	51,225,622	45,892,549
- Diluted	59,220,515	51,225,622	47,606,835

*See accompanying notes to the financial statements.*

NanoViricides, Inc.

Statement of Changes in Stockholders' Equity

For the Period from July 1, 2012 through June 30, 2015

	Series A Preferred Stock: Par \$0.001		Series C Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional		Total
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balance, June 30, 2012	2,820,357	\$2,820	672	\$1	44,460,629	\$44,460	\$43,227,028	\$(29,424,116)	\$13,850,192
Series A Preferred Shares issued for employee stock compensation	169,643	170					444,874		445,044
Series C Preferred Shares issued to SeaSide 88			714				2,541,872		2,541,872
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88			(864)	(1)			(1)		(1)
Redemption of Series C Convertible Preferred Shares			(522)	-	-	-	(1,714,334)		(1,714,334)
Shares issued in conversion of Series C Preferred Shares to Common					1,815,138	1,816	4,536		6,352

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

Stock									
Shares issued as Dividend to Seaside 88			56,051	55	90,053				90,108
Shares issued for consulting and legal services rendered			42,977	43	84,913				84,956
Warrants issued to Scientific Advisory Board					141,600				141,600
Common Shares issued for employee stock compensation			71,428	71	59,929				60,000
Common shares issued for debenture interest			571,429	571	664,926				665,497
Shares issued for Directors fees			8,521	10	18,740				18,750
Dividend to Seaside 88			-	-	(96,110 )				(96,110 )
Derivative liability - retirement of Preferred Series C			-	-	968,894				968,894
Placement agents fees related to sale of Convertible Preferred shares			-	-	(165,000 )				(165,000 )
Legal fees related to Sale of Convertible Preferred			-	-	(12,500 )				(12,500 )
Stock									
Net loss							(8,875,668 )		(8,875,668 )
Balance, June 30, 2013	2,990,000	2,990	-	-	47,026,173	47,026	46,259,420	(38,299,784)	8,009,652
Series A Preferred	203,079	204					2,122,810		2,123,014

Shares issued for employee stock compensation				
Shares issued for consulting and legal services rendered	29,662	31	101,970	102,001
Warrants issued to Scientific Advisory Board			199,849	199,849
Common Shares issued for employee stock compensation	71,430	72	287,788	287,860
Common Shares issued in connection with warrant conversion	142,500	142	735,482	735,624
Common shares issued for debenture interest	571,429	571	2,605,145	2,605,716
Shares issued for Directors fees	13,146	13	44,987	45,000
Common shares and warrants issued in connection with private placement of common stock	6,760,713	6,760	30,332,443	30,339,203
Common shares issues to round up financial shares arising from private placement	5,940	6	(6 )	-
Placement agents fees related to sale of Common shares and			(1,820,360 )	(1,820,360 )



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

Warrants Rule 16B payment to Additional Paid in Capital Restatement of Additional Paid in Capital to Derivative Liability Net loss							83,900		83,900
							(5,740,540 )		(5,740,540 )
					-			(13,601,616)	(13,601,616)
Balance, June 30, 2014	3,193,079	3,194	-	-	54,620,993	54,621	75,212,888	(51,901,400)	23,369,303
Series A Preferred Shares issued with Debt Series C Series A Preferred Shares issued for employee stock compensation Shares issued for consulting and legal services rendered Warrants issued to Scientific Advisory Board Common Shares issued for employee stock compensation Common Shares issued in connection with warrant exercises Common shares issued	187,000	187	-	-	-	-	1,152,110		1,152,297
	200,508	200	-	-	-	-	852,560		852,760
				35,154	35		109,325		109,360
				-	-		59,675		59,675
				71,430	71		124,932		125,003
				1,926,656	1,927		6,741,370		6,743,297
				571,429	572		1,502,298		1,502,870

for debenture interest Series A Preferred Shares issued for consulting and legal services rendered Shares issued for Directors fees Net loss	2,858	3					24,471		24,474
			16,408	16	44,984				45,000
				-				(2,198,172 )	(2,198,172 )
Balance, June 30, 2015	3,583,445	\$3,584	-	\$-	57,242,070	\$57,242	\$85,824,613	\$(54,099,572)	\$31,785,867

*See accompanying notes to the financial statements*

NanoViricides, Inc.

## Statements of Cash Flows

	Year Ended June 30		
	2015	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(2,198,172 )	\$(13,601,616)	\$(8,875,668 )
Adjustments to reconcile net loss to net cash used in operating activities			
Preferred shares issued as compensation and for services	877,234	2,123,014	445,044
Common shares issued as compensation and for services	279,363	434,861	163,710
Common shares issued for interest	1,502,870	2,605,716	665,497
Warrants granted to Scientific Advisory Board	59,675	199,849	141,600
Depreciation	294,217	203,234	210,877
Amortization	8,521	8,775	8,774
Change in fair value of derivative liability	(8,529,005 )	1,443,200	1,249,335
Amortization of debt discount convertible debentures	1,175,344	569,495	-
Changes in operating assets and liabilities:			
Prepaid expenses	(106,336 )	(56,492 )	(284,206 )
Prepaid expenses/accounts payable - related parties	266,741	(114,329 )	344,886
Other current assets	150,000	(150,000 )	-
Other long term assets	(142,531 )	-	-
Accounts payable	(286,930 )	113,188	24,900
Accrued expenses	(63,323 )	(112,521 )	107,479
Deferred interest payable	500,000	-	-
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(6,212,332 )</b>	<b>(6,333,625 )</b>	<b>(5,797,772 )</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Collateral advance for affiliate	1,000,000	-	(1,000,000 )
Purchase of property and equipment	(6,760,109 )	(5,231,094 )	(64,931 )
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(5,760,109 )</b>	<b>(5,231,094 )</b>	<b>(1,064,931 )</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of Convertible Debentures	-	5,000,000	6,000,000
Proceeds from issuance of Convertible Preferred Series C stock, net	-	-	510,963
Proceeds from issuance of common stock and warrants in connection with private placements of common stock, net of issuance costs	-	28,602,740	-
Proceeds from exercise of warrants	6,743,297	735,626	-
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>6,743,297</b>	<b>34,338,366</b>	<b>6,510,963</b>

Edgar Filing: NANOIRICIDES, INC. - Form 10-K

NET CHANGE IN CASH AND CASH EQUIVALENTS	(5,229,144 )	22,773,647	(351,740 )
Cash and cash equivalents at beginning of period	36,696,892	13,923,245	14,274,985
Cash and cash equivalents at end of period	\$31,467,748	\$36,696,892	\$13,923,245
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:			
Interest paid	\$480,000	\$480,000	\$197,589
Income tax paid	\$-	\$-	\$-
NON CASH FINANCING AND INVESTING ACTIVITIES:			
Series A Preferred stock issued as discount on debentures	\$1,152,297	\$-	\$-
Bifurcation of embedded derivative	1,879,428	-	-
Issuance of Series C Debenture for deposit received	5,000,000		
Common stock issued upon conversion of Series C Preferred Stock	-	-	3,028,464

*See accompanying notes to the financial statements*

NanoViricides, Inc.

June 30, 2015, 2014 and 2013

Notes to the Financial Statements

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

Pursuant to the terms of the Exchange, ECMM acquired NVI in exchange for an aggregate of 80,000,000 newly issued shares of ECMM common stock resulting in an aggregate of 35 million shares of ECMM common stock issued and outstanding. NVI then became a wholly-owned subsidiary of ECMM. The ECMM shares were issued to the NVI shareholders on a pro rata basis, on the basis of 4,000 shares of the Company’s common stock for each share of NVI common stock held by such NVI shareholder at the time of the Exchange.

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

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

NanoViricides, Inc. (the “Company”), is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. 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”), an entity owned and controlled by a significant stockholder, to which we have the necessary exclusive, worldwide licenses in perpetuity. The first agreement we executed with TheraCour Pharma on September 1, 2005, gave us an exclusive, worldwide license for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus.

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

**Note 2 – Summary of Significant Accounting Policies**

*Basis of Presentation*

The Company’s financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented.

*Reclassifications*

Certain accounts in the June 30, 2014 financial statements have been reclassified to conform to the current period presentation.

*Net Loss per Common Share*

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

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

	Potentially Outstanding Dilutive Common Shares	
	For the Year Ended June 30, 2015	For the Year Ended June 30, 2014
Stock options	535,715	535,715

Edgar Filing: NANOIRICIDES, INC. - Form 10-K

Warrants	5,976,675	8,887,211
Total potentially outstanding dilutive common shares	6,512,390	9,422,926

F-10



In addition, the Company has issued Convertible Debentures, to investors. A portion of the interest required to be paid on the debentures had been paid in shares of the Company's \$0.001 par value common stock ("Interest Shares") according to the terms of the Debenture. No additional Interest Shares are required to be issued under the terms of the debenture. The Company will need to issue 571,428 warrants on January 15, 2016 relating to the additional interest to be paid on the Series B debentures. Coupon interest payable quarterly related to the Series B Debentures is payable in cash or shares of Common Stock at the average of the open and close value on the date such interest payment is due at the option of the Holder. The Holders have elected to receive coupon interest in cash.

At June 30, 2015, the estimated number of potentially dilutive shares of the Company's common stock into which the Series B debentures can be converted based upon the conversion price of \$3.50 is 1,714,286. At June 30, 2015 the number of potential dilutive shares of the Company's common stock into which the Series C debentures can be converted based upon the conversion provisions contained in the debenture is 952,381.

The Company has also issued 3,583,445 of \$0.001 par value Preferred A shares to investors and others as of June 30, 2015. Only in the event of a "change of control" of the Company, each Series A preferred share is convertible to 3.5 shares of its new common stock. A "Change of Control" is defined as an event in which the Company's shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition. In the absence of a Change of Control event, the Series A stock is not convertible into Common Stock, and does not carry any dividend rights or any other financial effects. At June 30, 2015, the estimated number of potentially dilutive shares of the Company's common stock into which these Series A Preferred shares can be converted into is 12,542,058, and is not included in diluted earnings per share since the shares are contingently convertible only upon a Change of Control.

Pursuant to the Redemption provisions of the Series C Debentures, the Company, at its sole option, shall have the right, but not the obligation, to repurchase the Debenture at any time prior to the Maturity Date (the "Redemption"). If the Company intends to repurchase the Debenture, and if the closing bid price of the Common Stock is greater than \$5.25 on the Redemption Date, unless the Holder, on or prior to the Redemption Date, elects to receive the "Redemption Payment", as that term is defined herein, the Company shall pay to the Holder: (i) 952,381 shares of Common Stock in consideration of the exchange of the principal amount of the Debenture; and (ii) any and all accrued coupon interest. If on or prior to the Redemption Date, the Holder elects to receive the Redemption Payment, or the closing bid price of the Common Stock is less than \$5.25, the Company shall issue to the Holder: (i) the principal amount of the Debenture; (ii) any accrued coupon interest; (iii) additional interest of 7% per annum for the period from the date of issuance of the Debenture to the Redemption Date; and (iv) warrants to purchase 619,048 shares of Common Stock which shall expire in three years from the date of issuance at an exercise price of \$6.05 per share of Common Stock (the "Redemption Warrants", and collectively with (i) – (iii), the "Redemption Payment"). The Company shall use its best efforts to register the shares underlying the Redemption Warrants under a "shelf" registration statement, provided same is available to the Company, in accordance with the provisions of the Securities Act.

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

	For the Years Ended		
	June 30, 2015	June 30, 2014	June 30, 2013
Calculation of basic loss per share of common stock:			
Net loss attributable to common stockholders	\$(2,198,172 )	\$(13,601,616)	\$(8,875,668 )
Denominator for basic weighted average shares of common stock	56,553,848	51,225,622	45,892,549
Basic loss per share of common stock	\$(0.04 )	\$(0.27 )	\$(0.19 )
Calculation of diluted loss per share of common stock:			
Net loss attributable to common stockholders	\$(2,198,172 )	\$(13,601,616)	\$(8,875,668 )
Add: Loss impact of assumed conversion of Debentures	(3,077,864 )	-	(334,832 )
Net loss attributable to common stockholders plus assumed conversions	\$(5,276,036 )	\$(13,601,616)	\$(9,210,500 )
Denominator for basic weighted average shares of common stock	56,553,848	51,225,622	45,892,549
Incremental shares from assumed conversions of Debentures payable	2,666,667	-	1,714,286
Denominator for diluted weighted average shares of common stock	59,220,515	51,225,622	47,606,835
Diluted loss per share of common stock	\$(0.09 )	\$(0.27 )	\$(0.19 )

Series B Debentures were excluded from the loss per share calculation for year ended June 30, 2014 because the impact is anti-dilutive.

#### Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheet and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but

not limited to, accounting for share-based compensation, accounting for derivatives and accounting for income taxes. Actual results could differ from those estimates.

*Fair Value of Financial Instruments*

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value for applicable assets and liabilities, we consider the principal or most advantageous market in which we would transact and we consider assumptions market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. This guidance also establishes a fair value hierarchy to prioritize inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

### Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets and would be charged to earnings. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. The Company has not recorded an impairment charge for the years ended June 30, 2015, 2014 and 2013.

### Cash and Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents.

### Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, or lease term, if shorter, for leasehold improvement, using the straight-line method. The Company generally assigns useful lives of thirty years for assets classified as buildings, fifteen years for assets classified as land improvements and laboratory fixtures, ten years for assets classified as lab equipment, and five years for assets classified as office equipment and computers. Expenditures for major additions and betterments are capitalized. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of property and equipment, the related cost and accumulated depreciation are removed from the accounts and any gain or loss is reflected in statements of operations.

Intangible Assets Other Than Goodwill

The Company amortizes the costs of intangible assets other than goodwill on a straight-line basis over their estimated useful lives, the terms of the exclusive licenses and/or agreements, or the terms of legal lives of the patents, whichever is shorter. Upon becoming fully amortized, the related cost and accumulated amortization are removed from the accounts.

Research and Development

Research and development expenses consist primarily of costs associated with the preclinical and/ or clinical trials of drug candidates, compensation and other expenses for research and development, personnel, supplies and development materials, costs for consultants and related contract research and facility costs. Expenditures relating to research and development are expensed as incurred.

Stock-Based Compensation

The Company follows the provisions of ASC 718 – *Stock Compensation*, which requires the measurement of compensation expense for all shared-based payment awards made to employees and non-employee directors, including employee stock options. Shared-based compensation expense is based on the grant date fair value estimated in accordance with the provisions of ASC 718 and is generally recognized as an expense over the requisite service period, net of forfeitures.

The fair value of common stock issued as employee compensation is the average of the open and close share price on the date the common shares are issued. The Series A preferred shares are not traded in any market.

The assumptions used to determine the fair value of the Series A preferred shares issued as employee compensation are presented in Note 8 to the financial statements.

The fair value of each option award is estimated on the date of grant using a Black-Scholes option-pricing valuation model. The ranges of assumptions for inputs are as follows:

· Expected term of share options and similar instruments: The expected life of options and similar instruments represents the period of time the option and/or warrant are expected to be outstanding. Pursuant to Paragraph

718-10-50-2(f)(2)(i) of the FASB Accounting Standards Codification the expected term of share options and similar instruments represents the period of time the options and similar instruments are expected to be outstanding taking into consideration of the contractual term of the instruments and employees' expected exercise and post-vesting employment termination behavior into the fair value (or calculated value) of the instruments. Pursuant to paragraph 718-50-S99-1, it may be appropriate to use the *simplified method*, if (i) A company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded; (ii) A company significantly changes the terms of its share option grants or the types of employees that receive share option grants such that its historical exercise data may no longer provide a reasonable basis upon which to estimate expected term; or (iii) A company has or expects to have significant structural changes in its business such that its historical exercise data may no longer provide a reasonable basis upon which to estimate expected term. The Company uses the simplified method to calculate expected term of share options and similar instruments as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term.

Expected volatility of the Company's shares and the method used to estimate it: Expected volatility is based on the average historical volatility of the Company's common stock over the expected term of the option.

Expected annual rate of quarterly dividends: The expected dividend yield is based on the Company's current dividend yield as the best estimate of projected dividend yield for periods within the expected term of the option and similar instruments.

Risk-free rate(s): The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods within the expected term of the option and similar instruments.

The Company's policy is to recognize compensation cost for awards with only service conditions and a graded vesting schedule on a straight-line basis over the requisite service period for the entire award.

Equity Instruments Issued to Parties other than Employees for Acquiring Goods or Services

The Company follows the provisions of ASC 505 - Equity, which accounts for equity instruments issued to parties other than employees for acquiring goods or services. Pursuant to ASC 505, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the performance is complete or the date on which it is probable that performance will occur. The assumptions used in determining the fair value of the Series A Preferred shares are presented in Note 8 to the financial statements.

The Company uses the average of the open and close market value of the Company's common stock at each measurement date to determine the fair value of the restricted common stock issued as compensation.

The Company has issued securities to acquire goods or services at or after the delivery of the goods or services for which it contracted. The securities when issued are fully vested and the Company has recognized such issuances as an immediate expenses.

The fair value of share options and similar instruments is estimated on the date of grant using a Black-Scholes option-pricing valuation model. The ranges of assumptions for inputs are as follows:

Expected term of share options and similar instruments: The expected term of share options and similar instruments represents the contractual term of the instruments.

Expected volatility of the Company's shares and the method used to estimate it. Expected volatility is based on the average historical volatility of the Company's common stock over the contractual term of the option.

Expected annual rate of quarterly dividends. The expected dividend yield is based on the Company's current dividend yield as the best estimate of projected dividend yield for periods within the contractual term of the option and similar instruments.

Risk-free rate(s). The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods within the contractual term of the option and similar instruments.

F-14



*Income Tax Provision*

The Company uses the asset and liability method of accounting for deferred income taxes. Deferred income taxes are measured by applying enacted statutory rates to net operating loss carryforwards and to the differences between the financial reporting and tax bases of assets and liabilities. Deferred tax assets are reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company recognizes uncertainty in income taxes in the financial statements using a recognition threshold and measurement attribute of a tax position taken or expected to be taken in a tax return. The Company applies the “more-likely-than-not” recognition threshold to all tax positions, commencing at the adoption date of the applicable accounting guidance, which resulted in no unrecognized tax benefits as of such date. Additionally, there have been no unrecognized tax benefits subsequent to adoption. The Company has opted to classify interest and penalties that would accrue, if any, according to the provisions of relevant tax law as selling, general, and administrative expenses, in the consolidated statement of operations. For the years ended June 30, 2015, 2014 and 2013 there was no such interest or penalty.

*Concentrations of Risk*

Financial instruments that potentially subject us to a significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured institutions in excess of federally insured limits. The Company does not believe it is exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Recently Issued Accounting Pronouncements

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently evaluating the impact of the adoption of ASU 2014-15 on the Company's financial statements and disclosures.

In April 2015, the FASB issued ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30), "Simplifying the Presentation of Debt Issuance Costs," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU requires retrospective adoption and will be effective for fiscal years beginning after December 15, 2015 and for interim periods within those fiscal years. We expect the adoption of this guidance will not have a material impact on our financial statements.

**Note 3 – Financial Condition**

The Company's financial statements 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 June 30, 2015 (\$54,099,572) and had a net loss and net cash used in operating activities for the fiscal year then ended. 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 June 30, 2015 the Company had cash and cash equivalents of \$31,467,748. The Company has sufficient capital to continue its business, at least through March 31, 2017, at the current rate of expenditure.

While the Company continues to incur significant operating losses with significant capital requirements, the Company has been able to finance its business through sale of its securities. The Company may require additional capital to finance planned and currently unplanned capital costs and additional staffing requirements during the next 24 months. The Company has in the past adjusted its priorities and goals in line with the cash on hand and capital availability. The Company believes it can adjust its priorities of drug development and its plan of operations as necessary, if it is unable to raise additional funds.

#### **Note 4 – Related Party Transactions**

##### Related Parties

Related parties with whom the Company had transactions are:

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

Property and Equipment

	<b>For the Years Ended</b>	
	<b>June 30, 2015</b>	<b>June 30, 2014</b>
During the reporting period, the Company acquired 1 Controls Drive Shelton Ct from Inno-Haven, LLC	\$4,222,549	\$-
During the reporting period, Inno-Haven, LLC, acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, at cost, to the Company	\$-	\$4,500,000
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	\$255,019	\$528,720

Accounts Payable Related Party

	June 30, 2015	June 30, 2014
Pursuant to an Exclusive License Agreement and an Additional 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, and others. In consideration for obtaining these exclusive licenses, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed. (2) we will pay \$25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour, (3) we will pay \$2,000 per month or actual costs, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf. Accounts payable due TheraCour Pharma Inc. (including a two (2) month security advance):	\$316,196	\$49,455

Research and Development Costs Paid to Related Parties

For the Year ended		
June 30, 2015	June 30, 2014	<b>June 30, 2013</b>

Edgar Filing: NANOIRICIDES, INC. - Form 10-K

Development fees and other costs charged by and paid to TheraCour Pharma, Inc. pursuant to exclusive License Agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at June 30, 2015, 2014 and 2013

	\$2,403,126	\$2,611,754	\$1,988,046
--	-------------	-------------	-------------

F-17

Long Term Debenture Payable to a Director

	June 30, 2015	June 30, 2014
Series B Convertible Debentures - Milton Boniuk	\$4,000,000	\$4,000,000
Series C Convertible Debentures - Milton Boniuk	5,000,000	-
Total Long Term Debentures Payable to a Director	\$9,000,000	\$4,000,000

<u>Debenture Interest Paid to a Director</u>	June 30, 2015	June 30, 2014
--	------------------	---------------------

Debenture interest was paid or recognized to Milton Boniuk, or an entity controlled by him, pursuant to the terms of the Series B and Series C Convertible Debentures.

Coupon interest payable on \$5,000,000 Series C Convertible Debentures and deferred. The deferred interest will be paid out quarterly over the remaining term of the debenture:

Deferred interest payable - short term	\$166,667	\$ -
Deferred interest payable - long term	\$333,333	\$ -

Stock interest paid in kind on Series B Convertible Debentures to Dr. Milton Boniuk and recognized at fair value was \$1,001,532, \$1,730,763, and \$665,497 for the years ended June 30, 2015, 2014, and 2013 respectively.

Coupon interest paid on the Series B Debentures to Dr. Milton Boniuk for the years ending June 30, 2015, 2014 and 2013 was \$320,000, and \$320,000 and \$197,589 respectively.

**Note 5 – Property and Equipment**

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

June 30, 2015	June 30, 2014
------------------	------------------

Edgar Filing: NANOIRICIDES, INC. - Form 10-K

Land	\$260,000	\$-
Building GMP Facility	7,905,938	3,099,780
Office Equipment	65,241	30,048
Furniture and Fixtures	1,400	1,400
Lab Equipment & fixtures	5,264,272	3,605,514
Total Property and Equipment	13,496,851	6,736,742
Less Accumulated Depreciation	(1,534,203 )	(1,239,986)
Property and Equipment, Net	\$11,962,648	\$5,496,756

Depreciation expense for the years ended June 30, 2015, 2014 and 2013 was \$294,217, \$203,234 and \$210,877, respectively.

F-18

On December 31, 2014, the Company entered into and consummated an Agreement for the Purchase and Sale of a cGMP-compliant pilot manufacturing and lab facility at 1 Controls Drive, Shelton, Connecticut. The purchase price of the facility was comprised solely of the repayment of the direct costs of the seller, Inno-Haven, LLC (“Inno-Haven”), an entity owned and controlled by a significant stockholder, incurred in acquiring and renovating the property and the facility plus Inno-Haven’s closing costs in connection with the sale. The purchase price consisted of the repayment of Inno-Haven’s acquisition and renovation expenses of \$4,222,549 and closing costs of \$81,230.

**Note 6 – Trademark and Patents**

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

	June 30, 2015	June 30, 2014
Trademarks and Patents	\$458,954	\$458,954
Less Accumulated Amortization	(59,217 )	(50,696 )
Trademarks and Patents, Net	\$399,737	\$408,258

Amortization expense amounted to \$8,521, \$8,775, and \$8,774 for the years ended June 30, 2015, 2014 and 2013, respectively.

The Company amortizes our trademarks and patents over their expected original useful lives of 17 years.

Amortization expense in future years is as follows:

2016	\$8,521
2017	8,521
2018	8,521
2019	8,521
2020	8,521
Thereafter	357,132
Total amortization	\$399,737



**Note 7 – Convertible Debentures and Investor Warrants**

On February 1, 2013, the Company raised gross proceeds of \$6,000,000 which includes \$4,000,000 from a family investment office and a charitable foundation controlled by Dr. Milton Boniuk, a member of the Company’s board of directors, through the issuance of our Series B Debentures. The investors purchased unsecured convertible debentures with a 4-year term. The debentures bear an interest rate of 8% p.a. payable quarterly in cash or the Holder at its option may elect to receive such coupon interest payment in shares of common stock and calculated on the date of issuance, using the average of the open and close prices of the Company’s common stock on the date such interest payment is due. Additional interest was payable in restricted common stock of 571,429 shares at issuance and on January 15, 2014 and 2015, and additional interest of 571,429 warrants to be issued on January 15, 2016. The warrants are exercisable at \$3.50 per warrant and will be valid for 3 years after issuance. The investors can convert the principal and any accrued interest into common stock at a fixed price of \$3.50 per share. The Company can prepay the debentures, in which case the base interest rate shall increase by a 7% prepayment penalty. The Company agreed to use its best efforts to register the interest shares and the shares issuable from the interest warrants under a “shelf” registration statement provided same is available, in accordance with the provisions of the Securities Act.

The following table presents the balance of the Debenture payable – Series B, net of discount at June 30, 2015 and June 30, 2014. The debt discount is being accreted to interest expense over the term of the debenture:

	June 30, 2015	June 30, 2014
Proceeds	\$6,000,000	\$6,000,000
Debt discount for bifurcated derivative	(2,735,310)	(2,735,310)
	3,264,690	3,264,690
Amortization of debt discount	1,435,892	772,878
Debenture payable - Series B, net	\$4,700,582	\$4,037,568

The debenture contains embedded derivatives which are not clearly and closely related to the host instrument. The embedded derivatives are bifurcated from the host debt instrument and treated as a liability.

The single compound embedded derivative features valued include the:

1. Principal conversion feature at maturity based on a fixed conversion price subject to standard adjustments.
2. Redemption additional interest and Redemption Warrants offering.
3. Additional interest shares and interest warrants.

For the years ended June 30, 2015, 2014 and 2013, the Company recognized amortization of the debt discount as an additional interest charge to "Discount on convertible debentures" in the amounts of \$663,014, \$569,495, and \$203,383, respectively.

The Company used a lattice model that values the compound embedded derivatives of the Series B Convertible Debenture based on a probability weighted discounted cash flow model at June 30, 2015 and 2014.

The following assumptions were used for the valuation of the compound embedded derivative at June 30, 2015 and 2014:

- The balance of the Series B Convertible Debenture as of issuance and June 30, 2015 and 2014 is \$6,000,000;

The underlying stock price was used as the fair value of the common stock. The stock price decreased to **\$1.75** at June 30, 2015 which decreased the warrant value with the \$3.50 exercise price (further out to in the money). The stock price increased to \$4.23 at June 30, 2014 which increased the warrant value with the \$3.50 exercise price;

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

**1 year**

**06/30/2015 62%**

**06/30/2014 92%**

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

· The Company would redeem the debentures projected initially at 0% of the time and increase monthly by 1.0% to a maximum of **20.0%** (from alternative financing being available for a Redemption event to occur);

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

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

· The weighted cost of capital discount rate (based on the market value of the transactions at issuance) adjusted for changes in the risk free rate is 21.60%.

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

The fair value of the compound embedded derivatives of the Series B Convertible Debenture at June 30, 2015 and 2014 was \$366,764 and \$5,699,703, respectively.

F-20

On July 2, 2014 (the “Closing Date”), the Company accepted a subscription in the amount of \$5,000,000 for a 10% Coupon Series C Convertible Debenture (the “Debenture”) from Dr. Milton Boniuk, a member of the Company’s Board of Directors (the “Holder”). The \$5,000,000 funding of the Debenture had been received by the Company prior to June 30, 2014, the year-end reporting period and the Company has reported the said Debenture in the financial statements at June 30, 2015 under long term liabilities. The Debenture is due on June 30, 2018 (the “Maturity Date”) and is convertible, at the sole option of the Holder, into restricted shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”) at the conversion price of \$5.25 per share of Common Stock. The Debenture bears interest at the coupon rate of ten percent (10%) per annum, computed on an annual basis of a 365 day year, payable in quarterly installments on March 31, June 30, September 30 and December 31 of each calendar year until the Maturity Date. In accordance with the debenture agreement, the deferred interest for the initial year of debenture shall be deferred and amortized over the remainder of the term. The Holder at its option may choose to receive such coupon interest payment in shares of Common Stock calculated using the average of the open and close prices of the Company’s common stock on the date such interest payment is due. To date, the Holder has elected to take such coupon interest in cash as it becomes due. The Company has the right, but not the obligation, to repay the Debenture prior to the Maturity Date (the “Redemption Payment”). If the closing bid price of the Common Stock is in excess of \$5.25 when the Company notifies the Holder it has elected to prepay the Debenture (the “Redemption Date”), the Company must redeem the Debenture by delivering to the Holder 952,381 shares of Common Stock and any unpaid coupon interest in lieu of a cash Redemption Payment. If the Holder elects to receive the Redemption Payment in cash, or if the closing bid price of the Common Stock is less than \$5.25, the Company shall pay to the Holder a Redemption Payment in cash equal to the principal amount of the Debenture, plus any accrued coupon interest, plus additional interest of 7% per annum for the period from the Closing Date to the Redemption Date and warrants to purchase 619,048 shares of Common Stock which shall expire in three years from the date of issuance at the exercise price of \$6.05 per share of Common Stock. The Company cannot conclude that it has sufficient authorized and unissued shares to settle the contract after considering all other commitments that may require the issuance of stock during the maximum period the derivative instrument could remain outstanding. This is due to the fact that the interest payments are payable in stock of the Company, at the option of the Holder, based on the current market price of the common stock on the date such payments are due. Therefore, the number of shares due as interest payments is essentially indeterminate and the Company cannot conclude that it has sufficient authorized and unissued shares to settle the conversion feature. Accordingly, the Company bifurcated the embedded features from the host contract and recorded them as a derivative liability at fair value. A debt discount was recognized in the same amount as the derivative liability associated with embedded features bifurcated from the Series C Convertible Debenture.

On July 2, 2014, in conjunction with the issuance of the Company’s Series C Convertible Debentures, the Company issued 187,000 shares of its Series A Convertible Preferred stock (the “Series A”) to Dr. Milton Boniuk, pursuant to the terms of the Debenture. Proceeds received in a financing transaction are allocated to the instruments issued prior to evaluating hybrid contracts for bifurcation of embedded derivatives. Since the Series A Convertible Preferred Stock is classified as equity, the proceeds allocated to the Preferred Stock are recorded at relative fair value. The fair value of the Series A was \$1,645,606 at issuance and the relative fair value was calculated as \$1,152,297. The remaining amount of the proceeds was allocated to the Debenture and a debt discount of \$1,152,297 was recorded to offset the amount of the proceeds allocated to the Series A. Then, the embedded derivative was bifurcated at its fair value of \$1,879,428 with the remaining balance allocated to the host instrument (Debenture). The total debt discount will be amortized over the term of the Debenture using the effective interest method. For the year ended June 30, 2015, the Company recognized amortization of this discount as an additional interest charge to “Discount on convertible debentures” in the amount of \$512,330.

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

Proceeds	\$5,000,000
Debt discount	
Series A Preferred	(1,152,297)
Embedded derivative	(1,879,428)
	1,968,275
Amortization of debt discount for the year ended June 30, 2015	512,330
Balance at June 30, 2015	\$2,480,605

F-21

The Company used a lattice model that values the compound embedded derivatives of the Series C Convertible Debenture based on a probability weighted discounted cash flow model at issuance and June 30, 2015.

The following assumptions were used for the valuation of the compound embedded derivative at July 2, 2014:

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

- The underlying stock price was used as the fair value of the common stock. The stock price at issuance was **\$3.00**.  
· The warrant has a \$5.25 exercise price;

- The projected annual volatility was 92%;

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

- The Company would redeem the debentures projected initially at 0% of the time and increase monthly by 1.0% to a maximum of **5.0%** (from alternative financing being available for a Redemption event to occur);

- The Holder would automatically convert the interest if the Company was not in default and its shares value would 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 transactions at issuance) adjusted for changes in the risk free rate is 21.86%;

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

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

· The balance of the Series C Convertible Debenture as of June 30, 2015 is \$5,000,000;

· The underlying stock price was used as the fair value of the common stock. The stock price decreased to **\$1.75** at June 30, 2015 which decreased the warrant value with the \$5.25 exercise price (further out to in the money);

· The projected annual volatility was 62%;

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

· The Company would redeem the debentures projected initially at 0% of the time and increase monthly by 1.0% to a maximum of **5.0%** (from alternative financing being available for a Redemption event to occur);

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

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

· The weighted cost of capital discount rate (based on the market value of the transaction at issuance) adjusted for changes in the risk free rate is **21.97%**;

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

The fair value of the compound embedded derivatives of the Series C Convertible Debenture at issuance and June 30, 2015 was \$1,879,428 and \$476,289, respectively.

## **Note 8 – Equity Transactions**

On September 3, 2013, effective September 10, 2013, NanoViricides, Inc. filed a Certificate of Change to its Articles of Incorporation pursuant to Section 78.209 of the Nevada Revised Statutes (the “Amendment”). The Amendment effectuated a reverse stock split of the Company’s common stock, par value \$0.001 per share (the “Common Stock”) by simultaneously decreasing the number of the Company’s authorized and outstanding capital stock on a basis of 1 for 3.5 shares (the “Split”). All share amounts and per share amounts have been retroactively restated to reflect this reverse stock split.

Fiscal Year Ending June 30, 2013 Transactions

For the year ended June 30, 2013, the Board of Directors authorized the issuance of 571,429 shares of its \$.001 par value common stock with a restrictive legend for the payment of additional interest payable to the holders of the Company's Series B Convertible Debentures and recognized a charge for interest expense of \$665,497.

For the year ended June 30, 2013, the Board of Directors authorized the issuance of 71,428 shares of its \$.001 par value common stock with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$60,000.

F-22



For the year ended June 30, 2013, the Board of Directors authorized the issuance of 169,643 shares of its Series A Preferred stock \$.001 par value with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$445,044.

For the year ended June 30, 2013, the Scientific Advisory Board (SAB) was granted warrants to purchase 68,572 shares of common stock. The warrants expire during the fiscal year ending June 30, 2017. The Company recorded a consulting expense of \$141,600.

For the year ended June 30, 2013, the Company's Board of Directors authorized the issuance of 42,977 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$84,956.

For the year ended June 30, 2013, the Company's Board of Directors authorized the issuance of 8,521 shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of \$18,750.

*Fiscal Year Ending June 30, 2014 Transactions*

On September 9, 2013, the Company entered into a Securities Purchase Agreement (the "Agreement") with certain purchasers (the "Purchasers"), relating to the offering and sale (the "Offering") of units ("Units") at the aggregate purchase price of \$3.50 ("Purchase Price") per Unit, consisting of one share of the Company's common stock, par value \$0.001 per share (the "Common Stock") and a warrant to purchase one share of Common Stock ("Warrant"), issuable upon exercise of the Warrant at the exercise price of \$5.25 per share (the "Warrant Shares", collectively with the Units, Common Stock and Warrant, the "Securities") The Warrants are exercisable immediately and expire five years after issuance.

On September 12, 2013, post reverse split the Company and the Purchasers consummated the purchase and sale of the Securities (the "Closing"), and the Company raised gross proceeds of \$10,308,996 before expenses of the Offering of approximately \$618,540, which includes placement agent and attorneys' fees. The Company issued 2,945,428 Units. On September 25, 2013 certain of these Unit Holders exercised 35,357 Warrants to purchase 35,357 shares of the Company's common stock, par value \$0.001 per share, for gross proceeds of \$185,624. On January 21, 2014 and February 6, 2014 certain of these Unit Holders exercised 75,000 and 25,000 Warrants to respectively purchase 75,000 and 25,000 shares of the Company's common stock, par value \$0.001 per share, for gross proceeds of \$393,750 and \$131,750 respectively.

The Offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the Securities and Exchange Commission on December 21, 2012. The Company, pursuant to Rule 424(b) under the Securities Act of 1933, has filed with the Securities and Exchange Commission a prospectus supplement relating to the Offering.

F-23

In connection with the Offering, pursuant to a Placement Agency Agreement dated September 9, 2013 among Midtown Partners & Co., LLC and Chardan Capital Markets, LLC (collectively, the "Placement Agents"), the Company paid the Placement Agents an aggregate cash fee representing 6% (3% each) of the gross Purchase Price paid by the Purchasers and warrants to purchase an aggregate of 2% (1% each) of the number of shares of Common Stock sold in the Offering (the "Compensation Warrants") and substantially similar to the Warrants, at an exercise price equal to \$5.25 per share. The Compensation Warrants will otherwise comply with FINRA Rule 5110(g)(1) in that for a period of nine months after the issuance date of the Compensation Warrants, neither the Compensation Warrants nor any warrant shares issued upon exercise of the compensation warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the Closing. Upon issuance of the compensation warrants, the Company recognized Costs associated with the sale of securities ( a capital item ) of \$113,696 and a corresponding increase in additional paid in capital of \$113,696.

On September 25, 2013, the Company's Common Stock began trading on the NYSE MKT exchange under the symbol NNVC.

On January 21, 2014, the Company entered into a Securities Purchase Agreement (the "Agreement") with certain purchasers (the "Purchasers"), relating to the offering and sale (the "Offering") of units ("Units") at the aggregate purchase price of \$5.25 ("Purchase Price") per Unit. The price per Unit was equal to a four percent (4%) discount to the 20-day VWAP of the Company's stock price on Friday, January 17, 2014. The exercise price of the Warrant was equal to the closing price of the Company's stock on Friday, January 17, 2014. Each Unit consisted of one share of the Company's common stock, par value \$0.001 per share (the "Common Stock") and Sixty-Five Hundredths (65/100) of a warrant to purchase one share of Common Stock ("Warrant"), issuable upon exercise of the Warrant at the exercise price of \$6.05 per share (the "Warrant Shares", collectively with the Units, Common Stock and Warrant, the "Securities"). The Warrants are exercisable immediately and expire five years after issuance.

On January 24, 2014, the Company and the Purchasers consummated the purchase and sale of the Securities (the "Closing") of 3,815,285 shares of Common Stock and 2,479,935 Warrants, and the Company raised gross proceeds of \$20,030,207 before expenses of the Offering of approximately \$1,200,000, which includes placement agent fees but does not include attorneys' fees and other expenses. The Company intends to use the proceeds for general business purposes and expects that it will be able to accelerate the development of its drug candidate pipeline with this additional funding.

The Offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the Securities and Exchange Commission on December 21, 2012 and Form S-3MEF (File No. 333-193439).

In connection with the Offering, pursuant to a Placement Agency Agreement dated January 20, 2014 among Midtown Partners & Co., LLC and Chardan Capital Markets, LLC (collectively, the “Placement Agents”), the Company paid the Placement Agents an aggregate cash fee representing 6% of the gross Purchase Price paid by the Purchasers and warrants to purchase an aggregate of 2% of the number of shares of Common Stock sold in the Offering (the “Compensation Warrants”) representing two percent of the Shares and substantially similar to the Warrants, at an exercise price equal to \$6.05 per share. The Compensation Warrants will otherwise comply with FINRA Rule 5110(g)(1) in that for a period of six months after the issuance date of the Compensation Warrants, neither the Compensation Warrants nor any warrant shares issued upon exercise of the compensation warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the Closing.

F-24

Unregistered Securities

In December, 2013, the Company issued 7,143 shares of Common Stock with a restrictive legend at \$3.50 per share upon the exercise of Warrants.

For the year ended June 30, 2014, the Board of Directors authorized the issuance of 571,429 shares of its \$.001 par value common stock with a restrictive legend for the payment of additional interest payable to the holders of the Company's Series B Convertible Debentures and recognized a charge for interest expense of \$2,605,716.

For the year ended June 30, 2014, the Company's Board of Directors authorized the issuance of 29,662 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$102,001.

For the year ended June 30, 2014, the Company's Board of Directors authorized the issuance of 13,146 shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of \$45,000.

For the year ended June 30, 2014 the Board of Directors authorized the issuance of 203,079 shares of its Series A Preferred stock \$.001 par value with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$2,123,014.

For the year ended June 30, 2014, the Company authorized the issuance of 71,430 shares of its \$.001 par value common stock with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$287,860.

For the year ended June 30, 2014 the Scientific Advisory Board (SAB) was granted warrants to purchase 72,439 shares of common stock. The warrants expire during the fiscal year ending June 30, 2018. The Company recorded a consulting expense of \$199,849.

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

June 30,  
2014

Expected life (year)	4	
Expected volatility	78.39%-98.09%	
Expected annual rate of quarterly dividends	0.00	%
Risk-free rate(s)	.37-1.12	%

There is currently no market for the shares of Series A Preferred Stock and they can only be converted into shares of common stock upon a change of control of the Company. The Company, therefore, estimated the fair value of the Series A Preferred stock granted to various employees on the date of grant. The 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 either by the Company or a Change of Control. The valuation of the Series A Preferred Stock as of 6/30/14 used the following inputs:

a. The common stock price (post-reverse split) was in the range \$2.45 to \$3.90;

b. 47,026,173 to 54,614,930 shares outstanding and Series A Preferred shares with 2,572 (post-split 9/10/13) issued monthly; and 169,644 issued annually to employees;

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

d. 54,506,459 to 62,208,499 total voting shares and the monthly shares representing voting rights of 0.042% to 0.484% of the total; and the annual shares representing 1.02% to 2.389% of the total;

e. The conversion value is based on an assumption for calculation purposes only of a Change of Control in 4 years from 3/1/13 and a restricted term of 3.67 to 2.67 years;

f. 42.87% to 27.11% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 121.97% to 265.70% volatility, 0.37% to 1.62% risk-free rate) applied to the converted common.

Based upon the above assumptions the estimated fair value of the preferred shares issued to Company employees as a whole for the fiscal year ended June 30, 2014 was calculated to be \$2,123,014. There are no assurances that such estimated fair value represents a market value between a willing buyer and seller.

#### Fiscal Year Ending June 30, 2015 Transactions

On July 17, 2014, the Company filed a registration statement on Form S-3 (the "Form S-3") registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009, ("Old Warrants") as described more fully in the Form S-3 (the "Registered Warrants"). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. Holders of the Old Warrants were required to submit Notice of Exercise by August 15, 2014, or their warrants would expire. The Company received Notices to Exercise Warrants and the exercise price to purchase an aggregate of 1,926,656 shares of the Company's common stock at the exercise price of \$3.50 per share for an aggregate purchase price of \$6,743,297.

On February 1, 2015 the Company's Board of Directors authorized the issuance of 571,433 shares of the Company's \$0.001 par value common stock as annual interest payable to holders of the Company's Series B Debentures. The Company recorded interest expense of \$1,502,870 for the year ended June 30, 2015 calculated using the fair market value of the Company's common stock on the date issued.

#### Unregistered Securities

As discussed in Note 7, on July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debentures, the Company issued 187,000 Shares of its Series A Convertible Preferred stock to Dr. Milton Boniuk, pursuant to the terms of the Debenture. The Company allocated the proceeds received between the Debenture and the

Preferred Stock on a relative fair value basis. The amount allocated to the Preferred stock was \$1,152,297.

For the year ended June 30, 2015, the Scientific Advisory Board was granted fully vested warrants to purchase 68,592 shares of common stock at exercise prices between \$2.00- \$5.02 per share expiring in the fiscal year ending June 30, 2019. These warrants were valued at \$59,675 and recorded as consulting expense.

For the year ended June 30, 2015, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

Expected life (year)	4	
Expected volatility	37.44%	-45.84 %
Expected annual rate of quarterly dividends	0.00	%
Risk-free rate(s)	1.20 - 1.67	%



For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 35,154 shares of its common stock which are fully vested with a restrictive legend for consulting services. The Company recorded an expense of \$109,360 which is the fair value at date of issuance.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 16,408 shares of its common stock which are fully vested with a restrictive legend for Director services. The Company recorded an expense of \$45,000 which is the fair value at date of issuance.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 2,858 shares of its Series A Convertible Preferred Stock which are fully vested for consulting services. The Company recorded an expense of \$24,474.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 71,430 shares of its common stock which are fully vested with a restricted legend for employee compensation. The Company recorded an expense of \$125,003 which is the fair value at date of issuance.

For the year ended June 30, 2015, the Company's Board of Directors authorized the issuance of 200,508 shares of its Series A Convertible Preferred Stock which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of \$852,760 which is the fair value at date of issuance.

The fair value of the Series A Preferred stock at each date of issuance was as follows:

Date	Shares	Value
7/31/2014	2,572	\$25,821
8/31/2014	2,572	27,560
9/30/2014	2,572	19,602
10/31/2014	2,572	18,765
11/30/2014	2,572	22,025
12/31/2014	2,572	18,849
1/31/2015	2,572	16,501
2/28/2015	2,572	15,943
3/31/2015	2,572	16,299
4/30/2015	2,572	14,124

5/31/2015	2,572	11,460
6/30/2015	172,216	645,811
	200,508	\$852,760

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 \$2.29 to \$1.55;
- b. The calculated weighted average number of shares of common stock in the period;
- c. A 5.36% premium over the common shares for the voting preferences;
- d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 4.896% to 5.046% of the total;
- e. The conversion value is based on an assumption for calculation purposes only of a Change of Control in 4 years from March 1, 2013 and a remaining restricted term of 1.92 to 1.67 years;
- f. 30.86% to 31.42% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 63.52% to 69.38% volatility, 0.22% to 0.26% risk free rate) applied to the converted common.

## Note 9 – Stock Options and Warrants

The following table presents the activity of stock options issued for the period ended June 30, 2015 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, 2013	535,715	0.35	2.23	1,521,429

Edgar Filing: NANO VIRICIDES, INC. - Form 10-K

Granted	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding at June 30, 2014	535,715	\$ 0.35	1.23	\$2,094,643
Granted	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding at June 30, 2015	535,715	\$ 0.35	0.23	\$749,997

F-27

As of June 30, 2015 there was no unrecognized compensation cost.

Stock Warrants	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding at June 30, 2013	3,400,559	4.025	0.86	134,559
Granted	5,629,152	5.63	4.37	-
Exercised	142,500	3.50	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding and exercisable at June 30, 2014	8,887,211	\$ 5.01	2.78	\$2,278,458
Granted	68,592	3.63	-	-
Exercised	1,926,656	3.50	-	-
Expired	1,052,472	3.50	-	-
Canceled	-	-	-	-
Outstanding and exercisable at June 30, 2015	5,976,675	\$ 5.14	3.20	\$19,000

Of the above warrants; 345,720 expire in fiscal year ending June 30, 2016; 68,571 expire in fiscal year ending June 30, 2017; 68,570 in fiscal year ending June 30, 2018; 5,493,814 in fiscal year ending June 30, 2019.

## Note 10 – Fair Value Measurement

### Fair value measurements

At June 30, 2015 and 2014, 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 June 30, 2015 and 2014, the estimated fair values of the liabilities measured on a recurring basis are as follows:

Fair Value Measurements at  
June 30, 2015:

	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series B debentures	\$ -	-	\$ 366,764
Derivative liability – Series C debentures	-	-	476,289
Derivative liability – warrants	-	-	3,442,754
Total derivatives	\$ -	\$ -	\$ 4,285,808

Fair Value Measurements at  
June 30, 2014:

	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series B debentures	\$ -	\$ -	5,699,703
Derivative liability - warrants	-	-	5,235,682
Total derivatives	\$ -	\$ -	\$ 10,935,385

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, 2,910,071 and 2,379,935 respectively are outstanding at June 30, 2015. Additionally, the Company issued 58,910 and 76,306 warrants, respectively, to the placement agents which are also outstanding at June 30, 2015. During the fiscal year ended June 30, 2015 the Company issued 68,592 warrants to members of the Scientific Advisory board.

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 issuance, exercise, and the quarterly periods with the following assumptions:

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

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

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

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

1 Year	
9/12/13	87%
1/24/14	93%
6/30/14	92%
6/30/15	62%

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 year ended June 30, 2015:

	Fair Value Measurement Using Significant Unobservable Inputs		
	Derivative liability – Series B	Derivative liability – Series C	Derivative liability - warrant
Beginning balance at July 1, 2013	\$3,751,645	\$-	\$-
Additions during the year	-	-	5,740,540
Change in fair value	1,948,058	-	(504,858 )
Transfer in and/or out of Level 3	-	-	-
Balance at July 1, 2014	\$5,699,703	\$-	\$5,235,682
Additions during the year	-	1,879,428	-
Change in fair value	(5,332,938)	(1,403,139)	(1,792,928)
Transfer in and/or out of Level 3	-	-	-
Balance at June 30, 2015	\$366,765	\$476,289	\$3,442,754

#### Note 11 – Income Tax Provision

##### Deferred Tax Assets/(Liabilities)

The Company has no current tax expense due to its losses.

The income tax expense for the years ended June 30, 2015 and 2014 differed from the amounts computed by applying the U.S. federal income tax rate of 34% as follows:

	6.30.2015		6.30.2014	
Federal Statutory Rate	-34.00	%	-34.00	%
Permanent Differences	-37.00	%	-37.00	%
Valuation Allowance	71.00	%	71.00	%
Effective Tax Rate	0.00	%	0.00	%

The significant components of the Company's deferred tax assets and liabilities at June 30, 2015 and 2014 are as follows:

	<b>6.30.2015</b>	<b>6.30.2014</b>
Net operating losses	16,394,801	13,408,064
Research and Development Credit	4,800,186	3,422,745
Other	5,214,064	4,178,211
<b><i>Total gross deferred tax assets</i></b>	<b>26,409,051</b>	<b>21,009,020</b>
Less Valuation allowance	(26,409,051)	(21,009,020)
<b><i>Net deferred tax assets</i></b>	<b>-</b>	<b>-</b>

At June 30, 2015 and 2014, the Company has recorded a full valuation allowance against its net deferred tax assets of approximately \$26,409,000 and \$21,009,000 respectively. The change in the valuation allowance during the year ended 2015 was approximately \$5,400,000 and a full valuation allowance has been recorded since, in the judgement of management, these assets are not more likely than not to be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences and carryforwards become deductible or are utilized.

As of June 30, 2015, the Company has approximately \$43,400,000 of gross net operating loss carryforwards. As of June 30, 2015, credit carryforwards for federal and state purposes are approximately \$4,177,000 and \$623,000 respectively. The net operating loss and credit carryforwards begin to expire in 2025.

Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carry forwards could be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carry forwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carry forward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there could be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

The Company applies the elements of FASB ASC 740-10 "Income Taxes - Overall" regarding accounting for uncertainty in income taxes. This clarifies the accounting for uncertainty in income taxes recognized in financial statements and required impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. As of June 30, 2015 the Company did not have any unrecognized tax benefits and has not accrued any interest or penalties through 2015. The Company does not expect to have any unrecognized tax benefits within the next twelve months. The Company's policy is to recognize interest and



penalties related to tax matters within the income tax provision.

F-29

## Note 12 – Commitments and Contingencies

The Company maintains facilities located at 135 Wood Street, West Haven, Connecticut, that includes approximately 7,000 square feet of office and laboratory space at a base monthly rent of \$8,695. The lease expired on February 28, 2011 and is now on a month-by-month basis.

Total rent expense at 135 Wood Street, West Haven, Connecticut amounted to \$104,340, \$104,340 and \$102,030 for the years ended June 30, 2015, 2014 and 2013 respectively.

### 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

On March 3, 2010, the Company entered into employment agreements with its two executive officers, Eugene Seymour, Chief Executive Officer and Chief Financial Officer and Anil Diwan, President and Chairman of Board. Both agreements provided a minimum annual base salary of \$250,000 for a term of four (4) years (see subsequent event footnote.) In addition, Dr. Seymour and Dr. Diwan are eligible for an increase in base salary to \$275,000 if the Company consummates a financing with gross proceeds of at least \$5,000,000. Also, the base salary shall increase to \$300,000 for Dr. Seymour and \$300,000 for Dr. Diwan if the Company becomes listed on a national stock exchange. On September 13, 2013 the Company was listed on the NYSEMKT, a national exchange.

As additional compensation to each officer, under the employment agreements, the Company issued 71,430 shares of the Company's Common Stock on each anniversary of the respective employment agreements.

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 Compensation Committee of the Board of Directors 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 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 provides for a base salary of \$9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. On January 1, 2015 her compensation was increased to \$10,800 per month.

#### 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 14 – Subsequent Events**

On July 21, 2015 the Company entered into employment agreements with Anil Diwan, PhD, the Company's founder, President and Chairman, and Eugene Seymour, MD, MPH, the Company's Chief Executive Officer and Director effective July 1, 2015.

The Company and Dr. Diwan agreed Dr. Diwan would continue to serve as the Company's President and Chairman of the Board of Directors 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 that vest equally over the term of the employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Diwan. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017.

The Company and Dr. Seymour agreed that Dr. Seymour would continue to serve as the Company's Chief Executive Officer and Director 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 that vest equally over the term of employment agreement. Any unvested shares of Series A Preferred Stock are subject to forfeiture upon termination for cause or resignation of Dr. Seymour. The employment agreement also provides incentive bonuses of \$75,000 per year payable on or before July 31, 2015, 2016 and 2017.