





Table of Contents

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      o No      x

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      x No      o

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 o                      No x (Not required by smaller reporting companies)

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 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            ..  
Non-accelerated filer            ..                      Smaller reporting Company            x

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

Yes      o No      x

As of , 2011 there were 147,316,827 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on December 31, 2010 by non-affiliates of the registrant was \$132,756,355 based on the closing price of \$1.47 per share as reported on the OTC Bulletin Board on January 31, 2011, 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

## TABLE OF CONTENTS

## PART I

Item 1.	<u>Description of Business</u>	4
Item 1A	<u>Risk Factors</u>	56
Item 1B	<u>Unresolved Staff Comments</u>	75
Item 2.	<u>Properties</u>	75
Item 3.	<u>Legal Proceedings</u>	75
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	75

## PART II

Item 5.	<u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	76
Item 6.	<u>Selected Financial Data</u>	81
Item 7.	<u>Management's Discussion and Analysis of Plan of Operation</u>	81
Item 7A	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	81
Item 8.	<u>Financial Statements and Supplementary Data</u>	94
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	95
Item 9A(T)	<u>Controls and Procedures</u>	95
Item 9B.	<u>Other Information</u>	97

## PART III

Item 10.	<u>Directors, Executive Officers, Promoters and Control Persons, Compliance with Section 16(A) of the Exchange Act.</u>	97
Item 11.	<u>Executive Compensation</u>	98
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	100
Item 13.	<u>Certain Relationships and Related Transactions and Director Independence</u>	102
Item 14.	<u>Principal Accountant Fees and Services</u>	103

## PART IV

Item 15.	<u>Exhibits, Financial Statement Schedules</u>	104
----------	--	-----

<u>SIGNATURES</u>	105
-------------------	-----

Table of Contents

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,” 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: DESCRIPTION OF BUSINESS

Organization and Nature of Business

The 2010-2011 Financial Year (FY) in Review

NanoViricides, Inc. is a leading company in the application of nanomedicine technologies to the complex issues of viral diseases. The nanoviricide® technology permits direct attacks at multiple points on a virus particle. It is believed that such actions 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.

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. Then last year we added drug candidates effective against Dengue viruses to our pipeline. Thus, in just about five years we have developed a very broad pipeline of drug candidates. We believe that we will have clinically relevant drug candidates in many, if not all, of these disease areas.

With the extremely high efficacy levels of our anti-influenza drug candidates, we were able to combine our multiple influenza drug programs and formulate a single Pan-Influenza drug program, FluCide™, last year. We optimized the drug candidates in the FluCide program this year and were pleasantly surprised to achieve even greater levels of effectiveness, while the drug still appears to be as safe as in previous studies. This has enabled us to declare a clinical drug candidate against Influenza subsequent to the FY end.

## Table of Contents

A single dose therapy of normal influenza infection appears to be feasible with this anti-influenza nanoviricide. A single injection can be easily administered by a medical officer when the patient goes for the first clinical visit. The Company believes that in most instances no follow-on treatment would be necessary. This expectation is based on the following results from its animal studies: (1) the extremely high treatment effectiveness in inhibiting the cycle of infection, virus expansion and spread of infection and, (2) the significantly long lasting effects of the drug treatment after the drug is discontinued.

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.

This year we also conducted an anti-HIV study in the standard humanized mouse model in the HIVCide program. 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 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.

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; (3) quickly develop new drugs with different routes of administration; among many other benefits.

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

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

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

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

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



## Table of Contents

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.

Since a year ago, 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 received. 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 SARS will continue to occur. At present, there is no feasible therapeutic intervention for outbreaks of novel viruses.

This year we continued to raise financing successfully. To date, Seaside 88, LP, has continued its investment in the Company and has invested an aggregate of \$15M thus far. With this funding, and our continuing controlled rate of expenditure, as of the date hereof, we have over \$11M cash and cash equivalents in hand. This cash reserve now enables us to start moving our drug candidates forward in the US Food and Drug Administration (“FDA”) and International regulatory approval processes.

We now have five commercially significant active, drug development programs: (1) FluCide-I, against all Influenzas, (2) nanoviricide eye drops against adenoviral EKC and herpes keratitis, (3) HIVCide™-I against HIV/AIDS, (4) HerpeCide™-I skin cream formulation for herpes cold sores and genital warts, and (5) 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. All of our biological testing is conducted by third parties.

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

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, towards the end of this year, we engaged Biologics Consulting Group, Inc., to help us with the FDA regulatory submissions.

We have declared a clinical candidate in our FluCide program, subsequent to this fiscal year. We are working on filing a pre-IND application with the US FDA for this clinical candidate. A major roadblock for us in moving drugs forward in the regulatory process has been cGMP (“current Good Manufacturing Practices”) manufacturing capability. We have examined contract manufacturing as well as leasing options to resolve this issue. After carefully considering the costs and benefits of different approaches over the last few years, we decided on building a small pilot plant for cGMP manufacturing. A building with land was chosen and has been acquired by a separate entity. A group of private financiers that includes our founder Dr. Anil Diwan has acquired the building via , Inno-Haven, LLC, a company formed specifically for that purpose. We are now in the process of selecting experienced parties for the actual design and construction of the laboratory facilities and cGMP pilot plant. We intend to lease the building from Inno-Haven, LLC. The terms of the lease have not been finalized.

Because of the extremely high effectiveness of the nanoviricides drug candidates in animal studies, we believe that a small pilot plant with kilogram production scale cGMP capability should be sufficient to take us through human clinical studies. This is a strategic benefit resulting from our engaging into further optimization of the influenza candidates towards very high effectiveness levels. A smaller plant means lower capital expenditures. The Company

continues to seek cash-preserving means of financing for the new lab and cGMP capability. To this end, we plan to apply for Small Business Administration (“SBA”) loans as well as other loans from investor groups. Our founder, Dr. Anil Diwan, has agreed to provide certain personal guarantees for such transactions. We may also raise additional equity-based financing as needed.

## Table of Contents

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

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

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

Based on 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).

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 corroborating 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.

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

In 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.

Table of Contents

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

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.

This year we have also improved our laboratory infrastructure, adding several new instruments and further chemistry capabilities. We have recently purchased substantial amounts of laboratory equipment for the characterization of our nanomaterials. Much of this equipment is in the process of being set up and scientists are being trained to use the same. We did this with the objective of enabling us to file pre-IND applications for our drug candidates with the FDA, which is a step toward filing an IND application.

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

Table of Contents

In this year, as in the previous year, we have also made significant strides in achieving exposure for the Company and its technologies. Anil Diwan, PhD, President of the Company was invited to participate in a panel discussion on nanomedicines development entitled “NanoMedicine: Science, Business and Regulatory Perspectives” at the NanoBusiness 2010 meeting in Chicago, Illinois. Dr. Diwan was also invited to and presented a talk at the Second Annual Conference of the American Society for NanoMedicine (ASNM). This was a joint meeting, co-sponsored by the Office of AIDS Research, National Institutes of Health (NIH), the Division of AIDS, National Institute of Allergy and Infectious Diseases of the NIH, and ASNM. Dr. Diwan focused primarily on the first (old) anti-HIV nanoviricides animal study. Dr. Diwan was invited to present the Company’s anti-Dengue virus studies at the meeting “A Re-Emerging Challenge in the Americas: Opportunities for Dengue Research Collaborations” sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) held February 15-18, 2011 in San Juan, Puerto Rico. Dr. Diwan presented a talk entitled “Nanoviricides® as Anti-Influenza Agents” at the TechConnect World 2011 Conferences and Expo in Boston, Massachusetts on June 16, 2011. Dr. Diwan, was recently invited to present at the French Biotech Tour Infectious Diseases Meeting held at the MIT Faculty Club in Boston, Massachusetts, on September 21, 2011. He presented a summary of the nanoviricides® platform technology, the Company’s drug pipeline, its recent successes with animal studies for the Company’s influenza therapeutic FluCide™, and progress towards the initial FDA submission. In addition, he also had an opportunity to discuss the nanoviricides drug programs and progress with certain big pharma scientists and business development executives in one-on-one meetings.

Our collaborators are also presenting technical and scientific data on the evaluation of nanoviricides drug candidates. This year, the results of the evaluation of several of our nanoviricides® anti-Ebola agents were presented on July 17th at the 2010 Annual Meeting of the American Society for Virology. The studies were performed in the laboratory of Dr. Gene Olinger at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), Frederick, MD. Dr. Corinne Scully, USAMRIID, delivered the presentation, which was entitled “Polymeric Micelle Nanomaterials as Antiviral Compounds For Ebola Virus Infection.”

In addition to the technical and scientific meeting presentations, the Company was also invited to participate in meetings designed to showcase the Company to potential investors and the finance industry in general. Dr. Eugene Seymour, our CEO, discussed recent Company events and the Company’s technology at an Investor Conference sponsored by ProActive Investors held on June 16, 2011 in Denver, Colorado. Dr. Seymour was also invited to present at the OneMedForum New York 2011 on June 23rd-24th, 2011 at the Roosevelt Hotel in New York City. He updated the investors on the Company’s progress in the FluCide drug program and regarding the cGMP capability. Dr. Seymour also presented at the Rodman & Renshaw Annual Global Investment Conference held in New York City on September 13, 2011. He discussed the nanoviricides® platform technology, the Company’s drug pipeline, its recent successes with animal studies for the Company’s influenza therapeutic FluCide™, and progress towards the initial FDA submission.

We believe that these presentations, resulting exposure, and related meetings and discussions have been extremely beneficial to the Company. This exposure as well as our continuing successes in the drug development efforts have enabled us to achieve significant amounts of financing this year.

On September 16, 2010, Seaside 88, LP, exercised its option to invest an additional \$5,000,000 into the Company on substantially similar terms to their previous \$5M investment on May 12, 2010.

On April 19, 2011, the Company received a financing of \$5M from Seaside 88, LP. The first tranche of \$2.5M was received immediately upon closing. The Company received the second tranche of \$2.5M on July 27, 2011. The terms of this financing were substantially similar to the terms of the previous financing by Seaside 88.

To date, the investor firm Seaside 88, LP, has invested \$15M into our Company, drawing down from our “Universal Form S-3 Shelf Registration” which has been effective since April 29, 2010. This financing vehicle has enabled us to keep dilution to existing shareholders to a minimum. With this funding, and our continuing controlled rate of expenditure, we now have over \$11M cash in hand. This cash reserve now enables us to start moving our drug candidates forward in the US FDA and International regulatory approval processes.

With these successful financing efforts, and our continued low rate of expenditure, the Company estimates that it now has cash in hand sufficient for more than eighteen months of further R&D and operating expenses. In addition, the Company has successfully achieved the goal of securing a building for a new lab facility and cGMP capability without any capital expenditures. We plan to seek similar financing avenues to enable cGMP capability without incurring large capital expense.

## Table of Contents

We thus ended the financial year in a better financial position than the last year. This new financial strength has enabled us to move forward in our drug development programs. We are now tackling the major challenge of cGMP manufacturing capability. Our FluCide program is rapidly moving towards the Investigational New Drug (“IND”) filing stage. We believe that our other programs are also progressing successfully towards the regulatory submissions goal.

### 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.

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.





## Table of Contents

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 \$22,894,827 at June 30, 2011. For the year ended June 30, 2011 the Company had a net loss of \$6,155,084. 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.

## 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.

Table of Contents

SAR: Structure-Activity-Relationship study. When an initial lead drug compound is found that has activity, further studies on dug 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) Influenzas, (2) HIV, (3) Topical Eye Drops for viral diseases of the external eye, (4) Herpes “cold sores” and genital Herpes, and (5) 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™” 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. Our current relationships include:

For Influenza Viruses:

1. KARD Scientific, Inc., MA.
2. Southern Research Institute, AL.
3. TheVac, LLC, LA.
4. National (Central) Institute of Hygiene and Epidemiology (NIHE) (Vietnam), for H5N1 avian flu.

For HIV:

1. KARD Scientific, Inc., MA.
2. Southern Research Institute, Frederick, MD.
3. University of California at San Francisco (Dr. Cheryl Stoddart, PI), CA.

Table of Contents

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 Lab.

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. Gene Olinger Lab.

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, this year 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 additional collaborations in the process of formalization. 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, NV-INF-1, subsequent to the FY.

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.

## Table of Contents

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” it, 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 one 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.

## Table of Contents

Despite all evolutionary/spontaneous changes such as mutations, re-assortments, recombinations, etc., a particular virus retains its ability to bind to the same features on the cell surface at the same sites. 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 by a set of novel, multiple, concerted, mechanisms:

1. 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.
2. 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.
3. 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.

## Table of Contents

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 Part I, 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.

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.



## Table of Contents

We currently have, in early, active development, products against (1) HIV, (2) 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, Rabies, Dengue, (3) Eye drops against viral diseases of the eye such as conjunctivitis and keratitis, (4) Herpes virus cold sores and genital Herpes, and (5) Dengue viruses. In addition, we have research programs against Rabies virus, Ebola/Marburg family of viruses, as well as other Viral hemorrhagic fevers. We also have a research program called ADIF<sup>(TM)</sup> “Accurate-Drug-In-Field”, that we believe is the only way to combat a novel viral threat right in the field before it becomes an epidemic like SARS, bird flu H5N1, Ebola, or other viral outbreak. 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.

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.

## Table of Contents

### 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 \$21billion in 2013. The market for influenza drugs is estimated at about \$7billion. 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 candidate has shown efficacies animals that far exceed that of known drugs such as Oseltamivir (Tamiflu®, Roche) against common influenza in an animal model. We have consolidated all of our influenza drug programs into a single, broadly active, yet highly effective, pan-influenza FluCide program. The new FluCide is expected to be highly active against 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 anticipate significant cost savings as well as simplification in regulatory and eventual marketing efforts by consolidating these drug programs.

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 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.

We have declared one of these optimized drug candidates, NV-INF-1, as our clinical drug candidate against Influenzas, subsequent to this FY.

#### 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<sup>(TM)</sup> lead candidate was shown to rapidly resolve the clinical signs of the disease, when treatment was started after infection had set in. The clinical success included demonstration that no SEI's (immunoprecipitates) were formed in treated animals, as opposed to control group. SEI's are known to be the cause of blurred vision. There are currently no approved drugs available against EKC, and it is an active field of drug development research. 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).



## Table of Contents

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. Additional animal testing against HSV-1 infection of the eye is expected to be commissioned 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. 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.

## Table of Contents

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. 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.

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.

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.

## 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.

## Table of Contents

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 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. We believe that the term “Functional Cure” of HIV may be defined as:

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

While 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.

## Table of Contents

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.

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.

## Table of Contents

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 working on a pre-Investigational New Drug (“IND”) application for our anti-influenza clinical candidate, NV-INF-1, in the FluCide program, as of the date of this filing.

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.

Last year, we added two commercially important drug candidate to our pipeline, namely DengueCide and HerpeCide.

In addition, we simplified our anti-influenza drug programs because of the high efficacies of our new drug candidates into a single pan-Influenza broadly acting new FluCide. This single drug is being developed for all influenza indications including seasonal influenzas, highly pathogenic influenzas, bird flu, and novel epidemic influenzas such as the current novel H1N1/2009. We believe that this will reduce development costs significantly. This is also expected to help us gain expanded market share and easier market acceptance, including stockpiling, when a drug is approved. Emergency Use Authorization can occur under circumstances such as the current epidemic 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.

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 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

Page 23

---

## Table of Contents

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<sup>(TM)</sup> (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<sup>(TM)</sup>". 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.

## Table of Contents

### 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 nanoviricidides 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 nanoviricidides were effective at extremely low concentrations and many of them are considered by us to be drug candidates.

Four different nanoviricidides 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 nanoviricidides 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 nanoviricidide 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 nanoviricidide 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(TM)", 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 nanoviricidide 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-ITM", 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 nanoviricidide 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.



## Table of Contents

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 nanoviricidic 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 nanoviricidic 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 nanoviricidic (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 nanoviricidic 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 nanoviricidic 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 nanoviricidic compound was an effective treatment for human influenza in mice and that the concept of using a nanoviricidic 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 Nanoviricidic 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 nanoviricidic 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 nanoviricidic nanotechnology-based drug candidates were substantially more efficacious than Oseltamivir (Tamiflu®). Initial unpublished data suggest that this earliest nanoviricidic 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 nanoviricidic using an improved sialic-acid-based ligand as well as 100% of the mice treated with a nanoviricidic made using a ligand designed against the high path site of highly pathogenic influenzas including H5N1 were still surviving. Mice treated with H5N1-based nanoviricidic 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 nanoviricidic 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.

## Table of Contents

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  $121 \pm 2$  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  $435 \pm 5$  hrs. (or 18 days) on average. In contrast, mice treated with an extended Oseltamivir protocol (twice daily until death) survived for  $188 \pm 1$  hrs. (or 7.8 days) on average. Control infected mice survived for only  $121 \pm 1$  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.





## Table of Contents

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 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.

## Table of Contents

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.



## Table of Contents

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.

## Table of Contents

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 IIIB. 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 IIIB 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.

## Table of Contents

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).

## Table of Contents

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. About 50-100 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/>).

## Table of Contents

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(tm) 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.

## Table of Contents

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

### Other Work in Progress

The studies of biological testing of materials provide information that is easily understood and therefore readily reported. However, we continue to engage in substantial work that is needed for the 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 can be converted to c-GMP manufacturing processes. We have recently purchased substantial amounts of laboratory equipment for the characterization of our nanomaterials. Much of this equipment is in the process of being set up and scientists are being trained to use the same.

We have declared a clinical candidate for influenza in the FluCide program. We have prepared first drafts of a pre-IND application on this drug candidate. We are now working with our consultants, Biologics Consulting Group, (BCG), to finalize the draft. We will then file a pre-IND application with the FDA.

### 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.

These levels of efficacy differences between other product candidates against influenzas and bird flu can be easily seen to be insignificantly small compared to the ones established in our studies for the nanoviricides tested.

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 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 the evidence.



## Table of Contents

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.

## Table of Contents

### 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.

## Table of Contents

Development costs charged by TheraCour Pharma, Inc. for the year ended June 30, 2011 and 2010 were \$1,250,901 and \$1,086,927 respectively, and \$4,902,875 since inception. As of June 30, 2011, pursuant to its license agreement, the Company has paid a security advance of \$306,160 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, 2011.

On February 27, 2007, NanoViricides, Inc. entered into a sublease to occupy 5,000 square feet of space in Woodbridge, Connecticut. Performance of the Company's obligations was guaranteed by TheraCour Pharma, Inc., a principal shareholder of the Company and provider of the materials the Company uses in its operations. This lease expired on January 30, 2009, and we have relocated our operations to an expanded facility at 135 Wood Street, West Haven, Connecticut.

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 24.9% of the Common Stock of the Company.

TheraCour Pharma, Inc. owns 33,360,000 shares of the Company's outstanding Common Stock and 7,000,000 shares of the Company's Series A Convertible Preferred Stock as of June 30, 2010. 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. On December 3, 2009 TheraCour concluded its sales of the Company's stock pursuant to a Rule 10b5-1 trading plan selling, over a one year period, 1.8 million shares of the Company's common stock. The plan went into effect on February 17, 2009.

## 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.



## Table of Contents

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.

### Arrangement with KARD Scientific, Inc.

Owned and operated by Dr. Krishna Menon, KARD Scientific Inc. of Wilmington, Massachusetts, is currently our primary vendor for animal model study design and performance. KARD operates its own facilities in Beverly, Massachusetts.

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 by the executive officers of NanoViricides; and we retain all intellectual property resulting from the services by KARD.

Dr. Krishna Menon is the Company's Consulting Chief Regulatory Officer, a non-executive officer position.

Since inception, lab fees charged by KARD Scientific for services to the Company total \$1,352,537.

### 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™-I, AviFluCide™-I and FluCide-HP™ 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.

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.

Table of Contents

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 is 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 SRI in a ready to use form by the Company. Under this agreement, SRI 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 runs 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.

Research and Development Agreement with the University of California, San Francisco (UCSF)

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. Cheryl Stoddart, PhD, Assistant Professor in the UCSF Division of Experimental Medicine, will be the Principal Investigator. Dr. Stoddart is a recognized investigator in preclinical studies of anti-HIV compounds using the standard SCID-hu Thy/Liv humanized mouse model. In particular, she is well known for her work in validating that this mouse model is capable of accurately predicting clinical antiviral efficacy in humans. The National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), has recognized UCSF as an important site for anti-HIV drug screening studies. Dr. Stoddart's in-vivo testing of anti-HIV nanoviricides will complement the Company's previously announced in-vitro anti-HIV testing that is currently underway at the Southern Research Institute in Frederick, MD.

## Table of Contents

### 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).

### 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 coxsackie 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.



## Table of Contents

### 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.

## Table of Contents

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. However, we are fully aware that curing HIV will be a very long process.

### 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.

## Table of Contents

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<sup>(TM)</sup>) is a twice-a-day, orally active neuraminidase inhibitor, while GSK’s neuraminidase inhibitor, Relenza<sup>(TM)</sup> 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.





## Table of Contents

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.

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) is an enzyme that removes sialic acids from human cells, thus blocking entry of influenza virus. At present it is in Phase II clinical trials in the USA.

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.)

Table of Contents

- 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 Nooraa 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.

Table of Contents

## 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, 2011.

Table 1. Products in Development

	Project	Virus	Description	Development Stage
1	FluCide™	Influenza (Common), H5N1 Bird Flu, Highly Pathogenic Influenzas, novel H1N1/2009	Broad-Spectrum Anti-Influenza nanoviricide	Preclinical
2	HIVCide™	HIV/AIDS	Escape-resistant Anti-HIV nanoviricide	Preclinical
3	Nanoviricide Eye Drops	Adenoviruses, HSV-1	Eye Drops for Viral Diseases of the External Eye	Preclinical

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

4	HerpeCide (™)	HSV-1, HSV-2	Herpes “Cold Sores” and Genital Herpes, Topical Cream and Gel Formulations	Preclinical
5	DengueCide(™)	Dengue viruses, all types	Broad-Spectrum nanoviricide against all types of Dengue viruses	Preclinical
6	RabiCide (™)	Rabies	Anti-Rabies nanoviricide	Preclinical; Background Project
7	Nanoviricide against Ebola/Marburg	Filoviruses (Ebola, Marburg, various strains)	Broad-Spectrum nanoviricide against all strains of Ebola and Marburg filoviruses	Preclinical; Background Project
8	HepCCide (™)	HCV	Anti-HCV nanoviricide	R&D, project delayed, expect to restart in 2011-2012

## Table of Contents

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-I, 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.

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 undertook a new project last year 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. This year, we 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 expected to be conducted in the next six months.

HerpeCide - We undertook a new project this year and have already designed a ligand, made a nanoviricide drug, and tested in cell cultures successfully. HerpeCide is being developed as skin cream or gel formulation for the treatment of oral and genital herpes lesions.

DengueCide - We undertook a new project this year and have already designed a ligand, made a nanoviricide drug, and tested in cell cultures as well as in vivo successfully. We intend to continue optimizing the drug candidates.

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 during the economic crisis of the last year in order to conserve resources.

Nanoviricide against Ebola/Marburg - Our collaboration with USAMRIID for the development of a nanoviricide against Ebola/Marburg has resulted in significantly active drug candidates. We plan on further 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.





## Table of Contents

### 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. Our goals for the second generation of our anti-influenza drugs will be to develop an oral/bronchial administration that carries the drug into the bronchial/pulmonary space that is the primary site infection by influenza viruses. There can be no assurance that we will be able to develop a drug that may be administered orally or bronchially or that such a drug would be effective against influenza.

### Development Stage of Products

Our Influenza program is the most advanced and we anticipate filing a pre-IND application with the FDA soon. We will need cGMP drug product for filing an IND and conducting clinical trials in the future. [cGMP = current Good Manufacturing Practices]. We believe we will have cGMP capability next year.

All of the other products are in various stages of pre-clinical development. The Company believes that the anti-influenza drugs will advance into second stage of preclinical studies, known as “Tox Package” studies, as soon as appropriate facilities and finances are available. The Company believes that our anti-influenza drug candidates, anti-HIV drug candidates, as well as anti-viral eye drops 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 their research scale production facility in West Haven, Connecticut.

#### Manufacturing of Drugs

Subsequent to our fiscal year ended June 30, 2011, we have initiated lease discussions with Inno-Haven, LLC, a special purpose company formed for the purpose of real estate acquisition and improvements, which has acquired a light industrial building in Shelton, CT. Inno-Haven is controlled by Dr. Anil R. Diwan. The financing for this acquisition 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 is expected to perform improvements to the facility to enable modern laboratory space and cGMP facilities for the manufacture of the Nanoviricides' drug candidates. No lease agreement has been signed to date.

## Table of Contents

The Company intends to manufacture 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 or leased by the Company. In the event that we cannot secure funding that allows us to establish the necessary facilities to manufacture such drugs, we plan to subcontract with third party facilities that have the appropriate capabilities and regulatory licenses to manufacture our drugs and materials on a commercial scale.

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.

We have no commercial-scale manufacturing facilities at present. For our future 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.

Table of Contents

Development costs charged by and paid to TheraCour Pharma, Inc. were \$4,902,875 since inception through June 30, 2011 and \$1,250,901 and \$1,086,927 and \$828,952 for the years ended June 30, 2011, 2010 and 2009, respectively. No royalties are due or have been paid from inception through June 30, 2011.

TheraCour Pharma, Inc. owns 33,360,000 shares of the Company's 143,548,494 outstanding shares of common stock and 7,000,000 shares of our Series A Convertible Preferred Stock as of June 30, 2010. Anil Diwan, the Company's President and Chairman of the Board and Director, owns approximately seventy percent (70%) of the outstanding capital of TheraCour Pharma., Inc.

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

The Company believes that the drugs by themselves, FluCide, 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 either in-vitro or in-vivo studies that can be replicated by others.

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

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

	Patent or Application	Date of Issue/ Application	US Expiry Date	International	Owners
1	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].
2	PCT/US06/01820 (SOLUBILIZATION AND TARGETED DELIVERY OF DRUGS WITH SELF-ASSEMBLING AMPHIPHILIC	Applied: Jan 19, 2006 PCT Application.	Jan 18, 2023 (estimated)	Applications being filed.	TheraCour Pharma, Inc. [Exclusive License].

POLYMERS).

3	PCT/US2007/001607 SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTIVIRAL AGENTS	Applied: Jan 22, 2007	Jan 21, 2024 (estimated)	Applications to be filed.	TheraCour Pharma, Inc. [Exclusive License].
---	---	--------------------------	-----------------------------	------------------------------	--

## Table of Contents

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.

The counterpart of PCT/US06/01820 has issued as a Singapore National Patent Publication, a South African patent, and also as 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.

The counterpart of PCT/US2007/001607 has issued as a granted patent in New Zealand, OAPI, and Pakistan.

Prosecution in other countries is ongoing.

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.

## Table of Contents

### 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 and Relenza, anti-influenza drugs that are sold by Roche and Glaxo SmithKline (GSK), 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. BioCryst Pharmaceuticals, Inc. has recently developed IV infusion formulations of peramivir, an influenza neuraminidase inhibitor, for the treatment of influenza. 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 is in Phase II clinical studies. Aganocides, by virtue of their chemical structure, are generally not expected to be useful for any applications other than topical.



## Table of Contents

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, and its derivatives. However, their efficacy is limited or toxicities are high.

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 products or drugs in development include Valeant, Schering, Pharmasset, Vertex, Intermune, and Achillion, among others.

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.

## Table of Contents

### 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. The Company has subcontracted some of its animal studies to KARD Scientific, Inc. and to government, academic, 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.

Page 55

---

## Table of Contents

### Reports to Security Holders

As a result of its filing of Form 10-SB and listing on the FINRA OTC Bulletin Board, the Company has become 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.

### 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 135 Wood St. West Haven, Connecticut 06516 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 Us

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;

Table of Contents

- 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, 2010 we have a cash and cash equivalent balance of \$6,955,733. Also, the Company has incurred significant operating losses since its inception, resulting in an accumulated deficit of \$16,742,359 at June 30, 2010. 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 six quarters, i.e. through December 31, 2011.

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, 2011 we have a cash and cash equivalent balance of \$9,224,023 which combined with the \$2,500,000 obtained through the sale of the Company's common stock, after the close of the Company's year

end, will be sufficient to fund our operations for the next eighteen months. We expect to incur additional costs of approximately \$10~15 million dollars in the upcoming twenty-four months to construct or obtain facilities to support a initial new drug application filing with the FDA in accordance with our business plans.

## Table of Contents

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 exchange) 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.

## Table of Contents

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.



## Table of Contents

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 work-plan we have developed for the next twelve months is planned to enable us to file a pre-IND application with the US FDA.

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

IND application for at least one of our drug candidates, possibly influenza, HIV or the nanoviricide eye drops, in the 2011-2012 fiscal year. We believe that this work-plan will lead us to obtain certain information about the safety and efficacy of these drug candidates. We need 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. The data will then be used to file an IND application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

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.





## Table of Contents

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 \$ 14,245,218 on research and development from inception through June 30, 2011.

We have an R&D and other costs budget of \$2,500,000 for the next 12 months. In the last three years we have established lead compounds against a number of viral diseases and completed proof of principle studies 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, 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.

The Company has the cash on hand to complete the budgeted R&D work through December 31, 2012. Should the pre-clinical studies of our Influenza, HIV, Viral diseases of the Eye, and Oral and Genital Herpes drugs meet management's expectations the Company will require substantial additional funding to take any one or more of these drugs into ND filing(s) with the FDA. The Company projects it will need an additional \$15 million for the costs of hiring additional scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies required for filing an IND and for constructing or obtaining facilities to support such application.

The Company will be unable to proceed with its business plan beyond December 31, 2012, without obtaining additional financing of approximately \$3 - \$5 million 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.

Table of Contents

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.



## Table of Contents

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.

Table of Contents

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.



## Table of Contents

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.

## Table of Contents

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”) (an approximately 23.24% 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.

Development costs charged by and paid to TheraCour Pharma, Inc. were \$4,902,875 since inception through June 30, 2011. No royalties are due to TheraCour from the Company’s inception through June 30, 2011.

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.

## Table of Contents

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.

The Company believes the following persons are critical to the success of the Company as well as the terms of the employment agreements between them and the Company:

Page 67

---

Table of Contents

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 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.

As additional compensation under the employment agreements, the Company issued 250,000 shares of the Company's Series A Convertible Preferred Stock and shall issue an additional 250,000 shares of Series A Convertible Preferred 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 term of four years with a base salary of \$150,000. In addition, the Company issued 93,750 shares of Series A Convertible Preferred Stock and 125,000 shares of common stock, and will issue an additional 93,750 shares of Series A Convertible Preferred Stock and 125,000 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 125,000 shares of common stock, and will issue an additional 125,000 shares of common stock on each anniversary date of the agreement.

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

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 approximately twenty-seven percent (24.9%) of our Common 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 which has not been conducted on an arm's length basis to date, Dr. Diwan may have conflicting fiduciary duties between the Company and TheraCour.

Currently, the Company 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.



## Table of Contents

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.



## Table of Contents

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.

## Table of Contents

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.

## Table of Contents

### Risks Related to the Securities Markets and Investments in Our Common Stock

Because our common stock is quoted on the "OTC Bulletin Board," your ability to sell your shares in the secondary trading market may be limited.

Our common stock is currently quoted on the OTC Bulletin Board. Consequently, the liquidity of our common stock is impaired, not only in the number of shares that are bought and sold, but also through delays in the timing of transactions, and coverage by security analysts and the news media, if any, of our company. As a result, prices for shares of our common stock may be lower than might otherwise prevail if our common stock was quoted and traded on Nasdaq or a national securities exchange.

Because our shares are "penny stocks," you may have difficulty selling them in the secondary trading market.

Federal regulations under the Securities Exchange Act of 1934 regulate the trading of so-called "penny stocks," which are generally defined as any security not listed on a national securities exchange or Nasdaq, priced at less than \$5.00 per share and offered by an issuer with limited net tangible assets and revenues. Since our common stock currently is quoted on the OTC Bulletin Board at less than \$5.00 per share, our shares are "penny stocks" and may not be quoted unless a disclosure schedule explaining the penny stock market and the risks associated therewith is delivered to a potential purchaser prior to any trade.

In addition, because our common stock is not listed on Nasdaq or any national securities exchange and currently is quoted at and trades at less than \$5.00 per share, trading in our common stock is subject to Rule 15g-9 under the Securities Exchange Act. Under this rule, broker-dealers must take certain steps prior to selling a "penny stock," which steps include:

- obtaining financial and investment information from the investor;
- obtaining a written suitability questionnaire and purchase agreement signed by the investor; and
- providing the investor a written identification of the shares being offered and the quantity of the shares.

If these penny stock rules are not followed by the broker-dealer, the investor has no obligation to purchase the shares. The application of these comprehensive rules will make it more difficult for broker-dealers to sell our common stock and our shareholders, therefore, may have difficulty in selling their shares in the secondary trading market.

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 NASD OTC Bulletin Board, 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.





## Table of Contents

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, 2011, shareholders of the Company had 56,460,750 shares of restricted stock, or 39.33% 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 300,000,000 total shares of Common Stock without additional approval by shareholders. As of June 30, 2011, we had 143,548,494 of common stock outstanding, and warrants and options convertible to 11,421,950 shares of common stock outstanding.

Because our common stock is quoted only on the OTC Bulletin Board, your ability to sell your shares in the secondary trading market may be limited.

Our common stock is quoted only on the OTC Bulletin Board. Consequently, the liquidity of our common stock is impaired, not only in the number of shares that are bought and sold, but also through delays in the timing of transactions, and coverage by security analysts and the news media, if any, of our company. As a result, prices for shares of our common stock may be different than might otherwise prevail if our common stock was quoted or traded on a national securities exchange such as the New York Stock Exchange.



Table of Contents

Large amounts of our common stock will be eligible for resale under Rule 144.

As of June 30, 2011, 56,460,750 of 143,548,494 issued and outstanding shares 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.

Approximately 9,100,750 shares of our restricted shares of common stock 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 two-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.

Table of Contents

ITEM 1B: UNRESOLVED STAFF COMMENTS.

None.

ITEM 2: PROPERTIES

Description of Property

The Company's principal executive offices are located at 135 Wood Street, West Haven, Connecticut, and include approximately 7,000 square feet of office and laboratory space at a base monthly rent of \$7,311. Commencing September 1, 2008 the Company rented additional storage space and the base monthly rent increased to \$7,311. The lease expired on February 28, 2011 and the Company has continued to occupy the space on a month to month basis.

We subcontract the laboratory research and development work to TheraCour Pharma, Inc. which has a 5,000 square foot laboratory in the same building. Management believes that the space is sufficient for the Company to monitor the developmental progress at its subcontractors.

In February 27, 2007, NanoViricides, Inc. entered into a sublease to occupy 5,000 square feet of space at 4 Research Drive, in Woodbridge, Connecticut at a monthly rent of \$11,667, plus an additional \$500 per month for utilities. The term of the occupancy expired January 30, 2009. This sublease has since expired and the Company has decided not to extend the same. Instead, the Company has decided to consolidate and grow its operations at its principal location of 135 Wood Street, West Haven, Connecticut.

The company is currently engaged in a national search for an R&D as well as manufacturing facility. The manufacturing portion of the facility will eventually have to be certified by the FDA in order for the Company to produce experimental materials that can be sent to outside scientists for pharmaco-kinetic, pharmaco-dynamic and toxicology studies. These three sets of studies must be completed prior to the Company filing an IND with the FDA to begin the human safety and efficacy trials (Phase I and Phase II).

ITEM 3: LEGAL PROCEEDINGS.

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

ITEM 4: REMOVED AND RESERVED.

Table of Contents

## PART II

## ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock was initially traded on the Pink Sheets under the symbol NNVC. From June 29, 2007 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. 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, 2011	\$1.20	\$1.28
March 31, 2011	\$1.22	\$1.27
December 31, 2010	\$1.43	\$1.52
September 30, 2010	\$1.00	\$1.03
June 30, 2010	\$1.80	\$1.92
March 31, 2010	\$1.67	\$1.75
December 31, 2009	\$.81	\$.87
September 30, 2009	\$.80	\$.84

## Number of Shareholders.

As of June 30, 2011, a total of 143,548,494 of the Company's common stock (shares) are outstanding and held by approximately 197 shareholders of record of our common stock. This figure does not reflect the persons or entities that hold their stock in nominee or street name through various brokerage firms. Of this amount, 86,847,744 shares are unrestricted. Approximately 9,100,750 shares are restricted securities held by non-affiliates, and the remaining 47,600,000 shares are restricted securities held by affiliates. These shares may only be sold in accordance with Rule 144. As of June 30, 2011, there were 11,421,950 warrants and 1,875,000 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.

## Recent Sales of Unregistered Securities.

During the fiscal years ended June 30, 2011, 2010 and 2009, the Company issued the following securities exempt from the registration requirements of the Securities Act pursuant to Section 4(2) of the Securities Act. No

underwriting or other compensation was paid in connection with these transactions:

Page 76

---

Table of Contents

On February 4, 2011 the Company authorized the issuance of 25,000 shares of its \$.001 par value common stock with a restrictive legend for \$25,000 upon the exercise of 25,000 warrants issued pursuant to a prior year private placement

In February, 2011, the Scientific Advisory Board (SAB) was granted warrants to purchase 60,000 shares of common stock at \$1.47 per share. These warrants, if not exercised, will expire in February, 2015. The fair value of these warrants in the amount of \$54,000 was recorded as consulting expense.

In May, 2011, the Scientific Advisory Board (SAB) was granted warrants to purchase 60,000 shares of common stock at \$1.632 per share. These warrants, if not exercised, will expire in May, 2015.

On April 10, 2011 the Company authorized the issuance of 10,000 shares of its \$.001 par value common stock with a restrictive legend for \$10,000 upon the exercise of 10,000 warrants issued pursuant to a prior year private placement.

In March, 2011 the Company authorized the issuance of 250,000 shares of its \$.001 par value common stock with a restrictive legend pursuant to existing employment agreements and recorded an expense of \$316,250.

In March, 2011 the Company authorized the issuance of 593,750 shares of its Series A \$.001 par value Convertible Preferred stock with a restrictive legend pursuant to existing employment.

On December 10, 2010 the Company authorized the issuance of 25,000 shares of its \$.001 par value common stock with a restrictive legend for \$25,000 upon the exercise of 25,000 warrants issued pursuant to a prior year private placement.

In November, 2010, the Scientific Advisory Board (SAB) was granted warrants to purchase 60,000 shares of common stock at \$1.81 per share. These warrants, if not exercised, will expire in October, 2014

On November 1, 2010 the Company authorized the issuance of 30,000 shares of its Series A \$.001 par value Convertible Preferred Stock with a restrictive legend pursuant to a consulting.

In August, 2010, the Scientific Advisory Board (SAB) was granted warrants to purchase 60,000 shares of common stock at \$1.476 per share. These warrants, if not exercised, will expire in August, 2014

For the year ended June 30, 2010, the Company's Board of Directors authorized the issuance of 150,822 shares of the Company's .001 par value common stock with a restrictive legend, for services.

For the year ended June 30, 2011, the Company's Board of Directors authorized the issuance of 51,213 shares of the Company's \$0.001 par value common stock with a restrictive legend, for services.

On June 9, 2010, 195,000 warrants were converted into the Company's .001 par value common stock. The Company received \$195,000 upon this conversion.

In May, 2010, the SAB was granted warrants to purchase 50,000 shares of the Company's \$.001 par value common stock at \$1.38 per share. These warrants, if not exercised, will expire in May, 2014.

In April, 2010, the Company's Board of Directors authorized the issuance of 39,625 shares of the Company's \$.001 par value common stock with a restrictive legend in payment of a current account payable for laboratory equipment in the amount of \$31,700.

On March 3, 2010, the Company issued 250,000 shares of .001 par value common stock and 593,750 shares of Series A to certain of its employees pursuant to the terms of certain employment agreements. The Company recorded a salary expense of \$1,532,830.



Table of Contents

In February, 2010, the SAB was granted warrants to purchase 50,000 shares of the Company's \$.001 par value common stock at \$1.272 per share. These warrants, if not exercised, will expire in February 2014. The fair value of these warrants in the amount of \$40,200 was recorded as consulting expense.

On February 15, 2010 the Company approved an Additional License Agreement with TheraCour Pharma, Inc. ("TheraCour"). Pursuant to the exclusive Additional License Agreement, the Company was granted exclusive licenses, in perpetuity, for technologies, developed by TheraCour, for the development of drug candidates for the treatment of Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes. As consideration for obtaining these exclusive licenses, we agreed to pay a one time licensing fee equal to seven million shares 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 four 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 four votes per share. The Preferred Series A do not contain any rights to dividends; have no liquidation preference and are not to be amended without the holders approval. The issuance of the 7,000,000 shares was valued at their par value or \$7,000.

In November, 2009, the SAB was granted warrants to purchase 50,000 shares of the Company's .001 par value common stock at \$1.06 per share. These warrants, if not exercised, will expire in November 2013. The fair value of these warrants in the amount of \$39,600 was recorded as a consulting expense.

In November, 2009, the Company's Board of Directors authorized the issuance of 32,500 shares of the Company's restricted common stock in payment of a current account payable for laboratory equipment in the amount of \$25,200.

On November 10, 2009, 10,000 warrants were converted into the Company's .001 par value common stock. The Company received \$1,430 upon this conversion.

On September 30, 2009, the Company accepted subscriptions from certain accredited investors and warrant holders in the total aggregate amount of \$3,217,400. In the Company's offering of Units comprised of shares of the Company's \$.001 par value common stock and warrants to purchase the Company's \$.001 par value common stock, the Company accepted subscriptions for \$1,337,500 for Units consisting of 2,675,000 shares and Warrants to purchase an additional 1,337,500 shares. In the offering to its warrant holders, the Company raised an aggregate of \$1,879,900 for 3,759,800 shares and warrants to purchase 3,759,800 shares. The Company paid \$5,250 and issued 5,250 warrants as a Finder's Fee. The fair value of the warrants in the amount of \$3,570 was recorded as an expense.

In August 2009, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of the Company's \$.001 par value common stock at \$1.10 per share. These warrants, if not exercised, will expire in August 2013. The fair value of these warrants in the amount of \$41,400 was recorded as a consulting expense.

In June 2009, the Registrant accepted subscriptions from its warrant holders for an aggregate of \$1,025,350 for 2,050,700 shares of common stock and warrants to purchase 2,050,700 shares of common stock. In a separate offering which also closed on July 7, 2009, the Registrant accepted subscriptions of \$75,000 for 150,000 shares of common stock and warrants to purchase an additional 75,000 shares. The warrants in these offerings are exercisable at the price of \$1.00 per share of common stock and expire in 3 years.

In June 2009, 805,250 warrants were converted into common stock in a Warrant Conversion Offering, resulting in the issuance of 2,050,700 common shares. The Company received \$1,025,350 upon this conversion. All holders of the Company's warrants were provided an option to exercise their warrants during the period ending June 30, 2009 at a price of \$0.50 and to receive an additional Warrant convertible into one (1) restricted share of the Company's common

stock. The Warrants may be exercised at any time and expire on August 17, 2012.

For the year ended June 30, 2009, the Company's Board of Directors authorized the issuance of 244,530 shares of its common stock with a restrictive legend, for services.

## Table of Contents

In May 2009, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$0.78 per share. These warrants, if not exercised, will expire in May, 2013.

In April 2009 the Company's Board of Directors authorized the issuance of 172,500 shares of its common stock with a restrictive legend, in payment of a current account payable for laboratory equipment in the amount of \$137,500.

In February 2009, the Company's Board of Directors authorized the issuance of 50,000 shares of its common stock with a restrictive legend to a Scientific Advisory Board Member advising the Company for consulting services.

In February 2009, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$0.89 per share. These warrants, if not exercised, will expire in February 2013.

In November 2008, the Scientific Advisory Board (SAB) was granted warrants to purchase 50,000 shares of common stock at \$0.70 per share. These warrants, if not exercised, will expire in November 2012.

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

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

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

All of the securities set forth above were issued by the Company pursuant to Section 4(2) of the Securities Act of 1933, as amended, or the provisions of Rule 504 of Regulation D promulgated under the Securities Act. All such shares issued contained a restrictive legend and the holders confirmed that they were acquiring the shares for investment and without intent to distribute the shares. All of the purchasers were friends or business associates of the Company's management and all were experienced in making speculative investments, understood the risks associated with investments, and could afford a loss of the entire investment. The Company has never utilized an underwriter for an offering of its securities. Some of the investors were introduced to the Company by certain Agents that we call Finders. The Company had individual agreements with the Finders regarding fees payable to them. Fees paid to these agents were \$- 0- and \$29,400 in the years ended June 30, 2010 and June 30, 2009 respectively.

## USE OF PROCEEDS FROM SALES OF REGISTERED SECURITIES

In March, 2010, the Company filed a Form S-3 Shelf Registration with the Securities and Exchange Commission (SEC) for the sale from time to time of up to \$40 million of the Company's securities. The registration statement became effective on April 29, 2010.

On May 11, 2010, the Company entered into a Securities Purchase Agreement (the "Agreement") with Seaside 88, LP, a Florida limited partnership ("Seaside"), relating to the offering and sale of 500,000 shares of the Company's \$.001 par value Series B Convertible Preferred Stock, ("Series B") at the purchase price of \$10.00 per share (the "Purchase Price"). Under the terms of the agreement, 60,000 shares of Series B shall automatically convert into shares of the Company's .001 par value common stock at the closing and every fourteenth day thereafter at a conversion factor equal to the Purchase Price divided by the lower of (i) of the daily volume weighted average of actual trading prices of the Company's .001 par value common stock on the trading market (the "VWAP") for the ten consecutive trading days immediately prior to a conversion date multiplied by 0.85 or (ii) the VWAP for the trading day immediately prior to a conversion date multiplied by 0.88. The Agreement also provided that a 10% per annum dividend would accrue on all outstanding shares of Series B (the "Dividend"), to be paid on each conversion date either in cash or the Company's .001 par value common stock. If the Company chooses to pay the said dividends in stock, each share of the Company's .001 par value common stock would be valued at 85% of the 10-day VWAP.

Table of Contents

On May 12, 2010, the Company issued 500,000 shares of its Series B in accord with the aforementioned agreement. The Company received \$5,000,000 in consideration for the Series B. The Company recorded a placement agent fee of \$400,000 and legal fees of \$50,000 in association with this transaction.

On September 16, 2010, Seaside and the Company executed a Letter Agreement and Amendment (the “Letter Agreement”) regarding the purchase and sale of an additional 500,000 shares (the “Additional Shares”) of the Company’s Series B Convertible Preferred Stock (the “Series B Preferred Stock”) at the purchase price of \$10.00 per share as originally contemplated by that certain Securities Purchase Agreement, dated May 11, 2010, between the parties (the “Agreement”).

Pursuant to the Letter Agreement, the parties agreed to amend certain provisions of the Agreement so that the Additional Shares could be purchased in two (2) closings, at each of which the Company will issue and sell to Seaside 250,000 shares of Series B Preferred Stock. The parties also agreed that the second closing of the Additional Shares would occur ninety (90) days subsequent to the first closing of the Additional Shares (the “First Follow-on Closing Date”). The Company also agreed to decrease the number of shares of Series B Preferred Stock that automatically convert from 60,000 shares to 40,000 shares, commencing on the First Follow-on Closing Date and the date of the subsequent closing, and every 14th day thereafter, subject to certain limitations and qualifications, into shares of the Company’s Common Stock. Each share of Series B Preferred Stock converts into shares of Common Stock at a conversion factor equal to the Purchase Price divided by the lower of (i) of the daily volume weighted average of actual trading prices of the Common Stock on the trading market (the “VWAP”) for the ten consecutive trading days immediately prior to a conversion date multiplied by 0.85 or (ii) the VWAP for the trading day immediately prior to a conversion date multiplied by 0.88.

On September 21, 2010, the Company issued 250,000 shares of its Series B in accordance with the aforementioned agreement. The Company received \$2,500,000 in consideration for the Series B. The Company recorded a placement agent fee of \$195,000 and legal fees of \$10,000 in association with this transaction.

On December 21, 2010, the Company issued 250,000 shares of its Series B in accordance with the aforementioned Letter Agreement and Securities Purchase Agreement. The Company received \$2,500,000 in consideration for the Series B. The Company recorded a placement agent fee of \$200,000 in association with this transaction.

On April 18, 2011, the Company entered into a second Securities Purchase Agreement (the “Second Agreement”) with Seaside, relating to the offering and sale of 500,000 shares of the Company’s .001 par value Series B at the purchase price of \$10.00 per share (the “Purchase Price”). Under the terms of the agreement, 40,000 shares of Series B shall automatically convert into shares of the Company’s .001 par value common stock at the closing and every fourteenth day thereafter at a conversion factor equal to the Purchase Price divided by the lower of (i) of the daily volume weighted average of actual trading prices of the Company’s .001 par value common stock on the trading market (the “VWAP”) for the ten consecutive trading days immediately prior to a conversion date multiplied by 0.85 or (ii) the VWAP for the trading day immediately prior to a conversion date multiplied by 0.88. The Agreement also provided that a 10% per annum dividend would accrue on all outstanding shares of Series B (the “Dividend”), to be paid on each conversion date either in cash or the Company’s .001 par value common stock. If the Company chooses to pay the said dividends in stock, each share of the Company’s .001 par value common stock would be valued at 85% of the 10-day VWAP.

## Table of Contents

On April 18, 2011, the Company issued 250,000 shares of its Series B in accord with the aforementioned Second Agreement. The Company received \$2,500,000 in consideration for the Series B. The Company recorded a placement agent fee of \$150,000 and legal fees of \$10,000 in association with this transaction.

Thus far, the Company has used the net proceeds of the offering for working capital. See also Item 7 Subsequent Events .

### ITEM 6: SELECTED FINANCIAL DATA

Not required for smaller reporting companies.

### 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 consolidated financial statements of the Company and the notes thereto appearing elsewhere herein and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in (1) the Company's Annual Report on Form 10-K for the year ended June 30, 2010. 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.

## Table of Contents

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. 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

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.





## Table of Contents

We have 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 is expected to be renegotiated due to changes in funding requirements at WRAIR. The Company has not renewed this agreement.

We have 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 have 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. We have received significant interest from certain Pharmaceutical companies in this drug candidate.

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. At present, TheVac is performing biological testing of anti-herpes nanoviricides. TheVac is conducting studies on the effect of anti-herpes nanoviricide drug candidates against herpes cold sores and genital herpes in cell culture models. In addition, TheVac is also conducting studies on the effect of anti-herpes nanoviricides drug candidates in a mouse model of herpes keratitis. Professor Gus Kousoulas and his team at Louisiana State University have validated and published on this animal model extensively in peer-reviewed scientific journals.

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 (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. 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.

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. Cheryl Stoddart, PhD, Assistant Professor in the UCSF Division of Experimental Medicine, will be the Principal Investigator. Dr. Stoddart is a recognized investigator in preclinical studies of anti-HIV compounds using the standard SCID-hu Thy/Liv humanized mouse model. In particular, she is well known for her work in validating that this mouse model is capable of accurately predicting clinical antiviral efficacy in humans. The National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH), has recognized UCSF as an important site for anti-HIV drug screening studies. Dr. Stoddart's in-vivo testing of anti-HIV nanoviricides will complement the Company's previously announced in-vitro anti-HIV testing that is ongoing at the Southern Research Institute in Frederick, MD. Their expertise is in the testing of oral anti-HIV drugs. They need to implement successfully, protocols for injectable anti-HIV drug testing. Currently the Company's anti-HIV injectables animal testing is performed by KARD Scientific.

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).

#### Subsequent Event.

Management performed an evaluation of the Company's activity through October 13, 2011, the date these financials were issued to determine if they must be reported. The Management of the Company determined that the following reportable subsequent event should be disclosed.

On July 26, 2011, Seaside 88 LP ("Seaside") purchased an additional 250,000 shares of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock") in accordance with a certain Securities Purchase Agreement dated April 18, 2011, between the parties (the "Second Agreement"). The Company raised gross proceeds of \$2,500,000 at such First Follow-on Closing, before estimated offering expenses of approximately \$180,000 which includes placement agent and attorneys' fees.

The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-165221), which was declared effective by the Securities and Exchange Commission on April 29, 2010. 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.



## Table of Contents

In connection with the offering, pursuant to that certain Placement Agency Agreement, as amended by an Underwriter Agent Agreement Amendment No. 1, entered into by and between Midtown Partners & Co., LLC (“Midtown”) and the Company on March 28, 2011, the Company will pay Midtown a cash fee representing 6% of the gross purchase price paid by Seaside for the Series B Preferred Stock.

### 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 high efficacy lead drug candidates against five commercially important diseases, namely, (1) All Influenza viruses (FluCide-I), (2) HIV (HIVCide-I), (3) Nanoviricide Eye Drops for Viral Infections of the External Eye, (4) a nanoviricide against Herpes “Cold Sores” and genital herpes, and (5) 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<sup>(TM)</sup> technology; both of which are well suited for stockpiling to defend against known as well as novel infectious diseases.

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.

Management’s beliefs are based on results of pre-clinical cell culture studies and in vivo animal studies using mice.

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.

The Company continued its organizational efforts and has signed or is in the process of obtaining several new agreements and contracts that are expected to have a significant positive impact for us in the near future. In addition, the Company has improved its anti-influenza drug candidates further. The Company has now declared a clinical candidate against influenza. The Company anticipates that this single drug will be effective against all influenza viruses. Last year, the Company consolidated its anti-influenza drug programs into the development of a single, pan-influenza drug candidate in the FluCide program that is highly effective against H1N1 influenza, as well as H5N1 Clade 1 and H5N1 Clade 2, distinctly different bird flu viruses feared to be capable of causing a pandemic. This drug candidate is expected to be highly effective against the current pandemic novel Influenza A/H1N1/2009 “swine flu” virus as well. We plan on conducting testing of this nanoviricide against a number of different influenza virus strains in the very near future. Consolidation of the three different programs, namely FluCide, FluCide-HP and AviFluCide into one without compromising effectiveness or safety, is expected to yield significant benefits in that the drug development complexities may be expected to be reduced and drug development costs may be expected to be reduced substantially. In addition, the Company has further optimized the ligands for use in its anti-HIV drug program, and continues to optimize the resulting nanoviricides under the HIVCide program. Last year, the Company also added two new drug candidates to its pipeline (HerpeCide and DengueCide). Thus, despite the re-prioritization due to financial constraints and worldwide economic conditions, the Company has made a significant level of progress and has achieved significant accomplishments this year.



## Table of Contents

### Requirement for Additional Capital

As of June 30, 2011, we have a cash and cash equivalent balance of \$9,224,023 which combined with the \$2,500,000 obtained through the sale of the Company's preferred Series B stock, after the close of the Company's year end, will be sufficient to fund our currently budgeted operations for the next eighteen months at the Company's current rate of expense.

We estimate that we will need approximately an additional \$10M to \$15M over the next 18 months for further development of our drug pipeline. These additional funds, if raised, will enable us to perform Toxicology Package Studies and additional efficacy studies necessary to prepare the full dataset required for filing our first Investigational New Drug Application ("IND") with the US FDA on one of our drug candidates. 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 our first IND .

Further, we anticipate incurring additional capital costs in the upcoming eighteen months to construct or obtain facilities to support an initial new drug application filing with the FDA in accordance with our business plans. The Company has arranged for enabling cGMP production of its nanoviricides for the upcoming clinical studies without incurring any capital costs. A separate privately held company, Inno-Haven, LLC, raised funds privately to acquire a building in Shelton, CT. Inno-Haven intends to perform improvements and enable modern laboratory facilities and kg-scale pilot cGMP facility in this space.

We are currently evaluating several vehicles for raising these additional funds.

Assuming that we are successful in raising this additional financing, we anticipate that we will incur the following additional expenses over the next 18 months.

1. Research and Development of \$5,000,000: Planned costs for in-vivo and in-vitro studies for pan-influenza FluCide, Eye nanoviricide, HIVCide, HerpeCide, Dengue, and Ebola/Marburg and Rabies programs.
2. Corporate overhead of \$1,250,000: 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 \$1,500,000: This is the estimated cost for equipment and laboratory improvements..
4. Staffing costs of \$1,500,000: This is the estimated cost of hiring additional scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, 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.

In addition the Company anticipates estimated capital costs of \$5,000,000 for infrastructure and laboratory facilities for a scaled up research pilot production facility. The Company anticipates that some of this infrastructure funding will be obtained through real estate and industrial loans and related instruments.

In March, 2010, the Company filed a Form S-3 Shelf Registration with the Securities and Exchange Commission (SEC) for the sale from time to time of up to \$40 million of the Company's securities. The registration statement became effective on April 29, 2010. As of June 30, 2011 the Company drew down \$12,500,000 of the \$40 million S-3 Shelf Registration. The Company anticipates further draw downs on this S-3 Shelf Registration to fund its additional capital requirements and expenditures as required. . If we are unable to obtain additional financing, our business plan will be significantly delayed.

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



## Table of Contents

We believe that this coming year's work-plan will lead us to obtain certain information about the safety and efficacy of some of the drugs under development in animal models. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further studies in animal models to obtain necessary data regarding the pharmacokinetic and pharmacodynamic profiles of our drug candidates. We believe these data will then enable us to file an Investigational New Drug application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

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

Management intends to use capital and debt financing, as required, to fund the Company's operations. 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 Form 10-K.

Table of Contents

Table 3: R&amp;D Cost Allocations

	Year Ended June 30, 2011	Year Ended June 30, 2010	For the Cumulative Period From May 12, 2005 (Inception) through June 30, 2011
All Influenzas: FluCide™, (Note: FluCide-HP, and AviFluCide are now consolidated into a single drug candidate, viz. FluCide)	1,000,000	762,500	4,624,887
EKC-Cide™, other Eye Viral Infections	200,000	495,454	1,431,557
HIV-Cide™	1,000,000	410,604	2,609,409
Herpes infections	300,000	392,408	703,290
Dengue	300,000	201,620	
Other (Ebola, and other projects)	200,000	75,000	2,199,668
Unallocated stock compensation	555,846	1,029,823	1,591,591
Total Research and development	4,155,846	3,367,409	14,245,218

## 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	Drug Development of FluCide™ for All Influenzas
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, as well as the novel 2009/H1N1 epidemic virus. We expect to file a pre- IND application with the FDA soon.
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 \$2,500,000.

Anticipated completion date	Preclinical stage is expected to be completed in 12-18 months, depending upon financing. An IND could be filed within a few months after the completion of preclinical stage.
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The Company has not yet raised the financing necessary to complete the preclinical stage and file an IND with the FDA.
Timing of commencement of expected material net cash inflows	If we file an IND in the next 18~24 months, we can expect human clinical trials to be completed at the earliest by 2015. Revenues are expected to occur after FDA approval and marketing of the drug. Revenues may occur earlier 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.

Table of Contents

Project	Drug Development of Nanoviricide Eye Drops for all Viral Infections of the External Eye
Current status	This year, we 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. Majority of these viruses are adenoviruses or HSV.
Nature, timing and estimated costs	The Company has budgeted approximately \$750,000 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.
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	Drug Development of HIVCide™
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 during 2011-2012 to further optimize the drug candidate.
Nature, timing and estimated costs	The Company has budgeted approximately \$3,000,000 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 \$5000,000.
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.

Table of Contents

Project	Drug Development of 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 and gel formulations, which may result in two separate drugs. The Company is planning additional in-vivo and in-vitro studies at various institutions and subcontractors during 2011-2012.
Nature, timing and estimated costs	The Company has budgeted approximately \$1,500,000 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 \$2,000,000.
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.

Table of Contents

Project	Drug Development of DengueCide <sup>(TM)</sup>
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. The Company is planning additional in-vivo and in-vitro studies at various institutions and subcontractors during 2011-2012.
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 \$3,000,000.
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.

## Other drug candidates:

Nanoviricides against Rabies, Ebola/Marburg, Hepatitis C Virus (HCV), 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 Company is currently engaged in a national search for a manufacturing facility. The Company is in discussions with Inno-Haven, LLC, to develop a modern laboratory and cGMP facility suitable for its research and manufacturing needs. The manufacturing portion of the facility will eventually need to be certified by the FDA in order for the Company to produce experimental materials that can be used in human clinical trials. It is preferable to use the same

quality of materials for pharmaco-kinetic, pharmaco-dynamic and toxicology studies. These three sets of studies must be completed prior to the Company filing an Investigational New Drug (“IND”) with the FDA to begin the human safety and efficacy trials (Phase I, II and III).

The work-plan we have developed for the next twelve months is expected to enable us to file an investigational new drug application in our 2012-2013 fiscal year at the earliest, subject to availability of necessary levels of research and development funds. 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 will now be adequately addressed in our 2011-2012 fiscal year, with a kg-scale pilot cGMP facility becoming available. 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.



## Table of Contents

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.

Management intends to use capital and debt financing, as required, to fund the Company's operations. Management intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain the additional capital resources necessary to fund its anticipated obligations for the next twelve 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 development-stage biopharmaceutical company and does not have revenue for the year ending June 30, 2011.

Revenues - The Company is a non-revenue producing entity.

Operating Expenses - General and administrative expenses increased \$538,543 to \$2,273,609 for the year ended June 30, 2011, from \$1,735,066 for the year ended June 30, 2010. The increase resulted from the Company's recognition of the fair value of compensation paid in preferred and common stock.

Research and development expenses for the year ended June 30, 2011 increased \$788,437 to \$4,155,846 from \$3,367,409 for the year ended June 30, 2010. 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.

Research and Development expenses were offset in the amount of \$-0- and \$162,524 in the years ended June 30, 2011, and June 30, 2010, respectively, by a Connecticut Refundable Research and Development Credit.

Other Income (Expenses) – Net Interest income was \$14,339 and \$2,980 for the years ending June 30, 2011, and 2010, respectively. Net Interest income in 2011 included interest on cash equivalent deposits in an interest-bearing account.

Income Taxes – There is no provision for income taxes due to ongoing operating losses. As of June 30, 2011, we had federal net operating loss carryforwards of approximately \$16,738,806 and deferred Research and Development tax credits resulting in a deferred tax benefit of approximately \$8,750,309 for Federal reporting purposes. This amount has been offset by a full valuation allowance.

Net Operating Loss - For the year ended June 30, 2011, the Company had a net loss of \$6,477,165, or \$0.05 per share compared to a net loss of \$4,744,208, or \$0.04 per share for the year ending June 30, 2010.

## Table of Contents

### Liquidity and Capital Reserves

The Company had cash and cash equivalents of \$ 9,224,023 as of June 30, 2011. On the same date, accounts payable and accrued liabilities outstanding totaled \$ 587,176

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 \$23,216,909 at June 30, 2011.

As of June 30, 2011 we have a cash and cash equivalent balance of \$9,224,023. As of the date of the filing, the Company has raised gross proceeds of \$25,000,000, before estimated offering expenses of approximately \$635,000 which includes placement agent and attorneys' fees from the sale of its Series B convertible preferred Stock. The Company estimates that it can support current operations through the next six quarters, i.e. through December 31, 2012.

While this sum is sufficient for us to continue our operations through December 31, 2012, 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, the establishment of our own laboratory and/or research and development project.

### Off Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements during the year ended June 30, 2011.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

**Accounting Basis** – The Company has not earned any revenue from limited principal operations. Accordingly, the Company's activities have been accounted for as those of a "Development Stage Company" as set forth in Financial Accounting Standards Board Statement No. 7 ("SFAS 7"). Among the disclosures required by SFAS 7 are that the Company's financial statements be identified as those of a development stage company, and that the statements of operations and stockholders' equity and cash flows disclose activity since the date of the Company's inception.

**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 adopted the fair value recognition provisions of "FASB Statement No. 123(R) Share-Based Payment", using the modified prospective-transition method. Under that transition method, compensation cost recognized in the year ended June 30, 2011 includes compensation cost for all share-based payment granted based on the grant-date fair value estimated in accordance with provisions of FASB 123(R).

**Accounting for Non-Employee Stock Based Compensation** – The Company accounts for shares and options issued for non- employees in accordance with the provision of Emerging Issue Task Force Issue No. 96-18, "Accounting for Equity Instruments that are issued to other than Employees for Acquiring or in Conjunction with selling Goods or Services". According to the provisions of ETIF 96-18, the Company determines the fair value of stock and options granted to non-employees on the measurement date which is either the date of a commitment for performance has been reached or when performance has been completed, depending upon the facts and circumstances. The fair value of the shares and options valued at commitment date is expensed immediately if they were for past services.

## POLICY AFFECTING RECOGNITION OF REVENUE

The Company is a development stage company and does not have revenue arising from operations

Page 92

---

Table of Contents

RECENT ACCOUNTING PRONOUNCEMENTS

In May 2011, the FASB issued the FASB Accounting Standards Update No. 2011-04 “Fair Value Measurement” (“ASU 2011-04”). This amendment and guidance are the result of the work by the FASB and the IASB to develop common requirements for measuring fair value and for disclosing information about fair value measurements in accordance with U.S. GAAP and International Financial Reporting Standards (IFRSs).

This update does not modify the requirements for when fair value measurements apply; rather, they generally represent clarifications on how to measure and disclose fair value under ASC 820, Fair Value Measurement, including the following revisions:

- An entity that holds a group of financial assets and financial liabilities whose market risk (that is, interest rate risk, currency risk, or other price risk) and credit risk are managed on the basis of the entity’s net risk exposure may apply an exception to the fair value requirements in ASC 820 if certain criteria are met. The exception allows such financial instruments to be measured on the basis of the reporting entity’s net, rather than gross, exposure to those risks.
  - In the absence of a Level 1 input, a reporting entity should apply premiums or discounts when market participants would do so when pricing the asset or liability consistent with the unit of account.
  - Additional disclosures about fair value measurements.

The amendments in this Update are to be applied prospectively and are effective for public entity during interim and annual periods beginning after December 15, 2011.

In June 2011, the FASB issued the FASB Accounting Standards Update No. 2011-05 “ Comprehensive Income (“ASU 2011-05”), which was the result of a joint project with the IASB and amends the guidance in ASC 220, Comprehensive Income, by eliminating the option to present components of other comprehensive income (OCI) in the statement of stockholders’ equity. Instead, the new guidance now gives entities the option to present all nonowner changes in stockholders’ equity either as a single continuous statement of comprehensive income or as two separate but consecutive statements. Regardless of whether an entity chooses to present comprehensive income in a single continuous statement or in two separate but consecutive statements, the amendments require entities to present all reclassification adjustments from OCI to net income on the face of the statement of comprehensive income.

The amendments in this Update should be applied retrospectively and are effective for public entity for fiscal years, and interim periods within those years, beginning after December 15, 2011.

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

Table of Contents

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

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.

Page 94

---

Table of Contents

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A(T). CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

As required by Exchange Act Rule 13a-15(b), we have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2011.

## Table of Contents

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 10K our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC and is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

b) Changes in internal control over financial reporting. Since the Company is not listed on a national exchange or on an automated interdealer quotation system, it is not required to have an audit committee or independent directors. We consider this to be a material weakness. The Company is in the process of addressing this issue by establishing an Audit Committee, appointing independent directors with at least one having financial expertise.

### Management's Report on Internal Control Over Financial Reporting

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

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 ("COSO").

In connection with management's assessment of our internal control over financial reporting, we determined that there were no material weaknesses in our internal control over financial reporting as of June 30, 2011:

During the period ended June 30, 2009, the Company implemented additional segregation of responsibilities and authorizations for initiating, authorizing and recording transactions. In addition the Company has engaged the services of a financial consultant to assist in reviewing significant transactions and the Company's quarterly and annual financial statements.

### Changes in Internal Control Over Financial Reporting

Other than as described above, there were no material changes in our internal control over financial reporting (as defined in Rule 13a- 15(f) under the Exchange Act) that occurred as of June 30, 2011, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2011. Our management's evaluation of our internal control was based on the framework 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, due to the material weakness described above, management concluded that our internal control over financial reporting was not effective as of June 30, 2011. A material weakness is a control deficiency, or combination of control deficiencies, such that there is a reasonable possibility that a material misstatement of the financial statements will not be prevented or

detected on a timely basis by the Board in the normal course of their duties. See, AUDITOR'S OPINION PARAGRAPH BELOW.

Attestation Report of the Independent Registered Public Accounting Firm

This annual report includes an attestation report of our registered public accounting firm regarding internal control over financial reporting. The final paragraph of the Auditor's Report states:

“Also 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, 2011 and 2010 and the results of its operations and its cash flows for the fiscal years then ended and for the period from May 12, 2005 (inception) through June 30, 2011 in conformity with accounting principles generally accepted in the United States of America.”



Table of Contents

## ITEM 9B Other Information

None.

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS, COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT

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 annually by our Board of Directors. Each executive officer holds his office until he resigns, is removed by the Board or his successor is elected and qualified. Directors are elected annually by our stockholders at the annual meeting. Each director holds his office until his successor is elected and qualified or his earlier resignation or removal.

The following persons are the directors and executive officers of our company:

Name	Age	Title
Anil Diwan, PhD.	53	President; Chairman of the Board
Eugene Seymour, MD, MPH	70	Chief Executive Officer; Acting Chief Financial Officer; Director

The Company's executive officers and directors are elected annually and serve until the next annual meeting of stockholders.

Eugene Seymour, MD, MPH, age 70, 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 which 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 53, 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 four patents, one issued and three applied for, 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.

Table of Contents

## AUDIT COMMITTEE

Although its By-laws provide for the appointment of one, the Company is not yet required to have an Audit Committee as a result of the fact that our common stock is not considered a “listed security” as defined in Rule 10A-3 of the Exchange Act. There are currently no audit committee members that meet the criteria of “Financial Expert”, however, the company is actively working to appoint a “Financial Expert”.

## 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, 2011, 2010 and 2009.

Name and Principal Position	Year	Salary	Bonus (\$)	Stock Award(s) (\$)	Option Awards(#)	All Other Compensation (\$)	Total (\$)
E u g e n e Seymour, CEO, Director	2011	\$ 275,000	\$ —	574,581	—	\$ 1,917	\$ 851,498
	2010	\$ 254,167	\$ —	513,823	—	\$ —	\$ 767,990
	2009	\$ 250,000	\$ —	—	—	\$ —	\$ 250,000
A n i l D i w a n, P r e s i d e n t , Director	2011	\$ 275,000	\$ —	574,581	—	\$ 1,917	\$ 851,498
	2010	\$ 252,000	\$ —	513,823	-	\$ —	\$ 765,823
	2009	\$ 252,000	\$ —	-	-	\$ —	\$ 252,000

\* Deferred compensation paid in 2008, accrued in 2007.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth for each named executive officer certain information concerning the outstanding equity awards as of June 30, 2011.

Name and Principal Position	Option awards				Stock awards			
	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	Market Value of Shares or Units of Stock that	Equity Incentive Awards: Number of Shares,	Equity Incentive Awards: Market Payout Value

Edgar Filing: NANO VIRICIDES, INC. - Form 10-K/A

					Not Vested	Have Not Vested	Units or Other Rights that Have Not Vested	of Unearned Shares, Units or Other Rights that Have Not Vested
Eugene Seymour, CEO and Director	500,000	—	\$0.10	September 26, 2015	—	—	—	—
Anil Diwan, President and Director	1,000,000	—	\$0.10	September 26, 2015	—	—	—	—

Table of Contents

COMPENSATION OBJECTIVES

We believe that the compensation programs for the Company's NEOs 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, 2011, under the March 3, 2010 employment agreements, the Company issued 593,750 shares of the Company's Series A Convertible Preferred Stock and 250,000 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 which may not be realized.

Table of Contents

## 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 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 and no annual bonus. 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, 2009.

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	33,360,000	23.24	%
Anil Diwan (2) (3) 135 Wood Street West Haven, CT 06516	42,096,155	29.33	%
Eugene Seymour (4) 135 Wood Street West Haven, Connecticut 06516	6,500,000	4.53	%
All Directors and Executive Officers as a Group (2 persons) (5)	48,596,155	33.85	%

(1) For each shareholder, the calculation of percentage of beneficial ownership is based upon 143,548,494 shares of Common Stock outstanding as of June 30 2011 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 7,000,000 shares of the Company's Series A Convertible Preferred Stock (the "Series A") which votes at the rate of four shares of Common Stock per each share of Series A and is convertible into two shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.



## Table of Contents

(3) Anil Diwan, President and Chairman of the Board of Directors. Includes 7,736,155 shares of NanoViricides common stock received by Dr. Diwan as founder and 1,000,000 shares of NanoViricides common stock issuable upon exercise of options held by Dr. Diwan that are currently exercisable or will become exercisable within 60 days. Also includes 33,360,000 owned by TheraCour Pharma, Inc., over which Dr. Diwan holds voting and dispositive power. Does not include 500,000 shares of the Company's Series A Convertible Preferred Stock (the "Series A") which votes at the rate of four shares of Common Stock per each share of Series A and is convertible into two 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 6,000,000 shares of NanoViricides common stock held by Dr. Seymour and 500,000 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 500,000 shares of the Company's Series A Convertible Preferred Stock (the "Series A") which votes at the rate of four shares of Common Stock per each share of Series A and is convertible into two shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.

(5) Includes 33,360,000 shares of Common Stock indirectly owned by certain of the Executive Officers and Directors as a group.

## 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 provide a minimum annual base salary of \$250,000 for a term of four years. 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.

As additional compensation under the employment agreements, the Company issued 250,000 shares of the Company's Series A Convertible Preferred Stock and shall issue an additional 250,000 shares of Series A Convertible Preferred 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 term of four years with a base salary of \$150,000. In addition, the Company issued 93,750 shares of Series A Convertible Preferred Stock and 125,000 shares of common stock, and will issue an additional 93,750 shares of Series A Convertible Preferred Stock and 125,000 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 term of four years with a base salary of \$150,000. In addition, the Company issued 125,000 shares of common stock, and will issue an additional 125,000 shares of common stock on each anniversary date of the agreement.

## COMPENSATION OF DIRECTORS

At this time, directors receive no remuneration for their services as directors of the Company, nor does the Company reimburse directors for expenses incurred in their service to the Board of Directors. The Company does not expect to pay any fees to its directors for the 2011 fiscal year.

## 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 options will be granted on May 15, August 15, November 15, and February 15. The warrants will 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 year ended June 30, 2011, the SAB was granted a total of 200,000 stock warrants exercisable into common shares at prices from \$0.61 to \$1.56 per share.

Table of Contents

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Currently, we have no independent directors on our Board of Directors, and therefore have no formal procedures in effect for reviewing and pre-approving any transactions between us, our directors, officers and other affiliates. We will 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.

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 7,000,000 shares of the Company's Series A Convertible 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. was \$3,651,974 since inception through June 30, 2011, and \$1,086,927 and \$1,086,927 for the years ended June 30, 2011, and 2010, respectively. No royalties are due or have been paid from inception through June 30, 2011.

As of June 30, 2010, TheraCour owns 33,360,000 shares of the Company's outstanding common stock and 7,000,000 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. Lab fees charged by KARD Scientific for services for the years ended June 30, 2011, and 2010, were, \$719,462 and \$78,940, respectively, and \$1,352,637 since inception.

Table of Contents

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

## Audit Fees

The aggregate fees for each of the last four 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, 2011	\$90,000	Li & Company, P.C.
June 30, 2010	\$70,000	Li & Company, P.C.
June 30, 2009	\$35,000	Li & Company, P.C.
June 30, 2009	\$77,000	H o l t z R u b e n s t e i n Reminick LLP

## Audit Related Fees

The aggregate fees in each of the last four 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, 2011	\$0	Li & Company, P.C.
June 30, 2010	\$0	Li & Company, P.C.
June 30, 2009	\$0	Li & Company, P.C.
June 30, 2009	\$0	H o l t z R u b e n s t e i n Reminick LLP

We incurred these fees in connection with registration statements and financing transactions. Tax Fees

The aggregate fees in each of the last four years for the professional services rendered by the principal accountant for tax compliance, tax advice and tax planning were approximately:

June 30, 2011	\$0	Li & Company, P.C.
June 30, 2010	\$0	Li & Company, P.C.
June 30, 2009	\$0	Li & Company, P.C.
June 30, 2009	\$0	H o l t z R u b e n s t e i n

Reminick LLP

All Other Fees

The aggregate fees in each of the last four years for the products and services provided by the principal accountant, other than the services reported in paragraph (1) were approximately:

June 30, 2011	\$0	Li & Company, P.C.
June 30, 2010	\$0	Li & Company, P.C.
June 30, 2009	\$0	Li & Company, P.C.
June 30, 2009	\$0	H o l t z R u b e n s t e i n Reminick LLP

Table of Contents

## Pre-Approval Policies

The Board of Directors, which performs the equivalent functions of an audit committee, currently does not have any pre-approval policies or procedures concerning services performed by Holtz Rubenstein Reminick LLP, or Li & Company, P.C. All the services performed by Holtz Rubenstein Reminick LLP and Li & Company, P.C. as described above were pre-approved by the Board of Directors.

## 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
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
<u>31.1</u>	Certification of Chief Executive and Interim Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
<u>32.1</u>	Certification of Chief Executive Officer and Interim Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\*Incorporated by reference to the Company's registration statement on Form 10-SB, filed with the Securities Commission on November 14, 2006, as amended.

Table of Contents

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: October 13, 2011

NANOIRICIDES, INC.

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

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

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 indicate

October 13, 2011

/s/ Eugene Seymour, MD  
Eugene Seymour, MD  
Chief Executive Officer and  
Interim Chief Financial Officer and  
Director  
(Principal Executive and  
Accounting Officer)

October 13, 2011

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

Table of Contents

NANO VIRICIDES, INC.

(A DEVELOPMENT STAGE COMPANY)

June 30, 2011 and 2010

Index to Financial Statements

Contents	Page(s)
Reports of Independent Registered Public Accounting Firm	F-2
Balance Sheets at June 30, 2011 and 2010	F-4
Statements of Operations for the Fiscal Years Ended June 30, 2011 and 2010 and for the Period from May 12, 2005 (Inception) through June 30, 2011	F-5
Statements of Stockholders' Equity for the Period from May 12, 2005 (Inception) through June 30, 2011	F-6
Statements of Cash Flows for the Fiscal Years Ended June 30, 2011 and 2010 and for the Period from May 12, 2005 (Inception) through June 30, 2011	F-41
Notes to the Financial Statements	F-43

F-1

---



Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
Nanoviricides, Inc.  
(A development stage company)  
West Haven, Connecticut

We have audited the accompanying balance sheets of Nanoviricides, Inc., a development stage company, (the "Company") as of June 30, 2011 and 2010 and the related statements of operations, stockholders' equity and cash flows for the fiscal years then ended and for the period from May 12, 2005 (inception) through June 30, 2011. We have also audited the Company's internal control over financial reporting as of June 30, 2011, based on criteria established in "Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)". The management of the Company is responsible for these financial statements, 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 Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. Our audit of internal control over financial reporting 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 over financial reporting based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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 accounting principles generally accepted in the United States of America ("U.S. GAAP"). A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) 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 deficiency, or a 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 weaknesses have been

identified and included in management's assessment as of June 30, 2011:

The Company's board of directors has no audit committee, independent director or member with financial expertise which causes ineffective oversight of the Company's external financial reporting and internal control over financial reporting.

F-2

---

Table of Contents

These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the Company's June 30, 2011 financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of June 30, 2011, based on the criteria established in "Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)". Also 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, 2011 and 2010 and the results of its operations and its cash flows for the fiscal years then ended and for the period from May 12, 2005 (inception) through June 30, 2011 in conformity with accounting principles generally accepted in the United States of America.

/s/ Li & Company, PC

Skillman, New Jersey  
October 13, 2011

F-3

---

Table of Contents

NANO VIRICIDES, INC.  
(A DEVELOPMENT STAGE COMPANY) BALANCE SHEETS

	June 30, 2011	June 30, 2010
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$9,224,023	\$6,955,733
Prepaid expenses	332,294	291,272
Other current assets	-	209,902
<b>Total current assets</b>	<b>9,556,317</b>	<b>7,456,907</b>
<b>PROPERTY AND EQUIPMENT, net</b>	<b>802,367</b>	<b>1,168,374</b>
<b>TRADEMARK, net</b>	<b>399,383</b>	<b>367,077</b>
<b>TOTAL ASSETS</b>	<b>\$10,758,067</b>	<b>\$8,992,358</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$79,529	\$127,620
Accounts payable – related parties	462,955	1,193,593
Accrued expenses	27,173	85,716
Accrued payroll to officers and related payroll tax expense	-	22,917
Derivative liability	17,519	1,043,808
<b>TOTAL CURRENT LIABILITIES</b>	<b>587,176</b>	<b>2,473,654</b>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Series A Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, 8,217,500 and 7,593,750 shares issued and outstanding, respectively	8,218	7,594
Series B Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, 10,000 and 260,000 shares issued and outstanding, respectively	10	260
Common stock, \$0.001 par value; 300,000,000 shares authorized; 143,548,494 and 133,980,411 shares issued and outstanding, respectively	143,582	133,982
Additional paid-in capital	33,235,990	23,116,611
Deficit accumulated during the development stage	(23,216,909)	(16,739,743)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>10,170,891</b>	<b>6,518,704</b>
<b>TOTAL LIABILITIES AND STOCKHOLDER' EQUITY</b>	<b>\$10,758,067</b>	<b>\$8,992,358</b>

See accompanying notes to the financial statements.



Table of Contents

NANO VIRICIDES, INC.  
(A DEVELOPMENT STAGE COMPANY)  
STATEMENTS OF OPERATIONS

	Fiscal Year Ended June 30, 2011	Fiscal Year Ended June 30, 2010	For the Period from May 12, 2005 (Inception) through June 30, 2011
Revenues	\$-	\$-	
Operating expenses:			
Research and development	4,155,846	3,367,409	14,245,218
Refund credit research and development costs	-	(162,524)	(420,842)
General and administrative	2,273,609	1,735,066	8,901,562,
Total operating expenses	6,429,455	4,939,951	22,725,938
Loss from operations	(6,429,455)	(4,939,951)	(22,725,938)
Other income (expense):			
Interest income, net	14,339	2,980	165,324
Discount on convertible debentures	-	-	(73,930)
Beneficial conversion feature of convertible debentures	-	-	(713,079)
Change in fair market value of derivatives	(62,049)	192,736	130,714
Total other income (expense)	(47,710)	195,743	(490,971)
Loss before income taxes	(6,477,165)	(4,744,208)	(23,216,909)
Income tax provision	-	-	-
Net loss	\$(6,477,165)	\$(4,744,208)	\$(23,216,909)
Net loss per share: basic and diluted	\$(0.05)	\$(0.04)	
Weighted average shares outstanding: basic and diluted	139,180,915	130,497,982	

See accompanying notes to the financial statements.

Table of Contents

NANOIRICIDES, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD FROM MAY 12, 2005 (INCEPTION) THROUGH JUNE 30, 2011

	Common Stock		Additional	Stock	Accumulated	Total
	Number	Par	Paid-in	Subscription	Deficit	Shareholders'
	of Shares	Value	Capital	Receivable		Equity
Shares issued May 12, 2005 (Inception)	20,000	\$20	\$-	\$ (20 )	\$ -	\$ -
Share exchange with Edot- com.com Inc., June 1, 2005	(20,000 )	(20 )	-	20	-	-
Shares exchanged in reverse acquisition of Edot-com.com Inc., June 1, 2005	80,000,000	80,000	(79,980 )	(20 )	-	-
Shares outstanding Edot- com.com Inc., June 1, 2005	20,000,000	20,000	(20,000 )	-	-	-
Net loss period ended June 30, 2005	-	-	-	-	(66,005 )	(66,005 )
Balance at June 30, 2005	100,000,000	100,000	(99,980 )	(20 )	(66,005 )	(66,005 )
Discount related to beneficial conversion feature of Convertible debentures, July 13, 2005	-	-	5,277	-	-	5,277
Legal expenses related private placement of common stock, July 31, 2006	-	-	(2,175 )	-	-	(2,175 )
Discount related to beneficial conversion feature of Convertible debentures, July 31, 2005	-	-	5,302	-	-	5,302
Warrants issued to Scientific Advisory Board, August 15, 2005	-	-	4,094	-	-	4,094





Table of Contents

	Common Stock		Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value				
Options issued to officers, September 23, 2005	-	-	87,318	-	-	87,318
Shares issued for consulting services rendered at \$.081 per share, September 30, 2005	2,300,000	2,300	184,000	-	-	186,300
Shares issued for interest on debentures, September 30, 2005	48,177	48	4,267	-	-	4,315
Discount related to beneficial conversion feature of Convertible debentures, October 28, 2005	-	-	166,666	-	-	166,666
Discount related to beneficial conversion feature of Convertible debentures, November 9, 2005	-	-	166,667	-	-	166,667
Discount related to beneficial conversion feature of Convertible debentures, November 10, 2005	-	-	45,000	-	-	45,000
Discount related to beneficial conversion feature of Convertible debentures, November 11, 2005	-	-	275,000	-	-	275,000
Discount related to beneficial conversion feature of Convertible debentures, November 15, 2005	-	-	49,167	-	-	49,167
Warrants issued to Scientific Advisory Board, November 15, 2005	-	-	25,876	-	-	25,876
Shares and warrants issued in connection with private placement of common stock, November 28, 2005	340,000	340	169,660	-	-	170,000



Table of Contents

	Common Stock		Additional	Stock	Accumulated	Total
	Number	Par	Paid-in	Subscription	Deficit	Shareholders'
	of Shares	Value	Capital	Receivable		Equity
Shares and warrants issued in connection with private placement of common stock, November 29, 2005	300,000	300	149,700	-	-	150,000
Shares and warrants issued in connection with private placement of common stock, November 30, 2005	150,000	150	74,850	-	-	75,000
Shares and warrants issued in connection with private placement of common stock, December 2, 2005	100,000	100	49,900	-	-	50,000
Shares and warrants issued in connection with private placement of common stock, December 6, 2005	850,000	850	424,150	-	-	425,000
Shares issued for legal services rendered at \$.95 per share, December 6, 2005	20,000	20	18,980	-	-	19,000
Shares and warrants issued in connection with private placement of common stock, December 12, 2005	750,000	750	374,250	-	-	375,000
Shares and warrants issued in connection with private placement of common stock, December 13, 2005	50,000	50	24,950	-	-	25,000
Shares and warrants issued in connection with private placement of common stock, December 14, 2005	50,000	50	24,950	-	-	25,000
Shares issued in connection with debenture offering, December 15, 2005	50,000	50	48,950	-	-	49,000
	50,000	50	24,950	-	-	25,000

Shares and warrants issued in  
connection with private  
placement of common stock,  
December 20, 2005

F-8

---

Table of Contents

	Common Stock		Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value				
Shares and warrants issued in connection with private placement of common stock, December 29, 2005	50,000	50	24,950	-	-	25,000
Shares and warrants issued in connection with private placement of common stock, December 30, 2005.	50,000	50	24,950	-	-	25,000
Shares issued for interest on debentures, December 31, 2005	19,476	19	17,321	-	-	17,340
Shares issued for consulting services rendered at \$1.46 per share, January 9, 2006	3,425	4	4,997	-	-	5,001
Warrants issued to Scientific Advisory Board on February 15, 2006	-	-	49,067	-	-	49,067
Warrants issued to Scientific Advisory Board on May 15, 2006	-	-	51,048	-	-	51,048
Shares issued for interest on debentures, March 31, 2005	7,921	8	22,184	-	-	22,192
Options exercised, May 31, 2006	1,800,000	1,800	88,200	-	-	90,000
Shares and warrants issued in connection with private placement of common stock, June 15, 2006	1,875,000	1,875	1,873,125	-	-	1,875,000
Shares issued for interest on debentures, June 30, 2006	14,426	14	22,424	-	-	22,438
Net loss year ended June 30, 2006.	-	-	-	-	(3,284,432 )	(3,284,432 )
Balance at June 30, 2006	108,878,425	108,878	4,480,035	20	(3,350,437 )	1,238,456

F-9

---

Table of Contents

	Common Stock		Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value				
Shares issued for interest on debentures, July 31, 2006	5,744	6	7,638	-	-	7,644
Shares issued in connection with conversion of convertible debentures, July 31, 2006	3,333,333	3,333	996,667	-	-	1,000,000
Exercise of stock warrants, July 31, 2006	200,000	200	49,800	-	-	50,000
Warrants issued to Scientific Advisory Board on August 15, 2006	-	-	30,184	-	-	30,184
Warrants issued to Scientific Advisory Board on November 15, 2006	-	-	25,888	-	-	25,888
Shares issued for consulting and legal services rendered at \$0.76 per share, January 2, 2007	216,000	216	163,944	-	-	164,160
Warrants issued to Scientific Advisory Board on February 15, 2007	-	-	32,668	-	-	32,668
Warrants issued to Scientific Advisory Board on May 15, 2007	-	-	25,664	-	-	25,664
Shares issued for consulting services rendered at \$1.03 per share, June 12, 2007	752	1	774	-	-	775
Shares issued for consulting services rendered at \$1.15 per share, June 20, 2007	100,000	100	114,900	-	-	115,000
Shares issued upon conversion of convertible warrants at \$1.00 per share, June 20, 2007	930,000	930	619,070	-	-	620,000





Table of Contents

	Common Stock		Additional	Stock	Accumulated	Total
	Number	Par	Paid-in	Subscription	Deficit	Shareholders'
	of Shares	Value	Capital	Receivable		Equity
Shares issued upon conversion of convertible warrants at \$1.00 per share, June 25, 2007	75,000	75	49,925	-	-	50,000
Shares issued upon conversion of convertible warrants at \$1.00 per share, June 30, 2007	300,000	300	199,700	-	-	200,000
Shares issued for consulting and legal services rendered at \$1.06 per share, June 30, 2007	29,890	30	31,770	-	-	31,800
Options issued to officers June 30, 2007	-	-	27,062	-	-	27,062
Net loss year ended June 30, 2007.	-	-	-	-	(3,118,963 )	(3,118,963 )
Balance at June 30, 2007	114,069,144	114,069	6,855,689	(20 )	(6,469,400 )	500,338
Warrants issued to Scientific Advisory Board on August 15, 2007	-	-	14,800	-	-	14,800
Shares and warrants issued in connection with private placement of common stock, September 21, 2007	1,500,000	1,500	748,500	-	-	750,000
Shares issued for consulting and legal services rendered at \$.75 per share September 30, 2007	25,244	25	18,375	-	-	18,400
Shares and warrants issued in connection with private placement of common stock, October 16, 2007	3,250,000	3,250	1,621,750	-	-	1,625,000
Stock subscriptions received October 17, 2007	-	-	-	20	-	20



Table of Contents

	Common Stock		Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value				
Shares and warrants issued in connection with private placement of common stock, October 16, 2007	250,000	250	124,750	-	-	125,000
Warrants issued to Scientific Advisory Board on November 15, 2007	-	-	7,200	-	-	7,200
Shares issued for consulting and legal services rendered at \$.49 per share December 31, 2007	57,152	57	26,843	-	-	26,900
Options issued to officers January 1, 2008			7,044			7,044
Warrants issued to Scientific Advisory Board on February 15, 2008	-	-	8,500	-	-	8,500
Shares issued for consulting and legal services rendered at \$.45 per share March 31, 2008	61,546	62	27,838	-	-	27,900
Shares issued for consulting services rendered at \$.39 per share April, 2008	27,750	28	10,795	-	-	10,821
Warrants issued to Scientific Advisory Board on May 15, 2008	-	-	32,253	-	-	32,253
Shares issued for consulting services rendered at \$1.03 per share June 30, 2008	29,841	30	27,870	-	-	27,900
Net loss year ended June 30, 2008.	-	-	-	-	(2,738,337 )	(2,738,337 )
Balance at June 30, 2008	119,270,677	119,271	9,532,205	-	(9,207,737 )	443,739

Table of Contents

	Common Stock		Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value				
Shares issued for consulting and legal services rendered at \$ 1.22 per share July 31, 2008	4,098	4	4,996			5,000
Shares issued for consulting services rendered at \$1.22 per share July 31, 2008	2,295	2	2,798			2,800
Warrants issued to Scientific Advisory Board on August 15, 2008			47,500			47,500
Warrants issued in connection with finders fee 9849						0
Shares and warrants issued in connection with private placement of common stock, August 22, 2008	3,136,000	3,136	3,132,864			3,136,000
Shares issued to settle accounts payable August 22, 2008	150,000	150	149,850			150,000
Shares issued to settle account payable						
Payment of Finder's Fee including 9849 warrants to Biotech Capital			(14,696 )			(14,696 )
Shares issued in connection with Warrant Conversion, August 22, 2008	125,000	125	106,125			106,250
Shares issued for legal services rendered at \$1.24 per share August 31, 2008	4,032	4	4,996			5,000
Shares issued for consulting services rendered at \$1.24 per share August 31, 2008	2,258	2	2,798			2,800



Table of Contents

	Common Stock		Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value				
Shares issued for legal services rendered at \$1.00 per share September 30, 2008	5,000	5	4,995			5,000
Shares issued for consulting services rendered at \$1.00 per share September 30, 2008	5,600	6	5,594			5,600
Shares issued for consulting and legal services rendered at \$ .71 per share October 31, 2008	7,042	7	4,993			5,000
Shares issued for consulting services rendered at \$.71 per share October 31, 2008	7,887	8	5,592			5,600
Warrants issued to Scientific Advisory Board on November 15, 2008			30,500			30,500
Shares issued for consulting and legal services rendered at \$ .67 per share November 30, 2008	7,463	7	4,993			5,000
Shares issued for consulting services rendered at \$.67 per share November 30, 2008	8,358	8	5,592			5,600
Shares issued for consulting and legal services rendered at \$ .83 per share December 31, 2008	6,024	6	4,994			5,000
Shares issued for consulting services rendered at \$.83 per share December 31, 2008	6,747	7	5,593			5,600
Shares issued for legal services rendered at \$ .60 per share January 20, 2009	8,333	8	4,992			5,000



Table of Contents

	Common Stock		Additional	Stock	Accumulated	Total
	Number	Par	Paid-in	Subscription	Deficit	Shareholders'
	of Shares	Value	Capital	Receivable		Equity
Shares issued for consulting and legal services rendered at \$ .78 per share January 31, 2009	7,463	7	4,992			4,999
Shares issued for consulting services rendered at \$.78 per share January 31, 2009	8,358	8	5,592			5,600
Shares issued for consulting services rendered at \$ .70 per share February 1, 2009	50,000	50	34,950			35,000
Warrants issued to Scientific Advisory Board on February 15, 2009			29,000			29,000
Shares issued for consulting and legal services rendered at \$ .71 per share February 28, 2009	7,042	7	4,992			4,999
Shares issued for consulting services rendered at \$.71 per share February 15, 2009	7,887	8	5,592			5,600
Shares issued for consulting and legal services rendered at \$ .78 per share March 31, 2009	6,410	6	4,994			5,000
Shares issued for consulting services rendered at \$.78 per share March 31 , 2009	7,179	7	5,593			5,600
Shares issued to acquire equipment at \$ .79	172,500	173	137,327			137,500
Shares issued for consulting and legal services rendered at \$ .69 per share April 30, 2009	7,205	7	4,993			5,000



Table of Contents

	Common Stock					
	Number of Shares	Par Value	Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Shareholders' Equity
Shares issued for consulting services rendered at \$.69 per share April 30, 2009	8,069	8	5,592			5,600
Warrants issued to Scientific Advisory Board on May 15, 2009			30,600			30,600
Shares issued for consulting and legal services rendered at \$ .66 per share May 31, 2009	7,599	8	4,992			5,000
Shares issued for consulting services rendered at \$.66 per share May 31, 2009	8,511	9	5,590			5,599
Shares issued for consulting services rendered at \$ .61 per share June 30, 2009	24,721	25	14,975			15,000
Shares issued for consulting and legal services rendered at \$ .56 per share June 30, 2009	8,961	9	4,991			5,000
Shares issued for consulting services rendered at \$.56 per share June 30, 2009	10,038	10	5,590			5,600
Shares and warrants issued in connection with private placement of common stock, June 30, 2009	150,000	150	74,850			75,000
Shares and warrants issued in connection with warrant conversion, June 30, 2009 net of subscriptions receivable	2,050,700	2,051	1,023,299	(100,000 )		925,350

Net loss for the year ended June 30, 2009	--				(2,787,798 )	(2,787,798 )
	125,299,457	\$ 125,299	\$ 14,455,778	\$ (100,000 )	\$(11,995,535)	\$ 2,485,542

See accompanying notes to the financial statements.

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Shares issued for consulting and legal services rendered at \$ .66 per share July 31, 2009	7,576	8					4,992		5,000
Shares issued for consulting services rendered at \$.66 per share July 31, 2009	8,485	8					5,592		5,600
Warrants issued to Scientific Advisory Board on August 15, 2009							41,400		41,400
Shares issued for consulting and legal services rendered at \$ .86 per share August 31, 2009	6,512	7					4,993		5,000
Shares issued for consulting services rendered at \$.86 per share August 31, 2009	5,814	6					5,594		5,600
Shares issued for consulting services rendered at \$ .89 per share September 30, 2009	6,292	6					5,594		5,600
Shares issued for consulting and legal services	5,618	6					4,994		5,000

rendered at \$ .89 per share September 30, 2009				
Payment of Finder's Fee			(5,250 )	(5,250 )
Shares and warrants issued in connection with private placement of common stock, September 30, 2009	2,675,000	2,675	1,334,825	1,337,500
Shares and warrants issued in connection with warrant conversion, September 30, 2009	3,759,800	3,760	1,876,140	1,879,900
Shares issued for consulting and legal services rendered at \$ .57 per share October 1, 2009	35,088	35	19,965	20,000

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Shares issued for Legal services rendered at \$56.50 per share on October 26, 2009	12,500	13					7,050		7,063
Warrants issued for commissions on October 26, 2009							3,570		3,570
Shares issued for consulting and legal services rendered at \$ .73 per share October 31, 2009	6,859	7					4,993		5,000
Shares issued for consulting services rendered at \$.73 per share October 31, 2009	7,682	8					5,592		5,600
Shares issued upon conversion of Warrants on November 10, 2009	10,000	10					1,430		1,440

Warrants issued to Scientific Advisory Board on November 15, 2009			39,600	39,600
Shares issued in payment of accounts payable November 25, 2009	32,500	33	25,167	25,200
Shares issued for consulting and legal services rendered at \$ .86 per share November 30, 2009	5,814	6	4,994	5,000
Shares issued for consulting services rendered at \$.86 per share November 30, 2009	9,767	10	8,390	8,400
Shares issued for consulting services rendered at \$ .85 per share December 31, 2009	9,917	10	8,390	8,400
Shares issued for consulting and legal services rendered at \$ .85 per share	5,903	6	4,994	5,000

December  
31, 2009

F-18

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Shares issued for consulting and legal services rendered at \$1.043 per share on January 31, 2010	4,794	5					4,995		5,000
Warrants issued to Scientific Advisory Board on February 15, 2010							40,200		40,200
Series A Preferred Shares issued for TheraCour license .001 par value on February 15, 2010			7,000,000	7,000					7,000
Shares issued for consulting services rendered at \$1.096 per share on February 28, 2010	4,562	5					4,995		5,000
Shares issued for employee stock compensation at \$1.25 per share on	125,000	125					156,125		156,250



March 3, 2010

Shares issued  
for employee  
stock  
compensation  
at \$1.25 per  
share on

March 3, 2010	125,000	125	156,125	156,250
---------------	---------	-----	---------	---------

Series A  
Preferred  
Shares issued  
for employee  
stock  
compensation  
at .001 par  
value on

March 3, 2010		250,000	250	513,573	513,823
---------------	--	---------	-----	---------	---------

Series A  
Preferred  
Shares issued  
for employee  
stock  
compensation  
.001 par value  
on March 3,  
2010

		250,000	250	513,573	513,823
--	--	---------	-----	---------	---------

Series A  
Preferred  
Shares issued  
for employee  
stock  
compensation  
.001 par value  
on March 3,  
2010

		93,750	94	192,590	192,684
--	--	--------	----	---------	---------

Shares issued  
for consulting  
and legal  
services  
rendered at  
\$1.25 per  
share on

March 3, 2010	1,000	1	1,249	1,250
---------------	-------	---	-------	-------



Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Shares issued for consulting services rendered at \$1.417 per share on March 31, 2010	3,529	4					4,996		5,000
Shares issued in payment of accounts payable - All Sciences	39,625	40					31,660		31,700
Shares issued for consulting and legal services rendered at \$2.087 per share on April 30, 2010	2,396	2					4,998		5,000
Series B Preferred Shares issued to SeaSide 88, LP, \$.001 par value on May 12, 2010					500,000	500	4,999,500		5,000,000
Placement Agents Fees related to sale of							(400,000 )		(400,000 )

Convertible Preferred shares on May 12, 2010				
Legal Fees related to Sale of Convertible Preferred Stock May 12, 2010			(50,000 )	(50,000 )
Derivative Liability - Issuance of Preferred Series B			(1,787,379)	(1,787,379 )
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.88 per share, .001 par value, on May 12, 2010	319,331	319		319
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on May 12, 2010			(60,000 )	(60 )
Derivative Liability - Retirement			128,053	128,053

of Preferred  
Series B on  
May 12,  
2010

F-20

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Warrants issued to Scientific Advisory Board on May 15, 2010							82,800		82,800
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.51 per share, .001 par value, on May 26, 2010	398,189	398							398
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on May 26, 2010					(60,000)	(60 )			(60 )
Shares issued as Dividend to Seaside 88, LP, .001 par value	10,300	10					16,867		16,877

common stock at \$1.64 on May 26, 2010				
Dividend to Seaside 88, LP, paid on May 26, 2010			(16,877 )	(16,877 )
Derivative Liability - Retirement of Preferred Series B on May 26, 2010			151,852	151,841
Shares issued for consulting and legal services rendered at \$2.083 per share on May 31, 2010	2,400	2	4,998	5,000
Shares issued in conversion of warrants to restricted Common Stock at \$1.00 per share, .001 par value, on June 9, 2010	195,000	195	194,805	195,000
Shares issued in conversion of Series B Preferred Shares to	426,721	427		427

Common  
Stock at  
\$1.41 per  
share, .001  
par value,  
on June 9,  
2010

F-21

---



Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on June 9, 2010					(60,000)	(60 )			(60 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.41 on June 9, 2010	10,366	10					14,565		14,575
Dividend to Seaside 88, LP, paid on June 9, 2010							(14,575 )		(14,575 )
Derivative Liability - Retirement of Preferred Series B on June 9, 2010							149,364		149,354
	11,300	11					19,989		20,000

Shares issued for consulting and legal services rendered at \$1.77 per share on June 9, 2010				
Shares issued for consulting and legal services rendered at \$1.77 per share on June 9, 2010	2,000	2	3,538	3,540
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.59 per share, .001 par value, on June 23, 2010	377,905	378		378
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on June 23, 2010			(60,000)	(60)
	7,731	8	12,266	12,274

Shares  
issued as  
Dividend to  
Seaside 88,  
LP, .001  
par value  
common  
stock at  
\$1.59 on  
June 23,  
2010

Dividend to  
Seaside 88,  
LP, paid on  
June 23,  
2010

(12,274 )

(12,274 )

F-22

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Derivative Liability - Retirement of Preferred Series B on June 23, 2010							120,256		120,249
Shares issued for consulting and legal services rendered at \$1.043 per share on June 30, 2010	2,738	3					4,997		5,000
Net loss for the year ending 6/30/10								(4,744,208 )	(4,744,208 )
	133,980,471	133,983	7,593,750	7,594	260,000	260	23,116,611	(16,739,743)	6,518,677
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.51 per share, .001 par value, on July 7, 2010	397,088	397							397
							(60,000 )	(60 )	(60 )

Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on July 7, 2010				
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.65 on July 7, 2010	6,061	6	9,967	9,973
Dividend to Seaside 88, LP, paid on July 7, 2010			(9,973 )	(9,973 )
Derivative Liability - Retirement of Preferred Series B on July 7, 2010			116,715	116,715
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.30 per share, .001	463,177	463		463

par value,  
on July 21,  
2010

F-23

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on July 21, 2010					(60,000)	(60 )			(60 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.32 on July 21, 2010	5,794	6					7,665		7,671
Dividend to Seaside 88, LP, paid on July 21, 2010							(7,671 )		(7,671 )
Derivative Liability - Retirement of Preferred Series B on July 21, 2010							113,700		113,700
	3,086	3					4,997		5,000

Shares issued for consulting and legal services rendered at \$2.087 per share on July 31, 2010

Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.14 per share, .001 par value, on August 4, 2010

526,916 527

527

Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on August 4, 2010

(60,000) (60 )

(60 )

Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.14 on August 4, 2010

4,716 5

5,365

5,370



Dividend to Seaside 88, LP, paid on August 4, 2010	(5,370 )	(5,370 )
Derivative Liability - Retirement of Preferred Series B on August 4, 2010	104,480	104,480

F-24

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Warrants issued to Scientific Advisory Board on August 15, 2010					1		45,000		45,000
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$0.99 per share, .001 par value, on August 18, 2010	606,367	606							606
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on August 18, 2010					(60,000)	(60 )			(60 )
Shares issued as Dividend to Seaside 88, LP, .001 par value	3,101	3					3,065		3,068

common stock at \$0.99 on August 18, 2010				
Dividend to Seaside 88, LP, paid on August 18, 2010			(3,068 )	(3,068 )
Derivative Liability - Retirement of Preferred Series B on August 18, 2010			104,795	104,795
Shares issued for consulting and legal services rendered at \$1.24 per share on August 31, 2010	4,032	4	4,996	5,000
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$0.93 per share, .001 par value, on September 1, 2010	215,332	215		215
Retirement of Series B Preferred Shares			(20,000 )	(20 )

converted  
into  
common  
stock by  
SeaSide 88,  
LP, .001  
par value  
on  
September  
1, 2010

F-25

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.00 on September 1, 2010	766						766		767
Dividend to Seaside 88, LP, paid on September 1, 2010							(767 )		(767 )
Derivative Liability - Retirement of Preferred Series B on September 1, 2010							34,841		34,841
Series B Preferred Shares issued to SeaSide 88, LP, \$.001 par value on September 21, 2010					250,000	250	2,499,750		2,500,000
Placement Agents Fees related to sale of Convertible Preferred							(195,000 )		(195,000 )

shares on September 21, 2010				
Legal Fees related to Sale of Convertible Preferred Stock September 21, 2010			(10,000 )	(10,000 )
Derivative Liability - Issuance of Preferred Series B			(328,086 )	(328,086 )
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$0.93 per share, .001 par value, on September 21, 2010	430,015	430		430
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on September 21, 2010			(40,000 )	(40 )
Derivative Liability - Retirement			103,012	103,012

of Preferred  
Series B on  
September  
21, 2010

F-26

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Shares issued for consulting and legal services rendered at \$1.07 per share on September 30, 2010	4,673	5					4,995		5,000
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$0.87 per share, .001 par value, on October 5, 2010	460,346	460							460
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on October 5, 2010					(40,000)	(40 )			(40 )
Shares issued as Dividend to	9,268	9					8,046		8,055



Seaside 88, LP, .001 par value common stock at \$0.87 on October 5, 2010			
Dividend to Seaside 88, LP, paid on October 5, 2010		(8,055 )	(8,055 )
Derivative Liability - Retirement of Preferred Series B on October 5, 2010		103,330	103,330
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$0.88 per share, .001 par value, on October 19, 2010	452,965	452	452
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on October 19, 2010		(40,000 )	(40 )

Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$0.88 on October 19, 2010	7,384	7	6,514	6,521
--	-------	---	-------	-------

F-27

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Dividend to Seaside 88, LP, paid on October 19, 2010							(6,521 )	1	(6,521 )
Derivative Liability - Retirement of Preferred Series B on October 19, 2010							69,635		69,635
Shares issued for consulting and legal services rendered at \$1.03 per share on October 31, 2010	4,854	5					4,995		5,000
Series A Preferred Shares issued for employee stock compensation at .001 par value on November 1, 2010			30,000	30			53,903		53,933
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$0.87	461,313	461							461

per share, .001 par value, on November 2, 2010				
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on August 4, 2010			(40,000)	(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$0.87 on November 2, 2010	5,751	6	4,980	4,986
Dividend to Seaside 88, LP, paid on November 2, 2010			(4,986 )	(4,986 )
Derivative Liability - Retirement of Preferred Series B on November 2, 2010			69,104	69,104
Warrants issued to Scientific Advisory Board on November 15, 2010			55,800	55,800



Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.16 per share, .001 par value, on November 16, 2010	345,817	346							346
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on November 16, 2010					(40,000)	(40 )			(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.16 on November 16, 2010	2,984	3					3,449		3,452

Dividend to Seaside 88, LP, paid on November 16, 2010				(3,452 )	(3,452 )
Derivative Liability - Retirement of Preferred Series B on November 16, 2010				69,187	69,187
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.35 per share, .001 par value, on November 30, 2010	310,566	311			311
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on November 30, 2010				(40,000 )	(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value	1,417	1		1,917	1,918

common  
stock at  
\$1.35 on  
November  
30, 2010

Dividend to  
Seaside 88,  
LP, paid on  
November  
30, 2010

(1,918 )

(1,918 )

F-29

---



Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Derivative Liability - Retirement of Preferred Series B on November 30, 2010							69,449		69,449
Shares issued for consulting and legal services rendered at \$1.46 per share on November 30, 2010	3,425	3					4,997		5,000
Shares issued in conversion of warrants to restricted Common Stock at \$1.00 per share, .001 par value, on December 10, 2010	25,000	25					24,975		25,000
Shares issued as compensation pursuant to S-8 at \$1.28 per share on December 10, 2010	50,000	50					63,950		64,000
Shares issued in conversion of Series B Preferred	90,840	91							91

Shares to Common Stock at \$1.10 per share, .001 par value, on December 14, 2010					
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on December 14, 2010			(10,000)	(10 )	(10 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.10 on December 14, 2010	348	1		383	384
Dividend to Seaside 88, LP, paid on December 14 2010				(384 )	(384 )
Derivative Liability - Retirement of Preferred Series B on December 14, 2010				17,438	17,438

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Series B Preferred Shares issued to SeaSide 88, LP, \$.001 par value on December 21, 2010					250,000	250	2,499,750		2,500,000
Placement Agents Fees related to sale of Convertible Preferred shares on December 21, 2010							(200,000 )		(200,000 )
Shares issued for consulting and legal services rendered at \$1.32 per share on December 31, 2010	4,545	5					5,995		6,000
ROUNDING		2							2
adjusting entry		21							21
Shares issued in conversion of Series B Preferred Shares to Common Stock at	343,796	344							344

\$1.16 per share, .001 par value, on January 3, 2011					
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on July 7, 2010			(40,000 )	(40 )	(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.16 on January 3, 2011	7,653	8		8,896	8,904
Dividend to Seaside 88, LP, paid on January 3, 2011				(8,904 )	(8,904 )
Derivative Liability - Retirement of Preferred Series B on January 3, 2011				73,532	73,532

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.26 per share, .001 par value, on January 17, 2011	317,965	318						1	318
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on January 17, 2011					(40,000)	(40 )			(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.26 on January 17, 2011	6,403	6					8,049		8,055
Dividend to Seaside 88,							(8,055 )		(8,055 )

LP, paid on January 17, 2011					
Derivative Liability - Retirement of Preferred Series B on January 17, 2011				70,882	70,882
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.12 per share, .001 par value, on January 31, 2011	356,422	356			356
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on January 31, 2011			(40,000)	(40 )	(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.24 on January 31,	5,271	5		6,516	6,521

2011

Dividend to  
Seaside 88,  
LP, paid on  
January 31,  
2011

(6,521 )

(6,521 )

F-32

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Derivative Liability - Retirement of Preferred Series B on January 31, 2011							72,432		72,432
Shares issued for consulting and legal services rendered at \$1.47 per share on January 31, 2011	4,087	4					5,996		6,000
Shares issued in conversion of warrants to restricted Common Stock at \$1.00 per share, .001 par value, on February 4, 2011	25,000	25					24,975		25,000
Shares issued in conversion of Series B Preferred Shares to Common Stock at	370,017	375							375



\$1.08 per share, .001 par value, on February 14, 2011					
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on February 14, 2011			(40,000)	(40 )	(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.08 on February 14, 2011	4,613	5		4,981	4,986
Dividend to Seaside 88, LP, paid on February 14, 2011				(4,986 )	(4,986 )
Derivative Liability - Retirement of Preferred Series B on February 14, 2011				71,699	71,699
Warrants issued to				54,000	54,000

Scientific  
Advisory  
Board on  
February  
15, 2011

F-33

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$0.99 per share, .001 par value, on February 28, 2011	405,610	409							409
Derivative Liability - Retirement of Preferred Series B on February 28, 2011							71,490		71,490
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on February 28, 2011					(40,000)	(40 )			(40 )
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$0.99 on February 28, 2011	3,500	4					3,448		3,452

Dividend to Seaside 88, LP, paid on February 28, 2011				(3,452 )	(3,452 )
Shares issued for consulting and legal services rendered at \$1.22 per share on February 28, 2011	4,902	5		5,995	6,000
Shares issued for employee stock compensation at \$1.32 per share on March 3, 2010	125,000	125		158,000	158,125
Shares issued for employee stock compensation at \$1.32 per share on March 3, 2010	125,000	125		158,000	158,125
Series A Preferred Shares issued for employee stock compensation at .001 par value on March 3, 2010			250,000	250	574,331
					574,581

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Series A Preferred Shares issued for employee stock compensation .001 par value on March 3, 2010			250,000	250			574,331		574,581
Series A Preferred Shares issued for employee stock compensation .001 par value on March 3, 2010			93,750	94			215,374		215,468
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.09 per share, .001 par value, on March 14, 2011	367,274	367							367
Retirement of Series B Preferred Shares converted into common stock by Seaside 88, LP, .001 par value on March 14,					(40,000)	(40 )			(40 )

2011				
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.09 on March 14, 2011	1,761	2	1,916	1,918
Dividend to Seaside 88, LP, paid on March 14, 2011			(1,918 )	(1,918 )
Derivative Liability - Retirement of Preferred Series B on March 14, 2011			70,566	70,566
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.11 per share, .001 par value, on March 28, 2011	89,986	90		90
Retirement of Series B Preferred Shares converted into common stock by Seaside 88, LP, .001 par value on March 28, 2011			(10,000 )	(10 )



Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001	Number of Shares	Par Value \$.001			
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.11 on March 28, 2011	345	1					383		384
Dividend to Seaside 88, LP, paid on March 28, 2011							(384 )		(384 )
Derivative Liability - Retirement of Preferred Series B on March 28, 2011							17,525		17,525
Shares issued for consulting and legal services rendered at \$1.28 per share on March 31, 2011	4,680	5					5,995		6,000
Shares issued in conversion of warrants to restricted	10,000	10					9,990		10,000



Common Stock at \$1.00 per share, .001 par value, on April 10, 2011					
Series B Preferred Shares issued to SeaSide 88, LP, \$.001 par value on April 18, 2011	250,000	250	2,499,750		2,500,000
Placement Agents Fees related to sale of Convertible Preferred shares on April 18, 2011				(160,000 )	(160,000 )
Legal Fees related to Sale of Convertible Preferred Stock April 18, 2011				(25,000 )	(25,000 )
Derivative Liability - Issuance of Preferred Series B				(429,725 )	(429,725 )
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.28 per	312,163	312		(272 )	40

share, .001  
par value,  
on April 18,  
2011

F-36

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Retirement of Series B Preferred Shares converted into common stock by Seaside 88, LP, .001 par value on April 18, 2011					(40,000)	(40 )		1	(40 )
Derivative Liability - Retirement of Preferred Series B on April 18, 2011							68,756		68,756
Shares issued for consulting and legal services rendered at \$1.47 per share on April 30, 2011	4,087	4					5,996		6,000
Shares issued in conversion of Series B Preferred Shares to Common Stock at	339,726	340					(300 )		40

\$1.18 per share, .001 par value, on May 2, 2011				
Retirement of Series B Preferred Shares converted into common stock by Seaside 88, LP, .001 par value on May 2, 2011			(40,000 )	(40 )
Derivative Liability - Retirement of Preferred Series B on May 2, 2011			68,941	68,941
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at \$1.18 on May 2, 2011	6,841	7	8,048	8,055
Dividend to Seaside 88, LP, paid on May 2, 2011			(8,055 )	(8,055 )
Warrants issued to Scientific Advisory			50,400	50,400

Board on  
May 15,  
2011

F-37

---

Table of Contents

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001	Number of Shares	Par Value \$ .001			
Shares issued in conversion of Series B Preferred Shares to Common Stock at \$1.19 per share, .001 par value, on May 16, 2011	336,501	337					(297 )		40
Retirement of Series B Preferred Shares converted into common stock by Seaside 88, LP, .001 par value on May 16, 2011					(40,000 )	(40 )			(40 )
Derivative Liability - Retirement of Preferred Series B on May 16, 2011									