

NANO VIRICIDES, INC.
Form 10-K/A
March 22, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K/A

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

FOR THE FISCAL YEAR ENDED JUNE 30, 2009

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NO. 333-148471

NANO VIRICIDES, INC.
(Name of Business Issuer in Its Charter)

NEVADA

76-0674577

(State or other jurisdiction of incorporation or
organization)

(I.R.S. Employer Identification No.)

135 WOOD STREET, SUITE 205

WEST HAVEN, CONNECTICUT 06516

(Address of principal executive offices)

203-937-6137

(Issuer's telephone number, including area code)

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

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

COMMON STOCK, PAR VALUE \$.001 PER SHARE NONE

(Title of Class)

(Name of exchange on which registered)

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

Yes No

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

Yes No

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

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

Yes No (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.

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting Company	<input checked="" type="checkbox"/>

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

Yes No

As of October 1, 2009, there were 125,299,457 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on June 30, 2009 by non-affiliates of the registrant was \$41,250,063 based on the closing price of \$0.57 per share as reported on the OTC Bulletin Board on June 30, 2009, the last business day of the registrant's most recently completed fiscal year (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).

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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.

The following discussion and analysis should be read in conjunction with our financial statements, included herewith. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any conclusion reached herein will necessarily be indicative of actual operating results in the future. Such discussion represents only the best present assessment of our management.

ITEM I: DESCRIPTION OF BUSINESS

Corporate History

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

On June 1, 2005, Edot-com.com, Inc. acquired NanoViricides, 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 27% 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.OB. The Company is considered a development stage company at this time.

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

The Company has incurred significant operating losses since its inception resulting in an accumulated deficit of \$11,995,535 at June 30, 2009. For the year ended June 30, 2009 the Company had a net loss of \$2,787,798. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations.

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

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The accompanying financial statements on pages F-1 through F-27 -of this Form 10-K have been prepared assuming that the Company will continue as a going concern that contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, they do not reflect any adjustments relating to the realization of the carrying value of assets or the amounts and classification of liabilities that might be necessary should the company be unable to continue as a going concern.

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- is an agent which reliably deactivates or destroys a virus.

Nanoviricide TM – is 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- is a short peptide or chemical molecule fragment that has been designed to specifically recognize one particular type of virus.

Micelle- One of the structural units said to make up organized bodies.

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 (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.

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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 co-development relationships with other pharmaceutical companies. Such co-development relationships usually may entail upfront payments, milestones payments, cost-sharing, and eventual revenue-sharing, including royalty on sales. There is no guarantee that we will be able to negotiate agreements that are financially beneficial to the Company at the present stage. 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, and (4) Herpes "cold sores" and genital Herpes. 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. A grant application for developing a broad-spectrum nanoviricide against hemorrhagic fever viruses such as Ebola/Marburg and Dengue is currently pending with the Department of Defense.

Our development model is to employ collaborations with academic labs, government labs, as well as external service providers in order to minimize our capital requirements. We currently have collaborations with the Center for Disease Control and Prevention (CDC) and the National (Central) Institute of Hygiene and Epidemiology (NIHE) (Vietnam) for Rabies, with NIHE for H5N1 Avian Flu, the Walter Reed Army Institute of Research (WRAIR) for Dengue family viruses, United States Army Medical Institute of Infectious Diseases (USAMRIID) for Ebola/Marburg family of hemorrhagic viruses, and the Long Island Jewish Medical System, Feinstein Institute of Medical Research (LIJMS) for viral eye diseases such as epidemic kerato-conjunctivitis (EKC) and herpes keratitis. In addition, our HIV and common influenza studies were subcontracted to KARD Scientific, Inc., USA. Some of the biological testing work for Herpes Virus infection of the eye was subcontracted to 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. We have recently signed a Master Service Agreement to subcontract evaluation of nanoviricide drug candidates against various diseases including Influenzas and HIV with the Southern Research Institute, Infectious Diseases Division, Frederick, MD (SRI-F), a well known contract research organization that performs preclinical testing. Initially, we plan to perform additional testing of influenza drug candidates including High-Path or Highly Pathogenic Avian Influenzas (i.e. HPAI) at SRI-F. In addition to H5N1, several H9N and H7N influenza virus subtypes are highly pathogenic and have caused or have the potential to cause severe influenza epidemics. We also plan to perform additional testing of our HIV drug candidates at SRI-F.

We have additional collaborations in the process of formalization for work on Dengue viruses, HIV, Viral Conjunctivitis, HSV "cold sores" and genital herpes, and other viruses. 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 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.

Nanoviricides are designed to work by binding to and eliminating virus particles from the blood-stream, just as antibodies do, only potentially much better. This is expected to result in reduction in viremia. A nanoviricide is constructed by chemically attaching a ligand designed to bind to virus particle, to a polymeric material that forms a flexible nanomicelle by self-assembly. If antibodies are known to affect a viral disease, it is possible to construct a nanoviricide against it, and there can be a general expectation of some success, depending upon the ligand chosen. We can choose a ligand from any of a number of chemical classes, including small chemicals, peptides, or antibody fragments or even whole antibodies.

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The NanoViricides' Concept and Antiviral Strategy

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. A nanoviricide also is capable of simultaneously delivering a devastating payload of active pharmaceutical ingredients (API) into the virus particle, to destroy its genome (RNA/DNA).

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 uncoating themselves once they enter a cell, in order to expose the viral genomic material so that it 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.

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. 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 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.

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.

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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 it 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 as well. 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/>). 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.

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>).

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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 - cancer.

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

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The Company's headquarters are currently in West Haven, Connecticut.

Our Product Focus and Technologies

The Company plans to develop several different nanoviricide drugs against a number of human viral diseases. The Company has a 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. In addition, TheraCour has permitted the Company to use its nanomaterials to develop a treatment against Dengue viruses (including Dengue Hemorrhagic Fever), Ebola/Marburg viruses, and viruses causing certain eye diseases.

We currently have, in early, active development, products against HIV, 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, and Eye drops against viral diseases of the eye such as conjunctivitis and keratitis. Adnoviral 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. We plan on undertaking the development of drugs against other viruses when adequate financing becomes available. 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 vital diseases tend to have large market sizes, and we therefore expect to be able to develop collaborations with major pharmaceutical companies to pursue these programs. We have signed a Material Transfer Agreement with a major pharmaceutical company to evaluate the nanoviricide eye drops. The evaluation is currently in progress. There is no guarantee that the evaluation of the nanoviricide eye drops will lead to a licensing agreement. However, should a licensing agreement take place, we anticipate an initial payment, followed by milestone payments during drug development, and royalties upon commercialization of the drug.

We are pursuing similar opportunities for our other commercial drug programs as well. Traditionally, major pharmaceutical companies have licensed highly innovative drugs only after human clinical studies have established the value of the drug. In recent years, the trend is for major pharmaceutical companies to enter into very early stage agreements, as early as screening and discovery level, with other pharmaceutical companies. We cannot 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.

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

Commercially High Priority Drug Development Programs

To date, the Company has developed drug candidates against four virus types/disease areas with strong commercial prospects. These include Influenza, HIV, viral diseases of the external eye, and Herpes Cold Sores and Genital Herpes. 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.

"H1N1 Swine Flu", Common Influenzas, High Path Avian Influenzas, Bird Flu, Epidemic and Pandemic Influenzas

Our FluCide™ 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. Until last year, we had three different drug development programs for influenzas: FluCide for common influenzas, FluCide-HP™ for highly pathogenic influenzas, and AviFluCide™ specific to H5N1 bird flu. We have consolidated all three 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 influenzas, 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 influenzas, 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 previously used ligands in FluCide-HP. 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.

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

We are developing a nanoviricide against adenoviral Epidemic Kerato-Conjunctivitis (EKC). EKC is a severe disease of the eye which in some people causes long term or permanent blurred vision. In an animal study, our EKCCide™ lead candidate was shown to rapidly resolve the clinical signs of the disease, when treatment was started after infection had set in. The clinical success included demonstration that no SEI's (immunoprecipitates) were formed in treated animals, as opposed to control group. SEI's are known to be the cause of blurred vision. There are currently no approved drugs available against EKC, and it is an active field of drug development research. There are about 2.5 million cases of EKC annually in the USA alone.

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

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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 being commissioned at two independent external research centers.

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.

The Company reported on February 27, 2009 that it entered into a Material Transfer Agreement with a major pharmaceutical company. Pursuant to the terms of the agreement, the Company is not authorized to disclose the identity or the terms of the Agreement, except for securities reporting purposes. The pharmaceutical company will evaluate one of the Company’s compounds as a drug candidate for certain viral infections of the external eye. The Agreement also provides that following evaluation, should the pharmaceutical company so elect, the parties may enter into good faith negotiations for an exclusive, worldwide license for drug development and commercialization of the eye 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 developed for use 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.

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 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.

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.

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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.

Additional studies in cell cultures are planned to be conducted in the next six months. 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™ lead drug candidate.

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.

Herpes “Cold Sores” and Genital Herpes

We have developed nanoviricide drug candidates that are capable of attacking the herpes virus that causes cold sores and genital herpes. These drug candidates are designed so that they can be easily formulated as a skin cream or gel formulation in order to be able to apply readily to cold sores or genital lesions caused by herpes.

We have successfully tested these 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.