NANOVIRICIDES, INC.
Form 10-K/A
February 23, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

(Amendment No. 2)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED JUNE 30, 2014

NANOVIRICIDES, 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 $0.001 PER SHARE	NYSE MKT
(Title of Class)	(Name of exchange on which registered)

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

Yes ¨ No x

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 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¨

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.

YesxNo ¨

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 x Smaller reporting Company ¨

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

Yes ¨ No x

As of September 29, 2014, there were approximately 56,450,600 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on December 31, 2013 by non-affiliates of the registrant was approximately $201,817,163 based on the closing price of $4.95 per share, post-split, as reported on the NYSE MKT on December 31, 2013, 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).

Explanatory Note:

Restatement of Previously Issued Consolidated Financial Statements

NanoViricides, Inc. is filing this Amendment No. 2 to its Annual Report on Form 10-K/A for the fiscal year ended June 30, 2014, originally filed on September 29, 2014 and amended on September 30, 2014 (the “Original Filing”), to amend and restate our previously issued financial statements and the related disclosures in the Original Filing. This Form 10-K/A supersedes and replaces in its entirety the Original Filing.

During the preparation of the Company’s Quarterly Report on Form 10-Q for the period ending December 31, 2014, The Company and the Audit Committee of the Company’s Board of Directors (the “Audit Committee”) identified an accounting error in the financial statements as of June 30, 2014.

The restatement is the result of our reclassification attributable to the accounting for derivative functions contained in the anti-dilution provisions in certain warrants issued in connection with the company's issuances of registered direct offerings. Specifically, the warrants contained certain anti-dilution ratchet provisions that provided for an adjustment to the exercise price of the warrants if the company issued any stock equivalent securities at a lower price in the future while the option was still outstanding. The Company determined that the error caused a material understatement of its derivative liability for the year ended June 30, 2014. For the year ended June 30, 2014, this restatement resulted in an increase in the Company's Derivative Liability-Warrants account by $5,740,540, and a decrease in the Additional Paid in Capital account by $5,740,540. Additionally, the Company's loss for the year ended June 30, 2014 was reduced by $504,858 due to a reduction in the Change in Fair Value of Derivatives account. The reduction of the Company's loss by $504,858 decreased the Company's Accumulated Deficit by $504,858, and also reduced the Company's Derivative Liability account by $504,858. The Net Adjustment to the Derivative Liability account was $5,235,682.

In addition, we also have provided disclosure regarding the impact of the restatement on the adequacy of our internal control over financial reporting and disclosure controls and procedures for the relevant restatement periods in Part II, Item 9A- Controls and Procedures.

For a more detailed explanation of these matters and resulting restatements, please see Note 2 to the Financial Statements - Restatement of Previously Issued Financial Statements.

Unless expressly noted otherwise, the disclosures in this Annual Report continue to speak as of the date of the Original Filing, and do not reflect events occurring after the filing of the Original Filing. We have not amended any other of our previously-filed Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for any fiscal years affected by the restatement discussed above. Instead, the financial information that has been previously filed or otherwise reported for these periods is superseded and replaced by the information in this Annual Report, and the financial information contained in such previously-filed reports should no longer be relied upon.

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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,” “designed to,” “designed for,” or other variations or similar words. No assurances can be given that the future results anticipated by the forward-looking statements will be achieved. Forward-looking statements reflect management’s current expectations and are inherently uncertain. Our actual results may differ significantly from management’s expectations.

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

ITEM I: BUSINESS

Organization and Nature of Business

The 2013-2014 Financial Year in Review

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

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

Of note for the financial year ending June 30, 2014, is that the Company has made significant progress in advancing our pipeline, as well as improving our corporate governance and executive capabilities. As a result of these improvements in corporate governance and our technological achievements, as well as additional steps we took, we are happy to report that NanoViricides, Inc. common stock was uplisted on September 25, 2013, NanoViricides, common stock began trading under the symbol, “NNVC”, on the New York Stock Exchange MKT marketplace on that date . This is a very important milestone for our Company.

In the process of uplisting, we raised approximately $16 million ($6 million in convertible debentures from our prior investors in February 2013, and $10 million in a registered direct offering subsequent to the reverse split and immediately prior to uplisting in September 2013). In addition, we raised an additional $20 million in a second up-round registered direct offering in January 2014. With these transactions, we had cash in hand of approximately $36.9M as of June 30, 2014, and additional cash-like assets of approximately $1.5M in the form of prepaid expenses and security deposits. We spent approximately $7.0M in cash toward operating activities and approximately $5M in capital investment during this year. Thus we had approximately three years’ worth of cash in hand at the end of the reporting period. In addition, in order to conserve cash expenditures, we also pay compensation in stock and stock instruments to various parties. The stockholder’s equity stood at approximately $28.3M as of June 30, 2014.

Subsequent to the end of the fiscal year, on July 2, 2014, we accepted a subscription in the amount of $5,000,000 for a 10% Series C Convertible Debenture from Dr. Milton Boniuk, a member of the Company's Board of Directors. Additionally, on September 5, 2014, we accepted warrant exercises for the purchase of an aggregate of 2,136,655 shares of the Company's $0.001 par value Common Stock for an exercise price of $3.50 per share for aggregate proceeds of $7,478,292.

With these transactions, as of September 15, 2014, we have estimated cash in hand of approximately $48.6M. We have thus strengthened our balance sheet considerably, and now have sufficient funds in hand to advance our first drug, Injectable FluCide™, for treatment of hospitalized patients with influenza through at least the initial human clinical trials. In addition, given our current rate of expenditure, and projected low costs of clinical trials provided that FluCide is as successful in humans as it has been in small animals, we believe that we may have sufficient funds in hand to advance one more drug candidate into advanced preclinical and possibly first in human studies. We are now thus in a strong position to advance our drug pipeline towards clinical studies.

Even more important than the financing initiatives is the realization of a cGMP-capable production facility that can make sufficient quantities of our drug candidates for clinical trials and also for initial sales, should the drugs pass regulatory hurdles. Anil R. Diwan, PhD, our co-founder, President and Chairman, took an extreme risk and financed this facility project with funds from his friends and family and borrowings from financiers through Inno-Haven, LLC, a special purpose limited liability company ("Inno-Haven").

We have a strong team engaged on the total renovation project for building cGMP facility and associated R&D laboratories in the Shelton campus. Mr. Andrew Hahn, retired Director of Facilities (Global) for Bristol-Myers-Squibb is our lead designer and overall steward for this project. Mr. Phil Mader, previously the Senior Capital Project Manager at Bristol-Myers Squibb Company in Wallingford, CT ("BMS"), is our Project Manager. Mr. Mader's firm, MPH Engineering is engaged for engineering design. In addition, Ms. Kathy Cowles, founder of ID3A Architects serves as the lead architect.

We are happy to report that the construction of this state of the art, modern, cGMP capable, clinical scale, nanomedicines manufacturing facility at 1 Controls Drive, Shelton, CT, was completed in June 2014, while managing customized equipment delivery schedules and some weather-related delays.

The facility was inaugurated on July 21, 2014, by Honorable Congressman Jim Himes as the Chief Guest, with delegates from the offices of Honorable Senators Chris Murphy and Richard Blumenthal, with a felicitation from Honorable Governor Dannel Malloy, and local officials in attendance. On the same day, the Board of Directors unanimously agreed that it was in the best interests of our shareholders and the Company to purchase the facility from Inno-Haven, LLC (Dr. Diwan abstained from voting). We anticpate executing and consummating a Contract of Sale for the facility with Inno-Haven in the near future. We are now completing the special equipment fit-out modifications. We have contracted out the facility validation to a third party. Informally, we have started working in the new facility. Once the facility validation is complete, we intend to move most of our work in a phased manner over the next year or so to the new facility. This phased approach is necessary so that work on current projects may continue without any significant delays.

In June 2013, with an improved cash position, we were able to re-engage our anti-Dengue drug development program. We submitted an orphan drug designation application to the US FDA for our first anti-dengue drug candidate. This drug candidate received an orphan drug designation with the US FDA in August 2013. Subsequently, in November 2013, this drug candidate also received an orphan drug status with the European Medicines Agency (EMA). The orphan drug designation carries substantial benefits with it that could result in significant financial benefits to NanoViricides if the drug passes through the regulatory processes successfully. Additionally, in the USA, we can expect to be issued a Priority Review Voucher (PRV), in addition to other benefits. The PRV may be applied to fast track the development of another one of our drugs or can be sold to another pharmaceutical company for the same purpose. The value of a PRV for such a transaction has been estimated to be as much as $250 million, depending upon the circumstances, according to economists at the Duke University. Recently a small pharma traded a PRV to another company for approximately $60M, which may set the lower bound for such transactions.

NanoViricides' platform technology enables us to rapidly develop drug candidates against novel viruses, when appropriate information becomes available. We reported in May 2014, that we have developed drug candidates against Middle East Respiratory Syndrome (MERS) Virus in less than six months, including design, initial synthesis, and scaling up for initial biological screening. MERS virus, an emerging deadly infection, was considered a major emerging threat to global public health, at the time we engaged this project. The MERS virus was first identified in 2012, and its cognate receptor on cells, DPP-IV, was identified, and structural details of their interactions were published only in July, 2013. MERS became less of concern to public health authorities and these candidates have not yet been screened due to the lack of adequate test animal models and the altered priorities of the facilities that can develop such models systems and conduct the tests.

In August 2014, we announced that we restarted our anti-Ebola drug development program. An Ebola virus epidemic began in western Africa with an index case in December, 2013. The epidemic was identified only in March/April 2014, as it began to spread into multiple countries. It has continued to expand rapidly geographically, and also to grow exponentially in spite of the serious efforts by the international community to contain it. As of September 20, 2014, the World Health Organization (WHO), the United States Centers for Disease Control and Prevention (CDC) and local governments reported a total of 6,185 suspected cases and 2,909 deaths (3,424 cases and 1,705 deaths having been laboratory confirmed). WHO has updated the overall case fatality rate from an earlier estimate of 53% to 70% based on clinical outcome data on September 23, 2014 (See Wikipedia article (http://en.wikipedia.org/wiki/Ebola_virus_epidemic_in_West_Africa). Certain estimates by epidemiologists working with international organizations have projected that the epidemic may continue for another 12 to 18 months before it can be brought under control. This could cause not only major regional devastation, but also a significant global impact.

Currently there are neither any drugs nor vaccines against Ebola, although some vaccines and some drug candidates have advanced into clinical trials. This Ebola virus, a Zaire Ebola virus variant, has been shown by to mutate in the field frequently. This raises significant doubts regarding the success of standard antiviral approaches including vaccines, antibodies, antisense technologies, and siRNA approaches. In spite of the mutations, however, the cognate receptor of the virus on the cells and how the virus binds to it does not change. Fortunately, this receptor has now been identified for Ebola virus, as the Niemann-Pick C1 protein (NPC1), a cholesterol transporter whose function is essential for health. Thus, an approach of blocking NPC1, similar to the development of maraviroc to block CCR5 and thereby affect HIV/AIDS, is unlikely to be successful. In contrast, the nanoviricides approach of attacking the virus by presenting to the virus like a cell membrane studded with the same binding sites that the virus binds to, namely its site on NPC1, shows significant promise. Sufficient structural information has been elucidated recently about Eola virus-NPC1 interaction that it has become possible for us to develop novel drug candidates against Ebola that the virus is unlikely to escape.

In September 2014, we announced that we have already completed design of novel anti-Ebola drug candidates, based on "in silico" or molecular modeling approach, and synthesis has also begun. We believe that we will be able to work with our previous collaborators at the USAMRIID, and also at the NIH, to begin testing the potential utility of these drug candidates in cell cultures and animal models soon.

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As part of the advanced IND–enabling development of our Injectable FluCide drug candidate, we have continued to scale up our production processes for both the backbone polymer and the ligands. We have been able to make up to 200g batches in our existing facility. We believe that we will be able to make as much as a few kilograms in a single batch in the new cGMP-capable facility. If the course of treatment of a successful Ebola drug candidate is assumed to be a few grams, we would be able to make as many as a thousand courses of treatment per batch. Our production capacity would thus be responsive to the current requirements for the containment of the Ebola epidemic in West Africa.

Much of the R&D work this year, other than the programs listed above, was focused on the IND-enabling development of our anti-influenza drug candidate, Injectable FluCide. We have been actively studying different chemical processes and routes of synthesis of the backbone polymer, the ligand, and the nanoviricide drug itself, which is a chemical conjugate of the two. The objective of these studies is to develop pathways that will allow industrial manufacturing scale production of a well-defined drug substance, so that multiple batches will produce consistent product. Our studies also involve the development of methods of chemical and physical characterization of the materials at various stages in the entire production process. These studies also include performing the syntheses at different scales, and at least sufficiently characterizing the products at different stages to enable decision-making regarding different possible process variations. We are also continuing to develop additional tests that are needed for analyses of samples from animals that will be generated during the safety/toxicology studies, and later in the human clinical trials. Such tests are needed for estimating a drug’s distribution pattern in the body as well as the time profile of the distribution. Such tests are also needed to decipher the metabolic fate of the drug. Since a nanoviricide drug is not a simple small chemical or an antibody, development of these tests is relatively complex, and is taking a significant amount of time.

We have been able to produce the Injectable FluCide drug candidate in a batch as large as 200g in our existing facilities at present. We intend to begin our initial safety/toxicology studies with this batch of material in the near future.

We have engaged BASi Toxicology Services of West Lafayette, IN, to perform the IND-enabling safety/toxicology study for our Injectable FluCide drug candidate. Our contract with BASI is finalized. The protocol for the initial studies is being finalized as of this writing. We anticipate the initial safety/toxicology studies to begin very soon.

Presentations and Conferences

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

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

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

Our President, Dr. Anil Diwan, was invited to participate in the prestigious 29th Annual Chief Executive of the Year Gala Reception & Dinner held at the New York Stock Exchange on Thursday, July 17, 2014. In addition, he was also invited to participate in the CEO Roundtable Discussion, on the topic of “Enhancing CEO Effectiveness by Redefining the Role of the CFO”, which was held prior to the Reception.

On July 11, 2014, our President, Dr. Anil Diwan, was invited to present the FluCide™ data at the 3rd Annual Influenza Research and Development Conference. The Conference ran from July 9-11 at the Hyatt Regency in Boston, MA, and was held by GTC Bio (https://www.gtcbio.com/conferences/influenza-research-and-development-agenda).

Previously, Dr. Anil R. Diwan, President and Chairman of the Company, was invited to Chair the Section on “Designing Nanomedicines” at the First Annual Symposium on Nanomedicines: Charting a Roadmap to Commercialization, held by the Nanomedicines Alliance on March 6-7, 2013 at the Hilton Washington DC/Rockville, Maryland, USA. Also, Dr. Randall W. Barton, Chief Scientific Officer of the Company, was invited to co-Chair the Section on “Pre-Clinical Pharmacology” at the same event. NanoViricides, Inc. is a member of the Nanomedicines Alliance. Later that month, Dr. Diwan was invited to present a seminar at the University of California, Los Angeles. This seminar was hosted by the Center for Biological Physics, jointly with the California NanoSystems Institute on March 22, 2013.

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

On June 19, 2014, our President, Dr. Anil Diwan, presented an overview of the Company at the Wall Street Analyst Forum’s 25th Annual Institutional Investor Conference at the University Club in New York City.

On June 4, 2014, the Company’s CEO, Dr. Eugene Seymour, MD, MPH, presented an overview of the Company at the LD Micro Invitational Conference at the Luxe Sunset Boulevard Hotel in West Los Angeles.

On March 12, 2014, our CEO Dr. Seymour presented an overview of the Company at the annual Roth Capital Conference that is currently underway at the Ritz-Carlton Hotel in Laguna Niguel, California. This is the second year that Dr. Seymour has been asked to present at this invitation-only conference.

On March 11, 2014, the Company released NanoViricides CEO letter on our website at www.nanoviricides.com. Dr. Seymour provided a calendar year end overview of the Company for the benefit of the shareholders in this letter. In response to inquiries Dr. Seymour had received from several shareholders, this letter also discussed the strong performance of NanoViricides, Inc. since it was founded in 2005, the Company’s continued progress in developing its platform technology, its rich and wide pipeline of industry-leading broad-spectrum antiviral drug candidates, the global intellectual property leadership, the Company’s strong corporate governance, the Company’s frugal business strategy that has helped the Company produce a strong and wide drug pipeline at a very low cost of development compared to the industry, and select highlights of what the Company expects to achieve in calendar year 2014 and the near future.

On February 11, 2014, our CEO, Dr. Eugene Seymour, MD, MPH, was interviewed on radio by Yorba Media. The interview was live on the internet via the iheartradio.app app at the station KXFR, or in the Dallas, TX area on the AM radio station KXFR-1190.

On October 2, 2013, Eugene Seymour, MD, MPH, our Chief Executive Officer, presented a talk at the LD MICRO Invitational Conference held at the Luxe Sunset Bel Air Hotel in West Los Angeles.

On July 19, 2013, a video interview with the Company's CEO, Eugene Seymour, MD, MPH, was broadcast on the Fox Business News TV channel (FBN TV). This unsolicited interview was conducted by David Gentry of "The RedChip Money Report" of the Red Chip Companies, an international small cap research, investor relations and media company.

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Recognition and Awards

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

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

<u>Overview</u>

NanoViricides, Inc. is possibly the first company in the world in the entire field of nanomedicines to have developed a nanomedicine drug that is effective when taken orally (by mouth). Our oral anti-influenza drug candidate, NV-INF-2, has shown extremely high broad-spectrum effectiveness against two different influenza A viruses in animal models, in our FluCide™ program. We are also developing a highly effective injectable anti-influenza drug, NV-INF-1, in this program. The Company is developing this injectable drug (NV-INF-1) for hospitalized patients with severe influenza, including immuno-compromised patients. The Company believes that this drug may also be usable as a single-dose injection in a medical office for less severe cases of influenza. Both of these anti-influenza therapeutic candidates are “broad-spectrum”, i.e. they are expected to be effective against most if not all types of influenzas including the recently discovered novel strain of H7N9, Bird Flu H5N1, other Highly Pathogenic Influenzas (HPI/HPAI), Epidemic Influenzas such as the 2009 “swine flu” H1N1/A/2009, and Seasonal Influenzas including the recent H3N2 influenza. The Company has already demonstrated that our anti-influenza drugs have significantly superior activity when compared to oseltamivir (Tamiflu®) against two unrelated influenza A subtypes, namely, H1N1 and H3N2 in a highly lethal animal model.

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

The Company is also developing an anti-HIV drug. The drug candidates in this HIVCide™ program were found to have effectiveness equal to that of a triple drug HAART cocktail therapy in the standard humanized SCID-hu Thy/Liv mouse model. Moreover, the nanoviricides were long acting. Viral load suppression continued to hold for more than four weeks after stopping HIVCide treatment. The Company believes that this strong effect and sustained effect together indicate that HIVCide can be developed as a single agent that would provide “Functional Cure” from HIV/AIDS. The Company believes that substantially all HIV virus can be cleared upon HIVCide treatment, except the integrated viral genome in latent cells. This would enable discontinuation of treatment until HIV reemerges from the latent reservoir, which may be several months without any drugs. Moreover, the Company believes that this therapy would also minimize the chances of HIV transmission. The Company is currently optimizing the anti-HIV drug candidates. These drug candidates are effective against both the R5 and X4 subtypes of HIV-1 in cell cultures. The Company believes that these drug candidates are “broad-spectrum”, i.e. they are expected to be effective against most strains and mutants of HIV, and therefore escape of mutants from our drugs is expected to be minimal.

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

The Company is also developing a skin cream formulation for the treatment of herpes cold sores or genital warts.

Further, the Company is developing a broad-spectrum drug against Dengue viruses that is expected to be useful for the treatment of any of the four major serotypes of dengue viruses, including in severe cases of dengue (DSS) and dengue hemorrhagic fever (DHF). It is thought that DSS and DHF caused by prior antibodies against dengue that a patient's body creates to fight a second unrelated dengue infection, and the second virus uses these antibodies effectively to hitch a ride into human cells, thereby causing a more severe infection than in naive patients. The Company recently received an "Orphan Drug Designation" for our DengueCide™ drug from the USFDA as well as the European Medicines Agency (EMA). This orphan drug designation carries significant economic benefits for the Company.

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

With the achievement of extremely high levels of effectiveness in appropriate animal models for its current drug candidates listed above, the Company has progressed to advance its drugs into the clinical stage.

In March 2012, we held a pre-IND meeting with the United States Food & Drug Administration ("FDA") for our anti-influenza drug candidate, NV-INF-1. We obtained valuable advice from the US FDA regarding the requirements for filing an Investigational New Drug ("IND") for this anti-influenza drug candidate.

The drugs are required to be manufactured in cGMP-compliant manner (cGMP = "current Good Manufacturing Practices") for use in human clinical trials. The Company is steadily progressing on enabling cGMP manufacturing capability for all of its nanoviricides® drug candidates. The Company reported in June 2014 that the new facility had received its Certificate of Occupancy.

In addition, the process of making the materials has to be optimized and appropriate analytical and quality control methods must be developed. This is a part of CMC ("Chemistry, Manufacture and Controls") activities required before filing an Investigational New Drug application (IND) to allow human clinical studies. The Company is progressing steadily in satisfying the CMC requirements for its Injectable and Oral anti-Influenza drug candidates at present.

Because of the high level of safety observed in our animal studies, our Safety and Toxicology studies ("Tox Package" studies) have been estimated to require relatively large quantities of materials. This has necessitated that the Company enable scaled-up production and qualify the production processes at a much larger scale than what is needed for small animal studies. Tox Package does not require cGMP materials. Therefore, we have engaged in this scale up at our existing facilities rather than waiting for the cGMP facilities to be completed. We have completed the initial studies to verify that the scaled up production of our Injectable and Oral anti-Influenza drug candidates can be performed successfully.

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

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

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

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

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

In addition to technological progress for moving our drugs into the Clinic, we also strive to improve our Corporate Governance and Executive capabilities towards the goal of building a highly successful pharmaceutical company.

To this end, we announced that on May 13, 2013, Ms. Meeta R. Vyas, a seasoned executive, has joined the Company as Interim Chief Financial Officer. Ms. Vyas is a successful former CEO of a public company with significant experience advising senior executives in strategy and operations.

We also bolstered our Board of Directors. As reported previously, we have appointed Mr. Stanley Glick, an experienced CPA, as an Independent Director and the Chairman of our Audit Committee on June 22, 2012. We also added two more independent directors to the board, making the board independent of the executives.

Milton Boniuk, MD, the Caroline F. Elles Chair Professor of Ophthalmology in the Alkek Eye Center at the Baylor College of Medicine, joined our Board on May 28, 2013, as an independent member of the Company’s Board of Directors.

Mukund S. Kulkarni, Professor of Finance and Chancellor of Penn State University, Harrisburg, joined our Board on June 24, 2013, as an independent member of the Company’s Board of Directors.

As a result of the improvements in Corporate Governance and Executive Team, we became eligible for listing on major US national stock exchanges, except for the stock price criteria. We performed a uniform reverse split of our securities, at a 3.5 to 1 ratio to attain full eligibility for up-listing, on September 10, 2013. As a result of the reverse split, all of our outstanding pre-split warrants were also exchanged automatically for post-split warrants with numbers reduced by a factor of 3.5 and strike price increased by a factor of 3.5, to achieve the same effect in terms of the number of shares in the transaction. Thus, for example, 3.5 pre-split warrants that had a strike price of $1 to purchase the pre-split stock (i.e. a total of $3.5 would convert 3.5 of these pre-split warrants into 3.5 shares of pre-split stock), would be automatically exchanged into 1 post-split warrant with a strike price of $3.5 to purchase 1 post-split share. Concomitantly, we also performed a registered direct financing of approximately $10.33 million, with net proceeds to the Company of approximately $9.6 million, after deducting expenses and fees. The Company's shares began trading on the New York Stock Exchange MKT on September 25, 2013, under the same stock symbol, namely "NNVC".

On July 2, 2014, the Company reported that its common stock, NNVC, was added as a member of the U.S. small-cap Russell 2000 Index after the equity markets closed on June 27, when Russell Investments reconstituted its comprehensive family of global indexes. Membership in the Russell 2000, which remains in place for one year, is based on membership in the broad-market Russell 3000 Index. The stock was also added systematically to the appropriate growth and value indexes.

The Company also unveiled its completely redesigned website in time for its annual meeting for the fiscal year ending June 30, 2013 held on December 9, 2013. The new website provides access to the CEO's presentation, our press releases, our technologies, as well as our SEC filings and other documents. This website is built with modern technologies including CSS and HTML5 to allow flexible design and simplifying future updates.

Patents and Intellectual Property

We have previously announced certain important issuances of patents on the TheraCour® technology underlying our nanoviricides® drugs., A fundamental patent on the polymeric micelles composition, structure and uses was issued in the USA with substantially broad claims. This validates the novelty of our approach as well as our leadership position in the nanomedicines based on polymeric micelle technologies. This patent has so far been issued with substantially similar broad claims in ARIPO, Australia, Canada, China, Europe, Hong Kong, Indonesia, Israel, Japan, Korea, Mexico, New Zealand, OAPI, Phillippines, Pakistan, United States, Vietnam, and South Africa.

Another fundamental patent application on the antivirals developed using the polymeric micelles has so far been issued with substantially broad claims as well, in ARIPO, Australia, China, Japan, Mexico, New Zealand, OAPI, and South Africa.

A total of 28 patents have been issued globally as of September 24, 2014, on the basis of the two international PCT patent families that cover the fundamental aspects of our platform technology. Additional patent grants are expected to continue as the applications progress through prosecution processes.

These patents have nominal expiry dates in 2026 to 2028. The dates can be further extended in several countries and regions for the additional allowances due to the regulatory burden of drug development process. Many countries allow up to five years extension for regulatory delays.

No patent applications have been filed for the actual drug candidates that we intend to develop as drugs as of now. We intend to file the patent application for FluCide before entering human clinical trials. The estimated expiry date for the

FluCide patent, if issued, would be no earlier than 2034.

cGMP Production Capability

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

In 2011, as we advanced FluCide program further, the ability to produce clinical product quantities in cGMP compliant fashion became critical. However, the Company's finances at that time could not support such an expensive project. In order to keep our business plan on track, therefore, Anil R. Diwan, PhD, our co-founder, President and Chairman, took an extreme financial risk and decided to finance this facility project with funds from his friends and family and borrowings from financiers. He formed Inno-Haven, LLC, a private venture ("Inno-Haven") to handle this facility project. Inno-Haven raised funds from Dr. Diwan, his affiliates, friends and other financiers to initiate the project, and eventually selected and purchased the site at 1 Controls Drive, Shelton CT, with an 18,000 square foot building on 4.2 acres in a scenic area.

We declared our first pre-IND clinical drug candidate, NV-INF-1, otherwise known as Injectable FluCide™, in September, 2011, and held a pre-IND consultation with the US FDA in March, 2012. The need for cGMP production of clinical quantities of our state of the art nanomedicine drug candidates became urgent thereafter.

NanoViricides signed a Memorandum of Understanding (MoU) with Inno-Haven in February 2013. With this MoU, NanoViricides committed to support the security needs of certain financiers of Inno-Haven, and also committed to lease the facility upon meeting certain milestones, at rates to be determined with expert consultations. In addition, Inno-Haven was committed to conduct the project as per the requirements to be specified by NanoViricides. Subsequently, after the facility construction was completed, the Board of Directors of NanoViricides unanimously agreed that it was in the best interests of the Company and its shareholders to purchase this facility from Inno-Haven. Dr. Diwan abstained from the discussion and voting on this topic. Inno-Haven has agreed to the purchase of the facility by NanoViricides and it is anticipated an agreement for the sale will be entered into shortly.

With the constraints posed by the existing facility, the very special requirements of an injectable drug producing cGMP facility, and limited available financing, the project required extremely skilled and experienced team. In March 2013, NanoViricides retained Mr. Andrew Hahn, a highly experienced and skilled consultant for facility plan and design, and later also brought in Mr. Phil Mader, of MPH Engineering for Engineering and Design specifications, and Ms. Kathy Cowles of ID3A Architects. We have a strong team engaged on the total renovation project for building cGMP facility and associated R&D laboratories in the Shelton campus. Mr. Andrew Hahn, retired Director of Facilities (Global) for Bristol-Myers-Squibb is our lead designer and overall steward for this project. Mr. Phil Mader, previously the Senior Capital Project Manager at Bristol-Myers Squibb Company in Wallingford, CT ("BMS"), is our Project Manager. Mr. Mader's firm, MPH Engineering is engaged for engineering design. In addition, Ms. Kathy Cowles, founder of ID3A Architects serves as the lead architect. With the help of additional external and internal consultants, this team produced a highly optimized laboratory and manufacturing facility plan and specification that also met the financial constraints. As a result, Inno-Haven retained Mr. Mader's firm, MPH Engineering, as overall Project Coordinator and Construction Manager, and began construction in or about June, 2013. The construction was completed in June, 2014, while managing customized equipment delivery schedules and some weather-related delays.

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

The renovation was completed, and a certificate of occupancy was issued in June 2014 We held the inauguration ceremony on July 21st. Since then, we have been working on special equipment fitout modifications, and preparing for facility validation. We have contracted facility validation to a third party which is expected to commence shortly. We plan to move our operations to the new facility in phased manner over the next several months. This is necessary in order to keep current projects undisturbed. We will need to move our existing equipment, as well as install additional equipment at the new facility. We will need to test and validate each piece of equipment. We will need to validate, test and verify that all the systems are functioning as needed for being able to make cGMP drug substance batches. Then we will need to run several batches, analyze the resulting products, and establish that our manufacturing processes are performing satisfactorily to produce the desired drug substance. A minimum of two reproducible batches are required to be made before submitting an Investigational New Drug application (IND) to the US FDA. In addition, we will also need to seek and obtain US FDA registration as a cGMP facility.

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

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

We have been aggressively expanding our portfolio of virus targets and drug candidates every year since our inception in May 2005. We began with drug candidates against Influenza. We then shortly added a drug candidate against Rabies, one of the most difficult diseases to tackle. We started working on Ebola/Marburg viruses (filoviruses) and developed drug candidates worthy of further drug development. Shortly thereafter, we developed a drug candidate against Adenoviral Epidemic Kerato-conjunctivitis (EKC). In 2008, we added anti-HIV drug candidates to our growing portfolio. In 2009, we improved upon our EKC drug candidates to develop new drug candidates that may be effective potentially against most known viral diseases of the external eye. Most of these viral diseases are caused by a wide variety of adenoviruses and herpes simplex viruses. We also developed new drug candidates against the herpes viruses (HSV-1 and HSV-2), for the treatment of recurrent HSV skin infections, such as cold sores and genital warts in 2008-2009. In 2010, we added drug candidates effective against Dengue viruses to our pipeline. In 2011, we began focusing on activities needed for taking our anti-influenza drug into human clinical trials. In 2012, we developed an oral version of our anti-influenza drug candidate in the Flucide program. Thus, in just about seven 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.

We have continued to further advance the nanoviricide drug candidates against the six commercially important indications in our pipeline successfully this year.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We now have six commercially significant active drug development programs: (1) Oral FluCide™, against all Influenzas, (2) a Piggy-back (injectable or infusible) version of Flucide for hospitalized patients, (3) nanoviricide eye drops against adenoviral EKC and herpes keratitis, (4) HIVCide™-I against HIV/AIDS, (5) HerpeCide™-I skin cream formulation for herpes cold sores and genital warts, and (6) DengueCide™, a broad spectrum nanoviricide designed to attack all types of dengue viruses and expected to be effective in the Severe Dengue Disease syndromes including Dengue Hemorrhagic Fever (DHS) and Dengue Shock Syndrome (DSS). We continue to achieve very strong performance in the testing of these drug candidates.

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

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

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

After declaring the injectable FluCide drug candidate in February 2012, we have been focused on taking our technology from the small scale syntheses needed for small animal studies to the large scale syntheses for making large batches of our nanoviricides as would be needed for Safety and Toxicology ("Tox Package" studies) and later for human clinical trials. Because of the significant safety observed during the several animal studies designed to test the effectiveness of FluCide drug candidates in small animals, the scale required for the tox package studies was estimated at kilograms. Originally we had intended to perform kg-scale syntheses only after the new lab and facilities designed for such scale up was available. However, the facility program was significantly behind due to challenges related to resources availability as well as significant challenges posed by the need for designing complex functionality in a limited space while performing renovation of an existing space. We therefore decided to perform the synthesis of FluCide for tox package in our existing small-scale laboratory. We have been optimizing the processes and translating laboratory operations to appropriate chemical process unit operations in the subsequent time frame. This is a very significant undertaking, given the constraints of our current small-scale facility. After we have completed these process optimizations, we will still need to produce at least three to five batches of the injectable FluCide, analyze the product for comparability, and combine these batches to produce a master batch sufficient to perform the tox package studies with. These activities are currently in progress.

While we have made significant progress in this scale up program at our current facility, certain key equipment pieces that we need are still on back order at present with certain vendors. After these equipment pieces arrive, we will need to set them up, validate them and then use them for the operations they are intended for. This continues to be an item causing delays in our goal of making sufficient quantities of FluCide for the tox package study and it is outside of the Company's control.

During the last year, we have also been focused on the design of the cGMP clinical batch production facility and associated R&D laboratories to be commissioned in the Shelton campus.

In July-August 2011, we reported on the anti-HIV studies in animals that were designed to discriminate the comparative effectiveness of different ligands. We reported that our lead anti-HIV candidate achieved anti-HIV efficacy equivalent to a HAART (highly active anti-retroviral therapy) triple drug cocktail in this recently completed animal study. Treatment with this lead anti-HIV nanoviricide reduced HIV levels and protected the human T cells

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

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

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

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

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

In the case of FluCide™, we have completed these optimization studies resulting in two separate FluCide drugs, namely the injectable FluCide, and the oral FluCide. The injectable FluCide is further advanced in its development cycle and is anticipated to be our first drug candidate going towards and IND filing and human clinical studies in the near future as we complete its pre-clinical development and c-GMP manufacturing process development. The oral FluCide is anticipated to follow the injectable FluCide into human trials.

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

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

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

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

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

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

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

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

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

In addition to the antiviral effects, the oral FluCide drug candidates also led to generation of a strong antiviral antibody response. Two different anti-influenza drug candidates were tested in Oral vs. IV comparison. One of the FluCide drug candidates, when administered orally, resulted in 1866±90 micro-g/ml-plasma of anti-influenza antibody, and 1258±59 when administered as IV injections. Another FluCide candidate, when given orally, resulted in 1491±37 ug/ml plasma of anti-influenza antibody, and 1151±53 when administered as IV injections. The untreated infected animals had 190±22 ug/ml antibody response, which was the weakest of all, as expected. Of significance, oseltamivir (Tamiflu) resulted in only 950±64 ug/ml level of antibody response, which was far less than the two oral

FluCide groups (p-value <0.0003), and also substantially less than the two IV FluCide groups (p-value <0.04). These p-values were determined for a comparison of FluCide groups against the oseltamivir group using the most stringent parameters, viz. two-tailed, paired, t-test. A smaller p-value indicates a greater confidence that the difference in observations cannot be a result of pure chance. These data also indicated that the antibody response was stronger when FluCide was given orally rather than as IV injection.

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

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

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

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

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

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

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

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

The Company intends to develop data about effectiveness of its drug candidates against certain unrelated influenza A viruses using both cell culture studies and animal models in a reasonable manner. These data will be needed as part of the IND application that the Company is working on. An IND application will be required for the Company to enter into human clinical trials.

Previously, 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 this 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 corroborated our previous findings in animal studies. The Company had reported that its best nanoviricide drug candidate against HIV was more than 25 times superior to a three drug combo anti-HIV cocktail based on biomarker test response in all parameters tested. The parameters included improvement in human T cell populations in the animal model and reduction in HIV viral load. The Company has since performed additional studies to optimize the HIV binding ligand and has found ligands that are superior to the one that yielded these strong results. In September 2013, we announced successful anti-HIV drug development studies performed in this same laboratory. Anti-HIV studies are extremely expensive. As such, the Company’s HIVCide program has been slowed down.

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

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

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

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

The 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.

The Company also announced in May 2012 that a fundamental patent, on which the nanoviricides® technology is based, is due to be issued in the USA on May 8, 2012. The US Patent (No. 8,173,764) is granted for "Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers." It was issued on May 8, 2012. The patent term is expected to last through October 1, 2028, including anticipated extensions in compensation for time spent in clinical trials. This US Patent has been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The disclosed structures enable self-assembling, biomimetic nanomedicines. NanoViricides, Inc. holds exclusive, perpetual, worldwide licenses to these technologies for a broad range of antiviral applications and diseases. The other national and regional counterparts of the international Patent Cooperation Treaty ("PCT") application number PCT/US06/01820, which was filed in 2006, have issued as a Singapore National Patent Publication, a South African patent, and also as an OAPI regional patent covering Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo. It has also issued as a granted patent in New Zealand, China, Mexico, and Japan. Estimated expiry dates range nominally from 2026 to 2028 with various extensions accounting for delays in clinical trials. Additional issuances are expected in Europe, and in several other countries around the world.

In addition, the counterparts of the international PCT application PCT/US2007/001607 have issued as a granted patent in New Zealand, OAPI, Pakistan, Australia, South Africa, and Mexico to date. Additional issuances are expected in Europe, USA, and in several other countries around the world. This patent application teaches antivirals based on the TheraCour polymeric micelle technologies, their broad structures and compositions of matter, pharmaceutical compositions, methods of making the same, and their uses. The nominal expiry dates are expected to range from 2027 to 2029.

To date, these two international patent applications have resulted in twenty patents in different countries and regions. All of the resulting patents have substantially broad claims. Prosecution in several additional regions and countries is continuing.

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

In September 2011, we announced the acquisition by Inno-Haven, LLC of an 18,000 square foot building on 4 acres with possibility of expansion in Shelton, CT. Inno-Haven LLC, a special purpose company formed to acquire the facility, completed the purchase on August 31, 2011. Financing for the acquisition by Inno-Haven was provided by certain private investors that included Anil R. Diwan, PhD. Dr. Diwan is President and Chairman of the Company and Managing Member of Inno-Haven. Dr. Diwan's part of the financing came from his personal savings, personal borrowings, and a sale of some of his shares of NanoViricides, Inc. received as a founder. In October 2012, Dr. Diwan completed the programmed sale of the NanoViricides stock that he had obtained as a founder. The Company had agreed to this stock sale in order to help partially offset the costs for the acquisition of a facility and of architectural and engineering design of its renovation. Additionally, Dr. Diwan has agreed to provide personal guarantees, as needed, for certain additional contemplated transactions. The Company has previously announced that it had determined that this financing approach provided the best value for the Company and its shareholders. Inno-Haven has since raised substantial additional capital financing to enable total renovation of this facility into a cGMP manufacturing facility and associated R&D laboratories to suit the purpose of NanoViricides, Inc. The Company anticipates that it will be leasing the laboratory facilities and cGMP production facility from Inno-Haven, for the cGMP manufacture of clinical batches of its nanoviricides® drug candidates against various viral diseases. No lease has been signed yet.

In this year, as in the previous year, we have also made significant strides in achieving exposure for the Company and its technologies. The Company's President, Anil R. Diwan, PhD, was invited to speak at the 1st International Symposium on Nanomedicine and Cancer Diagnostics at the University of Delaware held on August 16, 2012. Dr. Diwan was also invited to participate on the Panel on Nanomedicine & Nanodiagnostics at the Nanomanufacturing Summit 2012 & 11th Annual NanoBusiness Conference on September 5, 2012, held at the Seaport Hotel, Boston, MA. Dr. Diwan also presented a poster at the Company Showcase in the Biotech2012 Symposium held by PennBio in Philadelphia, PA on October 22, 2012. Dr. Diwan also presented the Company's accomplishments at the BIO CEO 2013 Conference held at Waldorf Astoria, New York City on February 12, 2013. On March 22, 2013, Dr. Diwan gave an invited Special Seminar at the UCLA Center for Biological Physics, jointly with the California NanoSystems Institute, exploring the theoretical aspects as well as the experimental results of the nanoviricides approach. On April 24, 2013, Dr. Diwan, presented an overview of the company at the 2013 BIO International Convention held at the McCormick Center in Chicago, Illinois (http://convention.bio.org/). On June 27, 2013, Dr. Anil R. Diwan, presented an overview of the company at the OneMedForum-New York 2013 held at the Metropolitan Club, New York.

The Company's President, Dr. Anil Diwan, was invited to lead the Section 1, "Designing Nanomedicines", with Dr. Mostafa Analoui of the Livingston Group. In addition, Dr. Randall Barton, the Company's Chief Scientific Officer, lead Section 2, "Preclinical Pharmacology", with Dr. Benjamin Yerxa of Liquidia Technologies. These sections were part of the Symposium on Nanomedicines: Charting a Roadmap to Commercialization, a Conference that was divided into five sections. This Symposium was held at the Hilton Hotel in Rockville, MD, on the 6th and 7th of March, 2013.

In addition, the Company announced on October 24, 2011, that information about its novel, proprietary anti-virus platform technology has been published in the book “Bionanotechnology II: Global Prospects.” The chapter entitled “Nanoviricides - A Novel Approach to Antiviral Therapeutics” provides an in-depth presentation of the NanoViricides platform technology.

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.

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The Company has been successful in raising necessary funds this year as well as last year.

On September 10, 2013, the Company raised approximately $10.3 million in a registered direct offering to accredited investors and certain institutional investors. The Company received approximately $9.66 million in proceeds after deducting approximately $670 thousand for broker commissions and attorney fees. The Company executed the said registered direct offering to accredited family funds and investors and to institutional investors immediately following a reverse split of the stock at a 1 to 3.5 ratio that became effective on September 10th. Each unit of this registered direct offering consists of one share of (post-split) common stock and one 5-year warrant. The warrants have an exercise price of $5.25 per share. The units were offered by Nanoviricides pursuant to an effective shelf registration statement filed with the Securities and Exchange Commission dated October 26, 2012. Midtown Partners & Co., LLC and Chardan Capital Markets, LLC served as the exclusive placement agents for the transaction. In connection with the Offering, pursuant to a Placement Agency Agreement dated September 9, 2013 among Midtown Partners & Co., LLC and Chardan Capital Markets, LLC (collectively, the “Placement Agents”), the Company paid the Placement Agents an aggregate cash fee representing 6% (3% each) of the gross Purchase Price paid by the Purchasers and warrants to purchase an aggregate of 2% (1% each) of the number of shares of Common Stock sold in the Offering (the “Compensation Warrants”) representing two percent of the Shares and substantially similar to the Warrants, at an exercise price equal to $5.25 per share. The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the SEC on December 21, 2012.

On January 24, 2014, the Company successfully completed a registered direct offering (“Offering”) raising approximately $20 million. The Company sold 3,815,285 units and raised gross proceeds of $20,030,246.25 before estimated expenses of approximately $1,200,000, which includes placement agent fees but does not include and attorneys’ fees and other expenses. The price per Unit was $5.25, equal to a four percent (4%) discount to the 20-day VWAP of the NNVC stock price on January 17, 2014. The exercise price of the Warrant was equal to the closing price of NNVC stock on January 17, 2014. Each Unit consisted of one share of the Company’s common stock and 0.65 of a warrant to purchase one share of common stock, issuable upon exercise of the Warrant at the exercise price of $6.05 per share. The Warrants were exercisable immediately and expire five years after issuance. The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the Securities and Exchange Commission on December 21, 2012 and Form S-3MEF (File No. 333-193439). 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.

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

In addition, on September 5, 2014, we accepted the exercise of warrants for the purchase of an aggregate of 2,136,655 shares of the Company's common stock for an exercise price of $3.50 per share for aggregate proceeds of $7,478,292.

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 two years 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. The Company's strong financial position has now enabled us to decide to purchase the 1 Controls Drive, Shelton, CT facility 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. 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.

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

NanoViricides, Inc. (the “Company”), is a nano-biopharmaceutical (nanomedicine) company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. We are a development stage company with several drugs in various stages of early development. The Company’s drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. (“TheraCour®”), to which the Company has exclusive licenses in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Influenza including Asian Bird Flu Virus (INF), Herpes Simplex Virus (HSV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), and Rabies. On February 15, 2010, the Company entered into an Additional License Agreement with TheraCour granting the Company the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types for Dengue viruses (DENV), Japanese Encephalitis (JEV), West Nile Virus (WNV), viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses.

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

The Company has incurred significant operating losses since its inception resulting in an accumulated deficit of $38,299,783 at June 30, 2014. For the year ended June 30, 2014, the Company had a net loss of $8,875,667 Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations.

To date, we have engaged in organizational activities; sourcing compounds and materials; developing novel compounds and nanomaterials, and experimentation with studies on cell cultures and animals. We have generated funding through the issuances of debt, private placement of common stock, and sale of registered securities. We have not generated any revenues and we do not expect to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or that we will become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations.

The Company currently has no long term debt other than the Series B Convertible Debentures and the Series Convertible Debentures.

Glossary of Terms

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

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

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

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

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

Nanomicelle - Micelles on the scale of nanometers.

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

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

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

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

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

SAR: Structure-Activity-Relationship study. When an initial lead drug compound is found that has activity, further studies on 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) an injectable drug for hospitalized patients with Influenza, (2) an oral drug for outpatients with Influenza (3) HIV, (4) Topical Eye Drops for viral diseases of the external eye, (5) Herpes "cold sores" and genital Herpes, and (6) Dengue viruses. In addition, the Company believes that, as the holder of potentially paradigm-shifting antiviral drug development technologies, it has a social responsibility to develop drugs against diseases affecting large segments of worldwide populations. In our Social Responsibility programs, we are developing drugs against Neglected Tropical Diseases (NTDs) caused by viruses such as Dengue viruses and Rabies. The Company also has BioSecurity programs that include drug development against hemorrhagic fever viruses such as Ebola/Marburg, and a unique technology that we call "ADIF™" to combat natural or bioterrorism attacks by novel viruses as happened with SARS and may happen with engineered viruses. The Company plans to perform its NTD and BioSecurity R&D and drug development in collaboration with Institutes of renown and with public funding, in order to minimize the strain on our resources. The Company believes that this work provides direct benefits to our commercially important programs. The Company will continue its efforts to obtain federal financing for development of these technologies. However, the Company may not be successful in obtaining such financing. The Company has limited resources and its ability to work on such projects that are deemed of low commercial value is very limited.

Our Collaborations and Service Contracts in Brief

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

For Influenza Viruses:

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

For HIV:

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

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

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

For Herpes Virus Infections:

1. TheVac, LLC
2. Northeastern Ohio Medical University (NEOMED), previously NEOUCOM, Prof. Ken Rosenthal 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. Pamela Glass Lab.
2. Public Health England, UK

For Rabies Virus:

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

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

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

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

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

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

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

The Nanoviricides Concept and Antiviral Strategy

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

A nanoviricide is constructed by chemically attaching a ligand designed to bind to a virus particle, to a polymeric material that forms a flexible nanomicelle by self-assembly. If antibodies are known to affect a viral disease, it is possible to construct a nanoviricide against it, and there can be a general expectation of some success, depending upon the ligand chosen. We can choose a ligand from any of a number of chemical classes, including small chemicals, peptides, or antibody fragments or even whole antibodies.

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

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

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

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

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

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

Antibodies are a major defense of humans and animals against viruses. After a person is infected by a particular virus, he/she develops antibodies against the virus. The infection is fully controlled after a strong antibody response develops. Subsequent exposure to the same virus does not cause disease, because the appropriate memory cells are activated into producing the correct antibody. However, antibodies by themselves do not destroy a virus particle. After a few antibodies bind to a virus particle, several processes must take place that eventually lead to destruction of the virus particle. Many viruses have developed ways of dysregulating this complex immune response cascade.

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

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

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

The NanoViricides Technology and Approach

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

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).

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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, Preclinical Safety And Efficacy Studies.

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

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

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

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

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

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

Our Product Focus and Technologies

The Company plans to develop several different nanoviricide drugs against a number of human viral diseases. The Company initially obtained an exclusive license in perpetuity to develop drugs based on technologies originally created by TheraCour Pharma, Inc., (TheraCour) against the following human viral diseases: H5N1 (Avian Flu), Human Influenza, Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), and Rabies, including all known strains of these viruses. The Company has entered into an Additional License Agreement with TheraCour granting the Company the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types for Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses.

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

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

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

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

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

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

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

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

Commercially High Priority Drug Development Programs

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

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

Our FluCide(™) program lead drug candidates, both the Injectable FluCide, and the Oral FluCide, have shown efficacies animals that far exceed that of known drugs such as Oseltamivir (Tamiflu®, Roche) against common influenza in an animal model. Previously, we had planned on developing different drugs for different types influenza infections based on severity. However, we have now consolidated our strategy to develop broadly active, yet highly effective, pan-influenza FluCide drugs. This became feasible because of the significant improvements in efficacy that we were able achieve in optimizing our FluCide drug candidates. Both our Injectable and Oral FluCide are expected to be highly active against substantially 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 are developing an orally available form of FluCide for out-patients. In addition, we are developing a sterile concentrated solution that is suitable for "piggy-back" infusion for the treatment of hospitalized patients with influenza or influenza-like-illness. We have declared a clinical candidate for influenzas.

Recently, with additional SAR (structure-activity-relationship) studies, we have been able to develop influenza virus binding ligands that are expected to be superior to the ones we employed previously. The new ligands are designed to be closer mimics of the sialic acid receptors (than the previously employed ones), yet capable of binding to influenza virus hemagglutinin (and neuraminidase) proteins that use either the "avian" or the "human" types of sialic acid receptors. Pigs are known to be a "mixing vessel" species, exhibiting both avian and human types of sialic acid receptors, and thereby re-assortment (mixing) of genetic material from influenza strains, subtypes, or types, with different host specificities can occur readily in pigs. We are actively seeking partnerships, collaborations and government funding for our anti-influenza drug program.

In September 2012, we demonstrated oral efficacy of our anti-Influenza drug candidates against two different viruses namely H1N1 and H3N2. With these developments, the Company now intends to develop an oral influenza drug for out-patients. In addition, the Company intends to continue its injectable drug development as "piggy-back" infusion solution for hospitalized patients.

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

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

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

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

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

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

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

Herpes Cold Sores and Genital Herpes

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

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

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

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

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

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

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(™) lead drug candidate.

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

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

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

Resistance to HAART eventually leads to AIDS. It is possible that HIVCide can be used in addition to HAART to obtain even stronger beneficial effects, resulting in a “functional cure” of HIV.

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

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

Nanoviricides act by a different mechanism than standard anti-HIV therapy. The Company believes, therefore, that by combining a nanoviricide with current therapy, a functional cure of HIV may be already achievable. However, there is no way to predict whether such a treatment would be successful at providing a functional cure of HIV at present.

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

Dengue

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

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

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

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

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

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

Ebola, Marburg

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

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

Rabies

Our RabiCide(™) 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(™) 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(™)" or ADIF(™) technologies that may show efficacy in treating epidemics like H5N1, SARS or Ebola by developing a targeted therapeutic in the field to prevent the spread of the disease.

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

We have already demonstrated the ADIF technology capabilities successfully.

The Strength of Our Drug Pipeline

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

Our nanoviricides are designed as “cell biomimetics,” meaning that the nanoviricides “look like” a cell to the virus. The nanoviricide carries a portion of the broad-spectrum receptor on the nanomicelle surface that the virus attaches to and is then entrapped or dismantled by the nanoviricide. Such broad-spectrum nanoviricides could be stockpiled to enable treatment of many infectious agents with very few drugs, and thus would be valuable to worldwide disease programs, and Strategic National Stockpiling efforts.

We believe that the Company has a strong and wide pipeline of antiviral drugs. However, with relatively meager financial resources, the Company continues to juggle prioritization of the various programs, and program achievements.

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

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

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

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

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

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

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

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

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

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

Drug Development Studies

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

Preclinical Safety And Efficacy Studies

Preliminary Safety Studies In Vitro

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

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

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

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

Proof-of Principle

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

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

Efficacy Studies - Influenza

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

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

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

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

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

Another nanoviricide which is based on a ligand that we designed in-house, using rational drug design strategy, to be specific to the group of all or a majority of highly pathogenic avian influenza (HPAI) viruses, also showed a very high efficacy. This is being developed as "FluCide-HP(™)", 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.

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

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

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

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

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

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

In Vivo Efficacy Studies - Influenza

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

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

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

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

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

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

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

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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±21 pfu/ml by the H5N1-based candidate and 119±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± 115 pfu/ml at this sampling point. Thus, the reduction in viral load was approximately 1 log units for both of these candidates. Virus load reduction estimates depends upon various factors. Improvement in dosing regimen may be expected to provide a further reduction in viral load.

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

All of the mice treated with the new anti-influenza nanoviricides were surviving even when all of the mice from the Oseltamivir treated group had died. The new version of FluCide drug candidate extended the lifespan of lethally infected mice to 334±11 hrs. (or 14 days) on average. In contrast, mice treated with an extended Oseltamivir protocol (twice daily until death) survived for 193±3 hrs. (or 8 days) on average. Control infected mice survived for only 121±2 hrs. (or 5 days). FluCide was given as an IV injection, on alternate days, for five treatments. Oseltamivir was given as oral, twice daily, each at 20mg/kg through life (or 14 treatments). Increased length of Oseltamivir treatment led to an increase in survival of this group compared to our previous study. Viral load at 120h was reduced in the Oseltamivir treated group to only about half of (0.51x) that in untreated control. In contrast, viral load reduction at this time point in the nanoviricide treated group was approximately 0.13x that of untreated control, an improvement in viral load reduction by nearly a factor of four.

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

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

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

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

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

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

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

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

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

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

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

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

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

Preliminary Efficacy Studies In Vivo – Viral EKC

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

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

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

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

Preliminary Efficacy Studies In Vivo – HIV

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

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

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

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

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

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

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

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

In this study, we found that the effectiveness of one of the nanoviricides we tested was substantially comparable to the three-drug HAART cocktail. Both HAART and nanoviricide treatment had positive long term effects on reducing thymocyte depletion as shown by the proportion of CD4+CD8+ thymocytes (double-positive, or “DP”) at 48 days post-infection. Implants in the HAART and nanoviricide treatment groups exhibited 75-85% CD4+,CD8+ DP cells while the vehicle control groups had only approximately 30% CD4+CD8+ thymocytes. Similarly, viral load in the nanoviricide treated group was reduced by >0.7 logs, slightly less than that with the HAART cocktail.

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

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

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

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

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

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

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

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

Preliminary Efficacy Studies In Vitro (Cell Cultures) – HIV

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

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

Significantly, a subset of the anti-HIV nanoviricides tested in cell culture models at Southern Research had very similar activity against two distinctly different isolates of HIV-1, viz. Ba-L and 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.

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

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

Preliminary Efficacy Studies In Cell Cultures – HSV-1

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

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

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

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

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

Preliminary Efficacy Studies In Cell Cultures – Dengue

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

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

Preliminary Efficacy Studies In Vivo – Dengue

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

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

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

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

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

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

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

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

Preliminary Efficacy Studies In Vivo – Rabies

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

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

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

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

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

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

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

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

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

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

A Note on Our Studies to Date

Current pharmaceutical industry work in antiviral therapy generally results in small efficacy improvements. Thus, in the case of influenza, peramivir(™), (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.

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

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

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

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

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

A very small -level (e.g. 1%) is less likely to be more extreme than the critical value and so is more significant than high -level values (e.g. 5%). However, smaller -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 -level inevitably involves a compromise between significance an d 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.

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Escape Mutants

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

Ligand Tuning™

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

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

A Note on US FDA Priority Review Vouchers

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

Economists at Duke University, who proposed the voucher concept in 2006, have calculated that reduction of the FDA approval time from 18 to six months could be worth more than $300 million to a company with a top-selling drug with a net present value close to $3 billion. At this level, the voucher would be expected to offset the substantial investment and risk required for discovery and development of a new treatment for a neglected tropical disease. (David B. Ridley, Henry G. Grabowski and Jeffrey L. Moe, “Developing Drugs For Developing Countries”, Health Affairs, 25, no. 2

(2006): 313-324; doi: 10.1377/hlthaff.25.2.313; © 2006 by Project Hope. and (http://blogs.cgdev.org/globalhealth/2007/10/fda_priority_review.php).

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

Significant Alliances and Related Parties

TheraCour Pharma, Inc.

Pursuant to an Exclusive License Agreement we entered into with TheraCour Pharma, Inc., (TheraCour), the Company was granted exclusive licenses in perpetuity for technologies developed by TheraCour for the virus types: Human Immunodeficiency Virus (HIV/AIDS), Influenza including Asian Bird Flu Virus, Herpes Simplex Virus (HSV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), and Rabies. The Company has entered into an Additional License Agreement with TheraCour granting the Company the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types for Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses.

In consideration for obtaining these exclusive licenses, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of certain direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed; (2) to pay $25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour; (3) we will pay $2,000 or actual costs, whichever is higher, for other general and administrative expenses incurred by TheraCour on our behalf; (4) make royalty payments (calculated as a percentage of net sales of the licensed drugs) of 15% to TheraCour Pharma, Inc.; (5) TheraCour Pharma, Inc. retains the exclusive right to develop and manufacture the licensed drugs. TheraCour Pharma, Inc. will manufacture the licensed drugs exclusively for NanoViricides, and unless such license is terminated, will not manufacture such product for its own sake or for others; and (6) TheraCour may request and NanoViricides, Inc. will pay an advance payment (refundable) equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. TheraCour may terminate the license upon a material breach by us as specified in the agreement. However, we may avoid such termination if within 90 days of receipt of such termination notice we cure the breach.

Development costs charged by TheraCour Pharma, Inc. for the year ended June 30, 2014, 2012 and 2011 were $1,988,046, $2,965,030 and $1,250,901 respectively, and $8,605,050 since inception. As of June 30, 2014, pursuant to its license agreement, the Company has paid a security advance of $546,783 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, 2014.

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 21.44% 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 Preferred Stock, on a pre-reverse-split basis, as of June 30, 2014, corresponding to 9,531,429 shares of common stock and 2,000,000 shares of the Company’s Series A Preferred Stock, on a post-reverse-split basis. 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.

Collaborations and Subcontract Arrangements

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

The Company tries to choose the scientific laboratories with the most appropriate facilities and know-how relating to a particular field for the evaluation of an antiviral agent developed by the Company. The Company also tries to work with more than one laboratory for the evaluation of an antiviral agent developed by the Company. The Company also tries to work with more than one laboratory for a given group of viruses whenever possible. We seek to improve confidence by obtaining independent datasets for corroboration of the efficacy and safety of the nanoviricides we develop. In addition, the Company is not dependent on a particular Laboratory for the development of any specific drug candidate in our product pipeline.

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

Arrangement with KARD Scientific, Inc.

Owned and operated by Dr. Krishna Menon, KARD Scientific Inc. of Beverly, 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 $2,896,120.

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.

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.

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.

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 studied against two distinctly different strains of HIV-1 were conducted this year. These studies confirmed the efficacy of the nanoviricides against both HIV-I strains. We plan on continuing these studies towards the preparation of a Tox Package for filing an IND in the near future. These planned studies are elaborate, intensive, time-consuming, resource-intensive, and expensive. Our ability to conduct these studies depends upon adequate financing for the staff as well as for the materials required for the various experiments. We plan on continuing to rely upon external providers and collaborators for various services as before, wherever possible, in order to minimize capital expenses. The Company will strategically evaluate any outsourcing of the production of certain key intellectual property sensitive materials very carefully.

As the studies progress, we may find it necessary to accelerate the development of a second anti-HIV drug, HIVCide-II, in order to cover the various types, strains, quasi-species and mutants of the HIV viruses as completely as possible. Our objective is to develop anti- HIV drugs that together respond to the needs of combating the rapidly changing HIV viruses in the most complete fashion possible. The Company expects that these two anti-HIV drugs together should encompass the currently known array of HIV types and subtypes in the world. These first nanoviricides drugs have been designed to engulf the virus particles, and dismantle them.

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

Background: Influenza

Seasonal Influenza

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

Avian Influenza

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

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

Pandemic Influenza

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

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

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

Flu Prevention and Treatment

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

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

Inhibiting Influenza Neuraminidase

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

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

BioCryst has developed a neuraminidase inhibitor, peramivir, as an IV infusion, for the treatment of common influenza as well as H5N1. Peramivir previously failed its Phase II human trials, and BioCryst had stated that this may be due to the use of short needles in the Phase II study. In spite of various issues with efficacy and bioavailability, peramivir was approved for influenza treatment in Japan in January, 2010.

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(™) (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.

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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 RabiCideTM, 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). In addition, the World Health Organization has recently declared that the world will be free of canine rabies by the middle of the next decade. Thus the commercial potential, for the Company, of a rabies drug is uncertain.

Background: NanoViricides Company Philosophy

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

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

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

Products

NanoViricides, Inc. currently has no products for sale.

The following table summarizes NanoViricides active development projects as of June 30, 2014.

Table 1. Products in Development

	Project	**Virus**	**Description**	**Development Stage**
1	Injectable FluCide™ for hospitalized patients	Influenza (Common), H5N1 Bird Flu, Highly Pathogenic Influenzas, novel H1N1/2009	Broad-Spectrum Anti-Influenza nanoviricide	Advanced Preclinical; Pre-IND Meeting held with US FDA
2	Oral Flucide™ for outpatients	Influenza (Common), H5N1 Bird Flu, Highly Pathogenic Influenzas, novel H1N1/2009	Broad-Spectrum Anti-Influenza nanoviricide	Advanced Preclinical; Pre-IND Meeting held with US FDA
3.	Nanoviricide against Ebola	Ebola, Marburg	Broad-Spectrum nanoviricide against all strains of Ebola and Marburg filoviruses	Early Preclinical; High Priority due to current epidemic
4.	HIVCide ™	HIV/AIDS	Escape-resistant Anti-HIV nanoviricide	Preclinical
5.	Nanoviricide Eye Drops	Adenoviruses, HSV-1	Eye Drops for Viral Diseases of the External Eye	Preclinical
6.	HerpeCide ™	HSV-1, HSV-2	Herpes “Cold Sores” and Genital Herpes, Topical Cream and Gel Formulations	Preclinical
7.	DengueCide™	Dengue viruses, all types	Broad-Spectrum nanoviricide against all types of Dengue viruses	Preclinical
8.	RabiCide ™	Rabies	Anti-Rabies nanoviricide	Preclinical; Background Project
9.	HepCCide ™	HCV	Anti-HCV nanoviricide	Project on hold

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

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

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

HerpeCide - We are currently optimizing the anti-HSV ligands in cell culture studies. We believe we will be able to successfully advance the optimized drug candidates into animal studies against HSV. HerpeCide is being developed as skin cream or gel formulation for the treatment of oral and genital herpes lesions.

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

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

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

HCV - A Hepatitis C nanoviricide is planned for research and development to begin after we have an optimized drug candidate for Dengue Fever. The Company has not yet sourced the materials to target this disease. The cell culture models available for HCV are very limited in nature. In particular, their application to study relative efficacies of virus neutralizing drugs is not well established. The in vivo studies against HCV require specialized animal models. A highly specialized mouse model with a human liver xenograft has become available for HCV studies. However, the studies take a very long time and also are very expensive. The Company has only begun the early stages of a plan to develop nanoviricides against Hepatitis C. This project continues to be of major commercial interest. However, we plan to tackle it when appropriate levels of funding resources are available to the Company.

Drug Formulations

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

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

Development Stage of Products

Our Influenza program is the most advanced and we have engaged into advanced pre-clinical development activities after obtaining valuable advice from the US FDA in a pre-IND meeting held in March, 2012. We will need cGMP drug product for filing an IND and conducting clinical trials in the future. [cGMP = current Good Manufacturing Practices]. We are aggressively working on developing cGMP capability for our nanoviricides drug product lines.

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 the significantly large amounts of materials needed can be made. The excellent safety of our anti-influenza drug candidates observed in our animal efficacy studies led to very high levels of estimated drug requirements for the tox package studies. The Company believes that our anti-influenza drug candidates, anti-Dengue drug candidate, anti-HIV drug candidates, anti-viral eye drops drug candidates, as well as anti-HSV drug candidates, have all produced substantial positive results and should be developed further towards the goal of filing appropriate IND applications. All of our developments are subject to availability of appropriate levels of financing.

Drug Development Plan

The Company intends to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour Pharma, Inc. ("TheraCour"), the exclusive source for these nanomaterials. With sourcing of materials from TheraCour, the Company prefers to manufacture these drugs in our own facility. However, the Company may manufacture these drugs under subcontract arrangements with external manufacturers that carry the appropriate regulatory licenses and have appropriate capabilities. The Company intends to distribute these drugs via subcontracts with distributor companies or in partnership arrangements. The Company plans to market these drugs either on its own or in conjunction with marketing partners. The Company also plans to actively pursue co-development, as well as other licensing agreements with other pharmaceutical companies. Such agreements may entail up-front payments, milestone payments, royalties, and/or cost sharing, profit sharing and many other instruments that may bring early revenues to the Company. Such licensing and/or co-development agreements may shape the manufacturing and development options that the Company may pursue. The Company has received significant interest from certain pharmaceutical companies for potential licensing or co-development of some of our drug candidates. However, none of these distributor or co-development agreements is in place at the current time.

Manufacturing

Manufacturing of Research Materials

Nanomaterials that form the basis of our nanoviricide drugs are produced for research by TheraCour Pharma, Inc. at their research scale production facility in West Haven, Connecticut.

Manufacturing of Drugs

Subsequent to our fiscal year ended June 30, 2014, we have decided to purchase the facility in Shelton, CT from Inno-Haven, LLC, a special purpose company formed for the purpose of real estate acquisition and improvements, which has acquired and renovated a light industrial building in Shelton, CT. Inno-Haven is controlled by Dr. Anil R. Diwan. The financing for 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 has performed total renovation of the facility to enable modern laboratory space and cGMP facilities for the manufacture of the Nanoviricides' drug candidates. Inno-Haven has raised substantial capital financings for this project. The Board of Directors of NanoViricides, Inc. has unanimously agreed that the purchase of this facility from Inno-Haven is in the best interests of the Company and its shareholders, with Dr. Diwan abstaining from the discussion and voting. This determination was based on the potential lease costs derived in consultations with experts. Inno-Haven has agreed to the sale of the facility to NanoViricides, Inc. The attorneys of the parties are currently drafting the necessary agreements.

The Company intends to manufacture Injectable and Oral FluCide, HIVCide, Nanoviricide Eye Drops, HerpeCide, DengueCide, RabiCide as well as other drugs for pre-clinical animal studies and human clinical studies, in facilities potentially to be owned by the Company. In the event that we cannot secure funding that allows us to establish the necessary facilitiesto 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. Several countries in the world allow "c-GMP-like" materials to be used for early human clinical trials. We believe that Australia is one of them. A "c-GMP-like" material can be loosely defined as material that is produced in a c-GMP compliant facility that has not yet undergone FDA registration as a cGMP drug manufacturing facility.

We expect to acquire a small, commercial-scale manufacturing facility shortly. 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.

Development costs charged by and paid to TheraCour Pharma, Inc. were $1,988,046 and $2,965,030 and $1,250,901for the years ended June 30, 2014, 2012, and 2011, respectively and $8,605,050 since inception through June 30, 2014. No royalties are due or have been paid from inception through June 30, 2014.

TheraCour Pharma, Inc. owns 9,531,429 shares (as adjusted) of the Company’s issued and outstanding shares of common stock and 2,000,000 shares (as adjusted) of our Series A Preferred Stock as of June 30, 2014. 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, Injectable FluCide, Oral FluCide, DengueCide, HivCide, Nanoviricide Eye Drops, HerpeCide, RabiCide, and others, may be eligible for patent protection. The Company plans on filing patent applications for protecting these drugs when we have definitive results from in-vitro or in-vivo studies that enable further drug development and IND application filing.

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

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

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 POLYMERS).	Applied: Jan 19, 2006 PCT U.S. Issuance:May 8, 2012.	October, 2028 (estimated)	Applications are in various prosecution stages. twenty of these have been issued	TheraCour Pharma, Inc. [Exclusive License].
3	PCT/US2007/001607 SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTIVIRAL AGENTS	Applied: Jan 22, 2007	Ca. 2027 (estimated)	Applications are in various prosecution stages. Six of these have been issued	TheraCour Pharma, Inc. [Exclusive License].

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

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

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

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

A total of 28 patents have been issued globally as of September 24, 2014, on the basis of the two international PCT patent families that cover the fundamental aspects of our platform technology. Additional patent grants are expected to continue as the applications progress through prosecution processes.

These patents have nominal expiry dates in 2026 to 2028. The dates can be further extended in several countries and regions for the additional allowances due to the regulatory burden of drug development process. Many countries allow up to five years extension for regulatory delays.

No patent applications have been filed for the actual drug candidates that we intend to develop as drugs as of now. We intend to file the patent application for FluCide before entering human clinical trials. The estimated expiry date for the FluCide patent, if issued, would be no earlier than 2034.

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

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

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

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

Trademarks

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

Competition

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

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

The current approved drugs for influenza include the neuraminidase inhibitors Tamiflu 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. Alcon (a division of Novartis) discontinued further development of this drug following mixed results in a Phase II clinical trial. NovaBay has regained the rights to it and has continued further development. Aganocides, by virtue of their chemical structure, are generally not expected to be useful for any applications other than topical.

There are several drugs in the market that effectively control HSV cold sores and genital herpes lesions in most patients. These include the nucleoside analogues idoxuridine, vidarabine, acyclovir, 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, Gilead, 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:

<u>Preclinical Testing</u>

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.

<u>Clinical Trials</u>

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

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

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

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

FDA Approval Process

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

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

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

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

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

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

Employees and Service Providers

The Company had six full time employees. In addition, most of the business activities of the Company including accounting and legal work and business development are provided by subcontractors and consultants. Further, the Company has subcontracted nanomaterials research and development (“R&D”) to TheraCour. 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.

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 . Information included on the Web site is not part of this Form 10-K.

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

Website

Our website address is www.nanoviricides.com.

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.

ITEM 1A. RISK FACTORS

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

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

Risks Specific to Our Business

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

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

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

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

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

- the absence of an operating history;
- the lack of commercialized products;
- insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- limited experience in dealing with regulatory issues; the lack of manufacturing experience and limited marketing experience;
- an expected reliance on third parties for the development and commercialization of our proposed products;
- a competitive environment characterized by numerous, well-established and well capitalized competitors; and
- reliance on key personnel.

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

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

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

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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, 2014, we had a cash and cash equivalent balance of $13,923,245. Also, the Company has incurred significant operating losses since its inception, resulting in an accumulated deficit of $38,299,783 at June 30, 2014. Such losses are expected to continue for the foreseeable future. As a result of recent financing, the Company estimates that it has sufficient cash to support current operations through the next two years, i.e. through June, 2015.

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, 2014, we have a cash and cash equivalent balance of $13,923,245 which combined with the proceeds raised in the offering of $10.33 million after the close of the Company's year-end, will be sufficient to fund our operations for the next twenty four months at our budgeted rate of expenditures.

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

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

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

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

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

- enter into leases for new facilities and capital equipment;
- enter into additional licenses and collaborative agreements; and
- incur additional expenses associated with being a public company.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- The FDA or foreign regulators may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them.
- If regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution.
- In addition, many foreign countries control pricing and coverage under their respective national social security systems.
- The FDA or foreign regulators may not approve our manufacturing processes or manufacturing facilities.
- The FDA or foreign regulators may change their approval policies or adopt new regulations.

- Even if regulatory approval for any product is obtained, the marketing license will be subject to continual review, and newly discovered or developed safety or effectiveness data may result in suspension or revocation of the marketing license.
- If regulatory approval of the product candidate is granted, the marketing of that product would be subject to adverse event reporting requirements and a general prohibition against promoting products for unapproved or “off-label” uses.
- In some foreign countries, we may be subject to official release requirements that require each batch of the product we produce to be officially released by regulatory authorities prior to its distribution by us.
- We will be subject to continual regulatory review and periodic inspection and approval of manufacturing modifications, including compliance with current GMP regulations.

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

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

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

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

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

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

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

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

We have expended $28,804,060 on research and development from inception through June 30, 2014.

We have an R&D and other costs budget of approximately $5,000,000 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.

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

The Company will be unable to proceed with its business plan beyond June 30, 2016, without obtaining additional financing of approximately $10-15 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.

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 trails in accordance with standards required by the agencies that approve drugs for sale. If these subcontractors fail to meet these standards, the validation of our drugs would be adversely affected, causing a delay in our ability to meet revenue-generating operations.

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

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

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

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

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

Our ability to earn sufficient returns on our drug candidates may depend in part on the extent to which government health administration authorities, private health coverage insurers and other organizations will provide reimbursement for the costs of such drugs and related treatments. Significant uncertainty exists as to the reimbursement status of newly approved health care drugs, and we do not know whether adequate third-party coverage will be available for our drug candidates. If our current and proposed drugs are not considered cost-effective, reimbursement to the consumers may not be available or sufficient to allow us to sell drugs on a competitive basis. The failure of the government and third-party payors to provide adequate coverage and reimbursement rates for our drug candidates could adversely affect the market acceptance of our drug candidates, our competitive position and our financial performance.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have limited manufacturing experience.

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

We have no sales and marketing personnel.

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

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

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

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

The Company has entered into a Material License Agreement with TheraCour Pharma, Inc. ("TheraCour") (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 $8,605,050 since inception through June 30, 2014. No royalties are due to TheraCour from the Company's inception through June 30, 2014.

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

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

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

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

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

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

Management of our relationships with our collaborators will require:

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

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

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

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

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

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

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

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

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

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

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

On March 3, 2010, the Company entered into employment agreements with its two executive officers, Eugene Seymour, Chief Executive Officer and Chief Financial Officer and Anil Diwan, President and Chairman of Board. Both agreements provide a minimum annual base salary of $250,000 for a term of four years. In addition, Dr. Seymour and Dr. Diwan were eligible for an increase in base salary to $275,000 once the Company consummated a financing with gross proceeds of at least $5,000,000. Also, the base salary is eligible to be increased to $300,000 for Dr. Seymour and $300,000 for Dr. Diwan since the Company has been listed on a national stock exchange.

As additional compensation under the employment agreements, the Company issued 71,429 (as adjusted) shares of the Company’s Series A Preferred Stock and shall issue an additional 71,429 (as adjusted) shares of Series A Preferred Stock on each anniversary of the respective employment agreements.

On March 3, 2010, the Company entered into an employment agreement with Dr. Jayant Tatake to serve as Vice President of Research and Development. The employment agreement provides for a term of four years with a base salary of $150,000. In addition, the Company issued 26,786 (as adjusted) shares of Series A Preferred Stock and 35,715 (as adjusted) shares of common stock, and will issue an additional 26,786 (as adjusted) shares of Series A Preferred Stock and 35,715 (as adjusted) shares of common stock on each anniversary date of the agreement.

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

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

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

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-one and forty four one hundredths percent (21.44%) 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 that has not been conducted on an arm's length basis to date, Dr. Diwan may have conflicting fiduciary duties between the Company and TheraCour.

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.

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

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our existing contracts;
- reduce the scope and value of our existing contracts;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our drug candidates; and
- change certain terms and conditions in our contracts.

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

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

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

The U.S. government has undertaken commitments to help secure improved countermeasures against bio-terrorism. The process of obtaining government contracts is lengthy and uncertain, and we must compete for each contract. Moreover, the award of one government contract does not necessarily secure the award of future contracts covering the same drug. If the U.S. government makes significant future contract awards for the supply of its emergency stockpile to our competitors, our business will be harmed and it is unlikely that we will be able to ultimately commercialize our competitive drug candidate.

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

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

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

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

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

Risks Related to the Biotechnology/Biopharmaceutical Industry

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

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

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

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

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

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

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

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

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

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

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

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

Success in pre-clinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict.

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

If we do not meet the continued listing standards of the NYSE MKT our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.

As of September 25, 2013, our common stock is listed on the NYSE MKT, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If, however, we fail to satisfy the continued listing standards, such as, for example, the requirement that our shares not trade "for a substantial period of time at a low price per share" or that we not dispose of our principal operating assets or discontinue a substantial portion of our operations, among other requirements, the NYSE MKT may issue another non-compliance letter or initiate delisting proceedings.

If our securities are delisted from trading on the NYSE MKT and we are not able to list our securities on another exchange or to have them quoted on NASDAQ, our securities could be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

Our Company is subject to the periodic reporting requirements of the Securities Exchange Act of 1934 (the "Exchange Act"), which will require us to incur audit fees and legal fees in connection with the preparation of such reports. These additional costs will reduce or might eliminate our profitability.

Our Company is required to file periodic reports with the Commission pursuant to the Exchange Act and the rules and regulations promulgated thereunder. To comply with these requirements, our independent registered auditors will have to review our quarterly financial statements and audit our annual financial statements. Moreover, our legal counsel will have to review and assist in the preparation of such reports. The costs charged by these professionals for such services cannot be accurately predicted at this time, because factors such as the number and type of transactions that we engage in and the complexity of our reports cannot be determined at this time and will have a major affect on the amount of time to be spent by our auditors and attorneys. However, the incurrence of such costs will obviously be an expense to our operations and thus have a negative effect on our ability to meet our overhead requirements and earn a profit. We may be exposed to potential risks resulting from new requirements under Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, the trading price of our Common Stock, if a market ever develops, could drop significantly, or we could become subject to Commission enforcement proceedings.

As currently required under Section 404 of the Sarbanes-Oxley Act of 2002, we are required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. The Company conducted an evaluation of the effectiveness of its internal control over financial reporting as of June 30, 2012. Based on its evaluation, the Company concluded that its internal controls over financial reporting were not effective to provide reasonable assurance that information required to be disclosed is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the Commission. The material weakness relates to a lack of a functioning audit committee and a lack of outside directors on the Company's Board. The report of our independent registered public accounting firm for the period ending June 30, 2012 indicated that our internal control over financial reporting was not effective as of June 30, 2012. We expect to continue to incur additional expenses and diversion of management's time as a result of performing the system and process evaluation, testing, and remediation required to comply with the management certification and auditor attestation requirements.

If we continue to fail to achieve and maintain the adequacy of our internal controls, as such standards are modified, supplemented, or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results would be harmed, investors could lose confidence in our reported financial information, the trading price of our Common Stock, if a market ever develops, could drop significantly, or we could become subject to the Commission's enforcement proceedings.

Our Common Stock may be considered a "penny stock" and may be difficult to sell.

The Commission has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to specific exemptions. Historically, the price of our Common Stock has fluctuated greatly. If, the market price of the Common Stock is less than $5.00 per share it therefore may be designated as a "penny stock" according to Commission rules. The "penny stock" rules impose additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 together with their spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of securities and have received the purchaser's written consent to the transaction before the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the broker-dealer must deliver, before the transaction, a disclosure schedule prescribed by the Commission relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. These additional burdens imposed on broker-dealers may restrict the ability or decrease the willingness of broker-dealers to sell our common shares, and may result in decreased liquidity for our common shares and increased transaction costs for sales and purchases of our common shares as compared to other securities.

Our stock price may be volatile and your investment in our common stock could suffer a decline in value.

The price of our common stock, as quoted on the NYSE MKT may fluctuate significantly in response to a number of factors, many of which are beyond our control. These factors include:

- progress of our products through the regulatory process;
- results of preclinical studies and clinical trials;
- announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our products or our competitors' products in both the United States and foreign countries;
- developments or disputes concerning patent or proprietary rights;
- general market conditions for emerging growth and pharmaceutical companies;
- economic conditions in the United States or abroad;
- actual or anticipated fluctuations in our operating results;
- broad market fluctuations; and
- changes in financial estimates by securities analysts.

There is a risk of market fraud.

Shareholders should be aware that, according to SEC Release No. 34-29093, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include (1) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (2) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (3) boiler room practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (4) excessive and undisclosed bid-ask differential and markups by selling broker-dealers; and (5) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses. We are aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities. The occurrence of these patterns or practices could increase the volatility of our share price.

As of September 25, 2013, our common stock is listed on the NYSE MKT national exchange. However, shareholders should be aware that the occurrence of the above-mentioned patterns and practices cannot be entirely precluded and that the occurrence of these patterns or practices could increase the volatility of our share price.

A registration of a significant amount of our outstanding restricted stock may have a negative effect on the trading price of our stock.

At June 30, 2014, shareholders of the Company had 15,497,951 shares (as adjusted) of restricted stock, or 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 85,714,286 total shares of Common Stock on a post-split basis without additional approval by shareholders. As of June 30, 2014, we had approximately 54,620,000 shares of common stock outstanding, warrants and options convertible to 9,422,926 shares of common stock and 3,193,079 shares of Series A Preferred Stock convertible into 11,175,776 shares of Common Stock.

As of September 25, 2013, our common stock is listed on the NYSE MKT national exchange.

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

As of June 30, 2014, 15,131,405 of 53,782,057 issued and outstanding shares (as adjusted) of the Company's common stock were restricted securities as defined under Rule 144 of the Securities Act of 1933, as amended (the "Act") and under certain circumstances may be resold without registration pursuant to Rule 144.

Approximately 2,406,207 shares of our restricted shares of common stock (as adjusted) are held by non-affiliates who may avail themselves of the public information requirements and sell their shares in accordance with Rule 144. As a result, some or all of these shares may be sold in accordance with Rule 144 potentially causing the price of the Company's shares to decline.

In general, under Rule 144, a person (or persons whose shares are aggregated) who has satisfied a six month holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by a person who is not an Affiliate, as such term is defined in Rule 144(a)(1), of the Company and who has satisfied a one-year holding period. Any substantial sale of the Company's common stock pursuant to Rule 144 may have an adverse effect on the market price of the Company's shares. This filing will satisfy certain public information requirements necessary for such shares to be sold under Rule 144.

The requirements of complying with the Sarbanes-Oxley act may strain our resources and distract management.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Sarbanes-Oxley Act of 2002. The costs associated with these requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Historically, as a private company we have maintained a small accounting staff, but in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant additional resources and management oversight will be required. This includes, among other things, retaining independent public accountants. This effort may divert management’s attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we may need to hire additional accounting and financial persons with appropriate public company experience and technical accounting knowledge, and we cannot assure you that we will be able to do so in a timely fashion.

Sales of additional equity securities may adversely affect the market price of our common stock and your rights in the Company may be reduced.

We expect to continue to incur drug development and selling, general and administrative costs, and in order to satisfy our funding requirements, we may need to sell additional equity securities. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, any new securities issued may have greater rights, preferences or privileges than our existing common stock that may adversely affect the market price of our common stock and our stock price may decline substantially.

ITEM 1B: UNRESOLVED STAFF COMMENTS.

None.

ITEM 2: PROPERTIES

Description of Property

The Company's principal executive offices are located at 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 $8,695. 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.

The Company signed a Memorandum of Understanding with Inno-Haven, LLC to lease cGMP manufacturing facilities and associated R&D Laboratory facilities from Inno-Haven when it completes the total renovation of the building at 1 Controls Drive in Shelton, CT, to meet our requirements. Inno-Haven is controlled by Dr. Anil R. Diwan, our founder. Dr. Diwan has raised the initial funding for the purchase of the building and its maintenance and repairs through the sale of NanoViricides stock he obtained as a founder, under a 10b5-1 plan that was concluded in 2011, plus additional financing and personal loans obtained from his friends and associates. Inno-Haven has raised substantial additional capital from high net worth private individuals, and anticipates that it will have the full financing for this capital intensive total renovation project shortly. The project is in facility validation phase, after completing construction in June 2014. The manufacturing portion of the facility will eventually have to be registered under the US FDA as a cGMP drug substance manufacturing facility. This will be necessary before cGMP drug substance for human clinical trials can be made in this facility. Internationally, several countries require only a "c-GMP-like" material for human clinical trials, which can be produced in the facility even prior to FDA registration provided that the cGMP facilities and processes are in place, validated, and effective. NanoViricides, Inc. intends to purchase this facility from Inno-Haven, rather than leasing it. Our strong financial position has enabled us to choose the purchase option in lieu of a lease.

ITEM 3: LEGAL PROCEEDINGS.

Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and Nanoviricides, Inc. (Case No. A-12-659535-B)

On or about April 13, 2012, the Nevada Agency and Transfer Company, as agent for service of process for the Company in Nevada, was served with a Summons and Complaint in the case entitled Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and Nanoviricides, Inc. (Case No. A-12-659535-B) answerable in the Eighth Judicial District Court of the State of Nevada – Clark County ("Court"). The Complaint seeks to compel inspection of the Company's books and records. On or about May 2, 2012, the Company filed a Demand for Security of Costs. Upon filing of the Demand, proceedings relative to the Company are stayed pending posting of the demanded security (or plaintiff engages in motion practice about the Demand). The Company may seek dismissal of the complaint if plaintiff has not posted the demanded security (or engaged the court). The Complaint further seeks unspecified "injunctive relief" in furtherance of the demand for inspection to which the Company believes it is not entitled. The Complaint, by a holder of less than 1 percent of the common stock of the Company, seeks to, inter alia, inspect documents and records of the company to which it is not entitled and in a form and manner the Company argues is not authorized by statute. On or about July 18, 2012, the Plaintiff moved to amend its answer. On or about August 8, 2012, 2012, we filed our opposition to Plaintiff's Motion to Amend and a Motion to Dismiss the Complaint for failure to state a claim upon which relief can be granted. On or about September 13, 2012 the court granted the Plaintiff's Motion to Amend. On or about September 17, 2012 the Plaintiff served its "Second Amended Shareholder Derivative Complaint" upon our Counsel in Nevada. As in the prior two complaints that this Plaintiff has filed in this action, this Second Amended Complaint seeks to compel inspection of the Company's books and records, seeks injunctive relief, an accounting and alleges breach of Fiduciary by Dr. Seymour and Dr. Diwan. On or about October 11, 2012, we filed a Motion to Dismiss the Complaint for failure to state a claim upon which relief can be granted. On or about December 4, 2012, the Court granted the Company's Motion to Dismiss with respect to Dr. Seymour and Dr. Diwan and ordered the case dismissed as to all claims but the Plaintiff's request to compel documents required to be maintained by the Company's registered agent in Nevada pursuant to NRS 78.105. On or about December 26, 2012, the Company provided the Plaintiff with each of the documents to which it is entitled. Management believes that the Plaintiff does not have a legal or good faith basis for inspection or copying of its shareholder's list and intends to vigorously defend the production thereof. In May, 2013, the Plaintiff filed a motion for permission to file a third amended complaint. The Company subsequently filed a motion to dismiss and for Summary Judgment. The Court denied the Motion to Dismiss and for Summary Judgment and ordered the Plaintiff to file its Third Amended Complaint. On or about July 15, 2013 the Company Petitioned the Nevada Supreme Court for a Writ of Prohibition or Mandamus reversing the trial Court's denial of Summary Judgment. Thereafter, on or about September 20, 2013, the Nevada Supreme Court denied the Company's Writ Petition. The Company will be required to Answer the Third Amended Complaint, which contains only one cause of action which is identical to the sole cause of action which was not dismissed from the Second Amended Complaint. Specifically, the Third Amended Complaint seeks only to compel production of books and records required to be maintained by the Company's Registered Agent pursuant to NRS 78.105 Management believes that the Company's registered Agent has provided the Plaintiff with all documents to which it is entitled pursuant to NRS 78.105 and that this lawsuit has no merit or basis. The Company has vigorously defended this lawsuit. Specific monetary damages have not been claimed and as a result no accrual has been made in relation to this litigation. The parties to this litigation have determined that it is not in the interest of either party to continue this litigation and had agreed to a settlement of this dispute, subject to dismissal with prejudice of a substantially identical lawsuit initiated by the same plaintiff in The United States District Court for the District of Colorado. On September 11, 2014 a judgement of dismissal was entered by the court in Colorado. Pursuant to the Settlement Agreement, the Settlement Agreement and a proposed Order of Dismissal with Prejudice were submitted to the Nevada District Court for review and dismissal with prejudice. On September 17, 2014 the Nevada District Court dismissed the case with prejudice Upon dismissal of this matter in Nevada, the Company has agreed to reimburse the Plaintiff $150,000 for a portion of its legal fees.

Yidam, Ltd. v. Anil Diwan, Eugene Seymour and Nanoviricides, Inc. (Case No. 1:13-CV-01777).

A Shareholder Derivative complaint was filed in the United States District Court for the District of Colorado on or about July 15, 2013 by the same Plaintiff that has filed the repetitive complaints in the Nevada action as set forth in the preceding paragraph (Yidam, Ltd. v. Eugene Seymour, Anil Diwan, and Nanoviricides, Inc.). The Plaintiff asserts the action is a shareholder derivative action and the Company is solely a nominal defendant. The Company maintains that it, as well as the individual defendants, Messrs. Seymour and Diwan, have not been served in the action. The Complaint alleges that the Company has failed to deliver information requested by the Plaintiff, the identical information the Plaintiff is seeking inspection of in the Nevada action, and that the individual defendants, Messrs. Seymour and Diwan, breached their fiduciary duties to the Company and caused it financial harm. The Plaintiff demands an order to inspect the Company's records, an order revoking Messrs. Diwan and Seymour from the Board of Directors, equitable relief, and consequential and punitive damages. The Company believes these claims have no merit and, if served, the Company intends to defend this action vigorously. Specific monetary damages have not been claimed and as a result no accrual has been made in relation to this litigation. On September 11, 2014 an order dismissing the action with prejudice was entered by the court

There are no other 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: MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5: MARKET FOR REGISTRANT’S COMMON EQUITY RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our Common Stock commenced trading on the NYSE MKT on September 25, 2013 under the symbol “NNVC”. The Company’s Common Stock, after the Company became a publicly traded company in May 2005, was initially traded on the Pink Sheets under the symbol NNVC and from June 29, 2007, through September 24, 2013, the Company’s Common Stock has been quoted on the Over The Counter Bulletin Board. The table below sets forth the high and low prices for the Company’s Common Stock for the quarters included within the past two fiscal years adjusted for the Company’s 3.5 for reverse split which was effective on September 10, 2013. Quotations reflect inter-dealer prices, without retail mark-up, mark-down commission, and may not represent actual transactions. Since the Company’s common stock trades sporadically, there is not an established active public market for its common stock. No assurance can be given that an active market will exist for the Company’s common stock and the Company does not expect to declare dividends in the foreseeable future since the Company intends to utilize its earnings, if any, to finance its future growth, including possible acquisitions.

Quarter ended	Low price	High price
June 30, 2014	$ 3.03	$ 4.73
March 31, 2014	$ 2.67	$ 5.81
December 31, 2013	$ 4.57	$ 5.29
September 30, 2013	$ 2.21	$ 6.64
June 30, 2013	$ 1.89	$ 2.66
March 31, 2013	$ 1.12	$ 2.38
December 31, 2012	$ 1.58	$ 2.80
September 30, 2012	$ 1.58	$ 2.80

Number of Shareholders.

As of June 30, 2014, a total of 53,782,057 shares of the Company’s common stock are outstanding and held by approximately 186 shareholders of record of our common stock. This number of shareholders does not reflect the persons or entities that hold their stock in nominee or street name through various brokerage firms. Of this amount, 38,663,455 shares are unrestricted. Approximately 2,406,207 shares are restricted securities held by non-affiliates, and the remaining 12,725,198 shares are restricted securities held by affiliates. These shares may only be sold in accordance with Rule 144. As of June 30, 2014, there were 8,887,211 warrants and 535,714 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, 2014, 2013, and 2012, 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:

For the three months ended June 30, 2014, the Board of Directors authorized the issuance of 177,359 shares of the Company's Series A Preferred Stock, $0.001 par value, as employee compensation and recognized an expense of $7,524.

For the three months ended June 30, 2014 the Company's Board of Directors authorized the issuance of 3,178 shares of Common Stock with a restrictive legend for Director services. The Company recorded an expense of $11,250.

For the three months ended June 30, 2014, the Company's Board of Directors authorized the issuance of 10,304 shares of common stock with a restrictive legend for consulting services. The Company recorded an expense of $39,000.

In June, 2014, the Company authorized the issuance of 71,429 shares of its $.001 par value common stock with a restrictive legend pursuant to existing employment agreements and recorded an expense of $287,788.

In May, 2014, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,148 shares of Common Stock at $3.16 per share expiring in May, 2018. These warrants were valued at $26,584 and recorded as consulting expense

For the three months ended March 31, 2014, the Company's Board of Directors authorized the issuance of 4,988 shares of common stock with a restrictive legend for consulting services. The Company recorded an expense of $21,000.

For the three months ended March 31, 2014, the Board of Directors authorized the issuance of 20,695 shares of the Company's Series A Preferred Stock, $0.001 par value, as employee compensation and recognized an expense of $7,524.

In February 2014, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of common stock at $1.86 per share expiring in February, 2017

On February 1, 2014, the Company authorized the issuance of 571,429 shares of its $.001 par value common stock with a restrictive legend for the payment of additional interest payable to the holders of the Company's Series B Convertible Debentures.

For the three months ended December 31, 2013, the Company's Board of Directors authorized the issuance of 4,069 shares of its Common Stock with a restrictive legend for consulting services. The Company recorded an expense of $21,000.

In December, 2013 the Board of Directors authorized the issuance of 1,495 shares of the Company's Series A Preferred Stock, $0.001 par value, as employee compensation and recognized an expense of $26,998.

In December, 2013, the Company issued 7,143 shares of Common Stock with a restrictive legend at $3.50 per share upon the exercise of Warrants.

In November, 2013, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of Common Stock at $6.56 per share expiring in November, 2017. These warrants were valued at $31,552 and recorded as consulting expense.

In October, 2013, the Board of Directors authorized the issuance of 5,117 shares of the Company's Series A Preferred Stock, $0.001 par value as, employee compensation and recognized an expense of $35,995.

For the three months ended September 30, 2013, the Company's Board of Directors authorized the issuance of 10,311 shares of Common Stock with a restrictive legend for consulting services. The Company recorded an expense of $21,000.

For the three months ended September 30, 2013, the Company's Board of Directors authorized the issuance of 5,501 shares of Common Stock with a restrictive legend for Director services. The Company recorded an expense of $11,250.

In September, 2013, the Company's Board of Directors authorized the issuance of Warrants to Midtown Partners & Co., LLC and Chardan Capital Markets, LLC (collectively, the "Placement Agents") to purchase a total of 58,910 shares of Common Stock at $5.25 per share expiring in September, 2018. These warrants were valued at $113,696 and recorded as Placement Agents Fees related to the sale of Common Shares and Warrants on September 10, 2013

In August, 2013, the Scientific Advisory Board (SAB) was granted warrants to purchase 21,000 shares of Common Stock at $5.17 per share expiring in August, 2017. These warrants were valued at $106,050 and recorded as consulting expense.

For the year ended June 30, 2013, the Company's Board of Directors authorized the issuance of 42,979 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $84,960.

For the year ended June 30, 2013, the Company's Board of Directors authorized the issuance of 8,520 shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of $18,750.

In May , 2013, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of common stock at $2.44 per share expiring in February, 2017.

For the nine months ended March 31, 2013, the Company's Board of Directors authorized the issuance of 115,042 shares of its common stock with a restrictive legend for consulting services.

For the nine months ended March 31, 2013, the Company's Board of Directors authorized the issuance of 13,749 shares of its common stock with a restrictive legend for Director services.

In March, 2013, 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.

In March, 2013, the Company authorized the issuance of 593,750 shares of its Series A Preferred stock $.001 par value with a restrictive legend pursuant to existing employment agreements.

In February, 2013, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of common stock at $1.86 per share expiring in February, 2017.

On February 1, 2013, the Company authorized the issuance of 571,429 shares of its $.001 par value common stock with a restrictive legend for the payment of additional interest payable to the holders of the Company's Series B Convertible Debentures.

In February 2013, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of common stock at $1.86 per share expiring in February 2017.

On February 1, 2013, the Company consummated an offering (the "Offering") in the aggregate amount of $6,000,000 for its Unsecured 8% Coupon Series B Convertible Debenture (the "Debentures") to four equity investors comprised of private, family investment offices and a charitable foundation. The Company did not utilize an underwriter or a placement agent for this offering.

In November 2012, the Scientific Advisory Board (SAB) was granted warrants to purchase 60,000 shares of common stock at $0.57 per share expiring in November 2016. These warrants were valued at $34,200 and recorded as consulting expense.

For the six months ended December 31, 2012, the Company's Board of Directors authorized the issuance of 64,088 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $42,000.

For the six months ended December 31, 2012, the Company's Board of Directors authorized the issuance of 9,032 shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of $5,000.

For the three months ended September 30, 2012, the Company's Board of Directors authorized the issuance of 30,931 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $18,000.

In August, 2012, the SAB was granted warrants to purchase 60,000 shares of common stock at $0.68 per share expiring in August, 2016. These warrants were valued at $40,800 and recorded as consulting expense.

For the year ended June 30, 2012, the Company's Board of Directors authorized the issuance of 93,183 shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $72,000.

In June 2012, the Company's Board of Directors authorized the issuance of 10,000 shares of its Series A Preferred stock with a restrictive legend pursuant to a Consulting Agreement.

In June 2012, the Company authorized the issuance of 1,050,000 shares of its Series A Preferred stock $.001 par value with a restrictive legend as additional stock based compensation for successful prosecution of the Company's Patent applications.

In May, 2012, the Scientific Advisory Board (SAB) was granted warrants to purchase 60,000 shares of common stock at $0.79 per share expiring in May, 2016.

In March, 2012, the Company authorized the issuance of 593,750 shares of its Series A Preferred stock $.001 par value with a restrictive legend pursuant to existing employment agreements.

In March, 2012, 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.

In February, 2012, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of common stock at $3.82 per share expiring in February, 2016.

In November, 2011, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of common stock at $3.32 per share expiring in November, 2015.

In August, 2011, the Scientific Advisory Board (SAB) was granted warrants to purchase 17,143 shares of common stock at $4.94 per share expiring in February, 2015.

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. 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. The Company has not utilized an underwriter for an offering of its unregistered securities.

USE OF PROCEEDS FROM SALES OF REGISTERED SECURITIES

On December 21, 2012, the Company and Seaside 88, L.P. (“Seaside”) whereby Seaside converted 155.6092 shares of the Company’s Series C Convertible Preferred Stock, par value $0.001 per share (the “Series C Preferred Stock”) at the purchase price of $1,000.00 per share (the “Purchase Price”) into 357,259 shares of Common Stock at the conversion price of $0.43554, and the Company raised gross proceeds of $2,500,000 before estimated Offering expenses of approximately $175,000, which includes placement agent and attorneys’ fees. The proceeds were used for research and development and other working capital and general business purposes.

On September 9, 2013, the Company entered into a Securities Purchase Agreement (the “Agreement”) with certain purchasers (the “Purchasers”), relating to the offering and sale (the “Offering”) of units (“Units”) at the aggregate purchase price of $3.50 (“Purchase Price”) per Unit, consisting of one share of the Company’s common stock, par value $0.001 per share (the “Common Stock”) and a warrant to purchase one share of Common Stock (“Warrant”), issuable upon exercise of the Warrant at the exercise price of $5.25 per share (the “Warrant Shares”, collectively with the Units, Common Stock and Warrant, the “Securities”) The Warrants are exercisable immediately and expire five years after issuance.

On September 12, 2013, the Company and the Purchasers consummated the purchase and sale of the Securities (the “Closing”), and the Company raised gross proceeds of $10,308,996 before estimated expenses of the Offering of approximately $618,540, which includes placement agent and attorneys’ fees. The Company issued 2,945,428 Units. On September 25, 2013 certain of these Unit Holders exercised 35,357 Warrants to purchase 35,357 shares of the Company’s common stock, par value $0.001 per share, for gross proceeds of $185,624. On January 21, 2014 and February 6, 2014 certain of these Unit Holders exercised 75,000 and 25,000 Warrants to respectively purchase 75,000 and 25,000 shares of the Company’s common stock, par value $0.001 per share, for gross proceeds of $393,750 and $131,750 respectively.

The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the Securities and Exchange Commission on December 21, 2012. The Company, pursuant to Rule 424(b) under the Securities Act of 1933, has filed with the Securities and Exchange Commission a prospectus supplement relating to the Offering.

In connection with the Offering, pursuant to a Placement Agency Agreement dated September 9, 2013 among Midtown Partners & Co., LLC and Chardan Capital Markets, LLC (collectively, the “Placement Agents”), the Company paid the Placement Agents an aggregate cash fee representing 6% (3% each) of the gross Purchase Price paid by the Purchasers and warrants to purchase an aggregate of 2% (1% each) of the number of shares of Common Stock sold in the Offering (the “Compensation Warrants”) and substantially similar to the Warrants, at an exercise price equal to $5.25 per share. Upon issuance of the commission warrants , the company recognized costs associated with the sale of securities (a capital item) of $113,696 and a corresponding increase in additional paid in capital of $113,696. The proceeds were used for research and development and other working capital and general business purposes.

On January 21, 2014, the Company entered into a Securities Purchase Agreement (the “Agreement”) with certain purchasers (the “Purchasers”), relating to the offering and sale (the “Offering”) of units (“Units”) at the aggregate purchase price of $5.25 (“Purchase Price”) per Unit. The price per Unit was equal to a four percent (4%) discount to the 20-day VWAP of the Company’s stock price on January 17, 2014. The exercise price of the Warrant was equal to the closing price of the Company’s stock on January 17, 2014. Each Unit consisted of one share of the Company’s common stock, par value $0.001 per share (the “Common Stock”) and Sixty-Five Hundredths (65/100) of a warrant to purchase one share of Common Stock (“Warrant”), issuable upon exercise of the Warrant at the exercise price of $6.05 per share (the “Warrant Shares”, collectively with the Units, Common Stock and Warrant, the “Securities”). The Warrants are exercisable immediately and expire five years after issuance.

On January 24, 2014, the Company and the Purchasers consummated the purchase and sale of the Securities (the “Closing”) of 3,815,285 shares of Common Stock and 2,479,935 Warrants, and the Company raised gross proceeds of $20,030,206 before estimated expenses of the Offering of approximately $1,200,000, which includes placement agent fees but does not include and attorneys’ fees and other expenses. The Company has used a portion of and intends to use the proceeds for general business purposes and expects that it will be able to accelerate the development of its drug candidate pipeline with this additional funding.

The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-184626), which was declared effective by the Securities and Exchange Commission on December 21, 2012 and Form S-3MEF (File No. 333-193439).

Thus far, the Company has used a portion of the net proceeds of the offering, and intends to use the balance, for research and development and working capital See also Item 7 Subsequent Events.

ITEM 6: SELECTED FINANCIAL DATA

The selected consolidated financial data presented below are for each fiscal year in the five-year period ended June 30, 2014. This data is derived from, and qualified by reference to, our audited financial statements and notes thereto appearing elsewhere in this Form 10-K.

Statements of Operations Data:

(in thousands, except per share amounts)	**Years Ended June 30, 2014** (Restated)	**2013**	**2012**	**2011**	**2010**
Revenues:	–	–	–	–	–
Operating expenses:					
Research and development	5,131,523	4,292,909	4,265,933	4,155,846	3,204,885
General and administrative	3,535,849	2,297,470	1,815,816	2,273,609	1,735,066
Total operating expenses	8,667,372	6,590,379	6,081,749	6,429,455	4,939,951
Operating income (Loss)	(8,667,372)	(6,590,379)	(6,081,749)	(6,429,455)	(4,939,951)
Other income (expense):					
Interest income	171,001	55,587	46,787	14,339	2,980
Interest Expense	(3,092.550)	(177,038)			
Discount on convertible Debentures					
Change in Fair market value of securities	(1,443,200)	(1,249,335)	(172,245)	(62,049)	(192,763)
Total other expense, net	(4,934,244)	(2,285,289)	(125,458)	(47,710)	195,743
Loss before income tax expense (benefit)	(13,601,616)	(8,875,667)	(6,207,207)	(6,477,165)	(4,744,208)
Income tax expense (benefit)	-	-	-	-	-
Net loss	$ (13,601,616)	$ (8,875,667)	$ (6,207,207)	$ (6,477,165)	$ (4,744,208)
Net loss per share (1)	$ (0.27)	$ (0.19)	$ (0.15)	$ (0.16)	$ (0.13)
Weighted average shares outstanding	51,225,818	45,892,549	42,763,481	39,765,976	37,285,138

(1) See note 3 to the restated financial statements for information concerning the computation of net loss per share.

Balance Sheets Data:

	Years Ended June 30,				
	2014	2012	2011	2010	2009
(in thousands)	(Restated)				
Cash and Cash Equivalents	$ 36,696,892	$ 13,923,245	$ 14,274,985	$ 9,224,023	$ 6,955,733
Working capital	967,310	598,380	314,174	332,294	501,174
Total assets	44,569,216	16,407,554	15,629,808	10,758,067	8,992,358
Long term liabilities	19,972,953	7,219,718	-	-	-
Accumulated deficit	(51,901,400)	(38,299,783)	(29,424,116)	(23,216,909)	(16,739,743)
Stockholders’ equity	23,369,303	8,009,654	13,850,191	10,170,891	6,518,704

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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, 2014. 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 corporatio

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" an language. The forward-looking statements are based on the current expectations of NNVC and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report. Actual results may differ materially from results anticipated in these forward-looking statements. We base the forward-looking statements on information currently available to us, and we assume no obligation to update them.

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

Management's Plan of Operation

The Company's drug development business model was formed in May 2005 with a license to the patents and intellectual property held by TheraCour Pharma, Inc., that enabled creation of drugs engineered specifically to combat viral diseases in humans. This exclusive license from TheraCour Pharma serves as a foundation for our intellectual property. The Company was granted a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex

Virus (HSV), Influenza and Asian Bird Flu Virus. The Company has entered into an Additional License Agreement with TheraCour granting the Company the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types for Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses. The Company may want to add further virus types to its drug pipeline. The Company would then need to negotiate with TheraCour an amendment to the Licensing Agreement to include those of such additional viruses that the Company determines it wants to follow for further development. We are seeking to add to our existing portfolio of products through our internal discovery pre-clinical development programs and through an in-licensing strategy.

The Company intends to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour Pharma, Inc., the exclusive source for these nanomaterials. The Company may manufacture these drugs itself, or under subcontract arrangements with external manufacturers that carry the appropriate regulatory licenses and have appropriate capabilities. The Company intends to distribute these drugs via subcontracts with distributor companies or in partnership arrangements. The Company plans to market these drugs either on its own or in conjunction with marketing partners. The Company also plans to actively pursue co-development, as well as other licensing agreements with other Pharmaceutical companies. Such agreements may entail up-front payments, milestone payments, royalties, and/or cost sharing, profit sharing and many other instruments that may bring early revenues to the Company. Such licensing and/or co-development agreements may shape the manufacturing and development options that the company may pursue. The Company has received significant interest from certain pharmaceutical companies for potential licensing or co-development of some of our drug candidates. However, none of these distributor or co-development agreements is in place at the current time.

To date, we have engaged in organizational activities; developing and sourcing compounds and preparing nano-materials; and experimentation involving preclinical studies using cell cultures and animals. We have generated funding through the issuances of debt and the sales of securities under our shelf registration and the private placement of common stock (*See,* Item 5). The Company does not currently have any long term debt, other than Series B Convertible Debentures of $6M and the Series C Convertible Debentures of $5Mpresented in the Fiancial Statements and more fully described herein. We have not generated any revenues and we do not expect to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or we may not become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations.

Collaborative Agreements and Contracts

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 FluCideTM-I, AviFluCide-ITM and AviFluCide-HPTM were successfully performed at the laboratories of the National Institute of Hygiene and Epidemiology in Hanoi (NIHE), against both clade 1 and clade 2 of H5N1 virus isolated in Vietnam. Successful animal testing of RabiCide-ITM, the company's rabies drug, was performed in Vietnam during the first half of 2007, and reproducibly repeated in 2008. Rabies testing can safely be done at their BSL2 facility. The H5N1 animal testing requires a BSL3 (biological safety laboratory level 3) laboratory. NIHE has acquired a BSL3 animal testing capacity during 2008.

We have finalized execution of a Materials Cooperative Research and Development Agreement (M-CRADA) with the Centers for Disease Control and Prevention (CDC), Atlanta, GA in July, 2008. This agreement was initiated based on our success against Rabies in the animal studies conducted at NIHE Vietnam. Preliminary animal studies against Rabies were expected to start in the last quarter of calendar year 2009 or first quarter of calendar year 2010. The Company has lowered the priority of this program during the recent economic crisis in order to use our resources most effectively. Subsequent to the agreement execution, the Company has supplied certain materials to CDC for testing. This testing, if successful, is expected to expand to involve potential use of nanoviricides as (1) a post- infection therapeutic drug against rabies, possibly in conjunction with a rabies vaccine, and (2) a post-exposure prophylactic drug against rabies, to replace costly human or monoclonal antibodies, possibly in conjunction with a rabies vaccine. To date, there is no effective post-infection therapeutic against rabies. Post-exposure prophylaxis market has been estimated to be as much $300M to $500M worldwide.

We 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 will need 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-CideTM-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.

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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. Most recently, the Company’s anti-HIV injectables animal testing was 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).

In April, 2014, we finalized a Master Services Agreement (MSA) with Public Health England (PHE), UK the British government’s equivalent of the U.S. Centers for Disease Control,. This agreement allows for animal efficacy evaluation of various nanoviricides drug candidates against viruses of mutual interest at the BSL2, BSL3 or BSL4 facilities at PHE-UK as the case may be. Previously, we had signed a Non-Disclosure Agreement with PHE in July 2013. The MSA allows the scientists at Public Health England to develop a specific proposal for the testing of different nanoviricides, such as FluCide™, against viruses of “mutual interest” to both organizations.

In May 2014, we executed a Master Services Agreement with Integrated Biotherapeutics, Inc. ("IBT"), Gaithersberg, MD, a provider of pre-clinical anti-viral evaluation services. We intend to perform certain influenza drug candidate studies at IBT.

We have engaged BASi Toxicology Services of West Lafayette, IN, to perform the IND-enabling safety/toxicology study for our Injectable FluCide drug candidate. Our service contract with BASI was executed in September, 2014, Subsequent to the financial year end.

Subsequent Events.

On July 2, 2014, (the "Closing Date"), the Company accepted a subscription in the amount of $5,000,000 for a 10% Coupon Series C Convertible Debenture (the "Debenture") from Dr. Milton Boniuk, a member of the Company's Board of Directors (the "Holder"). The Debenture is due on June 30, 2018 (the "Maturity Date") and is convertible, at the sole option of the Holder, into restricted shares of the Company's common stock, par value $0.001 per share (the "Common Stock") at the conversion price of $5.25 per share of Common Stock. The Debenture bears interest at the coupon rate of ten percent (10%) per annum, computed on an annual basis of a 365 day year, payable in quarterly installments on March 31, June 30, September 30 and December 31 of each calendar year until the Maturity Date. Interest for the first quarter ending September 30, 2014 shall be calculated on a per diem basis from the Closing Date.

The Company has the right, but not the obligation, to repay the Debenture prior to the Maturity Date (the "Redemption Payment") in cash or, at the option of the Holder, a number of shares of the Company's Common Stock. If the closing bid price of the Common Stock is in excess of $5.25 when the Company notifies the Holder it has elected to prepay the Debenture (the "Redemption Date"), the Company must redeem the Debenture by delivering to the Holder 951,381 shares of Common Stock and any unpaid coupon interest in lieu of a cash Redemption Payment. If the Holder elects to receive the Redemption Payment in cash, or if the closing bid price of the Common Stock is less than $5.25, the Company shall pay to the Holder a Redemption Payment in cash equal to the principal amount of the Debenture, plus any accrued coupon interest, and additional interest of 7% per annum for the period from the Closing Date to the Redemption Date.

As additional interest on the Debenture, the Company shall issue 187,000 shares of its restricted Series A Preferred Stock (the "Series A") to the Holder. Each shares of Series A votes at 9 votes per share. In addition, only in the event of a "change of control" of the Company, each Series A preferred share is convertible to 3.5 shares of its new common stock. A "change of control" is defined as an event in which the Company's shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition. In the absence of a change of control event, the Series A stock is not convertible into Common Stock, and does not carry any dividend rights or any other financial effects.

The Offering was conducted directly by the Company without the use of a placement agent. Accordingly, no placement agent fees or other commissions were paid by the Company in connection with the Offering.

On September 5, 2014, NanoViricides, Inc. (the "Company") accepted notices to exercise warrants for the purchase of an aggregate of 2,136,655 shares of the Company's common stock at the exercise price of $3.50 per share for aggregate proceeds of $7,478,292.50. On July 17, 2014, the Company filed a registration statement on Form S-3 (the "Form S-3") registering an aggregate of 3,071,986 shares of common stock underlying warrants previously issued by the Company in various private placement offerings between 2005 and September 2009, as described more fully in the Form S-3 (the "Registered Warrants"). The Form S-3 was declared effective by the Securities and Exchange Commission on August 1, 2014. As of August 15, 2014, any Registered Warrants as specified above and not previously exercised have expired.

The Company's Drug Pipeline

Management believes that it has achieved significant milestones in the development of a number of antiviral nanoviricide drug candidates. We now have six high efficacy lead drug candidates against five commercially important diseases, namely, All Influenza viruses ((1) Injectable FluCide for hospitalized patients, and (2) Oral FluCide for the rest of the patients), (3) HIV (HIVCide-I), (4) Nanoviricide Eye Drops for Viral Infections of the External Eye, (5) HerpeCide™, a nanoviricide against Herpes "Cold Sores" and genital herpes, and (6) DengueCide™, a designated Orphan Drug against Dengue viruses. Further, the Company has identified highly active nanoviricide drug candidates against Ebola/Marburg, and against Rabies. In addition, the Company has also established the technology feasibility for (a) broad-spectrum nanoviricides, and (b) Just-in-Time ADIF™ technology; both of which are well suited for stockpiling to defend against known as well as novel infectious diseases.

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 small animals such as various types of specially engineered mice and rabbits, as appropriate.

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. The Company is developing this drug as an Injectable FluCide for hospitalized, severely ill, patients, and as an Oral FluCide for the rest of the patients. We plan on conducting testing of these two FluCide drugs against a number of different influenza virus strains in the very near future. 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. The Company's DengueCide drug candidate has been designated as an Orphan Drug against Dengue by the US FDA and the European Medicines Agency (EMA). As a result, plan on actively undertaking its further development towards an IND. In addition, we are optimizing the anti-HSV drug candidates in the HerpeCide drug program. In addition, we are developing a nearly "universal"antiviral drug for the viral infections of the external eye, which will be informed by our EKC and HSV drug development activities. The Company is getting closer to realizing large scale production of our drug candidates as needed for the Tox Package studies of the two FluCide drugs. In addition, the Company is also getting closer to realizing a cGMP capable pilot scale manufacturing facility to enable human clinical drug substance manufacture for any of its nanoviricides drug candidates. Thus, the Company has made a significant level of progress and has achieved significant accomplishments this year.

Requirement for Additional Capital

As of June 30, 2014, we have a cash and cash equivalent balance of $36,696,892 which combined with the approximately $12.5M raised through the acceptance of warrant conversion notices, and the Series C debenture to Dr. Boniuk, subsequent to the close of the Company's year-end, will be sufficient to fund our currently budgeted operations for more than the next twenty four months.

We believe we currently have sufficient funds on hand to take a drug candidate into human clinical trials. We believe we will be pursuing injectable Flucide™ as our first drug candidate for an IND and for initiating human clinical trials. After that, we estimate that we may need approximately an additional $10M to $15M for human clinical development of the oral FluCide and DengueCide drug candidates towards IND filing over the next 36-48 months. The additional funds will also be needed to pay additional personnel, increased subcontract costs related to the expansion and further development of our drug pipeline, and for additional capital and operational expenditures required to file the corresponding IND applications.

Further, we anticipate incurring additional capital costs in the upcoming eighteen months for the purchase of the 1 Controls Drive, Shelton, CT facility, and for further improvements to this facility, to support an initial new drug application filing with the FDA in accordance with our business plans..

We anticipate that we will incur the following additional expenses over the next 24 months.

1. Research and Development of $10,000,000: Planned costs for in-vivo and in-vitro studies for pan-influenza Injectable and Oral FluCide, Eye nanoviricide, HIVCide, HerpeCide, DengueCide, and Ebola/Marburg and Rabies programs, and planned costs for Phase I and Phase IIa human clinical trials of our injectable Flucide™ drug.

2. Corporate overhead of $2,000,000: This amount includes budgeted office salaries, legal, accounting, investor relations, public relations, and other costs expected to be incurred by being a public reporting company.

3. Capital costs of $2,000,000: This is the estimated cost for equipment and laboratory improvements.

4. Staffing costs of $2,000,000: 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.

5. Purchase of the 1 Controls Drive Facility. While the price has not yet been finalized, we have budgeted approximately $6 million for this purchase, in addition to the approximately $3 million we have provided for the facility renovation project to Inno-Haven in certain cost reimbursements.

6. If and when we initiate human clinical trials for Injectable FluCide, we anticipate approximately $2 million total costs for the Phase I clinical trials, and approximately $5 million for the Phase IIa (virus challenge human efficacy study) clinical trials. In a subsequent year, if Phase I and Phase IIa are successful, we anticipate approximately $10 million for Phase IIb human clinical trials. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional costs. These estimates assume that FluCide is highly effective and therefore would require relatively few patients in each arm of the each trial in order to establish statistically significant results.

We therefore believe that we have sufficient funds in hand to take Injectable FluCide through the initial human clinical trials.

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

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

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

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

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

Research and Development Costs

The Company does not maintain separate accounting line items for each project in development. The Company maintains aggregate expense records for all research and development conducted. Because at this time all of the Company's projects share a common core material, the Company allocates expenses across all projects at each period-end for purposes of providing accounting basis for each project. Project costs are allocated based upon labor hours performed for each project.

The Company has signed several cooperative research and development agreements with different agencies and institutions.

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

The following table summarizes the primary components of our research and development expenses as allocated, during the periods presented in this Form 10-K.

Table 3: R&D Cost Allocations

	Year Ended June 30, 2014	Year Ended June 30, 2013	Year Ended June 30, 2012	For the Cumulative Period From May 12, 2005 (Inception) through June 30, 2014
All Influenzas: FluCide™	$2,000,000	$ 1,300,000	$ 1,100,000	$ 7,024,887
EKC-Cide™, other Eye Viral Infections	100,000	100,000	700,000	2,231,557
HIV-Cide™	414,000-	800,000	600,000	4,009,409
Herpes infections	570,000	770,000	570,000	2,424,816
Dengue	600,000	267,000	267,000	1,237,290
Other (Ebola, and other projects)	99,730	100,000	100,000	2,399,668
Unallocated stock compensation	1,347,793	955,909	897,138	3,476,433
Total Research and development	$5,131,523	$ 4,292,909	$ 4,234,138	$ 22,804,060

Time Schedules, Milestones and Development Costs

In the event that funding can be achieved, we shall endeavor to achieve completion of the following events within the next twelve months:

The status of each of our major research and development projects is as follows:

Table 4: Drug Development Status

Project 1	**Injectable FluCide™ against All Influenzas for Hospitalized Patients**
Current status	We have declared a clinical candidate for influenza, NV-INF-1. This single drug is expected to be effective against most if not all influenza viruses. It is expected to be highly effective against all Influenza A viruses including bird flu H5N1 all clades, Highly Pathogenic Avian Influenzas of all types, subtypes and strains, seasonal Influenzas, H7N9, H3N2, as well as 2009/H1N1 epidemic virus. We are now engaging into advanced pre-clinical drug development, or IND-enabling studies. We are currently performing synthesis scale up studies and the studies required for the Chemistry, Manufacture and Controls section of an IND application. We have performed initial safety/toxicology studies in small animals intended at helping with the design of the full Safety and Toxicology studies (“Tox Package”). We have prepared a first batch of materials for initial tox package studies. We intend to perform full Tox Package Studies when sufficient quantities become availableWe also plan to perform additional animal studies as well as cell culture studies

	for efficacy of this drug candidate against a limited, unrelated influenza virus subtypes and strains. These studies are required for developing an Investigational New Drug (IND) application to the US FDA.
Nature, timing and estimated costs	The Company had budgeted approximately $1,500,000 for the material development, production and testing of this drug in 2012 and 2013. These costs were paid from our available cash balances. Management has determined the results to be satisfactory. We now need to perform material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at $2,500,000. If we are successful with the IND, we could begin Phase I and Phase II human clinical trials. We have estimated costs of approximately $5,000,000 for the initial human clinical trials and associated expenses of this drug candidate. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies and the initial human clinical trials.
Anticipated completion date	Preclinical stage is expected to be completed in 12-18 months, depending upon scheduling with third parties and prioritization of the project. The Company anticipates filing an IND application after completion of the preclinical IND-enabling studies. Phase I drug testing to begin after the IND filing, and requires availability of cGMP-like manufactured product. The cGMP production capability is expected to achieved in 9 to 12 months After we begin scale up production in the new facility.
Timing of commencement of expected material net cash inflows	If we complete our preclinical studies in the next 12~18 months, and also are able to produce clinical batches at the end of this period, we can expect Phase I and Phase II human clinical trials to be completed at the earliest by 2016-2017. Revenues may occur as a result of licensing the drug to another pharmaceutical partner at this stage. After Phase III clinical trials completion, revenues are expected to occur after FDA approval and marketing of the drug. Revenues may occur earlier if Flucide is approved for use in other countries or if the BARDA authority determines that FluCide should be stockpiled in the USG CDC stockpile of drugs for defense against pandemic influenza. If we are successful in partnering the drug with another pharmaceutical Company, we may see revenues much earlier than FDA approval. We anticipate that due to the high priority for our work on Ebola related to the current epidemic, our FluCide project plan may be delayed by an additional 6 to 9 months.

Project 2	**Oral FluCide™ against All Influenzas for Out-Patients**
Current status	We have developed a highly effective anti-influenza drug candidate that is active when given orally. We believe that we will be able to optimize this drug candidate and declare a clinical candidate with a limited amount of structure-activity-relationship (SAR) efficacy studies. This single drug is expected to be effective against most if not all influenza viruses. It is expected to be highly effective against all Influenza A viruses including bird flu H5N1 all clades, Highly Pathogenic Avian Influenzas of all types, subtypes and strains, seasonal Influenzas, H7N9, H3N2, as well as 2009/H1N1 epidemic virus. We are now engaging into advanced pre-clinical drug development, or IND-enabling studies. After completing the SAR studies, we will need to perform synthesis scale up studies and the studies required for the Chemistry, Manufacture and Controls section of an IND application. We believe that these studies will benefit from the studies already performed for the injectable FluCide version, as both the oral and injectable drug candidates employ the same virus-binding ligand. We intend to perform Safety and Toxicology studies (“Tox Package”) when sufficient quantities become available. We also plan to perform additional animal studies as well as cell culture studies for efficacy of this drug candidate against a limited, unrelated influenza virus subtypes and strains. These studies are required for developing an Investigational New Drug (IND) application to the US FDA.
Nature, timing and estimated costs	The Company had budgeted approximately $500,000 for the material development, production and testing of this drug in 2012 and 2013. These costs were paid from our available cash balances. Management has determined the results to be satisfactory. We now need to perform SAR, followed by material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at $2,500,000. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies. If we are successful with the IND, we could begin Phase I and Phase II human clinical trials. We have estimated costs of approximately $10,000,000 for the initial human clinical trials of this drug candidate.
Anticipated completion date	Preclinical stage is expected to be completed in 24-36 months, depending upon prioritization, scheduling, and external contractor dependencies. The Company anticipates filing an IND application after completion of the preclinical IND-enabling studies. Phase I drug testing to begin after the IND filing, and requires availability of cGMP-like manufactured product. . The cGMP production capability is expected to be achieved in 9 to 12 months following cGMP production of the injectable FluCide drug candidate.
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable.

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Timing of commencement of expected material net cash inflows	If we complete our preclinical studies in the next 24~30 months, and also are able to produce clinical batches at the end of this period, we can expect Phase I and Phase II human clinical trials to be completed at the earliest by 2017-2018 if we havethis project on fast track. Revenues may occur as a result of licensing the drug to another pharmaceutical partner at this stage. After Phase III clinical trials completion, revenues are expected to occur after FDA approval and marketing of the drug. Revenues may occur earlier if oral Flucide is approved for use in other countries or if the BARDA authority determines that oral FluCide should be stockpiled in the USG CDC stockpile of drugs for defense against pandemic influenza. If we are successful in partnering the drug with another pharmaceutical Company, we may see revenues much earlier than FDA approval. We anticipate that due to the high priority for our work on Ebola related to the current epidemic, our Oral FluCide project plan may be delayed by an additional 6 to 9 months
Project 3	**Nanoviricide Eye Drops for all Viral Infections of the External Eye**
Current status	We have developed new, broad-spectrum. ligands that should be capable of enabling nanoviricide binding to herpes simplex viruses, while retaining the features that were previously successful against adenoviral EKC in clinical studies. The resulting nanoviricides have been tested against HSV-1 in cell cultures against two different strains of HSV-1, and a lead drug candidate has been identified. We are developing nanoviricide eye drop solution that should be capable of resolving the broad range of viruses that can cause infections of the external eye resulting in conjunctivitis or keratitis. The majority of these viruses are adenoviruses or HSV.
Nature, timing and estimated costs	The Company has budgeted approximately $300,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. Should management determine the results to be satisfactory, we will need to obtain additional financing to perform material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at $1,500,000. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies.
Anticipated completion date	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.

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Project 4	**HIVCide™, nanoviricide against HIV/AIDS viruses**
Current status	HIV-Cide is currently in preclinical studies. It is designed to mimic the site at which all HIV gp120 bind to the CD4 receptor. It is therefore expected to work against all HIV-1 subtypes and strains. HIV-Cide has been successfully tested in SCID-huThy/Liv mouse model and was found to have very high efficacy, equal to that of >25X (2,500%) dosage level of the triple drug HAART combination therapy. In vitro studies against two different HIV-1 strains were very successful. The Company is planning additional in-vivo and in-vitro studies at various institutions and subcontractors during 2014-2014 to further optimize the drug candidate.
Nature, timing and estimated costs	The Company has budgeted approximately $2,000,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. Should management determine the results to be satisfactory, we will need to obtain additional financing to perform material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at $7,000,000. We conduct HIVCide development at a slow pace because of the inherent long nature of these studies, and also because we do not have sufficient funds to dedicate to this project.
Anticipated completion date	Not known
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence if ever, due to the uncertainties associated with the completion of the product, regulatory submissions, approvals and market purchases of this product.
Project 5	**HerpeCide™ for Oral and Genital Herpes Cold Sores, "Fever Blisters" and Herpetic Ulcers**
Current status	HerpeCide is currently in preclinical studies against oral and genital herpes virus infections. It is being developed as a skin cream 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 2014-2014.
Nature, timing and estimated costs	The Company has budgeted approximately $600,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. 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. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies.

Anticipated completion date	Not known

Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence if ever, due to the uncertainties associated with the completion of the product, regulatory submissions, approvals and market purchases of this product.
Project 6	**DengueCide™, a nanoviricide against all Dengue viruses**
Current status	Anti-dengue nanoviricide drug candidates are currently in preclinical studies. These candidates are being designed to mimic the human cell binding sites common to all types of dengue viruses. The best nanoviricide resulted in a 50% survival of mice in a uniformly lethal animal protocol simulating the ADE effect. This drug candidate has been designated an Orphan Drug for Dengue by the US FDA. This orphan drug designation carries with it several economic benefits. The Company therefore expects to expedite the development of this drug candidate.
	The Company is planning additional in-vivo and in-vitro studies at various institutions and subcontractors during 2014-2014.
Nature, timing and estimated costs	The Company has budgeted approximately $1,000,000 for the material development, production and testing of this drug. These costs will be paid from our available cash balances. Should management determine the results to be satisfactory, we will need to obtain additional financing to perform material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, which we have presently budgeted at $2,000,000. The Company has sufficient cash in hand to cover the costs associated with the aforesaid studies.
Anticipated completion date	Not known
Risks and uncertainties associated with completing development on schedule, and the consequences to operations, financial position and liquidity if not completed timely	The outcome of clinical testing cannot be known at this time, and this poses substantial risk and uncertainty as to whether or when if ever, this drug will become marketable.
Timing of commencement of expected material net cash inflows	It is not known or estimable when net cash inflows from this project will commence if ever, due to the uncertainties associated with the completion of the product, regulatory submissions, approvals and market purchases of this product.

Project 7	**EbolaCide™: Anti-Ebola nanoviricide**
Current status	We have restarted the anti-Ebola nanoviricides project due to the recent raging ebola epidemic in West Africa that has become a major global public health threat. We have designed novel ligands

	based on the cognate receptor of the ebola virus, namely, NPC1. We are currently performing syntheses of the novel nanoviricide candidates for biological testing in cell cultures and small animals.
Nature, timing and estimated costs	The Company has budgeted approximately $500,000 for the internal material development, production and testing of this drug in 2014. These costs are being paid from our available cash balances. If the animal studies are successful, we will attempt to further develop a drug candidate in response to the current Ebola epidemic. We have the manufacturing capacity to produce the necessary quantities of such a drug to respond to the current epidemic. WHO has recently developed guidelines for the use of unapproved drugs and drugs in development in the field in an effort to contain this epidemic. There are currently neither any drug nor any vaccines available for Ebola. Some vaccines as well as drug candidates have entered human clinical trials. However, the ebola virus has been found to mutate rapidly in the field. Thus, the effectiveness in the field of a vaccine or an antibody, siRNA, anti-sense or another conventional drug that the virus can escape by mutations is at present unknown at best. We believe that, if biological testing is successful, a nanoviricide may be deployed in the field under a special protocol due to the special circumstances in order to contain this epidemic..
Anticipated completion date	We do not have a completion date
Timing of commencement of expected material net cash inflows	We cannot project the timing of revenues, if any, from this project. We will continue to seek funding from non-dilutive sources for this project.

Other drug candidates:

Nanoviricides against Rabies, Hepatitis C Virus (HCV), Middle East Respiratory Syndrome human Coronavirus (MERS-CoV), and several other viral diseases are at various early stages of research and development and involve a substantial amount of uncertainty as to the development of these drug candidates. At this time, very little resources have been allocated to these drugs. However should the early studies of any of these drug candidates provide an indication of high efficacy, the corresponding drug candidate will become a full-fledged drug development project and the Company will endeavor to seek additional funding for the necessary drug development work.

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

The Company has agreed, in principle, 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 needs to be designed and built in compliance with FDA guidelines in order for the Company to produce experimental materials that can be used in Phase I human clinical trials. The cGMP facility will eventually need to be registered with the FDA and certified as a cGMP drug manufacturing facility for use of the manufactured drugs from this facility in Phase III human clinical trials.

The work-plan we have developed for the next twelve months is expected to enable us to file an investigational new drug application late in our 2014-2015 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 2014-2014 fiscal year, with a kg-scale pilot “cGMP-like” 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.

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 equity-based and debt financing, as required, to fund the Company’s operations. Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain the additional financial resources necessary to fund its anticipated obligations beyond the next twenty-four months.

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

Results of Operations

The Company is a development-stage biopharmaceutical company and does not have any revenue for the year ending June 30, 2014.

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

Operating Expenses - General and administrative expenses increased $ 1,238,379 to $ 3,535,849 for the year ended June 30, 2014, from $2,297,470 for the year ended June 30, 2013. The increase resulted from the Company's general increase in non-research and development expenditures associated with development of its various drug candidates.

Research and development expenses for the year ended June 30, 2014 increased $838,614 to $ 5,131,523 from 4,292,909 for the year ended June 30, 2013. This increase in the cost of Research and development is largely attributable to the development of additional drug candidates and increased research and development payroll costs.

Research and Development expenses were offset in the amount of $ -0-, $ -0- and $-0-, in the years ended June 30, 2014, 2013 and June 30, 2012, respectively, by a Connecticut Refundable Research and Development Credit.

Other Income (Expenses) – Net Interest income was $171,001 and $55,587 for the years ending June 30, 2014, and 2013, respectively. Net Interest income in 2014 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, 2014, we had estimated cumulative tax benefits resulting from federal net operating loss carry-forwards of approximately $11,104,134 and deferred Research and Development tax credits and other deferred tax credits resulting in a deferred tax benefit of approximately $20,172,664. This amount has been offset by a full valuation allowance.

Net Operating Loss - For the year ended June 30, 2014, the Company had a net loss of $13,601,616, or $ ($0.27) per share (as adjusted) compared to a net loss of $8,875,668, or ($0.19) per share (as adjusted) for the year ending June 30, 2013.

Liquidity and Capital Reserves

The Company had cash and cash equivalents of $36,696,892 as of June 30, 2014. On the same date, accounts payable and accrued liabilities outstanding totaled $1,226,960.

Since inception, the Company has expended substantial resources on research and development. Consequently, we have sustained substantial losses. The Company has an accumulated deficit of $51,901,400 at June 30, 2014.

As of June 30, 2014, we have a cash and cash equivalent balance of $36,696,892. As of the date of the filing, the Company has raised gross proceeds of $5,000,000 through the placement of the Company's Series C Convertible Debenture on July 2, 2014 and on September 5, 2014 accepted notices to exercise warrants for the purchase of an aggregate of 2,136,655 shares of the Company's common stock at the exercise price of $3.50 per share for aggregate proceeds of $7,478,292.50.The Company estimates that it can support current budgeted operations through June 30, 2016.

While our cash and cash equivalent balance is sufficient for us to continue our operations through June 30, 2016, 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, 2014.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Accounting Basis – The Company has not earned any revenue from its planned principal operations. Accordingly, the Company's activities have been accounted for as those of a "Development Stage Company" as defined by section 810-10-20 of the FASB Accounting Standards Codification. Among the disclosures required by section 810-10-20 of the FASB Accounting Standards Codification 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. All losses accumulated since inception have been considered as part of the Company's development stage activities.

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 accounts for its stock based compensation in which the Company obtains employee services in share-based payment transactions under the recognition and measurement principles of the fair value recognition provisions of section 718-10-30 of the FASB Accounting Standards Codification. Pursuant to paragraph 718-10-30-6 of the FASB Accounting Standards Codification, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the performance is complete or the date on which it is probable that performance will occur.

Accounting for Non-Employee Stock Based Compensation – The Company accounts for equity instruments issued to parties other than employees for acquiring goods or services under guidance of section 505-50-30 of the FASB Accounting Standards Codification ("FASB ASC Section 505-50-30"). Pursuant to FASB ASC Section 505-50-30, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the performance is complete or the date on which it is probable that performance will occur.

POLICY AFFECTING RECOGNITION OF REVENUE

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

RECENT ACCOUNTING PRONOUNCEMENTS

Recently Issued Accounting Pronouncements

In April 2014, the FASB issued ASU No. 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. The amendments in this Update change the requirements for reporting discontinued operations in Subtopic 205-20.

Under the new guidance, a discontinued operation is defined as a disposal of a component or group of components that is disposed of or is classified as held for sale and "represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results." The ASU states that a strategic shift could include a disposal of (i) a major geographical area of operations, (ii) a major line of business, (iii) a major equity method investment, or (iv) other major parts of an entity. Although "major" is not defined, the standard provides examples of when a disposal qualifies as a discontinued operation.

The ASU also requires additional disclosures about discontinued operations that will provide more information about the assets, liabilities, income and expenses of discontinued operations. In addition, the ASU requires disclosure of the pre-tax profit or loss attributable to a disposal of an individually significant component of an entity that does not qualify for discontinued operations presentation in the financial statements.

The ASU is effective for public business entities for annual periods beginning on or after December 15, 2014, and interim periods within those years. The adoption of the ASU would not have a material effect on the accompanying financial statements.

In May 2014, the FASB issued the FASB Accounting Standards Update No. 2014-09 "*Revenue from Contracts with Customers (Topic 606)" ("ASU 2014-09").*

This guidance amends the existing FASB Accounting Standards Codification, creating a new Topic 606, *Revenue from Contracts with Customer.* The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

To achieve that core principle, an entity should apply the following steps:

1. Identify the contract(s) with the customer
2. Identify the performance obligations in the contract
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations in the contract
5. Recognize revenue when (or as) the entity satisfies a performance obligations

The ASU also provides guidance on disclosures that should be provided to enable financial statement users to understand the nature, amount, timing, and uncertainty of revenue recognition and cash flows arising from contracts with customers. Qualitative and quantitative information is required about the following:

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Contracts with customers – including revenue and impairments recognized, disaggregation of revenue, and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations)

1. Significant judgments and changes in judgments – determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations
2. Assets recognized from the costs to obtain or fulfill a contract.

ASU 2014-09 is effective for periods beginning after December 15, 2016, including interim reporting periods within that reporting period for all public entities. Early application is not permitted. The adoption of the ASU would not have a material effect on the accompanying financial statements.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.

The amendments in this Update remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage.

The amendments also clarify that the guidance in Topic 275, Risks and Uncertainties, is applicable to entities that have not commenced planned principal operations.

Finally, the amendments remove paragraph 810-10-15-16. Paragraph 810-10-15-16 states that a development stage entity does not meet the condition in paragraph 810-10-15-14(a) to be a variable interest entity if (1) the entity can demonstrate that the equity invested in the legal entity is sufficient to permit it to finance the activities that it is currently engaged in and (2) the entity's governing documents and contractual arrangements allow additional equity investments.

The amendments in this Update also eliminate an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity on the basis of the amount of investment equity that is at risk. The amendments to eliminate that exception simplify U.S. GAAP by reducing avoidable complexity in existing accounting literature and improve the relevance of information provided to financial statement users by requiring the application of the same consolidation guidance by all reporting entities. The elimination of the exception may change the consolidation analysis, consolidation decision, and disclosure requirements for a reporting entity that has an interest in an entity in the development stage.

The amendments related to the elimination of inception-to-date information and the other remaining disclosure requirements of Topic 915 should be applied retrospectively except for the clarification to Topic 275, which shall be applied prospectively. For public business entities, those amendments are effective for annual reporting periods beginning after December 15, 2014, and interim periods therein.

The company has limited operations and is considered to be in the development stage. The Company has elected to early adopt Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. The adoption of this ASU allows the company to remove the inception to date information and all references to development stage. The Company adopted this guidance from June 30, 2014.

In June 2014, the FASB issued the FASB Accounting Standards Update No. 2014-12 "*Compensation—Stock Compensation (Topic 718)* : *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period" ("ASU 2014-12").*

The amendments clarify the proper method of accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The Update requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered.

The amendments in this Update are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The adoption of the ASU would not have a material effect on the accompanying financial statements.

In August 2014, the FASB issued the FASB Accounting Standards Update No. 2014-15 "*Presentation of Financial Statements— Going Concern (Subtopic 205-40) (Topic 718)*: *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15").*

The Update provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes.

This Update is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures.

The amendments in this Update are effective for annual periods and interim periods within those annual periods beginning after December 15, 2016. Earlier adoption is permitted. The amendments of the ASU would not have a material effect on the accompanying financial statements

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.

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

None.

ITEM 9A. 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, 2014.

(a) Based upon an evaluation of the effectiveness of disclosure controls and procedures, our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") have concluded that as of the end of the period covered by this Annual Report on Form 10-K our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) were 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. The Company has established an independent Board of Directors comprising three independent members. Under this Board the Company has established an Audit Committee, a Compensation Committee, a Nomination Committee, and an Executive Committee. The Company has met or exceeded corporate governance standards of the NYSE MKT, a national exchange. On September 25, 2013, the Company's common stock was listed and began trading on the NYSE MKT.

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.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting as of June 30, 2014. To evaluate the effectiveness of our internal control over financial reporting, management used the criteria described in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Framework"). Based on its evaluation under the *Internal Control - Evaluation Framework,* management concluded that our internal control over financial reporting was effective as of June 30, 2014. Based on the assessment, at the time that the Original Filing was filed on September 30, 2014, our management concluded that our internal control over financial reporting was effective as of June 30, 2014.

In connection with the restatement included in this Form 10-K/A, management, including our Chief Executive Officer and Chief Financial Officer, reassessed the effectiveness of our internal control over financial reporting as of June 30, 2014. Based on this reassessment using the COSO criteria, management concluded that we did not maintain effective internal control over financial reporting as of June 30, 2014 because of a deficiency in the control over the review of consultants engaged to advise the Company as to potential derivative liabilities. Management concluded that this deficiency was a material weakness as defined in the Securities and Exchange Commission regulations since it resulted in the misstatement of the Company's derivative liability and the related financial disclosures for the year ended June 30, 2014.

Remediation Plan

We are remediating this material weakness by, among other things, implementing a process of enhanced review of all financial transactions including engagement of outside specialists to evaluate our financial transactions as they arise The actions that we are taking are subject to ongoing senior management review and Audit Committee oversight. Management believes the foregoing efforts will effectively remediate the material weakness in the fourth quarter of 2015. As we continue to evaluate and work to improve our internal control over financial reporting, management may execute additional measures to address potential control deficiencies or modify the remediation plan described above and will continue to review and make necessary changes to the overall design of our internal controls.

Changes in Internal Control Over Financial Reporting

On May 13, 2013, the Company appointed Meeta Vyas as its Interim Chief Executive Officer, a seasoned executive with large, public company experience.

In June 2013 the Company appointed Milton Boniuk and Mukund Kulkarni as independent directors and members of the Audit Committee. In addition, previously in June 2012, the Company had appointed Mr. Stanley Glick, CPA, as an independent member of its Board of Directors, and as the Chair of its Audit Committee. Dr. Milton Boniuk and Dr. Mukund Kulkarni joined the Audit Committee upon their appointment as independent members of the Board of Directors.

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, 2014, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 revised Auditor's Report states:

"In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, the Company did not maintain, in all material respects, effective internal control over financial reporting as of June 30, 2014, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

ITEM 9B Other Information

None.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CORPORATE GOVERNANCE

The following table sets forth the names and ages of our current directors and executive officers, their principal offices and positions and the date each such person became a director or executive officer. Executive officers are elected Biannually by our Board of Directors. Each executive officer holds the office until he/she resigns, is removed by the Board or his/her successor is elected and qualified. Directors are elected annually by our stockholders at the annual meeting. Each director holds his/her office until the successor is elected and qualified or his/her earlier resignation or removal.

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

Name	Age	Title
Anil Diwan, PhD.	55	President; Chairman of the Board
Eugene Seymour, MD, MPH	73	Chief Executive Officer; Director
Stanley Glick, CPA	77	Director, Independent
Mukund S. Kulkarni, MD	66	Director, Independent
Milton Boniuk, MD	81	Director, Independent
Meeta Vyas	55	Chief Financial Officer

The Company’s executive officers and directors are elected Biannually and serve until their term expires.

Eugene Seymour, MD, MPH, age 73, has been Chief Executive Officer (CEO) and a director of the Company since consummation of the merger on June 1, 2005. From 1996 until May 2005 he has been a private investor and has held no corporate positions. During this period he formed a non-profit foundation that funded both testing and training programs for health workers in Asia and Africa. He was a consultant to the UN Global Program on AIDS and was sent to several countries, (Lithuania, Latvia, Estonia and Russia) to interact with local physicians and assist them in setting up testing programs. Dr. Seymour obtained a Master's degree in the Epidemiology of Infectious Diseases at UCLA in addition to his medical degree. He began clinical practice in Internal Medicine and joined the UCLA Medical School faculty. He left UCLA after two years and joined the USC faculty as Associate Professor. Dr. Seymour served in the Medical Corps of US Army Reserve during the Vietnam era and attained the rank of Major. In 1986, he was requested by the US government to establish a testing laboratory and run a large-scale surveillance program for HIV prevalence in the Hispanic population in Los Angeles. His laboratory ended up testing over 50,000 people. In 1989, he founded StatSure Diagnostic Systems, Inc. (SDS) (formerly Saliva Diagnostic Systems, Inc.), raised capital and developed the rapid HIV antibody blood test (Hema-Strip). He took the company public in 1993 as CEO and President. He left SDS in 1996. Dr. Seymour holds 8 issued patents, and is married with three children, two of whom are physicians. The Company concluded Dr. Seymour's extensive experience in treating infectious disease and viruses, plus his public company experience, make him an ideal candidate to serve in these capacities.

Anil Diwan, PhD, age 55, has been President and the Chairman of the Board of Directors of the Company since consummation of the merger on June 1, 2005. Dr. Diwan simultaneously therewith and since its formation, has also served as the Chief Executive Officer and Director of AllExcel, Inc. (from 1995 to the present) and TheraCour Pharma, Inc. (from 2004 to the present) and is the original inventor of the technologies licensed to NanoViricides Inc., as well as the TheraCour polymeric micelle technologies and products based on them. Since 1992, he has researched and developed TheraCour nanomaterials. Dr. Diwan was the first to propose the development of novel pendant polymers for drug delivery that led to an explosion of research in pharmacological applications of polymeric micelles. Anil has won over 12 NIH SBIR grants. Dr. Diwan holds several issued patents, and threePCT international patent applications in various stages of prosecution in a number of countries, and , and has made intellectual property depositions of several additional patentable discoveries with the patent attorney. Dr. Diwan has held several scholastic distinctions, including an All-India 9th rank on the Joint Entrance Examination of all IIT's. He holds a Ph.D. in Biochemical Engineering from Rice University (1986) and B.S. in Chemical Engineering from Indian Institute of Technology (IIT) Bombay (1980). We concluded Dr. Diwan's experience plus his status as creator of the Company's technologies render him uniquely qualified to serve in these capacities.

Stanley Glick, CPA, age 77, was appointed as an independent Director and as chair of the Audit Committee of the Company on June 22, 2012. Mr. Glick has over forty years of experience in his long career of providing auditing, accounting, tax, and management advisory services, to clients in various industries. Mr. Glick has been a member of several Boards of Directors for not-for-profit organizations in the Westport, CT area. In particular, he has served as a Director and member of Audit Committee of "A Better Chance" of Westport, CT, from 2000 to 2005. From 1977 until present, Mr. Glick has managed an independent practice as a Certified Public Accountant in Connecticut and New York States. Prior to forming his own CPA firm, Mr. Glick was employed by local and regional CPA firms where he performed and supervised audits and financial reporting. Mr. Glick is a member of the American Institute of Certified Public Accountants, The Connecticut Society of Certified Public Accountants, and the New York State Society of Certified Public Accountants. He holds a Bachelor of Business Administration degree in Accounting from Baruch College of Business (now Baruch College of the City University of New York). Mr. Glick is married and lives in Trumbull, CT. We concluded that Mr. Glick's broad business, accounting and auditing experience meets the criteria of an independent director and an “audit committee Financial Expert. The Company has expanded and enhanced its Board of Directors by the appointment of Stanley Glick CPA, as an independent director. The Company understands that as an SEC-filing company trading on the over-the-counter bulletin-board, the Company is currently not required to appoint independent board members, and is not required to appoint an independent board member financial expert to chair its Audit Committee. However, the Company believes that an independent board member with expertise in financial reporting and management advisory services, chairing the audit committee, would provide additional assurances to the financial community and other users of the Company’s financial statements. Mr. Glick’s appointment as an independent director and audit committee chairman, significantly improves the Company’s financial oversight and management.

Mukund S. Kulkarni, MBA, PhD, age 66, has been a Chancellor of Penn State Harrisburg since 2010 where Dr. Kulkarni joined in 1985 as a Professor of Finance in the School of Business Administration. Prior to becoming chancellor, he was senior associate dean for academic affairs from 2006-2010. Prior thereto and from 1996, he served as the director of the School of Business Administration. In addition to his administrative appointment, Dr. Kulkarni holds the rank of professor of finance. Dr. Kulkarni earned his bachelor’s degree from Shivaji University located in Kolhapur, India and master’s degrees from University of Pune located in Pune, India, and an M.B.A. from Marshall University. He also earned a Doctorate in Economics from the University of Kentucky. Dr. Kulkarni is widely published in academic journals and has presented papers at several scholarly conferences. Dr. Kulkarni is an invited lecturer and consultant to several academic institutions in the U.S. and abroad, in addition to state government and nonprofit organizations. Dr. Kulkarni is widely engaged in social and civic activities in and around the Harrisburg region. He is member of several boards of civic and nonprofit organizations including the Harrisburg Regional Chamber of Commerce, United Way of the Capital Region, Modern Transit Partnership, and Asian Indian Americans of Central Pennsylvania, among others. He has delivered lectures and provided consultations to other business schools, government agencies, and non-profit organizations, and he has valuable corporate experience in the commercial banking industry.As a result of his valuable experience in the commercial banking industry and his vast academic background in economics and finance, the Company concluded Dr. Kukarni was qualified to serve as a member of its Board of Directors.

Milton Boniuk, MD, age 81, is an astute and highly successful businessman and entrepreneur, in addition to being an accomplished eye surgeon, educator, and administrator. Dr. Boniuk is a renowned eye surgeon in private practice who specializes in Ocular Oncology and Oculoplastics. He is also the Caroline F. Elles Chair of Ophthalmology at the Alkek Eye Center at the Baylor College of Medicine. Dr. Boniuk has been a long term investor and strong supporter of NanoViricides, Inc. Dr. Boniuk is also well known for his philanthropic endeavors. Most recently, he gave $28.5M to Rice University to establish The Boniuk Institute for the Study and Advancement of Religious Tolerance, following up on a previous $5M gift for this cause. Dr. Boniuk earned his MD at the Dalhousie University, Halifax, Nova Scotia, Canada, followed by an internship at the Victoria General Hospital, Halifax, Nova Scotia, Canada, and Residency at the Center for Ophthalmology, Jefferson Medical College - Wills Eye Hospital, Philadelphia, PA. In addition, he served a Fellowship in Ophthalmic Pathology at the world-renowned Armed Forces Institute of Pathology, Washington, D.C. Dr. Boniuk has made significant contributions in cataract surgery, glaucoma, corneal dystrophies, retinal diseases and surgery. He is a nationally and internationally recognized expert in the pathology and surgical management of orbital and intra-ocular tumors. His description of the ocular pathology of the congenital rubella syndrome in 1967 was a landmark publication. Of note, Dr. Boniuk has made substantial medical contributions in areas that are of great significance to the Company, such as ocular adenoviral infections, that cause epidemic kerato-conjunctivitis (EKC). The Company has developed a drug candidate for EKC infection that was successfully tested in rabbits. These animals serve as a surrogate for the viral disease in human eyes. We concluded Dr. Boniuk's experience plus business acumen render him qualified to serve as a member of its Board of Directors.

Meeta Vyas, SB, MBA, age 55, is known as a strong leader with board level experience and successful achievements as a Senior Executive in a broad range of entities including publicly listed corporations, non-revenue generating entities, and medium to large size companies. Ms. Vyas has over twenty-five years of experience in performance and process improvement of both publicly listed companies and non-revenue producing entities, in areas ranging from Finance and Operations to Strategy and Management. Meeta holds the distinction of being the first Indian woman to be named CEO of a publicly listed U.S. corporation, Signature Brands, Inc., best known for "Mr. Coffee" and "Health-O-Meter" brand products. As CEO, acting COO and Vice Chairman of the Board of Signature Brands, Inc., she was responsible for the development and implementation of a turnaround plan, resulting in Signature's return to profitability and growth. Later, as the CEO of the World-Wide Fund for Nature - India (WWF-India) and then as a Vice President of the National Audubon Society (USA), both non-revenue generating entities, Meeta successfully raised unrestricted funding that significantly exceeded annual requirements and also instituted financial processes to measure a variety of performance metrics. Earlier in her career, she was responsible for designing the strategy and initiating the implementation plan for the highly successful information technology outsourcing program at General Electric ("GE"). Also at GE, Ms. Vyas ran GE Appliances' Range Products business unit having revenues exceeding $1 Billion where her team doubled operating income in less than two years. Prior to that, as a management consultant with McKinsey and Company, she served publicly listed companies in chemicals, industrial, and technology markets, primarily focusing on growth strategies, valuations, post-merger integrations, and logistics operations. Ms. Vyas is married to Anil Diwan, the Company's President and Chairman and principal shareholder of TheraCour Pharma, Inc. . Ms. Vyas holds a MBA in Finance from Columbia University's Graduate School of Business, and a SB in Chemical Engineering from the Massachusetts Institute of Technology.

AUDIT COMMITTEE

In June , 2012 Stanley Glick, CPA was elected, as an independent member, to the Company's Board of Directors and the Chair of the Company's Audit Committee. Due to his education and extensive experience as a Certified Public Accountant, Mr. Glick meets the criteria of an independent director and an "Audit Committee Financial Expert" as provided in Release 33-8173 and 34-47235. In addition, in June, 2013, Milton Boniuk and Mukund S. Kulkarni have been appointed as independent directors and members of the Audit Committee.

CODE OF ETHICS

We have adopted a code of ethics meeting the requirements of Section 406 of the Sarbanes-Oxley Act of 2002. We believe our code of ethics is reasonably designed to deter wrongdoing and promote honest and ethical conduct; provide full, fair, accurate, timely and understandable disclosure in public reports; comply with applicable laws; ensure prompt internal reporting of violations; and provide accountability for adherence to the provisions of the code of ethic. Our code of ethics is filed as an exhibit to this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The following table reflects all forms of compensation for the years ended June 30, 2014, 2013 and 2012: .

Name and Principal Position	Year	Salary	Bonus ($)	Stock Award(s) ($)	Option Awards(#)	All Other Compensation ($)	Total ($)
Eugene Seymour,	2014	$275,000	$ -	$187,387	-	$ -	$462,387
CEO, Director	2013	$275,000		$187,387		$ -	$462,387
	2012	$275,000	$ —	$267,119	—	$ -	$542,119
Anil Diwan	2014	$275,000	$ -	$187,387		$ -	$462,387
President, Director	2013	$275,000		$187,387		$ -	$462,387
	2012	$275,000	$ —	$431,486	-	$ —	$706,486
Stanley Glick	2014	15,000	—	15,000	—	—	30,000
Director*	2013	11,250	—	11,250	—	—	22,500
Appointed June 22, 2012.	2012	—	—	—	—	—	—
Meeta Vyas, interim CFO	2014	$108,000	—	283,221	—	—	391,221
Appointed May 13, 2013	2013	$12,000	---	9,000			21,000
Mukund Kalkarni Director	2014	$15,000	—	15,000	—	—	30,000
Appointed 6/24/13	2013	$3,750	—	3,750	—	—	7,000
Milton Boniuk Director	2014	$15,000	—	15,000	—	—	30,000
Appointed 5/28/13	2013	$3,750	—	3,750	—	—	7,000

The following table sets forth for each named executive officer certain information concerning the outstanding equity awards as of June 30, 2013,.

Name and Principal Position	**Number of Securities Underlying Unexercised**	**Number of Securities Underlying**	**Option Exercise Price ($)**	**Option Expiration Date**	**Number of Shares or**	**Market Value of Shares**	**Equity Incentive Plan Awards:**	**Equity Incentive Plan Awards:**

	Options Exercisable	Unexercised Options Unexercisable				Units of Stock that Have Not Vested	or Units of Stock that Have Not Vested	Number of Unearned Shares, Units or Other Rights that Have Not Vested	Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested
Eugene Seymour, CEO and Director	142,857	-	$	0.35	September 26, 2015	—	—	—	—
Anil Diwan, President and Director	285,714	-	$	0.35	September 26, 2015	—	—	—	—
Milton Boniuk, MD	-	-	$	-	-	—	—	—	—
Mukund Kulkarni	-	-	$	-	-	—	—	—	—
Stanley Glick	-	-	$	-	-	—	—	—	—
MeetaVyas	-	-	$	-	-	—	—	—	—

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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, 2014, under the March 3, 2010 employment agreements, the Company issued 593,750 shares of the Company's Series A 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 that may not be realized.

DETERMINATION OF COMPENSATION

The Company's executive compensation program for the named executive officers (NEOs) is administered by the Board of Directors. The Board of Directors makes independent decisions about all aspects of NEO compensation, and takes into account compensation data and benchmarks for comparable positions and companies in different applicable geographical areas. The Compensation Committee of the Board assists the Board in achieving these objectives.

The Company's current executives' compensation program as of the date of this report has been at the same level since 2005. The program is simplistic and is less structured than a more mature corporation. Two of our officers are founders or co-founders of the Company and their ownership in the Company has driven their philosophy to provide modest salaries 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, 2014, on a post-reverse-split adjusted basis.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner (1)	Percent of Class	
TheraCour Pharma, Inc.(2) 135 Wood Street West Haven, CT 06516	9,531,429	17.48	%
Anil Diwan (2) (3) 135 Wood Street West Haven, CT 06516	2,044,918	3.75	%
Eugene Seymour (4) 135 Wood Street West Haven, Connecticut 06516	1,721,429	3.16	%
Milton Boniuk (5) 135 Wood Street West Haven, CT 06516	937,249	1.79	%
MuKund Kulkarni 135 Wood Street West Haven, CT 06516	126,184	0..23	%
Stanley Glick 135 Wood Street West Haven, CT 06516	9,805	0.01	%
Meeta Vyas (6) 135 Wood Street West Haven, CT 06516	147,021	0.26	%
All Directors and Executive Officers as a Group (7 persons)	15,554,215	28.52	%

1) For each shareholder, the calculation of percentage of beneficial ownership is based upon approximately 54,536,000 shares of Common Stock outstanding as of June 30, 2014, and shares of Common Stock subject to options, warrants and/or conversion rights held by the shareholder that are currently exercisable or exercisable within 60 days, which are deemed to be outstanding and to be beneficially owned by the shareholder holding such options, warrants, or conversion rights. The percentage ownership of any shareholder is determined by assuming that the shareholder has exercised all options, warrants and conversion rights to obtain additional securities and that no other shareholder has exercised such rights.

(2) Anil Diwan, the Company’s President and Chairman, also serves as the CEO and Director of TheraCour Pharma Inc. and owns approximately 70% of the outstanding capital stock of TheraCour. Anil Diwan has both investment and dispositive power over the NanoViricides shares held by TheraCour Pharma, Inc. Does not include

2,000,000 shares of the Company’s Series A Preferred Stock (the “Series A”) which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.

(3) Anil Diwan, President and Chairman of the Board of Directors. Includes 285,714 shares of common stock issuable upon exercise of options held by Dr. Diwan that are currently exercisable or will become exercisable within 60 days. Does not include 16,531,429 shares owned by TheraCour Pharma, Inc. (after calculating the Series A Convertible Preferred Stock (the “Series A Preferred Stock”), over which Dr. Diwan holds voting and dispositive power. Does not include 500,000 shares of Series A Preferred Stock which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.

(4) Eugene Seymour, Chief Executive Officer and Director. Includes 1,571429 shares of NanoViricides common stock held by Dr. Seymour and 142,857 shares of NanoViricides common stock issuable upon exercise of options held by Dr. Seymour that are currently exercisable or will become exercisable within 60 days. . Does not include 250,001 shares of the Company’s Series A Preferred Stock (the “Series A”) which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock.

(5) Milton Boniuk, Independent Member of the Board of Directors. Includes 658,963 shares of common stock and warrants to purchase an additional 542,856 shares of common stock, held by Milton Boniuk and his wife Laurie. Does not include 190,477 shares of common stock held by the Boniuk Charitable Foundation, and 314,286 shares of common stock and warrants to purchase 257,142 shares of common stock currently exercisable held by Boniuk Interests Ltd. Does not include 952,381 shares of common stock issuable upon conversion of a 10% Coupon Series C Convertible Debenture or 187,000 shares of Series A Preferred Stock held by Milton Boniuk IRA. Does not include an indeterminate number of shares of common stock issuable upon conversion of debentures held by Boniuk Interests Ltd. Dr. Boniuk holds voting and dispositive power over the Boniuk Charitable Foundation and Boniuk Interests Ltd.

(6) Includes 26,001 shares held by Connect Capital LLC, over which Ms. Vytas holds voting and dispositive power. Does not include 38,572 shares of Series A Preferred Stock.

EMPLOYMENT AGREEMENTS

On May 30, 2013, the Company and Meeta Vyas, its Interim Chief Financial Officer, agreed that during the term of Ms. Vyas’ service, she will be compensated on the basis of $9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. Ms. Vyas is married to Anil Diwan, the President and Chairman of the Company.

On 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. The Compensation Committee of the Board of Directors extended the current provisions of these Employment Agreements pending its review of the current industry compensation arrangements and Employment agreements

As additional compensation under the employment agreements, the Company issued 71,429 shares of the Company’s Series A Preferred Stock and shall issue an additional 71,429 shares of Series A 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 26,786 shares of Series A Preferred Stock and 35,714 shares of common stock, and will issue an additional 26,786 shares of Series A Preferred Stock and 35,714 shares of common stock on each anniversary date of the agreement. The Compensation Committee of the Board of Directors extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements

On March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provides for term of four years with a base salary of $150,000. In addition, the Company issued 35,714 shares of common stock, and will issue an additional 35,714 shares of common stock on each anniversary date of the agreement. The Compensation Committee of the Board of Directors extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements

COMPENSATION OF DIRECTORS

At this time, directors, who are officers of the Company, receive no remuneration for their services as directors of the Company. The Company reimburses directors for expenses incurred in their service to the Board of Directors. The Company o pays fees to its independent directors for the 2014 fiscal year of $30,000 to each Director, of which half is to be paid in the Company's common stock .

COMPENSATION OF SCIENTIFIC ADVISORY BOARD

The Company anticipates holding four Scientific Advisory Board meetings per annum. As compensation, each member of the Scientific Advisory Board (SAB) will be granted each quarter 10,000 warrants to purchase the Company's common stock at 120% of the Company's closing stock quote on the day following the meeting. Should the Company not call a quarterly meeting, quarterly options will be granted on May 15, August 15, November 15, and February 15. The warrants have a four year expiration date. In addition the Company will reimburse each SAB member for travel and other out-of-pocket expenses incurred in the course of performing their services. [For the year ended June 30, 2014, the SAB was granted a total of 68,572 stock warrants exercisable into common shares at prices from $ 3.79 to $ 6.56 per share.]

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

On June 2, 2012, Stanley Glick, CPA was appointed as an independent member of our Board of Directors. Up until that time we did not have any independent directors on our Board of Directors, and therefore had no formal procedures in effect for reviewing and pre-approving any transactions between us, our directors, officers and other affiliates. We have used and will continue to use our best efforts to insure that all transactions are on terms at least as favorable to the Company as we would negotiate with unrelated third parties.

On February 1, 2013, Dr. Boniuk and entities over which Dr. Boniuk has voting and dispositive power subscribed for $4,000,000 of the Company's Unsecured 8% Coupon Series B Convertible Debentures. Subsequent to the reporting period, on September 10, 2013, Dr. Boniuk and entities affiliated to him subscribed to $3,000,000 of the Company's units issued in a registered direct offering. On June 2, 2014 the Company accepted a subscription from Dr. Boniuk to invest $5,000,000 in the Company's Series C Convertible Debenture.

On May 13, 2013, Meeta Vyas was appointed its interim Chief Financial Officer. During the term of Ms. Vyas' service, she will be compensated on the basis of $9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. Ms. Vyas is married to Anil Diwan, the President and Chairman of the Company.

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TheraCour Pharma, Inc.

On May 12, 2005, the Company entered into a Material License Agreement, amended as of January 8, 2007 (the "License") with TheraCour Pharma, Inc., ("TheraCour"), our largest shareholder. As of the present, TheraCour granted the Company an exclusive license in perpetuity for technologies developed by TheraCour for six virus types: HIV, HCV, Herpes, Rabies, Asian (bird) flu and Influenza. In consideration for obtaining this exclusive license, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of direct costs as a development fee and such development fees shall be due and payable in periodic installments as billed; (2) to pay $25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour; (3) to pay the greater of $2,000 or actual costs, for other general and administrative expenses incurred by TheraCour on our behalf; (4) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour; (5) that TheraCour Pharma, Inc. shall retain the exclusive right to develop and synthesize nanomicelle(s), a small (approximately twenty nanometers in size) long chain polymer based chemical structure, as component elements of the Licensed Products. TheraCour agreed that it will develop and synthesize such nanomicelles, to be used for the Licensed Products, exclusively for NanoViricides, and unless such license is terminated, will not develop or synthesize the nanomicelles to be used for the Licensed product for its own sake or for others; and (6) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. TheraCour may terminate the License upon a material breach by us as specified in the agreement. However, the Company has the opportunity to cure the breach within 90 days of receipt of notice to terminate the License. On February 15, 2010, the Company approved an Additional License Agreement with TheraCour Pharma, Inc. ("TheraCour"). Pursuant to the exclusive Additional License Agreement, in consideration for the issuance of 2,000,000 shares of the Company's Series A Preferred Stock, (the "Series A Preferred"), the Company was granted exclusive licenses, in perpetuity, for technologies, developed by TheraCour, for the development of drug candidates for the treatment of Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes.

Development costs charged by and paid to TheraCour Pharma, Inc. were $2,483,987, $1,988,046, and 2,965,030 for the fiscal years ended June 30, 2014, 2013 and 2012, respectively. No royalties are due or have been paid from inception through June 30, 2014.

As of June 30, 2014, TheraCour owns 9,531,429 shares of the Company's outstanding common stock and 2,000,000 shares of Series A Preferred. Anil Diwan, the Company's President and Chairman, also serves as the CEO and Director of TheraCour and owns approximately 70% of the outstanding capital stock of TheraCour.

KARD Scientific, Inc.

In June 2005, the Company engaged KARD Scientific to conduct pre clinical human influenza animal (mouse) studies and provide the Company with a full history of the study and final report with the data collected. This project is on-going. NanoViricides has a fee for service arrangement with KARD. We do not have an exclusive arrangement with KARD; we do not have a contract with KARD; all work performed by KARD must have prior approval of the executive officers of NanoViricides; and we retain all intellectual property resulting from the services by KARD. Dr.

Krishna Menon, the Company's Chief Regulatory Officer-Consulting, a non-executive officer position, is also an officer and principal owner of KARD Scientific. The Lab fees charged by KARD Scientific for services were $314,156, $1,035,983, and $507,500 for the fiscal years ended June 30, 2014, 2013 and 2012 respectively, and $ 3,210,276 since inception. Dr. Menon has resigned as our Chief Regulatory Officer-Consulting, a non-executive officer position, in 2014 due to personal health reasons. Dr. Randall W. Barton, our Chief Scientific Officer, has taken over the duties of Acting Regulatory Officer.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees for each of the last two years for professional services rendered by the principal accountant for our audits of our annual financial statements and interim reviews of our financial statements included in our fillings 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, 2014	$112,500	Li and Company, P.C.
June 30, 2013	$109,850	Li and Company, P.C.

Audit Related Fees

The aggregate fees in each of the last two years for the assurance and related services provided by the principal accountant that are not reasonably related to the performance of the audit or review of the Company's financial statements and are not reported in paragraph (1) were approximately:

June 30, 2014	$0	Li and Company, P.C.
June 30, 2013	$0	Li and Company, P.C.

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

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

June 30, 2014	$0	Li and Company, P.C.
June 30, 2013	$0	Li and Company, P.C.

<u>All Other Fees</u>

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

June 30, 2014	$0	Li and Company, P.C.
June 30, 2013	$0	Li and Company, P.C.

<u>Pre-Approval Policies</u>

The Board of Directors, and the Audit Committee appointed by the Board, currently do not have any pre-approval policies or procedures concerning services performed by Li and Company, P.C. All the services performed by Li and Company, P.C. as described above were pre-approved by the Audit Committee.

ITEM 15 . EXHIBITS

Exhibit No.	Description
3.1*	Articles of Incorporation, as amended, of the Registrant
3.2*	By-laws of the Registrant
4.1*	Specimen Stock Certificate of the Registrant
4.2*	Series A Convertible Debenture
4.3*	Form of Warrant
10.1*	Share Exchange Agreement between NanoViricide, Inc. and the Registrant
10.2*	Employment Agreement Eugene Seymour
10.3*	Employment agreement Anil Diwan
10.4*	Employment agreement Leo Ehrlich
10.5*	Form of Scientific Advisory Board Agreement

10.6*	Amended License Agreement with TheraCour Pharma, Inc.
10.7*	Lease with landlord
10.8*	Form of First Subscription Agreement
10.9*	Form of Second Subscription Agreement
10.10*	Code of Ethics
10.11*	Amended Agreement #2 with TheraCour Pharma, Inc.
10.12*	Memorandum of Understanding with Vietnam's National Institute of Hygiene and Epidemiology (NIHE) dated December 23, 2005
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2	Certification of Interim Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1	Certification of Chief Executive Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of 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.

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: February 23, 2015

NANOVIRICIDES, INC.

/s/ Eugene Seymour, MD
Name: Eugene Seymour, M.D.
Title: Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Meeta Vyas
Name: Meeta Vyas
Title: Interim Chief Financial Officer

(Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

February 23, 2015	*\/s/ Eugene Seymour, MD* Name: Eugene Seymour, MD Title: Chief Executive Officer and Interim Chief Financial Officer and Director (Principal Executive Officer)
February 23, 2015	*/s/ Anil Diwan* Name: Anil Diwan Title: President and Chairman of the Board of Directors
February 23, 2015	*/s/ Meeta Vyas* Name: Meeta Vyas Title: Interim Chief Financial Officer

(Principal Accounting Officer)

February 23, 2015	*/s/ Milton Boniuk* Name: Milton Boniuk Title: Director
February 23, 2015	*/s/ Mukund Kulkarni* Name: Mukund Kulkarni Title: Director
February 23, 2015	*/s/ Stanley Glick* Name: Stanley Glick Title: Director

NanoViricides, Inc.

June 30, 2014 and 2014

Index to the Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

NanoViricides, Inc.

West Haven, Connecticut

We have audited the accompanying balance sheets of NanoViricides, Inc. (the "Company") as of June 30, 2014 and 2013 and the related statements of operations, stockholders' equity and cash flows for each of the three fiscal years in the period ended June 30, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2014 and 2013 and the results of its operations and its cash flows for each of the three fiscal years in the period ended June 30, 2014 in conformity with U.S. generally accepted accounting principles.

The Company's balance sheet as of June 30, 2014 and the related statements of operations, stockholder's equity and cash flows for the fiscal year ended June 30, 2014 have been restated. The restatements of the financial statements are described in Note 2.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of June 30, 2014, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway

Commission, and our report dated September 29, 2014 (February 23, 2015, as to the effects of the material weakness described in Management’s Report on Internal Control Over Financial Reporting, as revised), expressed an adverse opinion on the effectiveness of the Company’s internal control over financial reporting because of the material weakness.

/s/ Li and Company, PC

Skillman, New Jersey

September 29, 2014

(Except for Notes 2 which are dated February 23, 2015)

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NanoViricides, Inc.

Balance Sheets

	June 30, 2014 (Restated)	June 30, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 36,696,892	$ 13,923,245
Prepaid expenses	108,089	51,597
Prepaid expenses - related parties	709,221	546,783
Other current assets	150,000	-
Total Current Assets	37,664,202	14,521,625
PROPERTY AND EQUIPMENT		
Property and equipment	6,736,742	1,505,648
Accumulated depreciation	(1,239,986)	(1,036,752)
Property and equipment, net	5,496,756	468,896
TRADEMARK and PATENTS		
Trademark	458,954	458,954
Accumulated amortization	(50,696)	(41,921)
Trademark and Patents, net	408,258	417,033
SECURITY DEPOSIT	1,000,000	1,000,000
Total Assets	$ 44,569,216	$ 16,407,554
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 376,446	$ 263,258
Accounts payable – related parties	758,676	710,567
Accrued expenses	91,838	204,359
Total Current Liabilities	1,226,960	1,178,184
LONG TERM LIABILITIES:		
Debentures payable - Series B Net of discount	4,037,568	3,468,073
Derivative liability	5,699,703	3,751,645
Debenture subscription deposit	5,000,000	-
Derivative liability - Warrants	5,235,682	-

Total Long Term Liabilities	19,972,953	7,219,718
Total Liabilities	21,199,913	8,397,902
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, $0.001 par value, 4,000,000 shares designated, 3,193,079, and 2,990,000 shares issued and outstanding, respectively	3,194	2,990
Series B Convertible Preferred stock, $0.001 par value, 10,000,000 shares designated, none issued and outstanding	-	-
Series C Convertible Preferred stock, $0.001 par value, 10,000,000 shares designated, none issued and outstanding	-	-
Common stock, $0.001 par value; 85,714,286 shares authorized; 54,620,993, and 47,026,173 shares issued and outstanding, respectively	54,621	47,026
Additional paid-in capital	75,212,888	46,259,420
Accumulated Deficit	(51,901,400)	(38,299,784)
Total Stockholders' Equity	23,369,303	8,009,652
Total Liabilities and Stockholders' Equity	$ 44,569,216	$ 16,407,554

See accompanying notes to the financial statements

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NanoViricides, Inc.

Statement of Operations

	For the Fiscal Year Ended June 30, 2014 (Restated)	For the Fiscal Year Ended June 30, 2013	For the Fiscal Year Ended June 30, 2012
OPERATING EXPENSES			
Research and development	$ 5,131,523	$ 4,292,909	$ 4,265,933
Refund credit research and development costs	-	-	-
General and administrative	3,535,849	2,297,470	1,815,816
Total operating expenses	8,667,372	6,590,379	6,081,749
LOSS FROM OPERATIONS	(8,667,372)	(6,590,379)	(6,081,749)
OTHER INCOME (EXPENSE):			
Interest income	171,001	55,587	46,787
Interest Expense	(3,092,550)	(962,535)	
Discount on convertible debentures	(569,495)	(129,006)	-
Beneficial conversion feature of convertible debentures	-	-	-
Change in fair market value of derivatives	(1,443,200)	(1,249,335)	(172,245)
Other income (expense), net	(4,934,244)	(2,285,289)	(125,458)
LOSS BEFORE INCOME TAXES	(13,601,616)	(8,875,668)	(6,207,207)
INCOME TAX PROVISION	-	-	-
NET LOSS	$ (13,601,616)	$ (8,875,668)	$ (6,207,207)
NET LOSS PER COMMON SHARE - BASIC AND DILUTED:	$ (0.27)	$ (0.19)	$ (0.15)
Weighted average common shares outstanding - basic and diluted	51,225,818	45,892,549	42,763,481

See accompanying notes to the financial statements

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NanoViricides, Inc.

Statement of Stockholders' Equity

For the period from July 1, 2011 through June 30, 2014

(Restated)

	Series A Preferred Stock: Par $0.001		Series B Preferred Stock: Par $0.001		Series C Preferred Stock: Par $0.001		Common Stock: Par $0.001		Additional
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital
Balance, June 30, 2011	2,347,857	2,348	2,857	3	-	-	41,013,828	41,012	33,344,43
Common shares issued for conversion of Series B Preferred Shares at $1.11 per share, July 11, 2011							25,710	26	64
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, July 11, 2011			(2,857)	(3)			-		(7
Derivative liability - retirement of Series B Preferred Shares, July 11, 2011							-		17,881
Dividend to Seaside 88, LP, paid on July 11, 2011							-		(381

Common shares issued as dividend to Seaside 88, LP at $1.18 per share, July 11, 2011			99	-	381
Series B Preferred Shares issued to SeaSide 88, LP, on July 26, 2011	71,429	71	-		2,499,929
Placement Agents fees related to sale of Convertible Preferred shares, July 26, 2011			-		(150,000
Derivative liability - issuance of Series B Preferred Shares			-		(429,768
Legal Fees related to Sale of Convertible Preferred Stock, July 26, 2011			-		(6,250
Common shares issued in conversion of Series B Preferred Shares to common stock at $1.18 per share, July 26, 2011			107,943	108	270
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, July 26, 2011	(11,429)	(11)	-		(29
Derivative liability - retirement of Series B Preferred Shares, July 26, 2011			-		68,425
Common shares issued for			1,361	1	5,999

consulting and legal services valued at $1.26 per share, July 31, 2011					
Warrants issued to Scientific Advisory Board, August 15, 2011			-		56,400
Common shares issued for conversion of Series B Preferred Shares at $0.92 per share, August 8, 2011			124,911	125	312
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, August 8, 2011	(11,428)	(12)	-		(28
Derivative liability - retirement of Series B Preferred Shares, August 8, 2011			-		69,193
Dividend to Seaside 88, LP, paid on August 8, 2011			-		(8,055
Common shares issued as Dividend to Seaside 88, LP at $0.98 per share, August 8, 2011			2,345	2	8,053
Common shares issued for conversion of Series B Preferred Shares at $0.95 per share, August 23, 2011			119,951	120	300
Retirement of Series B Preferred Shares	(11,429)	(11)	-		(29

converted into common stock by SeaSide 88, LP, August 23, 2011					
Derivative liability - retirement of Series B Preferred Shares, August 23, 2011			-		69,351
Dividend paid to Seaside 88, LP, August 23, 2011			-		(6,521
Common shares issued as Dividend to Seaside 88, LP at $0.95 per share, August 23, 2011			1,955	2	6,519
Common shares issued for consulting and legal services valued at $1.14 per share, August 31, 2011			1,504	2	5,998
Common shares issued for conversion of Series B Preferred Shares at $0.95 per share, September 6, 2011			120,821	121	302
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, September 6, 2011	(11,428)	(12)	-		(28
Derivative liability - retirement of Series B Preferred Shares, September 6, 2011			-		69,887
Dividend paid to Seaside 88, LP,			-		(4,986

September 6, 2011					
Common shares issued as Dividend to Seaside 88, LP at $0.95 per share, September 6, 2011			1,504	2	4,984
Common shares issued in conversion of Series B Preferred Shares at $0.94 per share, September 19, 2011			122,186	122	306
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, September 19, 2011	(11,429)	(11)	-		(29
Derivative liability - retirement of Series B Preferred Share, September 19, 2011			-		69,970
Dividend to Seaside 88, LP, paid on September 19, 2011			-		(3,452
Common shares issued as Dividend to Seaside 88, LP at $0.94 per share, September 19, 2011			1,055	-	3,452
Common shares issued for consulting and legal services valued at $1.07 per share, September 30,			1,602	2	5,998

2011					
Shares issued in conversion of Series B Preferred Shares to Common Stock at $.78 per share, .001 par value, on October 3, 2011			146,946	147	367
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on October 3, 2011	(11,428)	(12)	-	-	(28
Derivative Liability - Retirement of Preferred Series B on October 3, 2011			-	-	69,496
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.85 on October 3, 2011			649	1	1,917
Dividend to Seaside 88, LP, paid on October 3, 2011			-	-	(1,918
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.69 per share, .001 par value, on October 17, 2011			41,281	41	103
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on	(2,857)	(3)	-	-	(7

October 17, 2011 Derivative Liability - Retirement of Preferred Series B on October 17, 2011			-	-	17,790
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.75 on October 17, 2011			146	-	384
Dividend to Seaside 88, LP, paid on October 17, 2011			-	-	(384
Shares issued for consulting and legal services rendered at $0..92 per share on October 31, 2011			1,868	2	5,998
Series B Preferred Shares issued to SeaSide 88, LP, $.001 par value on November 1, 2011	71,429	71	-	-	2,499,929
Placement Agents Fees related to sale of Convertible Preferred shares on November 1, 2011			-	-	(160,000
Derivative Liability - Issuance of Preferred Series B			-	-	(429,804
Legal Fees related to Sale of Convertible Preferred Stock November 1, 2011			-	-	(25,000
			146,225	146	366

Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.78 per share, .001 par value, on November 1, 2011					
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on November 2, 2011	(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of Preferred Series B on November 1, 2011			-	-	68,297
Warrants issued to Scientific Advisory Board on November 15, 2011			-	-	56,400
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.69 per share, .001 par value, on November 15, 2011			165,313	165	414
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on November 15, 2011	(11,428)	(12)	-	-	(28
Derivative Liability -			-	-	68,411

Retirement of Preferred Series B on November 15, 2011					
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0..73 onNovember 15, 2011			2,946	3	7,476
Dividend to Seaside 88, LP, paid on November 15, 2011			-	-	(7,479
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.62 per share, .001 par value, on November 29, 2011			183,639	184	459
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on November 29, 2011	(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of Preferred Series B on November 29, 2011			-	-	68,591
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.64 on November 29, 2011			2,897	3	6,518
			-	-	(6,521

Dividend to Seaside 88, LP, paid on November 29, 2011					
Shares issued for consulting and legal services rendered at $0.81 per share on November 30, 2011			2,107	2	5,998
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.53 per share, .001 par value, on December 13, 2011			214,661	215	536
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on December 13, 2011	(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of Preferred Series B on December 13, 2011			-	-	68,753
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.57 on December 13, 2011			2,514	3	4,983
Dividend to Seaside 88, LP, paid on December 13, 2011			-	-	(4,986
			227,653	228	570

Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.51 per share, .001 par value, on December 27, 2011					
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on December 27, 2011	(11,428)	(12)	-	-	(28
Derivative Liability - Retirement of Preferred Series B on December 27, 2011			-	-	68,965
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.57 on December 27, 2011			1,948	2	3,448
Dividend to Seaside 88, LP, paid on December 27, 2011			-	-	(3,452
Shares issued for consulting and legal services rendered at $0.64 per share on December 31, 2011			2,687	3	5,997
Shares issued in conversion of Series B Preferred Shares to Common Stock at $.51 per			225,158	225	563

share, .001 par value, on January 10, 2012					
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on January 10, 2012	(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of Preferred Series B on January 10, 2012			-	-	69,222
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.51 onJanuary 10, 2012			1,069	1	1,917
Dividend to Seaside 88, LP, paid on January 10, 2012			-	-	(1,918
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.48 per share, .001 par value, on January 24, 2012			59,585	60	149
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on January 24, 2012	(2,857)	(3)	-	-	(7
Derivative Liability - Retirement of Preferred Series B on January 24, 2012			-	-	69,883

Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.49 on January 24, 2012			225	-	384
Dividend to Seaside 88, LP, paid on January 24, 2012			-	-	(384
Shares issued for consulting and legal services rendered at $0.58 per share on January 31, 2012			2,962	3	5,997
Series B Preferred Shares issued to SeaSide 88, LP, $.001 par value on February 8, 2012	71,429	71	-	-	2,499,929
Placement Agents Fees related to sale of Convertible Preferred shares on February 8, 2012			-	-	(150,000
Derivative Liability - Issuance of Preferred Series B			-	-	(430,283
Legal Fees related to Sale of Convertible Preferred Stock February 8, 2012			-	-	(6,250
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.56 per share, .001 par value, on February 8, 2012			204,898	205	512
Retirement of Series B	(11,429)	(11)	-	-	(29

Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on February 8, 2012					
Derivative Liability - Retirement of Preferred Series B on February 8, 2012			-	-	68,169
Warrants issued to Scientific Advisory Board on February 15, 2012			-	-	51,000
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.69 per share, .001 par value, on February 22, 2012			164,589	165	411
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on February 22, 2012	(11,428)	(12)	-	-	(28
Derivative Liability - Retirement of Preferred Series B on February 22, 2012			-	-	68,423
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.69 on February 22, 2012			3,314	3	7,476

Dividend to Seaside 88, LP, paid on February 22, 2012					-	-	(7,479
					-	-	-
Shares issued for consulting and legal services rendered at $0.77 per share on February 29, 2012					2,219	2	5,998
Common shares issued for employee stock compensation at $.73 per share, March 3, 2012					71,429	71	181,803
Series A Preferred Shares issued for employee stock compensation, March 3, 2012	169,643	169			-	-	634,239
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.64 per share, .001 par value, on March 07, 2012					179,511	180	448
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on March 7, 2012			(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of Preferred Series B on March 7, 2012					-	-	68,602
Shares issued as Dividend to Seaside 88, LP, .001 par value					2,926	3	6,518

common stock at $0.64 on March 7, 2012					
Dividend to Seaside 88, LP, paid on March 7, 2012			-	-	(6,521
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.63 per share, .001 par value, on March 21, 2012			181,712	182	454
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on March 21, 2012	(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of Preferred Series B on March 21, 2012			-	-	68,862
			-	-	-
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.64 on March 21, 2012			2,232	2	4,984
Dividend to Seaside 88, LP, paid on March 21, 2012			-	-	(4,986
Shares issued for consulting and legal services rendered at $0.78 per share on March 31, 2012			2,208	2	5,998
Shares issued in conversion of Series B			188,999	189	472

Preferred Shares to Common Stock at $.61 per share, .001 par value, on April 4, 2012					
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on April 4, 2012	(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of Preferred Series B on April 4, 2012			-	-	69,098
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.61 on April 4, 2012			1,631	2	3,450
Dividend to Seaside 88, LP, paid on April 4, 2012			-	-	(3,452
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.51 per share, .001 par value, on April 18, 2012			224,415	224	561
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on April 18, 2012	(11,429)	(11)	-	-	(29
Derivative Liability - Retirement of			-	-	69,224

Preferred Series B on April 18, 2012					
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.54 on April 18, 2012			1,023	1	1,917
Dividend to Seaside 88, LP, paid on April 18, 2012			-	-	(1,918
Shares issued for consulting and legal services rendered at $0.63 per share on April 30, 2012			2,728	3	5,997
Shares issued in conversion of Series B Preferred Shares to Common Stock at $0.50 per share, .001 par value, on May 2, 2012			56,673	57	142
Retirement of Series B Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on May 2, 2012	(2,857)	(3)	-	-	(7
Derivative Liability - Retirement of Preferred Series B on May 2, 2012			-	-	69,892
Warrants issued to Scientific Advisory Board on May 15, 2012			-	-	47,400
Shares issued as Dividend to Seaside 88, LP, .001 par value			215	-	384

common stock at $0.51 on May 2, 2012							
Dividend to Seaside 88, LP, paid on May 2, 2012					-	-	(384
Shares issued for consulting and legal services rendered at $0.67 per share on May 31, 2012					2,561	3	5,997
Series A Preferred Shares amendment of valuation arising from Amendment of certificate of Designation on June 26, 2012					-	-	-
Series C Preferred Shares issued to SeaSide 88, LP, $.001 par value on June 28, 2012			714	1	-	-	2,499,999
Placement Agents Fees related to sale of Convertible Preferred shares on June 28, 2012					-	-	(150,000
Derivative Liability - Issuance of Preferred Series C					-	-	(1,090,017
Legal Fees related to Sale of Convertible Preferred Stock June 28, 2012					-	-	(25,000
Sharees of Series A Preferred issued for legal services rendered	2,857	3			-	-	3,284
Shares issued in conversion of Series C					85,278	85	213

Preferred Shares to Common Stock at $0.49 per share, .001 par value, on June 28, 2012									
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on June 28, 2012					(42)	-	-	-	-
Derivative Liability - Retirement of Preferred Series C on June 28, 2012							-	-	63,704
Series A Preferred Shares issued for employee stock compensation, June 28, 2012	300,000	300					-	-	344,872
Shares issued for consulting and legal services rendered at $0.61 per share on June 30, 2012							2,814	2	5,997
Net loss for the year ended June 30, 2012							-	-	-
Balance, June 30, 2012	2,820,357	2,820	-	-	672	1	44,460,629	44,460	43,227,028
Shares issued in conversion of Series C Preferred Shares to Common Stock at $.49 per share, .001 par value, on July 12, 2012							60,685	61	151
					(29)	-	-	-	-

Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value onJuly 12, 2012				
Derivative Liability - Retirement of Preferred Series C on July 12, 2012		-	-	44,190
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.49 on JULY 12, 2012		5,256	5	9,021
Dividend to Seaside 88, LP, paid on July 12, 2012		-	-	(9,026
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.47 per share, .001 par value, on July 26, 2012		77,535	78	193
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on July 26, 2012	(37)	-	-	-
Derivative Liability - Retirement of Preferred Series B on July 26, 2012		-	-	53,032
Shares issued as Dividend to Seaside 88, LP,		5,221	5	8,624

.001 par value common stock at $0.47 on July 26, 2012				
Dividend to Seaside 88, LP, paid on July 26, 2012		-	-	(8,629
Shares issued for consulting and legal services rendered at $0.55 per share on July 31, 2012		3,117	3	5,997
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.42 per share, .001 par value, on August 8, 2012		80,270	80	201
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on August 8, 2012	(34)	-	-	-
Derivative Liability - Retirement of Preferred Series C on August 8, 2012		-	-	51,555
Warrants issued to Scientific Advisory Board on August 15, 2012		-	-	40,800
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.43 on August 8, 2012		5,391	5	8,133
Dividend to Seaside 88, LP,		-	-	(8,138

paid on August 8, 2012				
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.48 per share, .001 par value, on August 23, 2012		164,226	164	411
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on August 23, 2012	(79)	-	-	-
Derivative Liability - Retirement of Preferred Series C on August 23, 2012		-	-	121,054
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.43 on August 23, 2012		4,573	5	7,679
Dividend to Seaside 88, LP, paid on August 23, 2012		-	-	(7,684
Shares issued for consulting and legal services rendered at $0.58 per share on August 31, 2012		2,956	3	5,997
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.58 per share, .001 par value, on September 5,		218,039	218	545

2012					
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on September 5, 2012	(126)	(1)	-	-	-
Derivative Liability - Retirement of Preferred Series C on September 5, 2012			-	-	236,481
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.58 on September 5, 2012			3,279	3	6,622
Dividend to Seaside 88, LP, paid on September 5, 2012			-	-	(6,625
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.52 per share, .001 par value, on September 19, 2012			158,096	158	395
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on September 19, 2012	(81)	-	-	-	-
Derivative Liability - Retirement of			-	-	182,575

Preferred Series C on September 19, 2012				
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.52 on September 19, 2012		2,735	3	4,933
Dividend to Seaside 88, LP, paid on September 19 2012		-	-	(4,936
Shares issued for consulting and legal services rendered at $0.62 per share on September 30, 2012		2,765	3	5,997
Shares issued in conversion of Series C Preferred Shares to Common Stock at $.54 per share, .001 par value, on October 3, 2012		124,526	125	311
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on October 3, 2012	(67)	-	-	-
Derivative Liability - Retirement of Preferred Series C on October 3, 2012		-	-	39,945
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at		2,050	2	3,840

$0.54 on October 3, 2012				
Dividend to Seaside 88, LP, paid on October 3, 2012		-	-	(3,842
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.53 per share, .001 par value, on October 17, 2012		89,006	89	223
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on October 17, 2012	(47)	-	-	-
Derivative Liability - Retirement of Preferred Series C on October 3, 2012		-	-	28,413
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.53 on October 17, 2012		1,586	2	2,946
Dividend to Seaside 88, LP, paid on October 17, 2012		-	-	(2,948
Shares issued for consulting and legal services rendered at $0.61 per share on October 31, 2012		4,751	5	9,995
Shares issued in conversion of Series C Preferred Shares to Common		80,385	80	201

Stock at $0.52 per share, .001 par value, on October 31, 2012				
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on October 31, 2012	(41)	-	-	-
Derivative Liability - Retirement of Preferred Series C on October 31, 2012		-	-	24,955
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.53 on October 31, 2012		1,280	1	2,312
Dividend to Seaside 88, LP, paid on October 31, 2012		-	-	(2,313
Warrants issued to Scientific Advisory Board on November 15, 2012		-	-	34,200
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.43 on November 14, 2012		1,092	1	1,755
Dividend to Seaside 88, LP, paid on November 14, 2012		-	-	(1,756
Shares issued in conversion of Series C		109,470	109	274

Preferred Shares to Common Stock at $0.43 per share, .001 par value, on November 14, 2012				
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on November 14, 2012	(47)	-	-	-
Derivative Liability - Retirement of Preferred Series C on November 14, 2012		-	-	28,407
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.44 on November 29, 2012		734	1	1,120
Dividend to Seaside 88, LP, paid on November 29, 2012		-	-	(1,121
Shares issued for consulting and legal services rendered at $0.53 per share on November 30, 2012		3,774	4	6,996
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.44 per share, .001 par value, on November 29,		111,628	112	279

2012					
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on November 29, 2012	(49)		-	-	(1
Derivative Liability - Retirement of Preferred Series C on November 29, 2012			-	-	29,302
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.43 on December 13, 2012			309	-	468
Dividend to Seaside 88, LP, paid on December 13, 2012			-	-	(468
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.43per share, .001 par value, on December 13, 2012			80,680	81	201
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on December 13, 2012	(35)	-	-	-	-
Derivative Liability - Retirement of			-	-	20,953

Preferred Series C on December 13, 2012				
Series C Preferred Shares issued to SeaSide 88, LP, $.001 par value on December 21, 2012	714	-	-	2,541,872
Placement Agents Fees related to sale of Convertible Preferred shares on December 21, 2012		-	-	(165,000
Derivative Liability - Issuance of Preferred Series C		-	-	-
Legal Fees related to Sale of Convertible Preferred Stock December 21, 2012		-	-	(12,500
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.44 per share, .001 par value, on December 21, 2012		102,080	102	255
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on December 21, 2012	(45)	-	-	-
Derivative Liability - Retirement of Preferred Series		-	-	24,686

C on December 21, 2012				
Shares issued for consulting and legal services rendered at $0.50 per share on December 31 , 2012		4,000	4	6,996
Shares issued to a Director for services rendered at $0.55 per share on December 31 , 2012		2,581	3	4,997
Shares issued in conversion of Series C Preferred Shares to Common Stock at $..41 per share, .001 par value, on January 4, 2013		99,998	100	250
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on january 4, 2013	(41)	-	-	-
Derivative Liability - Retirement of Preferred Series C on January 4, 2013		-	-	22,488
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.41 on Jamuary 4, 2013		6,259	6	8,986
Dividend to Seaside 88, LP, paid on January 4,2013		-	-	(8,992
Shares issued in conversion of		110,842	111	277

Series C Preferred Shares to Common Stock at $0.42 per share, .001 par value, on January 17, 2013				
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on January 17, 2013	(47)	-	-	-
Derivative Liability - Retirement of Preferred Series C on January 17, 2013		-	-	26,329
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0..42on January 17, 2013		5,714	6	8,435
Dividend to Seaside 88, LP, paid on January 17, 2013		-	-	(8,441
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0..42 per share, .001 par value, on January 31, 2013		78,797	79	197
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on January 31, 2013	(32)	-	-	-
		-	-	18,502

Derivative Liability - Retirement of Preferred Series C on January 31, 2013			
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.41 on January 31, 2013	5,400	5	7,808
Dividend to Seaside 88, LP, paid on January 31, 2013	-	-	(7,813
Shares issued for consulting and legal services rendered at $0.49 per share on January 31, 2013	4,082	4	6,996
Shares issued at $0.48 in payment of Debenture interest on February 1, 2013	571,429	571	664,926
Warrants issued to Scientific Advisory Board on February 15, 2013	-	-	31,800
Shares issued as Dividend to Seaside 88, LP, .001 par value common stock at $0.41 on February 14, 2013	5,172	5	7,371
Dividend to Seaside 88, LP, paid on February 14, 2013	-	-	(7,376
Shares issued in conversion of Series C Preferred Shares to Common Stock at $0.41	68,875	69	172

per share, .001 par value, on February 14, 2013						
Retirement of Series C Preferred Shares converted into common stock by SeaSide 88, LP, .001 par value on February 14, 2013			(27)	-	-	-
Derivative Liability - Retirement of Preferred Series C on February 14, 2014				-	-	15,985
Redemption of Series C Convertible Preferred on February 26, 2013			(522)		-	(1,714,334
Dividend to Seaside 88, LP, paid on February 26, 2013				-	-	(6,002
Shares issued for consulting and legal services rendered at $0.46per share on February 28, 2013				4,348	4	6,996
Derivative Liability - Redemption of Preferred Series C on February 26, 2013				-	-	42
Common shares issued for employee stock compensation at $..48 per share, March 1, 2013				71,428	71	59,929
Series A Preferred Shares issued for	169,643	170		-	-	444,874

employee stock compensation, March 1, 2013			
Shares issued for consulting and legal services rendered at $0.65 per share on March 31, 2013	3,077	3	6,997
Shares issued to a Director for services rendered at $0.53 per share on March 31, 2013	1,348	2	2,498
Shares issued for consulting and legal services rendered at $0.48 per share on April 1, 2013	569	1	959
Shares issued for consulting and legal services rendered at $0.49 per share on April 30, 2013	3,175	3	6,997
Warrants issued to Scientific Advisory Board on May 15, 2013	-	-	34,800
Shares issued for consulting and legal services rendered at $0.46per share on May 31, 2013	3,333	3	6,997
Shares issued for consulting and legal services rendered at $0.65 per share on June 30, 2013	3,030	3	6,993
Shares issued for Directors fees at $0.70 pershare on June 30, 2013	4,592	5	11,245
Net loss		-	-

Balance, June 30, 2013	2,990,000	2,990	-	-	-	-	47,026,173	47,026	46,259,42(
Shares issued for consulting and legal services rendered at $1.93 per share on July 31, 2013							3,627	4	6,996
Warrants issued to Scientific Advisory Board on August 15, 2013							-	-	106,050
Shares issued for consulting and legal services rendered at $2.03 per share on August 31, 2013							3,449	4	6,996
Common shares and warrants issued in connection with private placement of common stock, September 10, 2013							2,945,428	2,945	10,306,05
Costs associated with sale of Securities									(113,696
Warrants issued for commissions, September 10, 2013							-	-	113,696
Placement Agents Fees related to sale of Common shares and Warrants on September 10, 2013							-	-	(618,545
Common Shares issued to round up fractional shares arising from private placement on September 10,2013							5,940	6	(6

Common Shares issued in connection with warrant conversion, September 25, 2013			35,357	35	185,589
Shares issued for consulting and legal services rendered at $2.17 per share on September 30, 2013			3,226	3	6,997
Shares issued for Directors fees at $2.04 per share on September 30, 2013			5,501	6	11,244
Series A Preferred Shares issued for employee stock compensation, October 1, 2013	5,025	5		-	35,995
Shares issued for consulting and legal services rendered at $5.29 per share on October 31, 2013			1,323	1	6,999
Warrants issued to Scientific Advisory Board on November 15, 2013			-	-	31,552
Shares issued for consulting and legal services rendered at $5.14 per share on November 30, 2013			1,362	1	6,999
Common Shares issued in connection with warrant conversion, December 16,			7,143	7	24,993

2013			
Shares issued for consulting and legal services rendered at $5.01 per share on December 31, 2013	1,383	2	6,999
Shares issued for Directors fees at $5.07 per share on December 31, 2013	2,220	2	11,248
Common Shares issued in connection with warrant conversion, January 21, 2014	75,000	75	393,675
Common shares and warrants issued in connection with private placement of common stock, January 24 ,2014	3,815,285	3,815	20,026,39
Costs associated with sale of Securities January 24, 2014			(135,062
Warrants issued for commissions, January 24, 2014	-	-	135,062
Placement Agents Fees related to sale of Common shares and Warrants on January 24, 2014	-	-	(1,201,81
Shares issued for consulting and legal services rendered at $5.01 per share on January 31, 2014	1,828	1	6,999
Shares issued at $0.48 in payment	571,429	571	2,605,145

of Debenture interest on February 1, 2013					
Warrants issued to Scientific Advisory Board on February 15, 2014			-	-	30,352
Shares issued for consulting and legal services rendered at $3.97 per share on February 28, 2014			1,763	2	6,998
Common Shares issued in connection with warrant conversion, February 6, 2014			25,000	25	131,225
Rule 16B payment to Additional paid in Capital					83,900
Shares issued for Directors fees at $5.01 per share on March 31, 2014			2,247	2	11,248
Shares issued for consulting and legal services rendered at $3.83 per share on March 31, 2014			1,397	2	6,998
Series A Preferred Shares issued for employee stock compensation, March 31, 2014	20,695	21	-	-	192,020
Shares issued for consulting and legal services rendered from October 1, 2013 through April1,			2,593	3	11,997

2014					
Series A Preferred Shares issued for employee stock compensation at April 30, 2014	2,572	2	-	-	20,894
Shares issued for consulting and legal services rendered at $3.25 per share on April 30, 2014			2,769	3	8,997
Shares issued for consulting and legal services rendered at $3.27 per share on May 31, 2014			2,752	3	8,997
Series A Preferred Shares issued for employee stock compensation at May 31, 2014	2,572	3	-	-	20,376
Warrants issued to Scientific Advisory Board on May 15, 2014			-	-	31,895
Shares issued for consulting and legal services rendered at $4.11 per share at June 30, 2014			2,190	2	8,998
Series A Preferred Shares issued for employee stock compensation at June 30, 2014	2,572	3	-	-	22,899
Common shares issued for employee stock compensation at $4.03 per share, June 30, 2014			71,430	72	287,788
Series A Preferred Shares issued for employee stock	169,643	170	-		1,830,626

compensation at June 30, 2014									
Shares issued for Directors fees at $4.11 per share on June 30, 2014							3,178	3	11,247
Restatement of Additional Paid in Capital to Derivative Liability									(5,740,540
Net loss								-	
Balance, June 30, 2014	3,193,079	3,194	-	-	-	-	54,620,993	54,621	75,212,88

See Accompanying Notes to Financial Statements

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NanoViricides, Inc.

Statements of Cash Flows

	For the Fiscal Year Ended June 30, 2014 (Restated)	For the Fiscal Year Ended June 30, 2013	For the Fiscal Year Ended June 30, 2012
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (13,601,616)	$ (8,875,668)	$ (6,207,207)
Adjustments to reconcile net loss to net cash used in operating activities			
Preferred shares issued for license	-	-	-
Preferred shares issued as compensation	2,123,017	445,044	982,867
Common shares and warrants issued for services	434,859	163,710	253,873
Common shares issued for interest	2,605,716	665,497	
Warrants granted to scientific advisory board	199,849	141,600	211,197
Amortization of Deferred Compensation			
Depreciation	203,234	210,877	210,877
Amortization	8,775	8,774	8,776
Change in fair value of derivative liability	1,443,200	1,249,335	172,251
Amortization of deferred financing expenses			
Discount convertible debentures	569,495	-	-
Beneficial conversion feature of convertible debentures			
Changes in operating assets and liabilities:			
Prepaid expenses	(56,492)	(284,206)	18,120
Prepaid expenses -related parties	(162,438)	-	
Other current assets	(150,000)	-	
Deferred expenses	-	-	-
Accounts payable - trade	113,188	24,900	158,829
Accounts payable - related parties	48,109	344,886	(97,274)
Accrued expenses	(112,521)	107,479	69,705
NET CASH USED IN OPERATING ACTIVITIES	(6,333,625)	(5,797,772)	(4,217,986)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Security Deposit	-	(1,000,000)	
Purchase of property and equipment	(5,231,094)	(64,931)	(23,352)
Purchase of trademark	-	-	(35,200)

NET CASH USED IN INVESTING ACTIVITIES	(5,231,094)	(1,064,931)	(58,552)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of Convertible Debentures	5,000,000	6,000,000	
Proceeds from issuance of Convertible Preferred Series B stock, net			7,002,500
Proceeds from issuance of Convertible Preferred Series C stock, net		510,963	2,325,000
Proceeds from issuance of common stock and warrants in connection with private placements of common stock, net of issuance costs	28,602,740	-	-
Proceeds from exercise of stock options	-	-	-
Proceeds from exercise of warrants	735,626	-	
Collection of stock subscriptions received	-	-	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	34,338,366	6,510,963	9,327,500
NET CHANGE IN CASH	22,773,647	(351,740)	5,050,962
Cash at beginning of period	13,923,245	14,274,985	9,224,023
Cash at end of period	$ 36,696,892	$ 13,923,245	$ 14,274,985
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:			
Interest paid	$ -	$ -	$ -
Income tax paid	$ -	$ -	$ -
NON CASH FINANCING AND INVESTING ACTIVITIES:			
Common stock issued for services rendered	$ 434,859	$ 163,710	$ 253,873
Common stock for interest	2,605,716	665,497	
Preferred stock issued as compensation	2,123,017	445,044	982,867
Stock options issued to the officers as compensation	-	-	-
Stock warrants granted to scientific advisory board	199,849	141,600	211,197
Stock warrants granted to brokers	-	-	-
Common stock issued for interest on debentures	-	-	-
Shares of common stock issued in connection with debenture offering	-	-	-
Common stock issued upon conversion of convertible debentures	-	-	-
Common stock issued upon conversion of Series B Preferred Stock			7,920,630
Common stock issued upon conversion of Series C Preferred Stock		3,028,464	298,472
Common stock issued for dividends on Series B Preferred Stock			79,467
		90,108	

Common stock issued for dividends on Series C Preferred Stock			
Debt discount related to beneficial conversion feature of convertible debt		-	-
Stock Warrants issued in connection with Private Placement	-	-	-
Common stock issued for accounts payable	-	-	-
Common stock issued for equipment	-	-	-

See accompanying notes to the financial statements

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NanoViricides, Inc.

June 30, 2014 and 2013

Notes to the Financial Statements

(Restated)

Note 1 - Organization and Nature of Business

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

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

Pursuant to the terms of the Exchange, ECMM acquired NVI in exchange for an aggregate of 22,857,143 newly issued shares of ECMM common stock resulting in an aggregate of 28,571,429 shares of ECMM common stock issued and outstanding. NVI then became a wholly-owned subsidiary of ECMM. The ECMM shares were issued to the NVI shareholders on a pro rata basis, on the basis of 1,143 shares of the Company's common stock for each share of NVI common stock held by such NVI shareholder at the time of the Exchange.

As a result of the Exchange transaction the former NVI stockholders held approximately 80% of the voting capital stock of the Company immediately after the Exchange. For financial accounting purposes, this acquisition was a reverse acquisition of the Company by NVI, under the purchase method of accounting, and was treated as a recapitalization with NVI as the acquirer. Accordingly, the financial statements have been prepared to give retroactive effect to May 12, 2005 (date of inception), of the reverse acquisition completed on June 01, 2005, and represent the operations of NVI.

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

NanoViricides, Inc. (the "Company"), is a nano-biopharmaceutical company whose business goals are to discover, develop and commercialize therapeutics to advance the care of patients suffering from life-threatening viral infections. We are a development stage company with several drugs in various stages of early development. Our drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. ("TheraCour"), to which we have the necessary licenses in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus.

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 onetime licensing fee equal to 2,000,000 shares of the Company's Series A 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 three and one half shares of common stock for each share of Series A Preferred Stock. The Series A Preferred Stock has a preferred voting preference at the rate of nine votes per share. The 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 2,000,000 shares were valued at $7,000.

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

NanoViricides, Inc. is the first in the world in the entire field of nanomedicines to have developed a nanomedicine drug that can be administered orally (by mouth). Our oral anti-influenza drug candidate, NV-INF-2, has shown extremely high broad-spectrum effectiveness against two different influenza A viruses in animal models, in our FluCide™ program. We are also developing a highly effective injectable anti-influenza drug, NV-INF-1, in this program. The Company held a pre-IND Meeting with the US FDA for its clinical drug candidate, NV-INF-1, in March, 2012. The Company is developing this injectable drug (NV-INF-1) for hospitalized patients with severe influenza, including immuno-compromised patients. The Company believes that this drug may also be usable as a single-dose injection in a medical office for less severe cases of influenza. Both of these anti-influenza therapeutic candidates are "broad-spectrum", i.e. they are expected to be effective against most if not all types of influenzas including the recently discovered novel strain of H7N9, Bird Flu H5N1, other Highly Pathogenic Influenzas (HPI/HPAI), Epidemic Influenzas such as the 2009 "swine flu" H1N1/A/2009, and Seasonal Influenzas including the recent H3N2 influenza. The Company has already demonstrated that our anti-influenza drugs have significantly superior activity when compared to oseltamivir (Tamiflu®) against two unrelated influenza A subtypes, namely, H1N1 and H3N2 in a highly lethal animal model. Both of these drug candidates can be used as prophylactics to protect at-risk personnel such as health-care workers and immediate family members and caretakers of a patient.

The Company is also developing an anti-HIV drug. The drug candidates in this HIVCide™ program were found to have effectiveness equal to that of a triple drug HAART cocktail therapy in the standard humanized SCID-hu Thy/Liv mouse model. Moreover, the nanoviricides were long acting. Viral load suppression continued to hold for more than four weeks after stopping HIVCide treatment. The Company believes that this strong effect and sustained effect together indicate that a HIVCide can be developed as a single agent that would provide "Functional Cure" from HIV/AIDS. The Company believes that substantially all HIV virus can be cleared upon HIVCide treatment, except the integrated viral genome in latent cells. This would enable discontinuation of treatment until HIV reemerges from the latent reservoir, which may be several months without any drugs. Moreover, the Company believes that this therapy would also minimize the chances of HIV transmission. The Company is currently optimizing the anti-HIV drug candidates. These drug candidates are effective against both the R5 and X4 subtypes of HIV-1 in cell cultures. The Company believes that these drug candidates are "broad-spectrum", i.e. they are expected to be effective against most strains and mutants of HIV, and therefore escape of mutants from our drugs is expected to be minimal.

The Company is also developing broad-spectrum eye drops that are expected to be effective against a majority of the viral infections of the external eye. Most of these viral infections are from adenoviruses or from herpes viruses. The Company has shown excellent efficacy of its drug candidates against EKC (adenoviral epidemic kerato-conjunctivitis) in an animal model. In addition, the anti-HSV drug candidates have shown excellent efficacy in cell culture studies. The Company is also developing a skin cream formulation for the treatment of herpes cold sores or genital warts. Further, the Company is developing a broad-spectrum drug against Dengue viruses that is expected to be useful for the treatment of any of the four major serotypes of dengue viruses, including in severe cases of dengue (DSS) and dengue hemorrhagic fever (DHF). DSS and DHF are thought to be caused by prior antibodies against dengue that a patient's body creates to fight a second unrelated dengue infection, and the second virus uses these antibodies effectively to hitch a ride into human cells, thereby causing a more severe infection than in naive patients. In addition to these six drugs in development, the Company also has research programs against Rabies virus, Ebola and Marburg viruses, and others. To date, the Company does not have any commercialized products. The Company continues to add to our existing portfolio of products through our internal discovery and clinical development programs and also seeks to do so through an in-licensing strategy.

Note 2- Restatement of Previously Issued Financial Statements

In connection with the preparation of our unaudited financial statements for the quarter ended December 31, 2014, we determined that in preparing our audited financial statements for the year ended June 30, 2014, we inadvertently overlooked the anti-dilution provision in certain warrants issued in connection with the company's private placements of securities, Specifically, the warrants issued contained certain anti-dilution ratchet provisions that provided for an adjustment to the exercise price of the warrants if the company issued any stock equivalent securities at a lower price in the future while the option was still outstanding. Adjustments to settlement amounts by future equity offerings or contractual terms of other equity-linked financial instruments issued in a subsequent period are not inputs to the fair value of a fixed-for-fixed opinion on equity shares. Accordingly, the warrants are not considered indexed to its own stock and thus must be accounted for as derivative liabilities which require initial measurement at fair value and adjustment to fair value in subsequent periods. The Company determined that the error caused a material understatement of its derivative liability for the year ended June 30, 2014. As a result of this error, we are restating our audited financial statements for the year ended June 30, 2014.

The correction of this error increased the Company's derivative liability and decreased Additional Paid in Capital by $5,235,682, decreased Accumulated deficit by $504,858 and reduced the Company's loss for the year ended June 30, 2014 by $504,858.

The combined impacts of all adjustments to the line items in our audited financial statements for the periods covered by this Form 10K/A are provided in the tables below.

Table 1 – Balance Sheet Adjustments

NanoViricides, Inc.

Balance Sheets

	June 30, 2014 **As Originally Reported**	Net Change	June 30, 2014 **As Restated**
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 36,696,892		$ 36,696,892
Prepaid expenses	108,089		108,089
Prepaid expenses - related parties	709,221		709,221
Other current assets	150,000		150,000
Total Current Assets	37,664,202		37,664,202
PROPERTY AND EQUIPMENT			
Property and equipment	6,736,742		6,736,742
Accumulated depreciation	(1,239,986)		(1,239,986)
Property and equipment, net	5,496,756		5,496,756
TRADEMARK and PATENTS			
Trademark	458,954		458,954
Accumulated amortization	(50,696)		(50,696)
Trademark and Patents, net	408,258		408,258
SECURITY DEPOSIT	1,000,000		1,000,000
Total Assets	$ 44,569,216		44,569,216
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Accounts payable	$ 376,446		$ 376,446
Accounts payable – related parties	758,676		758,676
Accrued expenses	91,838		91,838
Total Current Liabilities	1,226,960		1,226,960
LONG TERM LIABILITIES:			
Debentures payable - Series B Net of discount	4,037,568		4,037,568
Derivative liability - Series B Debentures	5,699,703		5,699,703

Debenture subscription deposit	5,000,000		5,000,000
Derivative liability - Warrants	-	5,235,682	5,235,682
Total Long Term Liabilities	14,737,271	5,235,682	19,972,953
Total Liabilities	15,964,231	5,235,682	21,199,913
COMMITMENTS AND CONTINGENCIES			
STOCKHOLDERS' EQUITY:			
Series A Convertible Preferred stock, $0.001 par value, 4,000,000 shares designated, 3,193,079, and 2,990,000 shares issued and outstanding, respectively	3,194		3,194
Series B Convertible Preferred stock, $0.001 par value, 10,000,000 shares designated, none issued and outstanding	-		-
Series C Convertible Preferred stock, $0.001 par value, 10,000,000 shares designated, none issued and outstanding	-		-
Common stock, $0.001 par value; 85,714,286 shares authorized; 54,620,993, and 47,026,173 shares issued and outstanding, respectively	54,621		54,621
Additional paid-in capital	80,953,428	(5,740,540)	75,212,888
Accumulated Deficit	(52,406,258)	504,858	(51,901,400)
Total Stockholders' Equity	28,604,985	(5,235,682)	23,369,303
Total Liabilities and Stockholders' Equity	$ 44,569,216	-	$ 44,569,216

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Table 2 – Statement of Operations adjustments

NanoViricides, Inc.

Statement of Operations

	For the Fiscal Year Ended June 30, 2014 **As Originally Reported**	Net Change	For the Fiscal Year Ended June 30,2014 **As Restated**
OPERATING EXPENSES			
Research and development	$ 5,131,523		$ 5,131,523
Refund credit research and development costs	-		-
General and administrative	3,535,849		3,535,849
Total operating expenses	8,667,372		8,667,372
LOSS FROM OPERATIONS	(8,667,372)		(8,667,372)
OTHER INCOME (EXPENSE):			
Interest income	171,001		171,001
Interest Expense	(3,092,550)		(3,092,550)
Discount on convertible debentures	(569,495)		(569,495)
Beneficial conversion feature of convertible debentures	-		-
Change in fair market value of derivatives	(1,948,058)	504,858	(1,443,200)
Other income (expense), net	(5,439,102)	504,858	(4,934,244)
LOSS BEFORE INCOME TAXES	(14,106,474)	504,858	(13,601,616)
INCOME TAX PROVISION	-		-
NET LOSS	$ (14,106,474)		$ (13,601,616)
NET LOSS PER COMMON SHARE - BASIC AND DILUTED:	$ (0.28)		$ (0.27)
Weighted average common shares outstanding - basic and diluted	51,225,818		51,225,818

Table 3 – Statement of Cash Flows adjustments

	For the Fiscal Year Ended June 30, 2014 **As Originally Reported**	Net Change	For the Fiscal Year Ended June 30, 2014 **As Restated**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (14,106,474)	$ 501,858	$ (14,106,474)
Adjustments to reconcile net loss to net cash used in operating activities			
Preferred shares issued for license	-		-
Preferred shares issued as compensation	2,123,017		2,123,017
Common shares and warrants issued for services	434,859		434,859
Common shares issued for interest	2,605,716		2,605,716
Warrants granted to scientific advisory board	199,849		199,849
Amortization of Deferred Compensation			
Depreciation	203,234		203,234
Amortization	8,775		8,775
Change in fair value of derivative liabilities	1,948,058	(504,858)	1,443,200
Amortization of deferred financing expenses			
Discount convertible debentures	569,495		569,495
Beneficial conversion feature of convertible debentures			
Changes in operating assets and liabilities:			
Prepaid expenses	(56,492)		(56,492)
Prepaid expenses -related parties	(162,438)		(162,438)
Other current assets	(150,000)		(150,000)
Deferred expenses	-		-
Accounts payable - trade	113,188		113,188
Accounts payable - related parties	48,109		48,109
Accrued expenses	(112,521)		(112,521)
NET CASH USED IN OPERATING ACTIVITIES	(6,333,625)	-	(6,333,625)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Security Deposit	-		-
Purchase of property and equipment	(5,231,094)		(5,231,094)
Purchase of trademark	-		-
NET CASH USED IN INVESTING ACTIVITIES	(5,231,094)		(5,231,094)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of Convertible Debentures	5,000,000		5,000,000
Proceeds from issuance of Convertible Preferred Series B stock, net			

Proceeds from issuance of Convertible Preferred Series C stock, net		
Proceeds from issuance of common stock and warrants in connection		
with private placements of common stock, net of issuance costs	28,602,740	28,602,740
Proceeds from exercise of stock options	-	-
Proceeds from exercise of warrants	735,626	735,626
Collection of stock subscriptions received	-	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	34,338,366	34,338,366
NET CHANGE IN CASH	22,773,647	22,773,647
Cash at beginning of period	13,923,245	13,923,245
Cash at end of period	$ 36,696,892	$ 36,696,892
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	$ -	$ -
Income tax paid	$ -	$ -
NON CASH FINANCING AND INVESTING ACTIVITIES:		
Common stock issued for services rendered	$ 434,859	$ 434,859.00
Common stock for interest	05,716	2,605,716.00
Preferred stock issued as compensation	2,123,017	2,123,017.00
Stock options issued to the officers as compensation	-	-
Stock warrants granted to scientific advisory board	199,849	199,849.00

Note 3 - Summary of Significant Accounting Policies

The Management of the Company is responsible for the selection and use of appropriate accounting policies and the appropriateness of accounting policies and their application. Critical accounting policies and practices are those that are both most important to the portrayal of the Company’s financial condition and results and require management’s most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. The Company’s significant and critical accounting policies and practices are disclosed below as required by generally accepted accounting principles.

Basis of Presentation

The Company’s financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

Fiscal Year End

The Company elected June 30th as its fiscal year end date upon its formation.

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Use of Estimates and Assumptions

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

The Company's significant estimates include the fair value of financial instruments; the carrying value, recoverability and impairment of long-lived assets, including the values assigned to and estimated useful lives of property and equipment and trade mark, and underlying assumptions to estimate the fair value of derivative financial instruments; income tax rate, income tax provision and valuation allowance of deferred tax assets. These significant accounting estimates bear the risk of change due to the fact that there are uncertainties attached to those estimates and certain estimates are difficult to measure or value.

Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Management regularly reviews its estimates utilizing currently available information, changes in facts and circumstances, historical experience and reasonable assumptions. After such reviews, if deemed appropriate, those estimates are adjusted accordingly.

Actual results could differ from those estimates.

Reclassification

Certain reclassifications have been made in prior year's financial statements to conform to the financial presentation used in the current year. These reclassifications from General and Administrative Expenses to Research and Development expenses had no effect on total operating expenses, operating loss or net loss for any period presented.

Derivatives and Fair Value of Financial Instruments

The Company applied paragraph 815-10-05-4 of the FASB Accounting Standards Codification to the Series B Convertible Debenture issued January 15, 2013, the private placement of Units of the Company's Common Stock and Warrants issued September 10,2013, and the private placement of Units of the Company's common Stock and Warrants issued January 21, 2014, Based on the guidance in paragraph 815-10-05-4 of the FASB Accounting Standards Codification the Company concluded these instruments were required to be accounted for as derivatives on issuance date. The Company records the fair value of the Series B Convertibel Debenture and certain warrants that are classified as derivatives on issuance date and the fair value changes on each reporting date reflected in the consolidated statements of operations as "Gain (loss) on derivative liabilities." These derivative instruments are not designated as hedging instruments under paragraph 815-10-05-4 of the FASB Accounting Standards Codification and are disclosed on the balance sheet under Derivative Liabilities.

The Company follows paragraph 820-10-35-37 of the FASB Accounting Standards Codification ("Paragraph 820-10-35-37") to measure the fair value of its financial instruments and paragraph 825-10-50-10 of the FASB Accounting Standards Codification for disclosures about fair value of its financial instruments. Paragraph 820-10-35-37 establishes a framework for measuring fair value in accounting principles generally accepted in the United States of America (U.S. GAAP), and expands disclosures about fair value measurements. To increase consistency and comparability in fair value measurements and related disclosures, Paragraph 820-10-35-37 establishes a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three (3) broad levels. The three (3) levels of fair value hierarchy defined by Paragraph 820-10-35-37 are described below:

Level 1	Quoted market prices available in active markets for identical assets or liabilities as of the reporting date.
Level 2	Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date.

Level 3 Pricing inputs that are generally observable inputs and not corroborated by market data.

Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable.

The fair value hierarchy gives the highest priority to quoted prices (unadjusted) in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The carrying amounts of the Company’s financial assets and liabilities, such as cash, prepayments and other current assets, accounts payable, and accrued expenses, approximate their fair values because of the short maturity of these instruments.

The Company’s Level 3 financial liabilities consist of the Series B convertible debenture issued January 15, 2013 and certain warrants issued on September 10, 2013 and January 21, 2014 with two private placements, for which there is no current market for these securities such that the determination of fair value requires significant judgment or estimation. We have valued the automatic conditional conversion, re-pricing/down-round, change of control; default and follow-on offering provisions using a lattice model, with the assistance of a valuation consultant, for which management understands the methodologies. These models incorporate transaction details such as Company stock price, contractual terms, maturity, risk free rates, as well as assumptions about future financings, volatility, and holder behavior as of issuance and June 30, 2014. The primary assumptions include: projected annual volatility of 92%-95%; the follow-on securities purchase option; the conversion feature as a percentage of Market; automatic/conditional conversions; market price trigger events.

As of June 30, 2014, the Company’s derivative financial instruments included:

1) Embedded derivatives associated with certain of the Company’s unsecured convertible debentures. The Company’s Series B convertible debenture issued to five (5) unrelated investors is a hybrid instrument, which warrants separate accounting as a derivative instrument. The embedded derivative feature has been bifurcated from the debt host contract, referred to as the Derivative Liability, which resulted in a reduction of the initial carrying amount (as unamortized discount) of the Debentures. The unamortized discount is amortized to interest expense using the effective interest method over the life of the Debentures. The embedded derivative feature includes the conversion feature within the notes and an early redemption option. The compound embedded derivatives within the convertible Debentures have been recorded at fair value at the date of issuance; and are marked-to-market each reporting period with changes in fair value recorded to the Company’s statement of operations as Change in fair value of derivative liabilities.

The Series B Convertible Debenture were valued at 6/30/14. The following assumptions were used for the valuation of the embedded derivative:

- The balance of the Series B Convertible Debenture as of 6/30/14 is $6,000,000 following the interest payment on 6/30/14;
- The underlying stock price was used as the fair value of the common stock;
- The stock price increased from $0.9143 to $1.2086 which significantly increased the warrant value with the $1.00 exercise price (from out to in the money);
- The projected annual volatility was based on the Company historical volatility:

3/31/14	95%
6/30/14	92%

- An event of default would occur 0% of the time, increasing 1.00% per month to a maximum of 10%;
- The company would redeem the debentures projected initially at 0% of the time and increase monthly by 1.0% to a maximum of 20.0% (from alternative financing being available for a Redemption event to occur);
- The Holder would automatically convert the interest if the company was not in default;
- The Holder would automatically convert the debenture at maturity if the registration was effective and the company was not in default.

Derivative Valuation – Additional Redemption and Interest Warrants

The Redemption and Interest Warrants potentially issued were valued as of 6/30/14 (for all scenarios based on the lattice projected stock prices and historical volatility of the company) and the following assumptions were used for the valuation of the derivative:

- The stock price would fluctuate with the Company projected volatility;
- The projected volatility curve for each valuation period was based on the historical volatility of the Company (see previous section);
- The Holder would exercise the warrant at maturity if the stock price was above the exercise price;
- The Holder would exercise the warrant at target prices starting at the greater of 2 times the exercise price or the stock price; and lowering such target as the warrants approached maturity.
- In this period no warrants were issued or exercised.

Based on these management assumptions, the fair value of the Redemption and Interest Warrants ("Additional Warrants" or "Warrants") derivative liability as of the projected issuance dates. Redemption Warrants assumed issuance as of the valuation dates and the Interest Warrants scenario valuations assume issuance 1/15/15.

Series B Convertible Debenture:

Series B Convertible Debenture	6,000,000	6,000,000

Derivative Value	3,824,987	5,699,703
Mark to Market	(3,752,933)	1,874,716

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2) Embedded derivatives associated with the Company's certain Warrants issued on September 10, 2013 and January 21,2014 (See Note 9-Equity Transactions). The Company's warrans issued in two private placements to investors were associated with full-ratchet anti-dilution feature that qualify as derivatives to be separately accounted. The embedded derivative feature has been bifurcated from the host contract, referred to as the Derivative Liability. The embedded derivatives within the Warrant have been recorded at fair value at the date of issuance; and are marked-to-market each reporting period with changes in fair value recorded to the Company's statemen of operations as Change in fair value of derivative liabilities.

The Company used a third party valuaton firm to develop a lattice model that values the liability of the warrants based on a probability weighted discounted cash flow model. This model is based on future projections of the various potential outcomes. The features that were analyzed and incorporated into the model included the exercise and full reset features.

The NanoViricides Warrants were valued as of issuance, exercise, and the quarterly periods with the following assumptions:

- The 5 year warrants issued on 9/9/13 and 1/21/14 included Investor and Placement Agent Warrants with an exercise price of $5.25 and $6.05 (subject to adjustments-full ratchet reset).
- The stock price would fluctuate with the Company projected volatility.
- The Holder would exercise the warrant as they become exercisable (effective registration at issuance) at target prices of the higher of **2 times** the projected exercise/reset price or **2 times** the stock price.
- The next capital raise would fluctuate with an annual volatility. The projected volatility curve was based on historical volatilities of the Company for the valuation periods. The projected annual volatility for the valuation dates are:

1 Year		1 Year	
9/9/13	87 %	1/22/14	93 %
9/25/13	87 %	3/31/14	96 %
9/30/13	87 %	3/31/14	96 %
12/31/13	92 %	6/30/14	92 %
1/21/14	93 %	9/30/14	85 %
12/31/14	75 %		

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

The fair value of the derivatives associated with the Series B Debentures was $2,735,310 as of January 15, 2013 upon issuance and was $5,699,703 at June 30, 2014.

The fair value of the derivatives associated with the September 10, 2013 Warrants was $3,210,617 as of September 10, 2013 upon issuance, The fair value of the derivatives associated with the January 21, 2014 Warrants was $2,687,125 as of January 21, 2014 upon issuance and the derivative value of the said Warrants was $5,235,682 at June 30, 2014.

The foregoing assumptions are reviewed quarterly and are subject to change based primarily on management's assessment of the probability of the events described occurring. Accordingly, changes to these assessments could materially affect the valuation.

The table below provides a summary of the changes in fair value, including net transfers in and/or out, of all financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the fiscal year ended June 30, 2014:

	Fair Value Measurements Using Level 3 Inputs Derivative Liabilities	Totals
Balance, June 30, 2011	17,519	17,519
Total Gains or Losses (realized/unrealized)		
Included in Net (Income) Loss	(172,245)	(172,245)
Included in Other Comprehensive Income		
Purchases, Issuances and Settlements	1,233,424	1,233,424
Transfers in and/or out of Level 3		
Balance, June 30, 2012	1,078,698	1,078,698
Total Gains or Losses (realized/unrealized)		
Included in Net (Income) Loss	(1,249,335)	(1,249,335)
Included in Other Comprehensive Income		
Purchases, Issuances and Settlements	3,922,282	3,922,282
Transfers in and/or out of Level 3	-	-
Balance, June 30, 2013	$ 3,751,645	$ 3,751,645
Included in Net (Income) Loss	1,443,200	1,443,200
Included in Other Comprehensive Income		
Purchases, Issuances and Settlements	5,897,742	5,897,742
Transfers in and/or out of Level 3	-	-
Balance, June 30, 2014	$ 10,935,385	$ 10,935,385

Transactions involving related parties cannot be presumed to be carried out on an arm's-length basis, as the requisite conditions of competitive, free-market dealings may not exist. Representations about transactions with related parties, if made, shall not imply that the related party transactions were consummated on terms equivalent to those that prevail in arm's-length transactions unless such representations can be substantiated.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Level 3 Financial Liabilities – Derivative Warrant Liabilities

The Company uses Level 3 of the fair value hierarchy to measure the fair value of the derivative liabilities and revalues its derivative warrant liability at every reporting period and recognizes gains or losses in the statements of operations that are attributable to the change in the fair value of the derivative warrant liability.

Financial assets and liabilities measured at fair value on a recurring basis are summarized below and disclosed on the balance sheet under Derivative Liabilities:

	As of June 30, 2014				
	Carrying	Fair Value Measurements Using			
	Value	Level 1	Level 2	Level 3	Total
Liabilities					
Derivative Liabilities associated with:					
Series B Convertible Debentures	5,699,703			5,699,703	5,699,703
Warrants	5,235,682			5,235,682	5,235,682
Total Derivative Liabilities	10,935,385			10,935,385	10,935,385

Carrying Value, Recoverability and Impairment of Long-Lived Assets

The Company has adopted paragraph 360-10-35-17 of the FASB Accounting Standards Codification for its long-lived assets. The Company's long-lived assets, which include property and equipment and trade mark and patents are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

The Company assesses the recoverability of its long-lived assets by comparing the projected undiscounted net cash flows associated with the related long-lived asset or group of long-lived assets over their remaining estimated useful lives against their respective carrying amounts. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets. Fair value is generally determined using the asset's expected future discounted cash flows or market value, if readily determinable. If long-lived assets are determined to be recoverable, but the newly determined remaining estimated useful lives are shorter than originally estimated, the net book values of the long-lived assets are depreciated over the newly determined remaining estimated useful lives.

The Company considers the following to be some examples of important indicators that may trigger an impairment review: (i) significant under-performance or losses of assets relative to expected historical or projected future operating results; (ii) significant changes in the manner or use of assets or in the Company's overall strategy with respect to the manner or use of the acquired assets or changes in the Company's overall business strategy; (iii) significant negative industry or economic trends; (iv) increased competitive pressures; (v) a significant decline in the Company's stock price for a sustained period of time; and (vi) regulatory changes. The Company evaluates acquired assets for potential impairment indicators at least annually and more frequently upon the occurrence of such events.

The impairment charges, if any, is included in operating expenses in the statements of operations.

The Company determined that there were no impairments of long-lived assets as of June 30, 2014 or 2013.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents.

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets (generally five (5) to seven (7) years), or lease term for leasehold improvement, using the straight-line method. Expenditures for major additions and betterments are capitalized. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of property and equipment, the related cost and accumulated depreciation are removed from the accounts and any gain or loss is reflected in statements of operations.

Intangible Assets Other Than Goodwill

The Company has adopted Subtopic 350-30 of the FASB Accounting Standards Codification for intangible assets other than goodwill. Under the requirements, the Company amortizes the acquisition costs of intangible assets other than goodwill on a straight-line basis over or their estimated useful lives, the terms of the exclusive licenses and/or agreements, or the terms of legal lives of the patents, whichever is shorter. Upon becoming fully amortized, the related cost and accumulated amortization are removed from the accounts.

Research and Development

Research and development expenses consist primarily of costs associated with the preclinical and/ or clinical trials of drug candidates, compensation and other expenses for research and development, personnel, supplies and development materials, costs for consultants and related contract research and facility costs. Expenditures relating to research and development are expensed as incurred.

Stock-Based Compensation for Obtaining Employee Services

The Company accounts for its stock based compensation in which the Company obtains employee services in share-based payment transactions under the recognition and measurement principles of the fair value recognition provisions of section 718-10-30 of the FASB Accounting Standards Codification. Pursuant to paragraph 718-10-30-6 of the FASB Accounting Standards Codification, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the performance is complete or the date on which it is probable that performance will occur. If shares of the Company are thinly traded the use of share prices established in the Company’s most recent private placement memorandum (“PPM”), or weekly or monthly price observations would generally be more appropriate than the use of daily price observations as such shares could be artificially inflated due to a larger spread between the bid and asked quotes and lack of consistent trading in the market.

The fair value of each option award is estimated on the date of grant using a Black-Scholes option-pricing valuation model. The ranges of assumptions for inputs are as follows:

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Expected term of share options and similar instruments: The expected life of options and similar instruments represents the period of time the option and/or warrant are expected to be outstanding. Pursuant to Paragraph 718-10-50-2(f)(2)(i) of the FASB Accounting Standards Codification the expected term of share options an