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

FORM 10-K

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

FOR THE FISCAL YEAR ENDED JUNE 30, 2018

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.)

1 CONTROLS DRIVE, SHELTON, CONNECTICUT, 06484
(Address of principal executive offices)

203-937-6137
(Issuer's telephone number, including area code)

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

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

COMMON STOCK, PAR VALUE $0.001 PER SHARE	NYSE MKT
(Title of Class)	(Name of exchange on which registered)

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the Company is a larger accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Yes ☐ No ☒

As of October 12, 2018, there were approximately 69,383,000 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on December 31, 2017 by non-affiliates of the registrant was approximately $37,865,000 based on the closing price of $0.90 per share, as reported on the NYSE American on December 31, 2017, 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).

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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

NanoViricides, Inc. (the “Company,” “we,” or “us”) was incorporated in Nevada on April 1, 2005. Our corporate offices are located at 1 Controls Drive, Shelton, Connecticut 06484 and our telephone number is (203) 937-6137. Our Website is located at http://www.Nanoviricides.com. We do not incorporate by reference into this Annual Report the information on or accessible through our website, and you should not consider it part of this Annual Report.

On September 25, 2013, the Company’s common stock began trading on the New York Stock Exchange American under the symbol, “NNVC”.

NanoViricides, Inc. is a global leader in the development of nanomedicine drugs against viruses. We are a development stage company with several drugs in various stages of pre-clinical development, including IND-enabling non-clinical studies. The Company is focused on bringing its topical treatment for shingles into human clinical trials, which we believe is our most advanced drug indication. Shingles is caused by reactivation of VZV (Varicella-Zoster Virus), which causes chickenpox in children. Several additional indications in the HerpeCide™ program are expected to follow. In addition, the Company has drug candidates in development against severe influenzas (including bird flu), HIV, Dengue, Ebola/Marburg and other viruses at different preclinical stages. The overall market size for our potential drugs is in the range of $40~70 Billion. This broad pipeline is enabled by our unique post-immunotherapeutic “bind-encapsulate-destroy” technology platform.

We are a development-stage company creating special-purpose nanomaterials for anti-viral drugs based on a novel, first-in-class mechanism. The Company's novel nanoviricide® class of drug candidates are designed to specifically attack enveloped virus particles, on the same sites that they use to bind to cells, and dismantle them. Our unique biomimetic approach promises that a virus cannot escape our nanoviricide drugs due to mutations, if the virus-binding ligands perform as designed.

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-1 and HSV-2, 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 keratitis, and Ebola/Marburg viruses. In addition, the Company is negotiating a license for the non-simplex herpes viruses, namely VZV (shingles, chicken pox virus), where it has developed a lead indication, and the remaining human herpes viruses, namely EBV, HCMV, HHV-6A, HHV6B, and HHV7, and KSHV, from TheraCour. For this purpose, the Company has conducted a valuation for the shingles and PHN ("postherpetic neuralgia") indications. The negotiation process has begun in earnest after the reporting period, with Dr. Irach Taraporewala being appointed as the new Chief Executive Officer of the Company, effective September 1, 2018. To date, TheraCour has not withheld any licenses for antiviral nanomedicines that NanoViricides has asked for, and we anticipate that the licenses to the remaining herpes viruses including VZV will be executed once the due diligence process is completed.

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's objectives are to create the best possible anti-viral nanoviricides and then subject these compounds to rigorous laboratory and animal testing towards US FDA and international regulatory approvals. Our long-term research efforts are aimed at augmenting the nanoviricides that we currently have in development with additional therapeutic agents to produce further improved anti-viral agents in the future. We believe that many viral infections that are at present untreatable or incurable would be curable using such an advanced approach.

The Nanoviricide® Platform Technology

NanoViricides, Inc. is a global leading company in the application of nanomedicine technologies to the complex issues of viral diseases. The nanoviricide® technology enables direct attacks at multiple points on a virus particle. It is believed that such attacks would lead to the virus particle becoming ineffective at infecting cells. Antibodies in contrast attack a virus particle at only a maximum of two attachment points per antibody. In addition, the nanoviricide technology also simultaneously enables attacking the rapid intracellular reproduction of the virus by incorporating one or more active pharmaceutical ingredients (APIs) within the core of the nanoviricide. The nanoviricide technology is the only technology in the world, to the best of our knowledge, that is capable of both (a) attacking extracellular virus thereby breaking the reinfection cycle, and simultaneously (b) disrupting intracellular production of the virus, thereby enabling complete control of a virus infection.

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

This powerful platform technology has enabled us to develop several drug candidates against a large number of different viruses that could be further improved into clinical drug candidates, thus building a very broad drug pipeline that may lead to exponential growth of the Company upon the approval of our first drug candidate.

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.

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. Nanoviricides are designed to accomplish this using a "Bind-Encapsulate-Destroy" strategy to eliminate the free virus.

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.

A nanoviricide is made by chemically covalently linking a "nanomicelle" - a globular polymeric micelle with pendant lipid chains inside, to one or more different small chemical ligands designed to mimic the cellular receptor to which the virus binds. In addition, the nanoviricide can carry additional active pharmaceutical ingredients (APIs), which may be chosen to affect the intracellular virus life cycle. Thus the nanoviricide platforms enables construction of complete virus-killing nanomachines that block the virus from entering the cell as well as that block further production of the virus inside the cell.

Attacking the "Achilles Heel" of the Virus- Unchanging Ability of the Virus to Bind to Its Cognate Receptor on Cell

We strive hard to develop virus-binding small chemical ligands that mimic the cognate cellular receptor of the virus, using rational design and molecular modeling strategies and our internal, accumulated expertise. This is the receptor to which a virus binds to gain entry into the human cell. Some viruses use more than one, different, receptors. The nanoviricide® platform technology allows use of different ligands on the same nanoviricide drug to be able to attack such difficult viruses.

It would be very difficult for a virus to become resistant to a nanoviricide that mimics the virus' cellular receptor. This is because, no matter how much a virus mutates or changes, its binding to the cellular receptor does not change. If the virus does not bind to the nanoviricide efficiently, it would likely have lost its ability to bind to the cellular receptor efficiently as well, resulting in an attenuated version with limited pathogenicity.

Beyond Antibodies or "Post-Immunotherapeutic" Approach: A Nanoviricide in Its Design is a Nanomachine Built to Destroy Viruses

A nanoviricide exposes a very high density of virus binding sites on its surface, in contrast to a human cell. Thus, a virus would be more likely to be captured by the nanoviricide than to bind to a cell. Once bound to the virus, it is thought that the nanoviricide would wrap itself around the virus, and the interior lipidic chains of the nanoviricide would merge into the lipid envelope of an enveloped virus, thus destabilizing the virus. This would result in loss of the viral glycoproteins that it uses to bind to cell and to fuse with the cell membrane, thus rendering the virus particle non-infectious. In contrast, for an antibody to be successful as a drug, as many as ten to fifteen antibodies must bind to saturate the virus surface. The resulting antibody-virus complex then may be subject to the complement protein system in the bloodstream, or it may bind to antibody-receptors on human immune cells. Thus the human immune system needs to be functional for an antibody to be effective as a "drug". In a sense, antibodies only "flag" the virus particle as foreign.

Almost any virus that causes pathology in humans is able to do so because it has developed intelligent and complicated pathways for disabling the human immune system at one or more points. This may be one of the reasons why many antiviral antibodies fail in the field use. Additionally, viruses readily escape antibodies by mutations. Such viral escape from antibodies has been witnessed in almost every viral epidemic, be it HIV/AIDS, Influenza pandemic of 2009, or the Ebola epidemic of 2014-15. In contrast, a nanoviricide would complete the job of making the virus particle non-infectious, without any help from the human immune system.

Broad-Spectrum Nanoviricide Drug Candidates

A nanoviricide is generally "broad-spectrum" in the sense that it would be effective against all viruses that use the same cellular receptor, binding to the same site on that cellular receptor.

Formulation is Inherent in the Design Aspect of a Nanoviricide

We believe that once we declare a clinical candidate for a given indication in our HerpeCide programs, further IND-enabling pre-clinical development will be rapid. Formulation development for novel drugs in normal pharmaceutical paradigm often takes years. However, in the nanoviricide approach, the nanomicelle polymeric backbone itself takes care of the formulation aspects. The nanomicelle is designed to optimize the drug for its intended route of administration, be it injectable, skin cream, eye drops, or even oral. Thus no specific or extensive formulation development is expected to be required after clinical candidate declaration. In addition, we have already short-listed the ligands as well as the nanomicelle backbones for the final candidates in the HerpeCide program. At present we are synthesizing these final candidate ligands and nanomicelle backbone candidates as required, for the studies leading to clinical candidate declaration. At the same time, we are also continuing to develop the necessary CMC aspects of the resulting candidates in parallel. We have already performed preliminary safety studies of our injectable FluCide™ drug candidate with excellent safety indications in both mouse (at KARD Scientific) and rat (at BASi) models. The HerpeCide program drug candidates are dermal or ocular topical treatments. Thus we believe that the safety/toxicology studies for these candidates will be relatively straightforward.

Uniform Polymer Nature Enables Nanomedicine Manufacturing Quality Assurance

A major problem in the field of nanomedicines has been that most nanomedicines have been found to be notoriously difficult to manufacture in a consistent manner from batch to batch. This is because of the complexity inherent in making large molecules, and the very nature of polymer and particle making processes.

The nanoviricide technology has been designed from the ground up to enable consistent manufacture and control. Thus, the nanoviricide backbone is a homopolymer of a single repeating unit or monomer, and not a block copolymer. In addition, the nanoviricide polymer is designed to dynamically and naturally self-assemble into micelles in a solution. Also, the virus-binding ligands are chemically attached to the polymer. The extent of attachment can be assessed by analytical techniques that we have developed and continue to develop as needed. Further we use specialized techniques in the polymer processing to minimize any contamination with endotoxins or other foreign particles. The final nanoviricide solutions can be sterile filtered using standard membrane filtration processes. The resulting solutions can be concentrated in a non-contaminating environment in our Process Scale-Up Lab or our cGMP-capable Manufacturing Facility.

Thus the nanoviricides platform has been designed from the ground up to enable simplifications in processes and analyses that need to be implemented in order to develop robust, reproducible, and scalable processes.

State of the Company – Drug Development Programs – Focus on HerpeCide™ Program

During the financial year ending June 30, 2018, we have focused our efforts primarily on the HerpeCide program. We are developing drugs against three indications in this program in parallel at present, namely, HSV-1 “cold sores” (orolabial herpes and recurrent herpes labialis or RHL), HSV-2 “genital ulcers”, and VZV shingles. We are developing topical treatments (skin creams or lotions) for these three indications. All of the drug candidates in these three leading indications comprise common chemistry features, and are based on the same family of ligands and polymers, enabling parallel development. Our parallel development of these indications maximizes return on investment and shareholder value. Of these, the shingles indication program has advanced to the level of IND-enabling Safety/Toxicology studies (i.e. “Tox Package” studies). We are currently advancing it towards an IND filing. We believe that the other two indications will advance to an IND stage in the very near future.

Our HerpeCide™ program has matured towards multiple drug indications. Besides the three indications listed above, modifications of the same drug candidates are anticipated to be developed into (iv) Eye Drops to treat ocular (i.e. external eye) Herpes Keratitis (HK) caused by HSV-1 or HSV-2, and possibly (v) Intra-Ocular injections to treat viral Acute Retinal Necrosis (vARN) caused by herpes viruses, primarily VZV, shingles (varicella zoster virus) and HSV-2, a cause of blindness.

In addition, we believe that the shingles drug candidate may be eligible for the PHN indication as well. PHN clinical studies are long and expensive, and we plan to advance the candidate for this indication only after its shingles indication clinical trials are completed. Further, the same drug candidate is expected to work against chickenpox in children. Chickenpox remains a sporadic epidemic disease despite vaccines.

Expansion to additional indications is likely, as we perform further studies. It is likely that some of these drug candidates with variations may be able to address diseases caused by the remaining human herpes viruses, namely EBV, HCMV, HHV-6A, HHV-6B, and HHV-7. Such expansions would enable maximization of return on investment (ROI) and maximization of shareholder value.

Including the HerpeCide program explained above, we currently have eight different drug development programs, attesting to the strength of our platform technology. We have now chosen to focus strategically on our HerpeCide™ program indications and drug candidates that are expected to result in a robust franchise with drug approvals against a number of different herpes virus indications.

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 codevelopment relationships with other pharmaceutical companies. Such licensing or codevelopment relationships usually may entail upfront payments, milestones payments, cost sharing, and eventual revenue sharing, including royalties 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. As and when needed, management plans to continue to raise additional funds for our continuing drug development efforts from public markets.

We believe we are one of the very few small pharmaceutical drug innovators that possess their own cGMP or cGMP-capable manufacturing facility. With our Shelton, Connecticut campus and pilot-scale cGMP-capable manufacturing facility, we are in a position to advance our drug candidates into clinical trials, produce the pre-clinical "tox package" batches, and the clinical drug substance batches.

The Company's cGMP-capable pilot-scale manufacturing facility in Connecticut may enable initial market entry for some of our products upon approval, allowing the Company to grow into a stand-alone Pharma company, in addition to a potential licensing strategy for success. The Company thus continues to minimize risk to investors by improving the potential for success.

While we have continued to make significant progress in advancing our HerpeCide program drug pipeline, we have also had to curtail our programs and slow down drug development towards the clinic due to fiscal constraints. In particular, R&D staffing at our affiliates has been reduced significantly, by about 25% in the last few years. This is expected to have the effect of lengthening our timeline to begin human clinical trials.

The HerpeCide™ Program is Now Our Top Priority – Shingles is Lead Indication moving into IND-enabling "Tox Package" Studies

We anticipate that our drug candidate against VZV is most likely to be our earliest nanoviricide drug candidate to enter human clinical trials. This is primarily because of the timelines for anticipated drug development studies required for the different indications of drug candidates in development. The Company does not currently have a license from TheraCour for the VZV area. The Company is in discussions with TheraCour after having obtained independent asset valuations to serve as the basis for such additional licenses. This process is advancing in earnest after the reporting period, with our new CEO, Dr. Irach Taraporewala, joining on September 1, 2018. Since then, the Company has extended Dr. Carolyn Myers' consulting agreement to help with development of the license agreements. However there can be no assurance that the Company will be able to enter into an agreement with TheraCour for such license or that the agreement will be on terms that are favorable to the Company. Nevertheless, to date, TheraCour has granted all license requests made by the Company.

Our most advanced drug candidate is a nanoviricide against VZV (varicella-zoster virus), the virus that causes debilitating shingles rash in adults and chickenpox in children. Its first indication is expected to be as topical treatment of shingles rash. About 500,000 to 1 million episodes of herpes zoster (shingles) occur annually in the United States alone. In spite of the new Shingrix™ vaccine, the market size for a therapeutic for shingles is estimated to be in the billions of dollars. There is currently no approved drug against shingles, PHN or chickenpox, indicating an unmet medical need.

The Company is also exploring additional indications of its anti-herpes drug candidates which will broaden the pipeline and require limited development work. In particular, certain eye diseases of the retina have been causatively linked to herpes viruses. For example, most cases of viral Acute Retinal Necrosis (ARN), a disease that leads to severe loss of vision and can lead to blindness, have been linked to VZV and HSV-2, with some also associated with HSV-1 or CMV infection of the eye. It is believed that, HSV-2 ARN in children and adolescents may result from undiagnosed and asymptomatic neonatal HSV-2 infection, which has reactivated several years later from latency in a cranial nerve and entered the retina. Currently, intravenous followed by oral acyclovir derivatives daily for several months to years and sometimes intravitreal (into the eye) foscarnet injections are therapeutically employed with limited effectiveness, establishing the potential of effective antiviral therapy to avoid blindness as well as multiple surgeries related to retinal detachment. A highly effective antiviral that can be injected into the eye infrequently and provides sustained antiviral therapeutic effect over a long period of time for ARN is an unmet medical need.

Neonatally acquired herpes virus infections, even when asymptomatic, are thought to have led to ARN as late as age 22. There are approximately 2,500 cases per year of diagnosed neonatal herpes virus infections in the USA.

The potential broad-spectrum nature of our anti-HSV drug candidates is expected to enable several anti-herpesviral indications. Thus, HSV-1 primarily affects skin and mucous membranes causing “cold sores”. HSV-2 primarily affects skin and mucous membranes leading to genital herpes. HSV-1 infection of the eye causes herpes keratitis that can lead to blindness in some cases. In addition, human herpesvirus-3 (HHV-3), aka varicella-zoster virus (VZV) causes chickenpox in children and, when reactivated in adults, causes shingles. Shingles breakouts are amenable to topical treatment, as are the HSV cold sores, genital lesions, and herpes keratitis of the eye.

Topical treatment is expected to result in extremely high antiviral efficacy. This is because such treatment would provide higher concentrations of the antiviral at the site where the virus is manifesting at its highest levels. Highly effective topical treatments in most of these scenarios remain unmet medical needs. Most of these indications do not have satisfactory treatments at present, if any. Further, the treatment of herpes virus infections caused by acyclovir- and famciclovir- resistant mutants is currently an unmet medical need.

With additional indications in the diseases caused by viruses in the herpes virus family, it is likely that our HerpeCide program could expand into a much broader product pipeline than currently anticipated. We anticipate that many of these new drugs would be variations on our current drug candidates. It is therefore expected that the incremental cost of drug development for such additional indications could be substantially smaller than the cost of developing drugs against other viruses in our portfolio.

Progress in Identifying Clinical Lead Drug Candidates against the Four HerpeCide Program Indications

Previously, in August 2015, we obtained confirmatory animal studies data on our then current lead anti-herpes virus drug candidate from TransPharm, LLC. The data confirmed the results earlier obtained in Professor Ken Rosenthal’s Lab at the NorthEast Ohio Medical Center (NEOMED). In both studies, dermal topical treatment with our anti-HSV drug candidate led to 85~100% survival in mice lethally infected with the zosteriform, neurotropic, clinically derived and relevant strain, namely HSV-1 H129. In contrast, all of the untreated mice had severe clinical morbidity and none of the untreated mice survived. These studies established this drug candidate as a viable, effective potential drug. Professor Rosenthal has since retired from NEOMED and is now Professor of Biomedical Sciences at the College of Medicine, Roseman University of Health Sciences, Summerlin, NV.

We have developed additional variations of the ligand used in this older herpecide drug candidate using molecular modeling and rational design strategies. The new ligands appear to have substantially improved effectiveness and with a similar level of safety as did the prior tested ligand. We are now performing studies on chemical covalent conjugates of these ligands with different “nanomicelle” polymer backbones. We are performing a set of studies to identify the lead clinical candidates for the different herpes virus indications based on these new nanoviricides.

We have found that the nanoviricides drug candidates developed against herpes HSV-1 and HSV-2 are also effective against the shingles virus, namely the Varicella Zoster Virus (VZV), also called HHV-3 (human herpesvirus-3) in cell culture studies in house. These data were presented at the American Society of Virology 2017 annual meeting held in June 2017 at Madison, WI. Additional studies have continued to demonstrate strong effectiveness as the development progresses.

We have also found that the shingles treatment nanoviricides drug candidates were highly effective in VZV infection studies using human skin-patch organ culture (SOC) model. We have repeatedly found strong effectiveness in the SOC studies using different variations of the drug candidates aimed at establishing the final clinical drug candidate. These studies were performed in the Professor Jennifer Moffat Lab at the Upstate Medical Center in SUNY, Syracuse, NY. The Moffat group presented some of these data at the 31st International Conference on Antiviral Research held in Porto, Portugal, on June 10-15, 2018.

At present, there is no well-established animal model of shingles infection, while animal models have been developed to test for shingles vaccines. We are employing the human skin explant-based SOC model for evaluation of drugs against VZV infection, in lieu of animal studies. This model is expected to be more relevant than an animal model. It is particularly suited for a topical drug such as ours. We believe that these human skin-patch SOC model experimental data will be sufficient to establish the effectiveness of a nanoviricide drug candidate to pursue further in human clinical studies.

Our drug candidates for shingles treatment were also found to be extremely safe in a preliminary rat safety/toxicology study, as we reported in April 2018. No clinically observable adverse safety and toxicology effects were seen in this study of the Company's optimized topical dermal drug candidates based on multiple parameters evaluated. There were no adverse effects on the skin at the treatment sites. Equally importantly, the results of the non-GLP safety and toxicology study showed that there were no overall observable systemic effects either. There were no observable direct effects on the primary organ function whether the drug was administered to the skin or administered systemically. This includes liver and kidney function. This is important as the liver and kidneys are major organs involved in drug toxicity. Dermal topical treatment of rats with formulated drug candidates was evaluated in this study as a primary objective, since skin is the primary breakout site of HSV-1, HSV-2, and VZV infections. Additionally, the same drug candidates as formulated for systemic delivery were employed to evaluate potential systemic safety/toxicological effects. We now also report herein that there were no observable changes in the histo-pathological study (tissue structure) of a panel of organs including the brain, heart, liver, lungs, spleen, kidney, intestines, uterus, testis, as well as skin upon treatment with the tested drug candidates. The study was conducted by AR Biosystems of Beverly, MA.

Of note, the drug candidates tested in this safety/toxicology study have previously shown broad-spectrum effectiveness against alphaherpesviruses, i.e. HSV-1, HSV-2, and VZV.

These results are consistent with the positive findings in a model of VZV (the shingles virus) infection of human skin in which no safety or toxicology concerns have been observed, further demonstrating the safety of these drug candidates. The drug candidates have shown strong effectiveness in these shingles virus studies as well, as previously reported. Further, these candidates have demonstrated strong anti-viral activities against HSV-1, HSV-2, and VZV in cell culture studies using multiple cell lines.

The Company's drug candidates in HerpeCide™ program are being developed for direct topical application on the affected areas to control the infections. Direct topical application enables delivery of the highest possible concentrations of the active substance directly at the site of infection. This allows for maximal clinical effectiveness, while at the same time minimizing side effects that are seen with systemic therapy (such as oral drugs or injectables).

The shingles drug candidates are thus advancing towards the full battery of GLP safety and toxicology studies that are needed for filing an Investigational New Drug (IND) application with the US FDA, prior to beginning human clinical trials.

Because of the strong safety observed in preliminary studies, the IND-enabling Tox Package study would be performed at the Maximum feasible Dose (MFD) level. Subsequent to the reporting period, in September 2018, the Company has started production in a GMP-like process at our cGMP-capable facility in Shelton, CT to manufacture sufficient quantities of the drug candidate for the planned IND-enabling Tox Package study. The Company expects to begin Tox Package studies once the drug is manufactured in the multi-kg quantities needed and is already in negotiation with a CRO site for the study.

These dermal safety/tox studies for the VZV skin cream are expected to be significantly shorter than the studies for ocular, injectable, or oral drugs. We anticipate filing an IND once the report of these studies is available.

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

Since these nanoviricides are designed to attack the virus directly, we believe that human clinical studies should reflect the success of the preclinical studies.

We are also continuing to work on developing relevant chemical identification and characterization assays, physicochemical and biochemical characterization assays, and chemical process optimization studies, that will be part of the CMC (Chemistry, Manufacture and Controls) section of the Investigational New Drug (IND) Application for the shingles drug. We believe this drug will be our first candidate into human clinical trials.

HerpeCide Program Collaborations and Program Update

We have engaged in several collaborations to help us finalize clinical candidates and develop IND-enabling pre-clinical data in our various programs this year. Notably, we have continued collaborations with the Collaborative Ophthalmic Research Laboratories (CORL), at the University of Wisconsin for HSV-1 and HSV-2, with focus on small animal models for ocular disease.

In addition, we have a continuing relationship with Bio-AnalyticalSystems, Inc. (“BASi”), Indiana, a CRO for GLP and non-GLP safety/toxicology (“Tox Package”) studies. We have engaged Biologics Consulting Group (BCG), Virginia, for advice and help with regulatory affairs.

We also have a collaboration with the Campbell Lab at the University of Pittsburgh for in vitro cell culture models of various ocular viruses including many adenovirus and herpes virus strains, as well as animal models for ocular herpes keratitis (HK) and adenoviral epidemic keratoconjunctivitis (EKC).

In addition, we have continued our agreement with SUNY Upstate Medical University for the testing of the Company’s nanoviricides® drug candidates against varicella zoster virus, i.e. the shingles virus. This research is being performed in the laboratory of Dr. Jennifer Moffat.

Initially, Dr. Moffat conducted cell culture studies i.e. in vitro studies. Upon finding that the nanoviricides drug candidates were effective against VZV in cell cultures, Dr. Moffat has advanced the studies to the ex vivo human skin-patch organ culture (SOC) model studies stage, wherein our drug candidates are being evaluated against VZV infection of human skin patches.

Dr. Moffat has extensive experience in varicella zoster virus (VZV) infection and antiviral agent discovery. The goal of these studies is to help select a clinical drug development candidate for toxicology and safety evaluation intended for clinical trials for the treatment of shingles in humans.

VZV is restricted to human tissue and only infects and replicates in human tissue. The ex vivo studies are continuing to evaluate the efficacy of the Company’s nanoviricides to inhibit VZV in human skin organ cultures. Dr. Moffat has developed the human skin organ culture VZV infection model for the evaluation of therapeutics. This model is a good representative model of natural VZV infection in humans as well as an important model for evaluating antiviral activity, because it demonstrates behavior similar to the skin lesions caused by VZV in human patients.

Dr. Moffat is an internationally recognized expert on varicella zoster virus, and her research has focused on the pathogenesis and treatment of infection by this virus. The National Institute of Health has recognized this VZV model via a contract with Dr. Moffat’s lab for evaluating antiviral compounds against VZV. Dr. Moffat is the director of two research core facilities at SUNY Upstate: the Center for Humanized Mouse Models and In vivo Imaging.

The Company has established a direct relationship with the Moffat lab, without NIH as an intermediary.

In addition, Dr. Brian Friedrich, Senior Virologist of the Company continues to perform extensive antiviral cell culture studies against VZV, HSV-1 and HSV-2 using multiple cell lines and multiple strains of the viruses, in our BSL-2+ anti-viral cell culture laboratory in Shelton, CT.

Dr. Friedrich presented a poster entitled "Novel Nanoviricides® Highly Effective Against Varicella Zoster Virus in Cell Culture" at the 36th Annual Meeting of the American Society of Virology (ASV) on June 26th, 2017. The ASV Meeting was hosted and held at the University of Wisconsin-Madison, from June 24th to 28th, 2017 (https://extensionconferencecenters.uwex.edu/asv2017/).

The two active nanoviricide® candidates presented therein inhibited VZV up to 5x better than acyclovir-sodium (the current standard of care), and completely inhibited VZV protein production/infection in cell culture studies. These results indicate a very high level of anti-VZV effectiveness. The nanoviricide candidates were non-cytotoxic even at the highest doses in all cell lines tested. Thus it should be possible to administer very high concentrations of the drug locally on the skin without any deleterious effects.

Importantly, the data presented demonstrated that the anti-viral activity of a nanoviricide is driven by the virus-specific ligand attached to it. Thus, two of the nanoviricide drug candidates were highly effective against VZV, whereas a third one was not as effective. All three ligands were derived by in silico computer-aided drug design based on known structures of HSV glycoprotein binding to the cellular receptor, namely the herpes virus entry mediator (HVEM), and thus were expected to be active against herpes simplex viruses, and only some of them were anticipated to be active against all alphaherpesviruses. VZV is an alphaherpesvirus. This has once again demonstrated the validity of our scientific drug development approach.

On July 10, 2017, the Company announced the results of initial testing of our anti-herpes drug candidates in the ex vivo human skin patch "SOC" model performed by Dr. Moffat.

The anti-shingles nanoviricides® drug candidates achieved dramatic reduction in infection of human skin by the varicella-zoster virus (VZV), the shingles virus in this study. These findings corroborate the previously reported findings of inhibition of VZV infection of human cells in culture. The antiviral effect of certain nanoviricide drug candidates was substantially greater than the effect of the standard positive control of cidofovir added into media. Even more remarkably, the effect of these nanoviricides drug candidates was equivalent to a topical formulation of 1% cidofovir applied directly onto the skin patch. A topical skin cream containing 2% cidofovir is clinically used in very severe cases of shingles. However, the cytotoxicity of cidofovir is known to cause ulceration of the skin to which it is applied, followed by natural wound healing.

Additional studies have continued at Dr. Moffat lab with small variations on the drug candidates in order to identify a clinical drug candidate. These studies have continued to demonstrate excellent efficacy of our nanoviricide drug candidates against the VZV virus infection. Dr. Moffat presented some of the data at the 31st International Conference on Antiviral Research held June 11 - June 15, 2018 in Porto, Portugal.

Additional studies towards selection of the final drug candidate to be studied in safety/toxicology are continuing at present. Selection of clinical candidate for an investigational new drug application (IND) and human clinical studies is anticipated as these studies progress. Subsequent to this reporting period, since September 2018, we have engaged in cGMP-like manufacture of the drug substance to supply the requirements for the impending Tox Package study. We are able to perform many of the production steps prior to declaring a clinical candidate because of the common processes in the production of the short-listed drug candidates. We believe that we are close to declaring a clinical candidate.

Shingles and Associated Pain, Postherpetic Neuralgia (PHN)

Shingles is caused by re-activation of the chickenpox virus that most humans acquire in childhood. The chickenpox vaccine for children is a live, attenuated virus (LAV). The LAV is not as pathogenic as the wild-type virus. However, this means the virus is present in the vaccinated individual, but remains suppressed by the immune system. In both vaccinated and unvaccinated persons, re-activation occurs when the immune system is suppressed which may be simply because of stress, advanced age, or some other immune modifying circumstances including immune-compromise due to organ transplants or other diseases. Generally, humans in the age range of 50-60 are more prone to shingles, with next reactivation occurring about 10~15 years later. There is a shingles vaccine approved for adults age 60 and above which is also available for adults younger than that.

Acyclovir-based oral drugs, such as valacyclovir (Valtrex®), are available as systemic therapy for shingles. Intravenous acyclovir is also employed for treatment of various VZV indications. However, VZV is substantially less sensitive to (val)acyclovir than is HSV-1. Thus the oral drug generally does not result in optimal level of the active drug at the site of VZV viral production, and does not result in significant control of the pathology. The antiviral drugs may be given for a period of 14 days or longer, with as much as 5g of dose per day, due to poor efficacy. In some indications, the treatment has been continued for a year or so. Thus, there is an unmet need for developing anti-VZV antivirals with high efficacy and safety.

A Phase 3 clinical study comparing FV-100 to valacyclovir for PHN and shingles was terminated by ContraVir Pharma. FV-100 is a nucleoside analog with an extremely restricted activity range. A helicase/primase inhibitor, ASP2151, was found to be non-inferior to valacyclovir in a shingles clinical study. Astellas has suspended its development due to serious side effects in some healthy volunteers. A drug with a novel mechanism of action such as our nanoviricides should be promising.

Most adults with shingles recover in about 15~30 days from the shingles rash. While the rash is unsightly, its stinging pain is often the debilitating pathology that leads to lost workdays and other effects. Further, 65~70% of patients develop postherpetic neuralgia, or PHN, a stinging, debilitating pain that lasts more than 30 days, and, in some patients, may last for years.

It is generally believed that PHN results from damage to the local nerve endings and nerve cells caused by the uncontrolled production of the shingles virus. However, VZV has been found to be present in at least 75% of PHN cases in a study, indicating a role for antivirals in controlling PHN. We believe that an effective therapy, such as our nanoviricide against VZV, which blocks progression of the virus to infect new cells and thereby limits further production of virus, would minimize the damage to nerve endings and nerve cells caused by the virus. We believe that this would minimize the occurrence, severity, and time period of PHN, in addition to having significant effects on the severity of shingles rash, lesions, and healing time.

In light of this we have conducted an animal study regarding the effect of our nanoviricide drug candidates against shingles on neuropathic pain in a classical animal model of pain (without VZV infection). On August 7, 2018, subsequent to the reporting period, we reported that our anti-Shingles drug candidates were effective in ameliorating pain sensations in an animal model of abnormal pain. In this animal study, topical treatment with the nanoviricides® anti-VZV compounds significantly reduced the measures of abnormal pain sensations in a rat model of neuropathic pain. The study was conducted at AR Biosystems in Tampa FL. A characteristic excruciating pain is a debilitating pathology of shingles presentation. Thus a direct pain-reducing effect of the Company’s anti-shingles drug candidates would be very important in ameliorating the pathology of shingles, in addition to the already demonstrated significant antiviral effect.

We believe that a skin cream would be the best form of treatment to provide rapid control of the virus and shingles lesions patch expansion, since the shingles outbreak remains highly localized. A skin cream would afford much greater local exposure of drug to virus compared to a systemic oral or injectable treatment.

An effective therapy for patients with severe shingles continues to be an unmet need.

HSV-1, HSV-2, Ocular Herpes Keratitis

We believe that a skin cream for the control of HSV-1 “cold sores” (herpes labialis, and recurrent herpes labialis or RHL) is another drug candidate that will be close to entering human clinical trials. We have already achieved strong success in animal studies against HSV-1, as discussed above.

We believe that we will be able to successfully develop a drug for Ocular Herpes Keratitis (HK) as well. It is caused by HSV-1 or HSV-2 infection of the external eye. We are developing this drug as topical eye drops or eye lotion, in order to achieve maximum local drug effect while minimizing systemic exposure. We plan on testing these drug candidates against adenoviruses as well, to determine if the same drug would also be effective against epidemic keratoconjunctivitis (EKC, the severe “pink eye” disease). If the same drug works against herpes virus and adenovirus infections of the eye, this drug would cover almost 99% of all external eye viral pathologies. However, there can be no assurance that we will successfully be able to develop drugs for any of these viruses.

We also believe that we will be able to develop a drug against HSV-2 genital herpes. We plan on developing a skin cream for this indication, to maximize local effectiveness.

The FluCide™ Program

We are continuing our development of the FluCide™ anti-influenza drug program at the next lower priority level after the HerpeCide program. We have two drugs in development in this program. The Injectable FluCide is designed to piggyback into IV infusions for severely ill, hospitalized influenza patients. There are approximately 100,000 to 300,000 such cases annually in the USA alone. No current anti-influenza drugs are sufficiently effective to be of help in this scenario. We believe that our injectable FluCide would be substantially superior to current anti-influenza drugs and would be able to save lives in this scenario, based on the strong effectiveness in animal studies that has been observed. Following this drug, we are working on an Oral FluCide drug candidate for outpatient influenza treatment.

We have a continuing collaboration with the Webster Lab at the St. Jude Children's Hospital, TN, for the pre-clinical development program for both injectable and oral anti-influenza nanoviricide drug development. Given the several failures of anti-influenza drug developments that have led to increased burden of pre-clinical studies, our FluCide pre-clinical development program is expected to take longer than our HerpeCide™ program IND-enabling pre-clinical studies.

NanoViricides, Inc. is possibly the first company in the world in the entire field of nanomedicines to have developed an orally available nanomedicine drug with high effective bioavailability. We have previously estimated an effective bioavailability of about 30-35% for the oral form of an anti-influenza drug candidate compared to the same drug given as injectable, based on animal studies. Our oral anti-influenza drug candidate has shown extremely high broad-spectrum effectiveness against two different influenza A viruses in animal models.

In addition, we are developing a highly effective injectable anti-influenza drug. The Company is developing this injectable drug 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 H7N9, Bird Flu H5N1, other Highly Pathogenic Influenzas (HPI/HPAI), Epidemic Influenzas such as the 2009 "swine flu" H1N1/A/2009, and Seasonal Influenzas including the recent H3N2 influenza. The Company has already demonstrated that our anti-influenza drugs have significantly superior activity when compared to oseltamivir (Tamiflu®) against two unrelated influenza A subtypes, namely, H1N1 and H3N2 in a highly lethal animal model.

Our position that an injectable drug against influenza is a viable option is now affirmed by the approval of the very first injectable drug for influenza in December 2014, namely peramivir (Rapivab, by BioCryst). Interestingly, peramivir as an injection was approved even though it did not appear to provide significant additional benefits over other drugs in its class. Overall, patients who received 600 mg of peramivir had symptom relief 21 hours sooner, on average, than those who received the placebo, which is consistent with other drugs in the same class. Additionally, peramivir injection was found to be not effective for hospitalized patients with severe influenza.

Thus, an effective therapy for patients hospitalized with severe influenza continues to be an unmet need.

In addition, a single injection treatment of non-hospitalized patients would be a viable drug if it provides superior benefits to existing therapies.

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

DengueCide™

We are developing a broad-spectrum anti-dengue nanoviricide which is in pre-clinical development in the DengueCide™ program at a lower priority than FluCide. 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 has 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. We have previously achieved significant survival of mice in a lethal infection animal model of dengue disease. This model simulates antibody-dependent enhancement of dengue, which is believed to lead in humans to severe dengue, and dengue hemorrhagic fever. These studies were performed by Professor Eva Harris at the University of Berkeley.

HIVCide™

Our HIVCide™ program is currently receiving the lowest development priority primarily due to the extremely expensive nature of this program. The drug candidates in the 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. Certain anti-HIV nanoviricides have already been demonstrated 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.

EKC

In addition, the Company is developing broad-spectrum eye drops that are expected to be effective against a majority of the viral infections of the external eye. Most of these viral infections are from adenoviruses or from herpes viruses. The Company has shown excellent efficacy of its drug candidates against EKC (adenoviral epidemic keratoconjunctivitis) in an animal model. If feasible, we are planning to merge the anti-EKC drug development program and the ocular Herpes Keratitis drug development program, to develop a single drug that is effective against both diseases, i.e. effective against both adenoviruses and herpes viruses. This work is in research stage.

Other Drug Programs: Ebola, Rabies and others

In addition to these eight 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. We will not be undertaking socially important programs such as the development of an anti-Zika virus drug candidate, or continuation of our efforts in developing anti-Ebola drug candidate, unless non-dilutive funding for such efforts becomes available.

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.

Thus, this year, we have further focused our programs and prioritized them in order to advance our first drug candidate into the clinic in the near future.

Safety and Toxicology Studies

As part of the IND–enabling development of our Injectable FluCide™ drug candidate, we previously performed initial safety-toxicology screening of an optimized FluCide® drug candidate in a GLP-like toxicology study in rats. We reported that a good safety profile was observed for this drug candidate in rats at the end of January 2015. These results are in agreement with the previously reported results of a non-GLP toxicology study in mice. The current study results also support the Company's positive findings in animal models of infection with different influenza A virus strains in which no safety or toxicology concerns were observed. The Company has previously reported that many of its FluCide candidates demonstrated extremely high anti-influenza activity in those models. These results are extremely important since they indicate that FluCide continues to look very promising as one of the most advanced candidates in the Company's drug development pipeline.

We believe that these safety/toxicology results are also applicable to other drug candidates as well in the sense that they have established the safety of the polymer backbones that we have employed. The polymer is made up of PEG (polyethylene glycol) chains put together into a single polymer chain with ligands and pendant lipids substantially uniformly attached at the connector points. This enables the nanoviricide to be substantially non-immunogenic. PEG chain attachment or PEGylation is a widely used technique for rendering antibodies and other drugs substantially non-immunogenic.

Successful preliminary safety study in an animal model has cleared the way for us to begin IND-enabling safety/toxicology study for our shingles treatment drug candidate, as described earlier.

Clinical and Regulatory Strategy

We have engaged Biologics Consulting Group, a well-known group of regulatory consultants, to advise us on the regulatory pathways, and the studies required for the IND applications for the various disease indications.

At present, the anti-VZV drug candidate appears to be our most advanced drug candidate, with the other HerpeCide™ program drug candidates following in its footsteps, as the necessary additional safety and efficacy studies in cell culture and animal models are performed. We depend upon external collaborators for animal safety and efficacy studies, limiting the speed of our drug development work. While we seek collaborators and providers that have animal models that may be predictive of efficacy in human clinical trials, pharmaceutical drug development relies on what is available and what is doable rather than this gold standard. Newly implemented animal models require validation studies to establish how reproducibly they can discriminate between placebo and drugs that are known to work in the clinic, when such drugs are available. In many cases, we have to rely upon research level animal models that have not yet established such robustness. Nevertheless, we can continue to use such models to obtain preliminary indications for drug candidate refinements.

We believe that the efficacy we have observed of our anti-VZV drug candidates in the ex vivo human skin patch "SOC" model in the Moffat Lab is a strong indicator that these drug candidates are worthy of clinical development. There is no well-established animal model for shingles at present. As such we assume that these datasets will be sufficient for filing an IND. Therefore, we have planned further screening to determine final clinical candidate(s) and further plan on taking one or two candidates through initial safety studies, followed by GLP Safety/Toxicology studies. We plan on obtaining a pre-IND meeting with the US FDA after the initial safety studies in order to obtain further guidance on the datasets expected in the IND.

We believe that our existing cGMP-capable manufacturing facilities are sufficient for the production of drug products for human clinical studies.

Large Market Sizes – The Company Targets an Overall Anti-Viral Drug Market Size that Exceeds $40B

The current market size for drugs for the treatment of different herpes simplex infections is about $2~4B. The current market size for the treatment of shingles is estimated at about $500M to $1B. We believe that when an effective topical treatment is introduced, the market size is likely to expand substantially.

The approximate market size for severe cases of shingles may be in the billion-dollar range. Severe cases of shingles may lead to hospitalization in several thousand cases in the USA. In addition, shingles appearing on the face may reach the eye and may cause significant vision issues. The outpatient treatment market size for shingles at present is limited, because of the limited effectiveness of existing drugs. An effective drug could expand this market into billions of dollars globally. Novel shingles vaccines with improved effectiveness are in development. However, as shingles is not seen as a life-threatening or life-modifying disease, the use of vaccines is limited, and may continue to be limited, especially if an effective drug is developed.

In addition, the estimated market size for an effective anti-Influenza drug is expected to be in tens of billions of dollars. The current estimate of anti-influenza drug market size is approximately $4B.

The current market size for anti-HIV treatments is in excess of $20B.

Our focus at present is on the topical treatments for different herpes virus infections in the HerpeCide program, as listed elsewhere in this report. We plan on re-engaging our Influenza and HIV programs when sufficient funding and skilled human resources are available.

Our Campus in Shelton, CT

With the expanded R&D labs, Analytical labs, the Bio labs, the Process Scale-Up production facility, and the cGMP-capable manufacturing facility established at our Shelton campus, we are in a much stronger position than ever to move our drug development programs into the clinic rapidly.

Process Scale-Up Production Capability

The Process Scale-up area is operational at scales of about 200g to 1kg per step for different chemical synthesis and processing steps. It comprises reactors and process vessels on chassis or skids, ranging from 1L to 30L capacities, as needed. Many of the reactors or vessels have been designed by us for specific tasks.

cGMP Production Capability

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

This cGMP-capable facility can handle multiple reactors on chassis of up to 75L capacities. Thus, we have sufficient cGMP manufacturing capability to produce multi-kg batches of our nanoviricide drug candidates.

We have planned certain minimal infrastructure modifications to improve the capabilities of the cGMP-compliant facility, based on our experience in the Scale-up operations. Certain of these improvements are expected to add a separate production suite for the manufacture of skin cream in an area that was designated for such further expansion. These infrastructure improvements will be undertaken only after appropriate level of funding becomes available, of which there can be no assurance.

After these infrastructure improvements, we plan to produce at least three consecutive batches of a drug product and satisfy that said drug product is within our own defined specifications. After we are satisfied with such strong reproducibility of our processes, we plan to register the facility as a cGMP manufacturing facility with the US FDA.

At present, we plan on moving operations to our cGMP-capable manufacturing facility as the operational steps are developed to the level needed for moving them into this facility. This requires the development of draft-level Standard Operating Procedures, training, and drill-through of operations. We will also need to establish a Quality Assurance and Quality Control Department.

Given the limited financing, we have not been able to attract the necessary talent for replacing the lost staff and for building out the additional resources such as QA/QC.

If we are able to attract and hire quality candidates that we severely need, we anticipate that it will take at least six months to one year for each such person to be fully productive as an integrated part of our team. In the past, we have been very fortunate that newly hired personnel were immediately productive in tasks delineated to them, and they were productively integrated within a short time frame of several months into independent but integrated parts of our team. However, this is not always the case.

We operate in a completely novel area of medicines, which is broadly described as polymeric-micelle based drug conjugates and complex nanomedicines. Our technologies are also completely novel, and unmatched in the industry. As such, we anticipate a longer training period for new employees than in normal small chemical or biological drugs. We need talented personnel with specialized training. With the extreme difficulties in hiring foreigners due to immigration requirements, there is only a severely limited talent pool that may be available or accessible to us.

Thus limited financing has a long-lasting effect on our ability to progress to the human clinical stage.

We employ the same team that developed the small-scale synthesis chemistry for translation of those chemical syntheses into clinical-scale processes, and also to perform the related chemical engineering, quality control, quality assurance, and regulatory tasks along the way. Because of the small size of our scientific staff, this results in significant serialization of efforts. However, the personnel cost, as well as the time and expense cost of transfer of knowledge and training of a separate dedicated team is avoided because the same expert scientists who have developed the chemistries are also involved in scaling them up into process scale. To enable such extensive multi-tasking, we have a continuous training program in place, with both formal and informal components. We believe that this approach helps us keep drug development costs as low as possible.

Our BSL-2 Certified Virology Lab

Most importantly, we have significantly enhanced our internal anti-viral cell culture testing capabilities at our Shelton campus. We have achieved BSL-2 (Biological Safety Level 2) certification from the State of Connecticut for our Virology suite at the new campus. This suite comprises three individual virology workrooms, enabling us to work on several different viruses and strains at the same time. This facility is designed only for cell culture studies on viruses, and no animal studies can be conducted at any of our own facilities. We have brought in Brian Friedrich, Ph.D., as the Company's Virologist. Dr. Friedrich has previously performed drug screening of hundreds of candidates against several viruses including alphaviruses, bunyaviruses, and filoviruses (namely, Ebola and Marburg, which are BSL-4), to discover potential therapeutics, while he was at United States Army Medical Research Institute of Infectious Diseases (USAMRIID). Brian has also worked extensively on Flaviviruses, specifically West Nile Virus, while at University of Texas Medical Branch (UTMB). He has also worked on HIV as part of his PhD thesis. Dengue viruses as well as the Zika virus belong to the Flavivirus family.

Dr. Friedrich has already established several different types of assays for screening of candidates against VZV, HSV-1 and HSV-2 in our lab. He is now in the process of establishing assays for Influenza viruses and HIV. We believe that having developed the internal capabilities for cell culture testing of our ligands and nanoviricides against a variety of viruses has substantially strengthened our drug development programs. We believe that this internal screening enables speedy evaluation of a much larger number of candidates than external collaborations allow. This has significantly improved our ability of finding highly effective ligands and performing structure-activity-relationship studies of the same in a short time period.

Manufacturing Requirements of Some of Our Drug Candidates

The HerpeCide program drug product batch requirements are estimated to be fairly modest because of the topical nature of treatment. In consultation with BASi and BCG, we have currently estimated a batch size of approximately 1kg will be sufficient for the "Tox Package" (i.e. safety and toxicology) studies of our dermal topical shingles drug candidate. We are estimating that a ~500g batch will be more than sufficient for initial Phase-I human clinical studies as well. Our current estimate for a Phase IIa human clinical efficacy study is also in the range of a ~500g batch requirement. We already have the facilities for producing up to 1kg per batch or more. Many of our synthesis steps have already been scaled up to 200g~500g scales. The "nanomicelle" polymer manufacture is already scaled to ~500g scale, with some steps already scaled up to multi-kg scale. Thus we believe that we have sufficient production capability for the amounts of the HerpeCide drugs that would be needed for tox package as well as clinical studies.

As we move our drug candidates into clinical studies, we plan to perform further scale-up studies to get to about 1kg per batch production scale. In the current facility, we may be able to manufacture about 20kg to 50kg of cGMP API (active pharmaceutical ingredient) annually. Depending upon the drug's potency and indication, this production size may fetch modest revenues of around $50M to $500M, depending upon the cost metrics, enabling profitable market entry. Such initial commercialization would allow the Company to turn itself into a stand-alone pharmaceutical company, by enabling capital formation for larger scale manufacturing facilities and fueling further growth.

Patents, Trademarks, Proprietary Rights: Intellectual Property

The Company has an exclusive license in perpetuity for technologies developed by TheraCour for the following virus types: HIV, Hepatitis C Virus, HSV-1 and HSV-2, 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. A license for VZV and the remaining herpes viruses is currently being negotiated with TheraCour. (Also please see under "Significant Alliances: Related Parties: TheraCour Pharma").

The Company has entered into a Memorandum of Understanding with TheraCour, whereby TheraCour will initiate discovery and development for drug candidates for a new virus or indication upon such request by the Company. If the resulting drug candidates are worthy of further drug development, NanoViricides may determine that it should enter into a licensing agreement with TheraCour. In such a case, NanoViricides would obtain an independent asset valuation for the asset(s) to be licensed from a party experienced in such valuations. NanoViricides and TheraCour would thereafter negotiate the terms of compensation for the new license agreement. However, there can be no assurance that an agreement for licenses for new viruses will be entered into on terms that are favorable to NanoViricides. We believe this process has been extremely beneficial for NanoViricides, since this process saves NanoViricides from the cost of acquiring and paying for licenses that it may not want to pursue further. At present, TheraCour has licensed the Company HSV-1 and HSV-2, but has not licensed the VZV area, nor has it licensed any of the remaining herpes viruses. NanoViricides has commissioned independent party asset valuations to serve as the basis for such additional licenses that it may seek in accordance with our process. However, there can be no assurance that the Company will be able to enter into an agreement with TheraCour for such license or that the agreement will be on terms that are favorable to the Company. The licenses granted by TheraCour are for entire sets of pathologies that the licensed virus is a causative agent for. The licenses are not for single drug entities, although that is the customary mode in the Pharmaceutical industry. Thus these are very broad licenses and enable NanoViricides to pursue a number of indications as well as develop drug candidates with different characteristics as is best suited for the indications, without having to license the resulting drugs separately.

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 1), 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 1: 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. Fifty two of these have been issued or validated	TheraCour Pharma, Inc. [Exclusive License].
3	PCT/US2007/001607 SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTIVIRAL AGENTS	Applied: Jan 22, 2007	Ca. 2029(estimated)	Applications are in various prosecution stages. Nine of these have been issued or validated	TheraCour Pharma, Inc. [Exclusive License].

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

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

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

These patents have nominal expiry dates in 2026 to 2029. The dates can be further extended in several countries and regions for the additional allowances due to the regulatory burden of drug development processes, or other local considerations, such as licensing to a local majority held company. Many countries allow up to a five year extension for regulatory delays.

No patent applications have been filed for the actual drug candidates that we currently intend to develop as drugs. We intend to file the patent application for FluCide and HerpeCide before entering human clinical trials. The estimated expiry date for the FluCide and HerpeCide patents, if and when issued, would be no earlier than 2037-2038.

Of the patents and technologies licensed, the Company believes that it 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 the existing patents or any future patents, of our licensor TheraCour Pharma, Inc., 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.

Recognition

On August 24, 2016, the Honorable U.S. Senator Chris Murphy visited the Company's campus in Shelton, CT. In addition the Honorable U.S. Richard Blumenthal has previously visited our company. Further, the Honorable U.S. Representative Jim Himes visited our company in the recent past.

On July 25, 2016, our President, Dr. Anil Diwan, was invited to participate in the prestigious 31st Annual Chief Executive of the Year Gala Reception & Dinner held at the New York Stock Exchange. In addition, he was also invited to participate in the CEO Roundtable Discussion on Innovation.

Previously, on April 18, 2016, the Company announced that it has been recognized as one of the "Most Innovative Business Leaders of 2016" by AI Global Media, publisher of Acquisition International Magazine and Website ("AI") (http://www.acquisition-intl.com). A focus article on NanoViricides was published in AI Magazine, February 2016 issue.

Presentations and Conferences

The Company continues its efforts at connecting with additional investors and presenting in investor-oriented business conferences. Some of these are listed below.

Our collaborator, the Moffat group at Upstate Medical Center, SUNY, Syracuse, NY, presented a poster entitled describing the effectiveness on nanoviricide candidates against VZV virus in a human skin patch organ culture ("SOC") model of shingles, at the 31st International Conference on Antiviral Research held June 11 - June 15, 2018 in Porto, Portugal.

The Company presented a poster entitled "Novel Nanoviricides® Highly Effective Against Varicella Zoster Virus in Cell Culture" at the 36th Annual Meeting of the American Society of Virology (ASV) on June 26, 2017. The ASV Meeting was hosted and held at the University of Wisconsin-Madison, from June 24th to 28th, 2017 (https://extensionconferencecenters.uwex.edu/asv2017/). Dr. Brian Friedrich, Senior Virologist of the Company, presented the Company's work on the evaluation of nanoviricides drug candidates for effectiveness against the shingles virus (Varicella Zoster Virus, VZV, aka Human HerpesVirus-3 or HHV-3) in this poster.

The Company gave an oral presentation on the "Effect of NanoViricide Anti-viral Agents in a Mouse Model of Acute Retinal Necrosis", at the 51st Annual Meeting of the Ocular Microbiology and Immunology Group (OMIG) held at the Astor Crowne Plaza Hotel in New Orleans, LA, on November 10, 2017. Both tested nanoviricide candidates were effective in decreasing viral load by about 2 to 3 logs at day 3 and demonstrated significant positive clinical effects on controlling HSV-2 G infection in the mouse eye. The study was conducted in Dr. Brandt Lab at the CORL, University of Wisconsin, Madison, WI.

Anil R. Diwan, PhD, President and Chairman of the Company, is regarded as an expert in nanomedicines and has been invited to present regarding critical issues in nanomedicines drug development including regulatory processes, with special emphasis on CMC (chemistry, manufacture, and controls).

Subsequent to the reporting period, on October 1, 2018, Dr. Irach Taraporewala, the new CEO of the Company provided a corporate overview at the MicroCap Conference in New York City.

Subsequent to the reporting period, on September 25, 2018, Dr. Irach Taraporewala, the new CEO of the Company and Dr. Anil Diwan, President of the Company, provided a corporate overview at the NYC-Inaugural LD Micro Conference in New York City.

Subsequent to the reporting period, on September 17, 2018, Dr. Diwan presented a talk entitled "NanoViricides – On the Road to Clinical Trials – cGMP Manufacturing of Antiviral Nanomedicines" at the 16th Annual International Conference in Nanomedicines, entitled "The Road from Nanomedicine to Precision Medicine" held at the Albany College of Pharmacy and Health Sciences, Albany, NY.

Subsequent to the reporting period, on September 6, 2018, Anil R. Diwan, PhD, President and Chairman of the Company presented an overview of the Company at the 20th Annual Rodman & Renshaw Global Investment Conference, sponsored by H.C. Wainwright & Co., LLC, held at the St. Regis Hotel in New York City.

On April 9, 2018, Dr. Diwan presented the recent safety data from preliminary safety/toxicology study for the shingles drug candidates and provided a corporate update at the MicroCap Conference held at the Essex House in New York City.

Previously, on February 22, 2016, the Company announced that information on its novel proprietary anti-virus platform technology has been published in the book "Handbook of Clinical Nanomedicine, Vol. 1. Nanoparticles, Imaging, Therapy, and Clinical Applications", a CRC Press publication. The chapter entitled "Nanoviricides: Targeted Anti-Viral Nanomaterials" provides an in-depth presentation of the NanoViricides platform technology, evidence for how nanoviricides® are believed to act plus dramatic results of nanoviricides specifically targeting certain viral diseases, such as Influenza.

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 that reliably deactivates or destroys a virus.

Nanoviricide ® – An agent that 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 - A term coined to describe the micelles formed from the backbone polymer of a nanoviricide sans attached ligands.

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. Mutant viruses are 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 that the Company files with the FDA. After the FDA approves an IND application, the Company may conduct human clinical studies. A Phase I human clinical trial is designed typically to evaluate safety of the drug and maximum permissible dosage level. A Phase II human clinical trial that follows is designed to evaluate effectiveness of the drug against the disease in a small cohort of patients. A Phase III human clinical trial thereafter is designed to evaluate effectiveness and safety in larger groups of patients, often at multiple sites. The Company may then submit an NDA (New Drug Application) with the data collected in the clinical trials. The FDA may approve the NDA. Once the NDA is approved, the Company can sell the drug in the USA. European countries have similar processes under the European Medicines Agency (EMA). Other countries have similar processes.

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

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). Some of the PRVs have been "sold" for as much as $250M or so recently.

While there is no indication whether NanoViricides, Inc. can obtain priority review vouchers 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). The Zika virus was added to this list recently.

Products

NanoViricides, Inc. currently has no products for sale. The Company currently has developed reasonably safe and effective drug candidates against several different indications as demonstrated in pre-clinical cell culture and animal studies. The Company believes that with the funds on hand, it should be able to take at least one of these drug candidates into IND filing stage in the near future. The Company will need to raise additional funds for commencing and executing human clinical trials.

Reports to Security Holders

As of November 2006, as a result of its filing of Form 10-SB and listing on the FINRA OTC Bulletin Board, the Company became subject to the reporting obligations of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These obligations include filing an annual report under cover of Form 10-K, with audited financial statements, unaudited quarterly reports on Form 10-Q and the requisite proxy statements with regard to annual shareholder meetings. The public may read and copy any materials the Company files with the Securities and Exchange Commission (the "Commission") at the Commission's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0030. The Commission maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the Commission. Information about the Company is also available on its Web site at www.nanoviricides.com. Information included on the Web site is not part of this Form 10-K.

Further, the Company's common stock has been listed on the NYSE MKT (a US national exchange) since September 25, 2013. The NYSE-American Exchange requires additional corporate governance, financial and reporting requirements. NYSE MKT has changed its name to "NYSE American" in July 2017.

On July 3, 2018, NanoViricides, Inc. (the "Company") received a notice from the New York Stock Exchange (the "NYSE") indicating that the Company is not in compliance with the NYSE's continued listing requirements set forth in Part 8 of the NYSE American Company Guide (the "Company Guide"). The NYSE noted that the Company is not in compliance with Section 803(B)(2)(a) of the Company Guide in that it no longer has at least three members on the audit committee, effective as of June 29, 2018 when an Independent Director Dr. Mukund Kulkarni advised the Company that he resigned as a member of its audit committee.

On July 10, 2018, Dr. Kulkarni advised the Company that he rescinded his resignation as a member of the audit committee and the Company accepted the same. Dr. Kulkarni rescinded his resignation from the Audit Committee subsequent to Dr. Boniuk's resignation as a Director and from all committees of the Board of Directors, on the same date. Due to Dr. Boniuk's resignation, the non-compliance item continues to persist until the Company appoints additional independent directors to the Board. The Company is already interviewing pharmaceutical industry expert candidates for the directorship and hopes to complete the selection process soon.

Under the NYSE's rules, the Company will have until the earlier of its next annual meeting or one year from the occurrence of the event that caused the failure to comply with the board of directors composition requirements, provided, however, that if the annual shareholders' meeting occurs no later than 180 days following the event that caused the failure to comply with these requirements, the Company shall instead have 180 days from such event to regain compliance.

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 Contact Information

Our principal executive offices are currently located at 1 Controls Drive, Shelton, Connecticut 06484 and our telephone number is (203) 937-6137 (voice mail). 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 or the risks described elsewhere in this report 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,” “predict” or “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 candidate in our pipeline;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- the successful commercialization of our product candidates; and
- market acceptance of our products.

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

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

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

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

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

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

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

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

We have incurred significant operating losses and may not ever be profitable. As of June 30, 2018, we had a cash and cash equivalent balance of $7,081,771. Also, the Company has incurred significant operating losses since its inception, resulting in an accumulated deficit of $83,692,146 at June 30, 2018. Such losses are expected to continue for the foreseeable future.

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.

While we believe we will be able to raise sufficient cash in the capital markets, to be able to take at least one of our drug candidates into initial human clinical trials, we currently do not have sufficient resources to complete the development and commercialization of any of our proposed products.

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;
- 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 real estate taxes and facility and equipment maintenance, rent, 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 if they:

- are found to be unsafe or ineffective or fail to meet the appropriate endpoints 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.

All of our products in development are still in the pre-clinical stage, and not submitted to any regulatory agencies in any formal drug licensing or approval processes. We have previously held a pre-IND meeting with the US FDA regarding our anti-influenza drug candidates, in March 2012. However, since then, we have re-evaluated our priorities. We have now prioritized our HerpeCide™ program drug candidates as our highest priority candidates. We believe that we have obtained valuable information at the pre-IND meeting for our FluCide program that we believe we can apply to our HerpeCide program in a generalized manner.

Such strategic changes are necessitated due to the limited resources available to us for drug development. We perform such strategic changes in order to maximize our chances of entering into human clinical trials in the regulatory process in the earliest time frame possible, and within the funding available to the Company, guided by input from a number of sources. Such changes are designed to accelerate some programs and would lead to delays in some other programs that receive lower priority, due to our limited resources. We may not be able to accurately assess the effect of such changes on our business plan.

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. 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 currently have sufficient funds on hand to take at least one drug candidate into IND application stage. We believe we will be pursuing a candidate from our HerpeCide™ program for an IND and initiating human clinical trials with the limited financial resources in hand.

The Company will be unable to proceed with its business plan beyond approximately September 30, 2019, without obtaining additional financing to support its budgeted Research and Development and other costs.

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

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

  the number, extent, and outcome of pre-clinical studies we are planning to conduct; for example, our R&D expenses may increase based on the number and extent of IND-enabling pre-clinical studies including CMC Studies, Tox Package Studies, and Quality Programs 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 limited experience in conducting or supervising clinical trials and must outsource all clinical trials.

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

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

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

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

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

Efforts of government and third-party payers 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 payers 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 exclusive licenses from TheraCour Pharma, Inc. to novel technologies, proprietary technologies, and knowhow, some of which has been filed in patent applications, and we 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 Licensing Agreements with TheraCour Pharma Inc. ("TheraCour"). While we hold the licenses in perpetuity, the Agreements may be terminated by TheraCour as a result of: the insolvency or bankruptcy proceedings by or against the Company, a general assignment by the Company to its creditors, the dissolution of the Company, cessation by the Company of business operations for ninety (90) days or more or the commencement by the Company or an affiliate to challenge or invalidate the issued patents.

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

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

The Company does not have facilities that could be used to conduct clinical testing. We expect to contract with third parties to conduct all clinical testing required to obtain approvals for any drugs that we might develop. We currently outsource all clinical testing to a number of third parties in various collaborations and service contracts. 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 now own facilities that could be used to manufacture clinical quantities of any products that might be developed by the Company. We believe that this cGMP-capable facility may allow us to produce limited quantities of a drug after approval for initial market entry, and that such an effort may make commercial sense if the treatment course requirements and afflicted patient populations are limited, and if the remuneration for the treatment course is appropriate. However, we do not own, nor lease facilities suitable for cGMP manufacture of any of our drug candidates in large commercial quantities, nor do we have the resources at this time to acquire or lease suitable facilities. At present, we have not retained any contract manufacturing organizations (CMO) for commercial manufacture or for clinical product manufacture.

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 a 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 approximately thirty employees including the employees of affiliates, 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. All other consultant/contractors would be more readily replaceable. We have recently significantly expanded our operations and staff materially and our new employees include a number of key managerial, technical, financial, R&D and operations personnel. The expansion of our business will continue 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 Material License Agreements with TheraCourPharma, Inc. ("TheraCour") (an approximately 13.6% shareholder of the Company's common stock) as of June 30, 2018, whereby TheraCour has exclusive rights to develop exclusively for us, the materials that comprise the core drugs of our planned business. TheraCour is a development stage company with limited financial resources and needs the Company's progress payments to further the development of the nanoviricides. The Company controls the research and work TheraCour performs on its behalf and no costs may be incurred without the prior authorization or approval of the Company. No royalties are due to TheraCour from the Company's inception through June 30, 2018.

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 collaboration 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 $8,000,000 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 current executive officers, Irach Taraporewala, Chief Executive Officer, and Anil Diwan, President, are critical to the success of the Company. The Company is a limited beneficiary of a certain amount of key man insurance for Anil Diwan 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.

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

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

Certain of our executive officers and directors and their affiliates are engaged in other activities and have interests in other entities on their own behalf or on behalf of other persons. Neither we, nor our stockholders will have any rights in these ventures or their income or profits. Specifically, Anil Diwan owns approximately 90% of the capital stock of TheraCour Pharma, Inc., which as of June 30, 2018 owned 13.6% of our Common Stock, and 2,000,000 shares of the Company's Series A Preferred stock, and provides the nanomaterials to the Company 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 Pharma, Inc., for which he must recuse himself from certain decision-making processes of the Company.

In addition, a former independent director, Dr. Milton Boniuk has dispositive power over 10,601,258 shares of common stock, and 337,000 shares of Series A preferred stock as of June 30, 2018.

The Company does not allow a conflicted Shareholder, Director, or Executive Officer to vote on matters wherein a conflict may be perceived. The conflicted entity is not allowed to nominate an alternate person to vote for them either. Other than this safeguard, the Company currently does not have any policy in place, 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 would compete for each contract. Moreover, the award of one government contract would 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 shingles drug candidate would compete with Valtrex®, an approved drug (valacyclovir), and other acyclovir-related nucleoside analogs, and new drugs in the pipeline. The approved drugs are known to have very limited benefit. FV-100, a VZV-specific nucleoside analog was in Phase III clinical trials that were terminated. Development of ASP2151, a helicase/primase inhibitor, was terminated due to adverse events in healthy persons in clinical trials. We are not aware of any further drugs in clinical trials for the treatment of shingles. Painkillers such as lidocaine formulations and oxycodone formulations were in clinical trials for symptomatic relief of PHN.

Our HSV-1 and HSV-2 skin cream drug candidates would compete with branded and unbranded available skin creams, such as Abreva™, as well as with branded and unbranded oral drug candidates against herpes, such as those based on acyclovir, valacyclovir, gancyclovir, among others. All of these drugs are known to have limited benefits. It is not known until after human clinical trials whether our drug candidates provide patient benefits beyond those of these drugs. Other drugs against herpes that are in the pipeline, if approved prior to our drug approval, would also be competition. Several drugs are in clinical trials for HSV-1 and/or HSV-2 treatment. These include brincidofovir, cyclopropavir, valamocyclovir, pritelivir, letermovir, as well as antibodies. Their patient benefit profiles are not known at present.

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. BioCryst Pharmaceuticals, Inc. has achieved US FDA approval for IV Infusions formulations of peramivir, an influenza neuraminidase inhibitor, for the treatment of uncomplicated influenza. Peramivir is approved in Japan and had obtained emergency use authorization in the US. Its effectiveness during multiple clinical trials was found to be severely limited. Recently, a new drug, Xofluza (Baloxavir marboxil), developed by Shionogi, Inc., has been approved in Japan, and licensed in the US and the rest of the world by Genetech/Roche. It is in fast track Phase 3 clinical trials under the US FDA. It is an influenza viral endonuclease PA inhibitor. Other drugs in this class are in clinical trials. So are drugs targeting the m7G cap-snatching activity (PB2) of influenza virus such as VX787, and antibodies. Several H5N1 bird flu, and influenza novelH1N1/2009 vaccines are also in development worldwide. Several companies are developing anti-influenza drugs and vaccines.

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

Our nanoviricide eye drops for viral diseases of the eye are currently under development. We have shown significant clinical efficacy in an animal model of EKC (adenoviral epidemic keratoconjunctivitis). 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, but did not meet its desired end points in a clinical trial recently. We believe that the nanoviricide eye drops should have a significant advantage in terms of reduced frequency of application needed and simple application procedure.

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 American 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 became listed on the NYSE MKT (now known as "NYSE American"), 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 American may issue anon-compliance letter or initiate delisting proceedings. If our securities are delisted from trading on the NYSE American 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).

On July 3, 2018, NanoViricides, Inc. (the "Company") received a notice from the New York Stock Exchange (the "NYSE") indicating that the Company is not in compliance with the NYSE's continued listing requirements set forth in Part 8 of the NYSE American Company Guide (the "Company Guide"). The NYSE noted that the Company is not in compliance with Section 803(B)(2)(a) of the Company Guide in that it no longer has at least three members on the audit committee, effective as of June 29, 2018 when an Independent Director Dr. Mukund Kulkarni advised the Company that he resigned as a member of its audit committee.

On July 10, 2018, Dr. Kulkarni advised the Company that he rescinded his resignation as a member of the audit committee and the Company accepted the same. Dr. Kulkarni rescinded his resignation from the Audit Committee subsequent to Dr. Boniuk's resignation as a Director and from all committees of the Board of Directors, on the same date. Due to Dr. Boniuk's resignation, the non-compliance item continues to persist until the Company appoints additional independent directors to the Board. The Company is already interviewing pharmaceutical industry expert candidates for the directorship and hopes to complete the selection process soon.

Under the NYSE's rules, the Company will have until the earlier of its next annual meeting or one year from the occurrence of the event that caused the failure to comply with the board of directors composition requirements, provided, however, that if the annual shareholders' meeting occurs no later than 180 days following the event that caused the failure to comply with these requirements, the Company shall instead have 180 days from such event to regain compliance.

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

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

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 American, may fluctuate significantly in response to a number of factors, many of which are beyond our control. These factors include but are not limited to:

- progress of our products through the regulatory process
- results of preclinical studies and clinical trials;
- announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our products or our competitors' products in both the United States and foreign countries;
- developments or disputes concerning patent or proprietary rights;
- general market conditions for emerging growth and pharmaceutical companies;

- economic conditions in the United States or abroad;
- actual or anticipated fluctuations in our operating results;
- broad market fluctuations; and
- changes in financial estimates by securities analysts.

There is a risk of market fraud.

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

As of September 25, 2013, our common stock was listed on the NYSE American 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, 2018, shareholders of the Company held 21,000,399 shares (as adjusted) of restricted stock, or approximately 30.4% of the outstanding common stock. If we were to file a registration statement including all of these shares, and the registration is allowed by the SEC, these shares would be freely tradable upon the effectiveness of the planned registration statement. If investors holding a significant number of freely tradable shares decide to sell them in a short period of time following the effectiveness of a registration statement, such sales could contribute to significant downward pressure on the price of our stock.

We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our capital stock must come from increases in the fair market value and trading price of the capital stock.

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements, which we may enter into with institutional lenders, may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements and any other factors that the board of directors decides is relevant. Therefore, any return on your investment in our capital stock must come from increases in the fair market value and trading price of the capital stock.

We may issue additional equity shares to fund the Company's operational requirements, which would dilute share ownership.

The Company's continued viability depends on its ability to raise capital. Changes in economic, regulatory or competitive conditions may lead to cost increases. Management may also determine that it is in the best interest of the Company to develop new services or products. In any such case additional financing is required for the Company to meet its operational requirements. There can be no assurances that the Company will be able to obtain such financing on terms acceptable to the Company and at times required by the Company, if at all. In such event, the Company may be required to materially alter its business plan or curtail all or a part of its operational plans as detailed further in Management's Discussion and Analysis in this Form 10-K. While the Company currently has no offers to sell its securities to obtain financing, sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. In the event that the Company is unable to raise or borrow additional funds, the Company may be required to curtail significantly its operational plans as further detailed in Requirements for Additional Capital in the Management Discussion and Analysis of this Form 10-K.

The Company is authorized to issue up to 150,000,000 shares of Common Stock without additional approval by shareholders. As of June 30, 2018, we had 69,171,740 shares of common stock outstanding, 6,969,588 warrants convertible to 6,969,588 shares of common stock and 4,531,394 shares of Series A Preferred Stock convertible into 15,859,879 shares of Common Stock only in the event of a change in control. Subsequent to the reporting period, 2,868,891 warrants have expired on September 9, 2018.

As of September 25, 2013, our common stock has been listed on the NYSE American national exchange.

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

As of June 30, 2018, 20,997,362 of 69,171,740 issued and outstanding shares of the Company's common stock were restricted securities as defined under Rule 144 of the Securities Act of 1933, as amended (the "Act") and under certain circumstances may be resold without registration pursuant to Rule 144. In addition the 4,531,394 shares of Series A Preferred Stock are restricted and convertible into 15,859,879 shares of Common Stock only in the event of a Change of Control of the Company.

Approximately 2,854,614 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, 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, activities necessary for supporting our independent public auditors. This effort may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we may need to hire additional accounting and financial persons with appropriate public company experience and technical accounting knowledge, and we cannot assure you that we will be able to do so in a timely fashion.

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

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

ITEM 1B: UNRESOLVED STAFF COMMENTS.

None.

ITEM 2: PROPERTIES

Description of Property

The Company's principal executive offices are located at 1 Controls Drive, Shelton, CT, and include approximately 18,000 square feet of office, laboratory, and cGMP-capable drug manufacturing space. These facilities are fully owned by the Company. There is no mortgage on these facilities.

We subcontract the laboratory research and development work to TheraCour Pharma, Inc., under the License Agreement with TheraCour. Management believes that the space is sufficient for the Company to monitor the developmental progress at its subcontractors.

ITEM 3: LEGAL PROCEEDINGS.

From time to time, we are a party to legal proceedings arising in the ordinary course of business. We are not currently a party to any other legal proceedings that we believe could have a material adverse effect on financial condition or results of operations.

ITEM 4: MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Our Common Stock commenced trading on the NYSE MKT on September 25, 2013 under the symbol "NNVC". The Company's Common Stock, after the Company became a publicly traded company in May 2005, was initially traded on the Pink Sheets under the symbol NNVC and from June 29, 2007, through September 24, 2013, the Company's Common Stock has been quoted on the Over The Counter Bulletin Board. The table below sets forth the high and low prices for the Company's Common Stock for the quarters included within the past two fiscal years. Quotations reflect inter-dealer prices, without retail markup, markdown commission, and may not represent actual transactions. 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, 2018	$ .36	$ .86
March 31, 2018	$ .80	$ 1.08
December 31,2017	$ .87	$ 1.23
September 30, 2017	$ .94	$ 1.64
June 30, 2017	$ 1.06	$ 1.43
March 31, 2017	$ 1.10	$ 1.34

December 31,2016	$ 1.03	$ 1.65
September 30, 2016	$ 1.51	$ 1.77

Number of Shareholders.

As of June 30, 2018, a total of 69,171,740 shares of the Company's common stock are outstanding and held by approximately 163 shareholders of record. 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, 48,174,378 shares are unrestricted, of which, 5,500,000 shares are held by affiliates. Approximately 2,854,614 shares are restricted securities held by non-affiliates, and the remaining 18,142,748, shares are restricted securities held by affiliates. These shares may only be sold in accordance with Rule 144. As of June 30, 2018, there were 6,969,588 warrants to purchase the Company's Common Stock outstanding. Of these, subsequent to the reporting period, approximately 2,868,981 of the warrants have expired on September 9, 2018.

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.

Fiscal Year Ending June 30, 2016 Transactions

On January 23, 2016, the Company's Board of Directors and a majority of the holders of the Company's Series A Convertible Preferred Shares (the "Series A Shares") approved an amendment to the Certificate of Designation of the Series A Shares to increase the number of authorized Series A Shares from 4,000,000 to 8,500,000.

On February 1, 2016, 571,433 warrants were issued for interest in accordance with the terms of the Series B debenture. The warrants are exercisable at $3.50 per warrant and will be valid for 3 years after issuance. The Company recorded an expense of $56,115 for the fair value of the warrants. The Company estimated the fair value of the warrants issued to the Holders of the Company's Series B Debentures on the date of issuance using the Black-Scholes Option-Pricing Model.

For the year ended June 30, 2016, the Scientific Advisory Board was granted fully vested warrants to purchase 68,592 shares of common stock at exercise prices between $1.44- $2.18 per share expiring in the fiscal year ending June 30, 2020. These warrants were valued at $42,886 and recorded as consulting expense.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 57,649 shares of its Series A Convertible Preferred Stock, which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of $263,698, which is the fair value at date of issuance.

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Anil Diwan, the Company's president. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 of the Company's Series A preferred shares to Dr. Diwan. 75,000 shares vested on June 30, 2016 and the remainder of the shares will vest over the remaining two years of the employment agreement and are subject to forfeiture. The Company recognized a noncash compensation expense related to the issuance of the Series A Preferred Shares of $309,344 for the year ended June 30, 2016. The balance of $564,410 will be recognized as the remaining shares are vested.

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Eugene Seymour, the Company's then Chief Executive Officer. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 Series A preferred shares to Dr. Seymour. 75,000 shares vested on June 30, 2016 and the remainder of the shares will vest over the remaining two years of the employment agreement and are subject to forfeiture. The Company recognized a noncash compensation expense related to the issuance of the Series A Preferred Shares of $309,344 for the year ended June 30, 2016. The balance of $564,410 will be recognized as the remaining shares are vested.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 106,554 shares of its common stock, which are fully vested with a restrictive legend for consulting services. The Company recorded an expense of $158,000, which is the fair value at date of issuance.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 29,852 shares of its common stock, which are fully vested with a restrictive legend for Director services. The Company recorded an expense of $45,000, which is the fair value at date of issuance.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 72,725 shares of its common stock, which are fully vested with a restricted legend for employee compensation. The Company recorded an expense of $142,589, which is the fair value at date of issuance.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 313,155 shares of its common stock for the exercise of 428,573 stock options on a cashless exercise basis.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 101,558 shares of its common stock to holders of the Company's Series B Debentures. Two Holders of the Company's Series B Debentures elected to receive a total of $160,000 of the quarterly interest payments in restricted common stock of the Company. The Holders are entities controlled by Dr. Milton Boniuk, a then Director of the Company.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 313,785 shares of its common stock to the Holder of the Company's Series C Debentures. The Holder of the Company's Series C Debentures elected to receive $375,000 of the quarterly interest payments and $125,000 of the deferred interest in restricted common stock of the Company. The Holder is an entity controlled by Dr. Milton Boniuk, a then Director of the Company.

Fiscal Year Ending June 30, 2017 Transactions

For the year ended June 30, 2017, the Scientific Advisory Board was granted fully vested warrants to purchase 57,160 shares of common stock at exercise prices between $1.40- $2.04 per share expiring in the fiscal year ending June 30, 2021.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 57,650 shares of its Series A Convertible Preferred Stock that are fully vested with a restrictive legend for employee compensation.

On January 25, 2017 the Board of Directors authorized the issuance of 200,000 fully vested shares of its Series A Convertible Preferred stock to Anil Diwan.

For the year ended June 30, 2017, the Company recognized a noncash compensation expense of $297,267 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Anil Diwan's employment agreement that vest over three years. The remaining balance of $267,143 will be recognized as the remaining shares are vested over the term of the contract.

For the year ended June 30, 2017, the Company recognized a noncash compensation expense of $297,267 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Eugene Seymour's employment agreement that vest over three years. The remaining balance of $267,143 will be recognized as the remaining shares are vested over the term of the contract.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 71,430 fully vested shares of its common stock for employee compensation.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 164,465 fully vested shares of its common stock with a restrictive legend for consulting services.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 33,933 fully vested shares of its common stock with a restrictive legend for Director services.

On February 8, 2017 two Holders of the Company's Series B Debentures elected to convert $5,000,000 of the principal into restricted common stock of the Company. The Company's Board of Directors authorized the issuance of 4,335,386 of the Company's restricted common stock. One of the Holders is controlled by Dr. Milton Boniuk, a then Director of the Company. The second Holder is a foundation established by Dr. Milton Boniuk.

For the year ended June 30, 2017 two Holders of the Company's Series B Debentures elected to receive $107,178 in restricted common stock of the Company. For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 97,999 shares of the Company's restricted common stock for interest payable to the Holders. One of the Holders is controlled by Dr. Milton Boniuk, a then Director of the Company. The second Holder is a foundation established by Dr. Milton Boniuk.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 423,862 shares of its common stock to the Holder of the Company's Series C Debentures. The Holder of the Company's Series C Debentures elected to receive $375,000 of the quarterly interest payments and $125,000 of the deferred interest in restricted common stock of the Company. One Holder is an entity controlled by Dr. Milton Boniuk, a then Director of the Company. The other Holder is a charitable foundation established by Dr. Milton Boniuk.

Redemption and Conversion of Debenture Series B Into Common Stock

A substantial portion of the Company's Series B Convertible Debentures, with a maturity date of January 31, 2017, were redeemed with restricted common stock, effectively retaining $5 million in cash for the Company.

On February 8, 2017, the Company entered into agreements with certain holders (the "Holders") of the Company's Series B Convertible Debentures (the "Debentures")., The Company and the Holders agreed to redeem an aggregate of $5,000,000 of principal and accrued interest of $27,178 of the Debentures, which was payable on January 31, 2017 (the "Maturity Date") into 4,359,652 newly-issued, restricted shares (the "Redemption Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"). The redemption price of the Redemption Shares for the principal amount was $1.1533 representing the volume weighted average price of the Common Stock on the NYSE MKT from December 15, 2016 to January 30, 2017, as recommended by the Company's Board of Directors on December 11, 2016 at a Board meeting. Dr. Boniuk abstained from voting at the meeting. This redemption price was at a premium of the closing bid price of the Common Stock on the Maturity Date of $1.1500. The price for the interest amount, pursuant to the terms of the Debentures was the closing price of the Common Stock on the Maturity Date. In connection with the conversion, the Holders agreed to waive any and all prepayment, redemption and conversion rights under the original Debentures in full and final satisfaction for the acceptance of the Conversion Shares.

The Company offered this redemption proposal to all holders of the Series B Convertible Debentures, with a total principal value of $6,000,000. Holders of Debentures in the aggregate principal amount of $5,000,000 accepted the Company's offer. The holders that accepted the offer included Dr. Milton Boniuk, a then Director of the Company, and a foundation established by him. The remaining Debentures in the amount of $1,000,000 principal, with accrued interest as of the Maturity Date, were repaid to the holders thereof in cash.

This redemption, permitted the Company to retain $5,000,000 of cash and, with the repayment to the other holders, decrease current liabilities by approximately $6,000,000. No agents were retained and no commissions or fees were paid for this conversion, other than usual attorneys' fees.

Fiscal Year Ending June 30, 2018 Transactions

For the year ended June 30, 2018, the Scientific Advisory Board was granted fully vested warrants to purchase 45,728 shares of common stock at exercise prices between $0.64- $1.56 per share expiring in the fiscal year ending June 30, 2022. These warrants were valued at $16,770 and recorded as consulting expense .

For the year ended June 30, 2018, Eugene Seymour was granted five year warrants (the "Warrants") to purchase 250,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock") at an exercise price of $2.00 per share, vesting in three, equal installments over three years with the last installment vesting on May 1, 2021, as part of the Severance Agreement. The fair value of these warrants were valued at $53,500 and recorded as Employee compensation expense.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 57,650 shares of its Series A Convertible Preferred Stock, which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of $136,106, which is the fair value at date of issuance.

For the year ended June 30, 2018, the Company recognized a noncash compensation expense of $267,144 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Anil Diwan's employment agreement that vest over the three years ended June 30, 2018.

For the year ended June 30, 2018, the Company recognized a noncash compensation expense of $121,008 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Eugene Seymour's employment agreement that vested over three years. On January 27, 2018, Dr. Eugene Seymour resigned as Chief Executive Officer and as a Director of the Company. See Note 12 to the Financial Statements.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 150,000 shares of its Series A Convertible Preferred Stock, which are fully vested with a restrictive legend to the Holder of the company's Series C Convertible Debenture in consideration for its waiver of all early redemption payments provided for in the Debenture. The Company recorded an expense of $314,343, which is the fair value at date of issuance.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 71,430 fully vested shares of its common stock for employee compensation for severance. The Company recognized a noncash compensation expense of $65,716.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 243,759 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $156,190, which was the fair value at the dates of issuance.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 49,777 fully vested shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of $45,000, which was the fair value at date of issuance.

For the year ended June 30, 2018 the Holders of the Company's Series C Debentures elected to receive 5,500,000 shares of the Company's restricted common stock in redemption for its $5,000,000 Series C Debenture, quarterly interest payments of $375,000 and deferred interest of $125,000. For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 5,500,000 shares of the Company's restricted common stock for the redemption of the debenture payable to the Holder and quarterly and deferred interest payments. The holders that accepted the election to redeem the Series C debenture included Dr. Milton Boniuk, a then Director of the Company, and a foundation established by him. See Note 7 to the Financial Statements.

USE OF PROCEEDS FROM SALES OF REGISTERED SECURITIES

Thus far, the Company has used a portion of the net proceeds of the past offering, and intends to use the balance, for research and development and working capital.

ITEM 6: SELECTED FINANCIAL DATA

The selected financial data presented below are for each fiscal year in the five-year period ended June 30, 2015. This data is derived from, and qualified by reference to, our audited financial statements and notes thereto appearing elsewhere in this Form 10-K.

Statements of Operations Data:

	Years Ended June 30,				
	2018	**2017**	**2016**	**2015**	**2014**
Operating expenses:					
Research and development	$ 4,826,840	$ 5,531,708	$ 5,028,970	$ 3,660,322	$ 5,131,523
General and administrative	4,498,329	4,069,016	3,830,531	3,402,778	3,535,849
Total operating expenses	9,325,169	9,600,724	8,859,501	7,063,100	8,667,372
Loss from operations	(9,325,169)	(9,600,724)	(8,859,501)	(7,063,100)	(8,667,372)
Other income (expense):					
Interest income	100,429	60,955	62,638	160,859	171,001
Interest expense on convertible debentures	(185,274)	(780,767)	(1,042,470)	(2,649,592)	(3,092,550)
Loss on extinguishment of debt	(1,348,247)	(332,524)	-	-	-
Discount on convertible debentures	(359,214)	(1,347,748)	(1,427,218)	(1,175,344)	(569,495)
Change in fair value of derivatives	2,554,020	1,696,318	541,922	8,529,005	(1,443,200)
Other income (expense), net	761,714	(703,766)	(1,865,128	4,864,928	(4,934,244)
Loss before income tax provision	(8,563,455)	(10,304,490)	(10,724,629)	(2,198,172)	(13,601,616)
Income tax provision	-	-	-	-	-
Net loss	$ (8,563,455)	$ (10,304,490)	$ (10,724,629)	$ (2,198,172)	$ (13,601,616)
NET LOSS PER COMMON SHARE					
- Basic	$ (0.13)	$ (0.17)	$ (0.19)	$ (0.04)	$ (0.27)
- Diluted	$ (0.13)	$ (0.17)	$ (0.19)	$ (0.09)	$ (0.27)
Weighted average common shares outstanding					
- Basic	64,920,856	60,102,855	57,669,472	56,553,848	51,225,622
- Diluted	64,920,856	60,102,855	57,699,472	59,220,515	51,225,622

Balance Sheets Data:

	As of June 30,				
	2018	**2017**	**2016**	**2015**	**2014**
Cash and cash equivalents	$ 7,081,771	$ 15,099,461	$ 24,162,185	$ 31,467,748	$ 36,696,892
Working capital	6,440,080	10,624,109	17,637,629	31,081,278	36,437,242
Total assets	18,546,212	27,002,814	36,633,418	44,187,089	43,859,995
Long-term liabilities	-	2,015,354	6,841,190	11,800,327	19,972,953
Accumulated deficit	(83,692,146)	(75,128,691)	(64,824,201)	(54,099,572)	(51,901,400)
Stockholders' equity	17,664,264	20,321,942	23,048,214	31,785,867	23,369,303

ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the information contained in the financial statements of the Company and the notes thereto appearing elsewhere herein and in conjunction with the Company's Annual Report on Form 10-K for the year ended June 30, 2018. Readers should carefully review the risk factors disclosed in this Form 10-K and other documents filed by the Company with the SEC.

As used in this report, the terms "Company", "we", "our", "us" and "NNVC" refer to NanoViricides, Inc., a Nevada corporation.

PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of the federal securities laws. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "we believe," "NNVC believes," "management believes" and similar language. The forward-looking statements are based on the current expectations of NNVC and are subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this report. Actual results may differ materially from results anticipated in these forward-looking statements. We base the forward-looking statements on information currently available to us, and we assume no obligation to update them.

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

Management's Plan of Operation

The Company's drug development business model was formed in May 2005 with a license to the patents and intellectual property held by TheraCour Pharma, Inc. that enabled creation of drugs engineered specifically to combat viral diseases in humans. This exclusive license from TheraCour Pharma serves as a foundation for our intellectual property. The Company was granted a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex Virus (HSV-1 and HSV-2), Influenza and Asian Bird Flu Virus. 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: Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses. At present, the Company has a license for herpes simplex virus areas, but not for the non-simplex human herpes viruses that include VZV. The Company has been performing due diligence activities necessary prior to engaging in additional license negotiations with TheraCour for these fields. The Company has retained the consulting firm Bio-Ensemble, LLC ("BEL") to help with the due diligence processes as well as with developing license agreements that meet pharma industry standards with the view that NanoViricides is likely to engage into partnership with another Pharma company and sublicense the drug candidates at suitable stages. Dr. Carolyn Myers, Principal of BEL, has over 25 years of experience in the field of licensing and negotiations in the drug development field from Startups, Small Pharma, Mid-Pharma as well as Big Pharma perspectives, having acted in very senior business development roles from both sides of the equation. Dr. Myers is helping the Company strategize the HerpeCide™ program. License negotiations with TheraCour for the remaining human herpes viruses are now active in earnest with our new CEO, Dr. Irach Taraporewala, taking the lead since he joined on September 1, 2018. Dr. Taraporewala is a pharma industry veteran who has been previously involved in licensing and regulatory pathway development of pharma drug candidate assets, as well as due diligence consulting on drug candidate asset acquisition opportunities to pharma industry clients. NanoViricides thus has a strong team of industry experts helping the Company with this process.

The Company discloses the risk that while we are working with the assumption that we will be able to come to mutually agreeable terms for an additional license for the VZV area with TheraCour, there can be no assurance that the Company will be able to enter into an agreement with TheraCour for such license or that the agreement will be on terms that are favorable to the Company. The Company may want to add further virus types to its drug pipeline as the Company progresses further. The Company would then need to negotiate with TheraCour appropriate license agreements 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 licenses granted by TheraCour are for entire set of pathologies that the licensed virus is a causative agent for. The licenses are not for single drug/indication pairs, which is the customary mode of licensing in the Pharmaceutical industry. Thus these are very broad licenses and enable NanoViricides to pursue a number of indications as well as develop drug candidates with different characteristics as is best suited for the indications, without having to license the resulting drugs for each indication separately, as with normal pharmaceutical industry licensing.

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 have 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.

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.

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, or an effective drug may be developed by competitors that becomes difficult to compete against with our limited resources

Our goal, which we can give no assurance that we will achieve, is for NanoViricides, Inc. to become the premier company developing highly safe and effective drugs that employ an integrated multiplicity of actions as enabled by our nanomedicine approach for anti-viral therapy.

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 animal models of efficacy and safety. We have generated funding through the issuances of debt and the sales of securities under our shelf registration and the private placement of common stock (See, Item 5). The Company does not currently have any long-term debt. We have not generated any revenues and we do not expect to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or we may not become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations.

The Company's Drug Pipeline

Over the first several years of our operations, we continued to work on different viruses every year, creating a broad pipeline of drug candidates. This provided a validation for our novel technologies. In addition, we were pursuing non-dilutive drug development and partnering opportunities such as government grants and contracts as well as partnering with other non-governmental agencies, or other medium and big pharma companies. Our drug development proposal for dengue viruses and other viruses was received favorably by DTRA in 2009-2010 and went into contract negotiations phase, but did not result in an approved grant or contract.

We had realized that the current pharma industry contract manufacturing operations (CMOs) do not have the expertise in our kinds of nanomedicines. We therefore acquired the cGMP-capable nanomedicines drug development and manufacturing facility from Inno-Haven LLC in 2014 at cost. Dr. Anil Diwan, our co-founder, had established Inno-Haven LLC to acquire and develop lab facilities appropriate for his work. On December 31, 2014, the Company entered into and consummated an Agreement for the Purchase and Sale of this cGMP-compliant pilot manufacturing and lab facility and property located in Shelton, Connecticut. The purchase price of the facility was comprised solely of the repayment of the direct costs of the seller, Inno-Haven, LLC incurred in acquiring and renovating the property and the facility plus Inno- Haven's closing costs in connection with the sale.

We were able to drive our drug development programs towards regulatory approval processes only after this modern facility for nanomedicines synthesis, characterization, scale-up, and cGMP-like production became available. The facility became substantially operational at the end of December 2015. Since then, we have engaged in activities necessary for filing an IND (Investigational New Drug application) with the US FDA or another international regulatory agency to begin Phase I human clinical trials of our first drug candidate.

We chose our HerpeCide drug program, and in particular, skin cream for topical treatment of pathologies caused by herpes simplex viruses as our lead program based on regulatory requirements, resource requirements, commercial opportunity, ROI maximization opportunities, and other considerations. We had developed certain broad-spectrum ligands based on molecular modeling for binding to herpes simplex virus and potentially interfere with this virus' binding to its human cell entry receptor, namely HVEM ("herpes virus entry mediator"). The nanoviricides designed using these ligands have shown broad-spectrum activity in cell cultures against multiple HSV strains and both HSV-1 and HSV-2. Our early drug candidates have also shown substantial effectiveness in an animal model of HSV-1 skin disease (for HSV-1 "cold sores" treatment). Additionally, we found that the same drug candidates also demonstrated effectiveness against VZV, the cause of shingles in adults and chickenpox in children.

This has led to our new strategy for drug development with the goal of entering our first drug candidate into human clinical trials at the earliest possible timeframe. Table 2 below summarizes our drug development programs, specific disease indications we plan on developing against, and the priority for each drug in the development pipeline.

Table 2. NanoViricides Drug Products in Development

	Program	Drug	Virus	Indication	Development Stage	Priority
I	HerpeCide™ Dermal Topical and Eye Drops	1a	Varicella-Zoster Virus (VZV)	Shingles	IND-Enabling	A
		1b		PHN	Advanced Preclinical	C
		1c		Chickenpox	Advanced Preclinical	C
		2a	HSV-1	Herpes "Cold Sores"	Advanced Preclinical	B
		2b		Recurrent Herpes Labialis (RHL)	Advanced Preclinical	C
		3	HSV-2	Genital Herpes	Preclinical	B
		4	HSV-1, HSV-2	Ocular Herpes Keratitis (HK)	Preclinical	C
	HerpeCide™ IntraOcular Injection	5	VZV, HSV-2, HSV-1	viral Acute Retinal Necrosis (vARN)	Preclinical	C
II	FluCide™ Broad-Spectrum Anti-Influenza nanoviricide	6	All Influenza A	Injectable FluCide™ for hospitalized patients	Advanced Preclinical Pre-IND Meeting held with US FDA	D
		7	All Influenza A	Oral Flucide™ for outpatients	Advanced Preclinical Pre-IND Meeting held with US FDA	D
III	Nanoviricide Eye	8	Adenoviruses, HSV-1	Eye Drops for Viral Diseases of the	Preclinical	E

	Drops			External Eye		
IV	DengueCide™	9	Dengue viruses, all types	Broad-Spectrum nanoviricide against all types of Dengue viruses	Preclinical	F
V	HIVCide ™	10	HIV/AIDS	Escape-resistant Anti-HIV nanoviricide	Preclinical	D
VI	Other Nanoviricides Drug Projects	-	Ebola/Marburg, Rabies, MERS, Others	Broad-Spectrum nanoviricide drugs against different viruses and indications	R&D	F
VII	HerpeCide™ Program Expansion Drug Projects	-	Possible EBV, HCMV, HHV-6A, HHV-6B, HHV7, KSHV	Broad-Spectrum nanoviricide drugs against different herpes viruses for different indications	R&D	F
VIII	Long Term Projects	-	Various	Technologies for Cures for Persistent Viral Diseases	R&D	F

The Company currently has drug candidates for more than eight different indications in various stages of development in the HerpeCide program alone. Of these, we believe that the Skin Cream against VZV and the Skin Cream against Herpes Labialis (or Recurrent Herpes Labialis, RHL) present the most rapid opportunities for maturing into clinical trials. We have recently expanded the HerpeCide program to include additional indications for which we are developing drugs that are the same as or simple modifications of the existing drug candidates in the HerpeCide program, generally with a different formulation due to a different delivery pathway. This enables us to maximally leverage current R&D while expanding our drug pipeline and potential market, and making a greater impact on patient lives. Given the limited financing available to the Company, and given the large development costs associated with FluCide, HIVCide and other drug programs, we believe that the FluCide drug candidates will follow later because of the significant development work that needs to be performed in pre-clinical studies against a number of different influenza virus strains and subtypes.

Management's beliefs are based on results of pre-clinical cell culture studies, ex vivo tissue based studies (e.g. human skin patch), and in vivo animal studies using small animals such as various types of specially engineered mice and rabbits, as appropriate.

The Company is scaling up the production of its nanoviricide drug candidates for skin cream against VZV as shingles treatment. Subsequent to the reporting period, we are have commissioned our first large-scale batch synthesis program for making sufficient quantities of a drug candidate for the ensuing IND-enabling Safety/Toxicology studies. In preliminary safety/toxicology studies, our shingles drug candidates were found to be extremely safe. As a result, the "Tox Package" program is being designed for maximum feasible dose, increasing the required quantities.

HerpeCide - We are close to finalizing the clinical candidate for the shingles indication. In addition, we continue to conduct studies for optimizing the anti-HSV ligands in animal studies for the other disease indications listed in Table 2. We believe we will be able to successfully advance the optimized drug candidates into an IND and human clinical trials. We are developing anti-herpes virus drugs against several different indications at present, namely, (1) skin cream for topical treatment of shingles, chickenpox, and PHN (VZV), (2) skin cream for treating herpes labialis ("cold sores") and recurrent herpes labialis (RHL) (HSV-1), (3) Eye drops for Herpes Keratitis treatment, (4) skin cream for genital herpes (HSV-2) treatment, and (5) intravitreal injection for Viral Acute Retinal Necrosis (viral ARN, wherein causative agents are mostly VZV, HSV-2, HSV-1 or other viruses). We have continued to expand the HerpeCide program to include additional indications to take full advantage of the development synergies. We have expanded this program to include topical treatment of shingles and were able to very quickly bring this indication to the status of our most advanced program. This has been possible because of the extremely high synergy between the different HerpeCide drug programs, and because of the extremely high effectiveness of our nanoviricides drug candidates we observed against VZV both in cell cultures and in an ex vivo human skin patch organ culture ("SOC") model. We continue to harness additional synergies in the HerpeCide program. For example, viral Acute Retinal Necrosis (vARN) is a pathology that leads to severely reduced vision, and can lead to blindness. Research and clinical lab testing has identified that a large proportion of cases are linked to herpes viruses. Of these, a majority of cases are caused by HSV-2 or VZV. Thus reformulating our topical drug candidates against HSV-2 and VZV for intravitreal treatment of ARN caused by these viruses presents an exciting opportunity. Successful treatment would result in significant patient benefits as well as a significant commercial opportunity. Since vARN is a relatively rare disease, with only a few hundred new cases per year diagnosed in the USA, we believe it should be eligible for the "orphan drug" incentive programs. In addition, we could potentially supply the patient pool with commercial drug product from our existing facility alone, without having to invest in or develop additional commercial large scale manufacturing facilities.

An intravitreal injection requires significantly increased burden in manufacturing, because it requires sterile manufacturing. In addition, it may require a longer Safety/Toxicology program than the skin topical treatments, if it is found to release the drug into systemic circulation. Our FluCide and HIVCide drug candidates are also injectables and require sterile manufacturing and extensive Safety/Toxicology studies because of systemic delivery (compared to dermal topical drugs that may not have systemic availability). While we do have sterile API and Drug Product Manufacturing Capabilities, the CMC program, QA/QC program, and production timelines for injectable drugs are significantly more burdensome and therefore more time-consuming than topical formulations such as dermal topical formulations or external eye drops/gels.

All of the above HerpeCide programs share substantial common drug manufacturing processes and chemicals. Some of these may be the same drugs with different formulations to account for different routes of administration. Thus these programs are strategically developing in parallel to maximize return on investment, (ROI) and therefore shareholder value. These programs are our current development focus and have been given priority ratings of A, B, and C. The priority ratings may change as a program develops. We have seen this happen with the newly introduced shingles program which quickly moved to priority A due to rapid development, even ahead of our HSV-1 and HSV-2 drug candidates.

The HerpeCide indications listed in Table 2 alone represent a market size opportunity of over $5B to $7B. After introduction of the new Shingrix™ vaccine for shingles, and existing vaccines, the market size for shingles treatment is still estimated to be in the range of a billion dollars, and that for shingles+PHN treatment is estimated to be in the tens of billions dollar range.

FluCide. Injectable and Oral forms of the broad-spectrum anti-influenza drug candidate are currently in preclinical studies against all common influenzas as well as avian influenza H5N1. 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 may 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. This program is continuing with our collaboration with the Webster Lab St. Jude's Children's Hospital, TN (Dr. Robert Webster has retired; we continue to refer to the lab as "Webster Lab").

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 keratoconjunctivitis (EKC). 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.

DengueCide - We obtained an orphan drug designation from the US FDA for our lead drug candidate in this program. This program is assigned Priority Level F, and will be activated if sufficient resources become available.

Further, there are several additional indications under the HerpeCide program that we can continue to expand into, which would maximize ROI and shareholder value, as we make further progress into the clinic with our first drug.

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. In particular, we are working on longer term research projects for the purpose of eliminating persistent viruses, thus providing true cures for many intractable diseases such as HIV/AIDS, Herpes, Shingles, Epstein-Barr Virus, among others.

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. We are advancing our drug candidates into IND-enabling "Tox Package" studies, as they mature through animal model efficacy and preliminary safety studies. Management intends to use capital and debt financing to enable the completion of these goals.

Drug Development Plan

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

Manufacturing

Manufacturing of Research Materials

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

Manufacturing of Drugs

The Company intends to manufacture Dermal Topical anti-HSV-1, anti-HSV-2, and anti-VZV drug candidates and drugs, as well as anti-HSV Eye Drops/Gels, Injectable and Oral FluCide, HIVCide, DengueCide, RabiCide as well as other drugs for pre-clinical animal studies and human clinical studies, in facilities owned by the Company. Our cGMP-capable manufacturing facility in Shelton, CT has sufficient capacity for supply of the pre-clinical and clinical batches needed for all of our drug candidates as and when they are anticipated to be needed. The Company may go to a cGMP third party provider for the final fill-and-finish of the clinical drug products if necessary.

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

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

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

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 many of 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. When and 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.

There are several drugs in the market that effectively control HSV cold sores and genital herpes lesions in most patients. These include the nucleoside analogues idoxuridine, vidarabine, acyclovir, famciclovir, ganciclovir, and derivatives. However, their efficacy is limited or toxicities are high. Brincidofovir, based on the toxic drug cidofovir, is in development by Chimerix, but certain clinical trials involving brincidofovir have failed to meet the desired end points. Foscarnet is also used for VZV and ARN, but its toxicity is high. FV-100 is in clinical development against VZV, but it had previously failed in certain clinical studies. In addition, pritelivir, antibodies, and some other drugs are in advanced stages of development against HSV-1 or HSV-2. A gamma globulin was recently approved.

The prevalence of herpes simplex virus type 1 (HSV-1) and HSV-2 is 47.8% and 11.9%, respectively, for individuals aged 14 to 49 years, and increases with age, in the USA, according to CDC. HSV-2 causes a more severe disease that also has significant social costs to the patient. In spite of the existing drugs, both HSV-1 and HSV-2 cause lifelong infection that continues to reactivate at different rates in different patients. Thus in spite of several existing drugs that are already generic, the market size for a highly effective drug is estimated to be in tens of billions of dollars for each of HSV-1 and HSV-2 treatments.

There are currently no approved drugs for the treatment of diseases caused by VZV, namely, shingles, PHN, and chickenpox. Valcyclovir or other acyclovir-class drugs are often prescribed orally but have little effect on shingles. Cidofovir is used in extreme cases of shingles, but it is highly toxic, limiting benefit of the drug, limiting drug dosage and causing significant side effects. Several pain relievers are being developed to treat shingles pain and also the PHN pain. Thus a safe and effective treatment against VZV is an unmet medical need.

There are currently no approved drugs for the treatment of viral diseases of the external eye.

The current approved drugs for influenza include the neuraminidase inhibitors Tamiflu, Relenza, and Peramivir, anti-influenza drugs that are sold by Roche, Glaxo SmithKline (GSK), and BioCryst partners, respectively. In addition, M2 channel inhibitors, generic drugs include amantadine and rimantadine, both oral tablets that only inhibit the replication of the influenza A virus. There is significant viral resistance to the approved M2 channel inhibitors especially in the US. Several companies are developing anti-influenza drugs at present. Small chemical classes include neuraminidase inhibitors, M2-channel inhibitors, and RDRP inhibitors, among others. There are also monoclonal, polyclonal, and mixed antibodies, as well as enzymes as drugs in development. Xofluza, developed by Shionogi Pharma (Japan) is approved in Japan and is in Phase III clinical trials in the USA, licensed by Roche/Genentech. It is an influenza endonuclease inhibitor. It appears to be substantially more effective than existing drugs in reducing viral load and viral shedding, but did not have any effect on the length of the influenza disease course.

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.

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 would 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.

FDA Approval Process

The FDA must "license" a drug before it can be sold in the United States. Other countries have similar regulatory processes, and most are being harmonized under the ICH guidelines. As of the date of this filing, the FDA has approved other nano-particulate drugs including Emend® by Merck and Rapamune® by Wyeth, as well as others. The general process for FDA approval is as follows:

Preclinical Testing

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

Clinical Trials

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

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

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

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

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.

Time Schedules, Milestones and Development Costs

We shall endeavor to achieve completion of the following events within the next twelve months:

- Clinical candidate declaration for shingles and chickenpox
- Production of sufficient material of clinical candidate for the “Tox Package” study of the clinical candidate
- Continue cell culture and human skin organ culture model (SOC) studies as needed for the IND filing
- Develop Chemistry, Manufacture, and Consistency (“CMC”) Package for the clinical candidate
- Develop bio-assays for the ensuing PK/PD studies
- Commission Tox Package studies for the clinical candidate
- Complete licensing agreement with TheraCour Pharma for at least the VZV field, and possibly for all remaining human herpes viruses, based on feedback from experts
- Hold a pre-IND Meeting with the US FDA after a report of the initial non-GLP portion of the formal GLP Tox Package study becomes available to us
- Continue IND-enabling developments
- File an IND application
- Begin Phase I human clinical studies

We believe we have sufficient funds available to accomplish the above goals. We have estimated approximately $750,000 for the Tox Package study and approximately $500,000 for initiation of Phase I clinical trials. The total cost of Phase I and Phase IIa trials will be significantly more. We will need to raise additional funds so that we do not run out of money, and to support continued program development through Phase II studies at least and revenue realization.

In addition to the shingles program milestones listed above, we will continue to advance the HSV-1 and HSV-2 skin cream drug candidates towards IND-enabling studies. Additional HerpeCide drug indications (See Table 2) will be advanced as opportunities become available, depending upon available resources (fiscal and manpower). We plan on continuing the work in the FluCide program albeit at a slow rate, with a view towards obtaining a drug development partnership or other external sources of funding for this program. We plan on continuing internal development of the HIVCide program at a slow rate. Other programs are currently heavily deprioritized and will be further developed if appropriate opportunities present themselves.

Drug Development Status

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

The work-plan we have developed for the next twelve months is expected to enable us to file an investigational new drug application (IND) late in fiscal year 2018 at best (i.e. around May/June 2019), and we believe we have the funding needed for the same. Our work-plan is extremely dependent on external factors, collaborations, and unanticipated delays can occur. We have experienced unanticipated delays in construction, post-construction modifications, and equipment set-up at our new Shelton facility that cumulatively effectively delayed our work-plan towards IND filing of our first drug candidate by more than 24 months. We are now experiencing extreme staffing constraints as well as financing constraints that have already caused delays of more than 12 months and may continue to cause further delays in our estimated timelines, unless we are successful at raising additional funds and at attracting and retaining highly skilled employees with specific skill-sets.

Enabling the cGMP facility has been the major issue for us in the past in our progress towards regulatory filings. We believe that this issue should be resolved in the ensuing fiscal year, with a kg-scale pilot “cGMP-like” facility coming on line. A non-GMP 200g to 1kg scale production setup is being worked on at present. This Production Scale-up Lab is now being scaled up for production of ~1kg batches of our anti-VZV drug candidates. A ~1kg scale is sufficient for all of our anti-herpes drug candidates for Safety/Tox Package studies as well as for Phase I and Phase IIa human clinical trials, as per our current estimates.

During the scale up and optimization of our production level operations, we continue to work on a number of different polymer backbones (“nanomicelles”) and several antiviral ligands in order to make sure that different formulation and pharmacokinetic-pharmacodynamic (PK-PD) needs can be met during the PK-PD programs for our various drug candidates. While this loads up our initial activities, it is expected to de-risk the further drug development towards IND or regulatory filings by making available backup drug candidates with different PK-PD profiles. In FY 2017, we have been able to identify a minimal set of 2-3 polymer backbones and 2 ligands with additional variations on each polymer as well as each ligand for developing a clinical drug candidate. Thus, drug space exploration activities are now drawing to completion for the anti-VZV drug candidate.

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. We believe these data will enable us to file an Investigational New Drug (“IND”) application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

We believe that because we are working in the infectious agents area, our studies will have objective response end points, and further, studies on acute viral infectious diseases are expected to be of relatively short durations. Our business plan is based on these assumptions. If we find that we have underestimated the time duration of our studies, or we have to undertake additional studies, due to various reasons within or outside of our control, this will grossly and adversely impact both our timelines and our financing needs.

We believe that we have sufficient funding for taking at least one of our drug candidates into IND, but we do not believe we have sufficient funding for performing extended human clinical trials at present. Management intends to use equity-based and debt financing, as required, to fund the Company's operations and to raise additional capital for conducting human clinical trials as we advance our pipeline towards IND stage. 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.

Our Collaborations and Service Contract Agreements

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.

All of our agreements provide for the evaluation of Nanoviricides® substances created and provided by the Company to the Laboratory (or Collaborator). 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 and protocols, 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 tries to minimize dependence 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® research materials and drug candidates at different laboratories.

Our current relationships are summarized below:

For Herpes Virus Infections, Shingles, and for Viral Diseases of the Eye (Adenoviruses, Herpesviruses - Epidemic Kerato-conjunctivitis (EKC), Herpes Keratitis, viral Acute Retinal Necrosis (vARN)):

1. The Moffat Lab at SUNY Upstate Medical Center, Syracuse, NY.
2. The CORL at the University of Wisconsin, Madison, WI

For Influenza Viruses:

1. The Webster Lab at St Jude Children's Hospital, TN

For IND-enabling non-GLP and cGLP Safety/Toxicology Studies:

1. AR Biosystems, Inc., Odessa, FL (non-GLP studies)
2. Bio-Analytical Services, Inc., MI, ("BASi") – IND-Enabling non-GLP and GLP "Tox Package" studies

For Regulatory Pathway and Business Development:

1. Biologics Consulting Group (BCG), Alexandria, Virginia (FDA regulatory pathway)
2. Bio-Ensemble, LLC, NJ (Business Development)

Consulting Agreement with Bio-Ensemble, LLC, NJ (BEL)

In September 2017, we signed a consulting agreement with BEL and its Principal, Dr. Carolyn Myers. The scope is evaluation of the business opportunity for VZV virus field of drug development, and structuring new license agreements with TheraCour Pharma, Inc., keeping in mind the express intent of the Company of sublicensing its drug candidates to other Mid Pharma and Big Pharma partners. Dr. Myers is a pharma industry veteran with over 25 years of experience in business development. Her experience spans from leading roles in small to big pharma in business development, obtaining partnering opportunities and performing deals from startups and small pharma side, to evaluating hundreds of technology and licensing proposals and performing partnering, collaboration, and outright purchase deals from the big pharma side.

Regulatory Consulting and Advisory Agreement with Biologics Consulting Group, VA (BCG).

In July 2011 we signed an agreement with Biologics Consulting Group to help us with our regulatory strategy and filings. Several of the members of the BCG faculty had experience working as part of the US FDA. BCG helps us with the US FDA regulatory pathway strategies, applications processes, and with the development of applications as well as drug development program strategies, as needed.

Safety/Toxicology Studies Agreement with Bio-Analytical Services, Inc. (BASi), MI

In September 2014, we signed an agreement with BASi. BASi is a pre-clinical contract services organization that specializes in cGLP and GLP-like safety and toxicological testing of drug candidates and preparation of the "Tox Package" section of an IND application. BASi performed a GLP-like preliminary safety and toxicology study in which there were no significant compound related adverse events found. Our safety and toxicology studies for FluCide are being conducted by BASi for submission with an IND application. BASi will also perform the safety toxicology studies for the anti-herpes nanoviricide drug candidates in our HerpeCide program. We have signed a Master Services Agreement with Bio-Analytical Services, Inc., MI, ("BASi") to perform cGLP and GLP-like safety and toxicological studies that are necessary for filing an IND for each of our drugs.

AR Biosystems, Inc., Odessa, FL

We do not have a Master Services Agreement with AR Bio. From time to time, we discuss certain non-GLP studies, and if suitable, engage this CRO as needed.

VZV (HHV-3) Nanoviricides Efficacy Evaluation Agreement with the Moffat Lab at the SUNY Upstate Medical Center, Syracuse, NY.

In October 2016, we entered into an agreement with SUNY Upstate Medical University for the testing of its nanoviricides® drug candidates against varicella zoster virus, i.e. the shingles virus. The research will be performed in the laboratory of Dr. Jennifer Moffat and will include in vitro, ex vivo and possibly in vivo studies. Dr. Moffat has extensive experience in varicella zoster virus (VZV) infection and antiviral agent discovery. The goal of these studies is to help select a clinical drug development candidate for toxicology and safety evaluation intended for clinical trials for the treatment of shingles in humans.

VZV is restricted to human tissue and only infects and replicates in human tissue. The in vitro studies will evaluate the effectiveness of the Company's nanoviricides antiviral agents against VZV infection of certain human cells in culture.

The ex vivo studies will evaluate the efficacy of the Company's nanoviricides to inhibit VZV in human skin organ cultures. Dr. Moffat has developed the human skin organ culture VZV infection model for the evaluation of therapeutics. This model is a good representative model of natural VZV infection in humans as well as an important model for evaluating antiviral activity, because it demonstrates behavior similar to the skin lesions caused by VZV in human patients.

Dr. Moffat is an internationally recognized expert on varicella zoster virus, and her research has focused on the pathogenesis and treatment of infection by this virus. The National Institutes of Health has recognized this VZV model via a contract with Dr. Moffat's lab for evaluating antiviral compounds against VZV. Dr. Moffat is the director of two research core facilities at SUNY Upstate: the Center for Humanized Mouse Models and In vivo Imaging.

The Company has established a direct relationship with the Moffat lab, without NIH as an intermediary.

On July 10, 2017, the Company announced the results of successful initial testing of our anti-herpes drug candidates in the ex vivo human skin patch organ culture ("SOC") model performed by Dr. Moffat.

The anti-shingles nanoviricides® drug candidates achieved dramatic reduction in infection of human skin by the varicella-zoster virus (VZV), the shingles virus in this study. These findings corroborate the previously reported findings of inhibition of VZV infection of human cells in culture. The antiviral effect of certain nanoviricide drug candidates was substantially greater than the effect of the standard positive control of cidofovir added into media. Even more remarkably, the effect of these nanoviricides drug candidates was equivalent to a topical formulation of 1% cidofovir applied directly onto the skin patch. A topical skin cream containing 2% cidofovir is clinically used in very severe cases of shingles. However, the cytotoxicity of cidofovir is known to cause ulceration of the skin to which it is applied, followed by natural wound healing.

We have continued our work with the Moffat Lab, initially for optimization of the drug candidates and chemistries, and recently, driving towards clinical drug candidate selection.

With these results that corroborate findings in cell culture studies in both our lab and Dr. Moffat's Lab, we believe that the anti-shingles topical drug candidate is worthy of advancing into further IND-enabling pre-clinical development i.e. safety/toxicology studies.

We believe that the VZV drug candidate program is now our most advanced program to advance into Safety/Toxicology studies that are needed for an IND filing and human clinical trials. However, at present, we do not have a license from TheraCour to develop and commercialize drugs against VZV and there can be no assurance that the Company will be able to enter into an agreement with TheraCour for such license on terms that are favorable to the Company. License negotiations are now in progress in earnest with our new CEO, Dr. Irach Taraporewala leading the team.

HSV-1 and HSV-2 Nanoviricides Efficacy Evaluation Agreement with the Collaborative Ophthalmic Research Laboratories (CORL) at the University of Wisconsin, Madison, WI.

In January 2016, we signed an agreement with CORL. Under this agreement, CORL will perform evaluation of efficacy of our nanoviricides drug candidates in cell culture assays as well as in small animal studies towards the goal of filing an IND application for ocular Herpes Keratitis, and possibly for Recurrent Herpes Labialis (RHL, "cold sores").

This agreement has been extended to include drug and research material efficacy evaluation studies in animal models of viral Acute Retinal Necrosis (vARN), and in animal models of HSV-2 genital ulcer. The studies will be performed in the laboratory of Dr. Curtis Brandt, an expert in herpes simplex virus infections and in evaluating anti-viral agents.

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.

On August 16, 2010, the Company reported that its anti-Herpes drug candidates demonstrated significant efficacy in the recently completed cell culture studies in Dr. Rosenthal Lab at NEOMED. Several of the anti-Herpes nanoviricides® demonstrated a dose-dependent maximal inhibition of Herpes virus infectivity in a cell culture model. Almost complete inhibition of the virus production was observed at clinically usable concentrations. These studies employed the H129 strain of herpes simplex virus type 1 (HSV-1). H129 is an encephalitic strain that closely resembles a clinical isolate; it is known to be more virulent than classic HSV-1 laboratory strains. The H129 strain will be used in subsequent animal testing of nanoviricides. Since then the Company was optimizing formulations for use in the dermal HSV-1 H129c infection animal model in the Rosenthal lab. The Company also continued to further optimize the anti-herpes nanoviricides. Our herpes program was run at a lower priority than other programs until recently. In April 2015, after only 4 cycles of SAR (Structure-Activity-Relationship based improvements), our anti-herpes nanoviricides demonstrated strong effectiveness in the lethal HSV-1 H129c dermal infection model in the Rosenthal Lab at NEOMED. Treatment with certain nanoviricides caused significant improvements in the clinical observations, and led to >85% survival of the infected animals, wherein 100% of the untreated animals died within 10 days. In August 2015, the Company reported that these results were reproduced in dermal animal model at Transpharm, with 100% of the nanoviricides treated animals surviving.

Professor Rosenthal retired in December 2014, continued his laboratory and our R&D through April 2015, and has closed the lab thereafter. He is now Professor at Roseman University of Health Sciences College of Medicine, NV. He continues as Professor Emeritus at Northeast Ohio Medical University (NEOMED). However, his laboratory is no longer active.

The HSV-1 topical treatment drug candidates in the HerpeCide program have thus advanced to the lead identification stage. This program is now assigned second priority, following the top priority of the VZV program, primarily because the regulatory development of anti-VZV drug candidate was projected to occur much more rapidly than that of the anti-HSV-1 drug candidate.

Anti-Influenza Drug Development Agreement with the Webster Lab at St Jude Children's Hospital, Memphis, TN

In May 2016, we signed an agreement with the Webster Lab at St. Jude Children's Hospital. Under this Agreement, the Webster Lab will evaluate nanoviricide drug candidates in cell culture studies against a large number of Influenza viruses to optimize the efficacy and broad-spectrum for a clinical development candidate. Variations on the previously selected ligand in NV-INF-1 and NV-INF-2 will be performed if necessary.

The testing of these candidates for anti-influenza activity will be performed in the laboratory of Dr. Elena Govorkova in collaboration with Dr. Robert G. Webster and will include both in vitro and in vivo studies. They have extensive experience in influenza virus infections with a large number of different influenza strains, and in anti-viral agents discovery. The overall objective of these studies will be to help select clinical drug development candidates for the treatment of influenza virus in humans, using both the injectable and oral administration routes. Injectable administration is preferable for hospitalized patients that are extremely sick, while oral administration is preferred for outpatients.

The most optimal candidate will then be evaluated against a wide variety of Influenza viruses in small animal efficacy studies with a goal of obtaining data for an IND submission for Injectable FluCide drug candidate for severely ill hospitalized patients, and also for Oral FluCide drug candidate for outpatients with Influenza.

The Influenza program has been relegated to lower priority levels due to (a) our belief that the topical drug candidates in the HerpeCide program would reach the clinic faster and would also have much more rapid clinical development pathway than FluCide, (b) the rapid expansion in breadth of the HerpeCide program pipeline that has occurred due to efficacy of closely related drug candidates against different viruses in the Herpes family and against different indications, and (c) extreme resource constraints in terms of both available skilled manpower and available financing for driving our programs.

Nevertheless, we believe that FluCide has strong market potential, and therefore we are keeping this program active albeit with limited resource allocation, which has slowed down the program significantly.

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

The term of this agreement was three years from its execution. The Company agrees to supply necessary quantities of its products in order for Southern to complete specific studies as to the efficacy and safety of the Company's compounds. The Company shall pay charges associated with each task order and provide payment in the amount and as indicated therein. Under this agreement, Southern will estimate the work load and invoices for additional task orders, subject to the Company's agreement on costs.

The Company's anti-HIV drug testing in cell cultures is performed at the Southern Research Institute in Frederick, MD.

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-1 and HSV-2), 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 a specified portion of certain direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed; (2) we will pay $2,000 or actual costs monthly, whichever is higher, for other general and administrative expenses incurred by TheraCour on our behalf; (3) make royalty payments (calculated as a percentage of net sales of the licensed drugs) of 15% to TheraCour; (4) TheraCour retains the exclusive right to develop and manufacture the licensed drugs. TheraCour 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 (5) TheraCour may request and NanoViricides, Inc. will pay an advance payment (refundable) equal to twice the amount of the previous month's 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 and other costs charged by TheraCour for the years ended June 30, 2018, 2017 and 2016 were $3,176,977, $3,368,919, and $3,731,498 respectively. At June 30, 2018, $107,468 was due to TheraCour.

No royalties are due TheraCour from the Company's inception through June 30, 2018.

TheraCour Pharma, Inc., is affiliated with the Company through Anil Diwan, President, who is a director of each corporation, and owns approximately 90 % of the capital stock of TheraCour Pharma, Inc., which itself owns approximately 13.6% of the Common Stock of the Company at June 30, 2018.

TheraCour Pharma, Inc. owns 9,419,170 shares of the Company's outstanding Common Stock and 2,000,000 shares of the Company's Series A Preferred Stock at June 30, 2018.

Results of Operations

The Company is a biopharmaceutical company and does not have any revenue for the years ended June 30, 2018, 2017 and 2016.

Comparison of the Year End June 30, 2018 to the Year Ended June 30, 2017

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

Operating Expenses - Research and development expenses for the year ended June 30, 2018 decreased $704,868 to $4,826,840 from $5,531,708 for the year ended June 30, 2017. This year-to-year decrease is generally attributable to a decrease in stock compensation to research scientists including Dr. Anil Diwan and to reduced staffing that also led to reduced expense in chemicals and supplies.

General and administrative expenses increased $429,313 to $4,498,329 for the year ended June 30, 2018 from $4,069,016 for the year ended June 30, 2017. The increase in general and administrative expenses is generally attributable to recognition of stock and cash compensation paid to Dr. Seymour upon his resignation and an increase in legal, professional and consultant costs.

Other Income (Expenses) - Interest income was $100,429 and $60,955 for the years ended June 30, 2018, and 2017, respectively. Interest income included interest on cash or cash equivalent deposits in interest-bearing accounts. Interest income increased due to an increase in interest rates paid on deposits. The Company has incurred interest expense of $185,274 and $780,767 for the years ended June 30, 2018 and June 30, 2017, respectively. The decrease was due to the redemption of the Series B Debentures on February 1, 2017 and the Series C Debenture at November 13, 2017. The Company amortized the discount on its Series B and Series C Debentures, which were calculated at issuance. The Company recognized an amortization of debt discount expense of $359,214 and $1,347,748 for the years ended June 30, 2018 and 2017, respectively. The decrease in amortization of debt discount is a result of the maturity of the Series B Debentures and the redemption of the Series C Debenture.

Income Taxes - There is no provision for income taxes due to ongoing operating losses. As of June 30, 2018 we had estimated cumulative tax benefits and development tax credits and other deferred tax credits resulting in a deferred tax asset of approximately $37,085,072. This amount has been offset by a full valuation allowance.

Net Loss - For the year ended June 30, 2018, the Company had a net loss of $8,563,455, or a basic loss per share of $0.13 and fully diluted loss per share of $0.13 compared to a net loss of $10,304,490, or a basic loss per share of $0.17 and a fully diluted loss per share of $0.17 for the year ended June 30, 2017. The decrease in the Company's net loss from the year ended June 30, 2017 to the year ended June 30, 2018 of $1,741,035 is generally attributable to the larger gain resulting from the change in fair value of derivatives, lower discount on convertible debenture expense, and interest expense, and being partially offset by a loss on extinguishment of debt of $1,348,247.

Liquidity and Capital Reserves

The Company had cash and cash equivalents of $7,081,771 and $15,099,461 at June 30, 2018 and 2017, respectively. On the same dates, current liabilities outstanding totaled $881,948 and $4,665,518, respectively. For the year ended June 30, 2018 the derivative liability associated with its outstanding warrants was reported as a current liability of $298,092. For the year ended June 30, 2017 the derivative liability associated with its outstanding warrants was reported as a long term liability of $2,015,354.

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 $83,692,146 and $75,128,691 at June 30, 2018 and 2017, respectively. These factors, among others, raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments to the recoverability and classifications of assets carrying amounts or the amounts and classifications of liabilities that might result from the outcome of these uncertainties. Accordingly, we need to raise additional capital and are exploring potential transactions to improve our capital position. Unless we are able to generate additional capital or secure financing from other transactions, our current cash resources will only satisfy our working capital needs for a limited period of time.

The Company is exploring potential transactions to raise additional cash in the capital markets and support current budgeted operations through October 2019. The Company has made several adjustments to the ensuing annual budget, eliminating several expenses including a reduction in workforce and consultants to the extent feasible without affecting its program of drug development. In addition, the Company has focused its efforts primarily on a single lead program to minimize cost outlays, namely taking the shingles drug candidate against VZV into human clinical trials. Management's budget indicates that these changes have freed up sufficient funds to allow for the ensuing costs of the external advanced IND-enabling studies of this drug candidate. Management has considered

several options for financing the net working capital deficit as well as to obtain additional funds that will be needed for future human clinical trials. The Company has received interest from public capital market investors with various financial instruments being proposed to us, that we believe are more than sufficient to cover the working capital deficit and to enable the Company to continue as a going concern. Currently, we do not have any definitive agreements with any third-party for such transactions and there can be no assurance; however, that we will be successful in raising additional capital or securing financing when needed on terms satisfactory to the Company. In addition, the Company entered into an agreement with TheraCour Pharma, Inc., a Related Party, on October 2, 2018 for a waiver of the two month's advance of anticipated invoicing and the application of the current advance as a credit against current open invoices. Additionally, TheraCour has agreed to defer $25,000 per month of development fees for six months.

In addition, the Company believes that it has several important milestones that it will be achieving in the ensuing year. In brief, these include the declaration of a final clinical candidate for its lead drug indication, achieving successful cGMP-like production of the drug as required for the ensuing "Tox Package" studies, initiation and completion of the Tox Package studies, a "Pre-IND" meeting with the FDA, filing of an IND, and the beginning of initial human clinical trials. In general, as a pharmaceutical company achieves these milestones, its risk-profile with investors improves, allowing appreciation in the stock price, in the market capitalization, as well as in the trading volumes. Management believes that as it achieves these milestones, the Company would experience substantial improvement in the liquidity of the Company's stock, and would significantly improve the Company's ability to raise funds on the public markets at terms that may be substantially superior to the terms we are offered at present.

We believe that our cash and cash equivalent balance and the estimated proceeds from capital market transactions we are considering (of which there can be no assurance) will provide sufficient funds for us to continue our operations through October 2019. Our current cash position is insufficient to fully execute the Company's business plan. If the Company is unable to obtain debt or equity financing to meet its cash needs, it may have to severely limit its business plan by reducing the funds it hopes to expend on pre-clinical studies and trials, and/or research and development projects, any of which would have a material adverse effect on our business, financial condition and results of operations.

Comparison of the Year End June 30, 2018 to the Year Ended June 30, 2017

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

Operating Expenses - Research and development expenses for the year ended June 30, 2017 increased $502,738 to $5,531,708 from $5,028,970 for the year ended June 30, 2016. This year-to-year increase is generally attributable to an increase in lab supplies and chemicals and an increase in stock compensation to research scientists including Dr. Anil Diwan.

General and administrative expenses increased $ 238,485 to $ 4,069,016 for the year ended June 30, 2017 from $3,830,531 for the year ended June 30, 2016. The increase in general and administrative expenses is generally attributable to an increase in stock compensation paid to employees other than research scientists, and an increase in legal, professional and consultant costs.

Other Income (Expenses) - Interest income was $60,955 and $62,638 for the years ended June 30, 2017, and 2016, respectively. Interest income included interest on cash or cash equivalent deposits in interest-bearing account. Interest income decreased due to a decrease in deposits. The Company has incurred interest expense of $780,767 and $1,042,470 for the years ended June 30, 2017 and June 30, 2016, respectively. The decrease was due to the redemption of the Series B Debentures at maturity. The Company amortizes the discount on its Series B and Series C Debentures, which were calculated at issuance. The Company recognized an amortization of bond discount expense of $1,347,748 and $1,427,218 for the years ended June 30, 2017 and 2016, respectively.

Income Taxes - There is no provision for income taxes due to ongoing operating losses. As of June 30, 2017, we had estimated cumulative tax benefits and development tax credits and other deferred tax credits resulting in a deferred tax asset of approximately $40,393,660. This amount has been offset by a full valuation allowance.

Net Loss - For the year ended June 30, 2017, the Company had a net loss of $10,304,490, or a basic loss per share of $0.17 and fully diluted loss per share of $0.17 compared to a net loss of $10,724,629, or a basic loss per share of $0.19 and a fully diluted loss per share of $0.19 for the year ended June 30, 2016. The decrease in the Company's net loss from the year ended June 30, 2017 to the year ended June 30, 2016 of $420,139 is generally attributable to the larger gain resulting from the change in fair value of derivatives, and decreases in interest expenses.

Current Financial Status

NanoViricides technology is now maturing rapidly toward clinical drug trials, with the new facility, expanded staff, and the financial strength that we have attained since uplisting to NYSE-MKT (now NYSE American) in September 2013.

As of June 30, 2018, the end of the reporting period, we have $7,081,771 in cash and cash equivalents, prepaid expenses of $240,257 and $10,841,093 of property and equipment net of accumulated depreciation. Our short-term liabilities are $881,948 with stockholders' equity of $17,664,264. In comparison, as of June 30, 2017, we had $15,099,461 in cash and cash equivalents, and additional assets of $190,166 in the form of prepaid expenses. Property and equipment was $11,271,060 net of accumulated depreciation. Our short-term liabilities were at $4,665,518 and long-term liabilities were $2,015,354 with stockholders' equity at $20,321,942.

During the reporting period we spent approximately $7.8 million in cash toward operating activities and approximately $242 thousand in capital investment. In contrast, we spent approximately $7.9 million in cash toward operating activities and approximately $165 thousand in capital investment in the year ended June 30, 2017. We do not anticipate any major capital costs going forward in the near future.

While our cash and cash equivalent balance, and our estimated ability to raise additional funds in the capital markets will provide sufficient funds for us to continue our operations through October 2019, our current cash position 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 in the future it may have to severely limit its business plan by reducing the funds it plans to expend on pre-clinical studies and clinical trials, and/or research and development projects.

The Company has incurred significant operating losses since its inception resulting in an accumulated deficit of $83,692,146 at June 30, 2018. For the year ended June 30, 2018, the Company had a net loss of $8,563,455. 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.

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 4 summarizes the primary components of our research and development expenses as allocated, during the periods presented in this Annual Report on Form 10-K.

Table 4: R&D Cost Allocations

	Year Ended June 30, 2018	Year Ended June 30, 2017	Year Ended June 30, 2016
HerpeCide™ Program. Herpes Simplex virus infections (HSV-1, HSV-2). Also: VZV. Indications: Cold Sores, Genital Ulcers, Shingles, and ARN	$ 4,456,840	$ 3,602,008	$ 1,600,000
All Influenzas: FluCide™	$ 150,000	$ 400,000	$ 670,000
HIV-Cide™	$ 20,000	$ 100,000	$ 100,000
EKC-Cide™, other Eye Viral Infections	$ 0	$ 540,000	$ 1,670,000
Dengue	$ 0	$ 50,000	$ 100,000
Other (Ebola, and other projects)	$ 0	$ 50,000	$ 300,000
Unallocated stock compensation	$ 200,000	$ 789,700	$ 588,970
Total Research and development	**$ 4,826,840**	**$ 5,531,708**	$ **5,028,970**

Anticipated Budgets and Expenditures in the Near Future

The Company has ended the year on a reasonable financial footing by controlling costs and expenditures. We project, based on various estimates that we have obtained, that our current available financing is sufficient for accomplishing the goal of filing one IND or equivalent regulatory applications. We will need additional financing to execute on our business plan and to engage into human clinical trials of our drug candidates. Two of our drug programs, namely our Shingles Skin Cream, and our HerpeCide skin cream for herpes labialis, are in IND-enabling studies. At present, we are working on the scale up of manufacturing of these drug candidates in a manner that will be compliant with US FDA cGMP and corresponding ICH guidelines. We intend to request a pre-IND meeting with the USFDA at an appropriate time, as we develop the dataset for this discussion. A pre-IND meeting will help us determine the level of detail needed in the cGLP Safety/Toxicology study required for the IND application, and also to refine our human clinical trials design. We anticipate that these drug candidates will move forward into IND or equivalent regulatory filings, and ensuing human clinical trials. As these drug candidates are advancing into the clinic, we believe that our additional drug candidates, including two more drug candidates in the HerpeCide program, and the two drug candidates in the FluCide program, will also move forward into IND-enabling studies. We are thus poised for strong growth with a number of drug candidates in a number of disease indications.

Financings

The Company has not performed any equity based raises or debentures or loans in the reported time period. The Company had no revenues in the reported time period. Thus the Company's operating expenditures were supported from cash in hand and using stock-based compensation where appropriate.

Requirement for Additional Capital

As of June 30, 2018, we have a cash and cash equivalent balance of $7,081,771 that is expected to be insufficient to fund our currently budgeted operations for approximately one year from the filing of the Company's Form 10K without additional funding through the capital or credit markets. The Company believes that it will need to raise additional funds in the capital markets to continue its operations through October 2019.

The Company believes that our cash and cash equivalent balance and the estimated proceeds from capital market transactions we are considering (of which there can be no assurance) will provide sufficient funds for us to continue our operations through October 2019 and to be able to advance at least one of its drug candidates into IND stage with the available cash. The Company estimates that it will need additional funding to continue further development of its drug candidates through human clinical trials if it does not form a collaborative licensing or partnership agreement with a party that would provide such funding, such as Big pharma.

Based on our current rate of expenditures and anticipated changes, we have estimated a total cash expenditure budget of approximately $9M for the next 12 months, of which approximately $6M is expected to go towards research and development for our drug candidates, including IND-enabling studies of one of our lead drug candidates, namely Skin Cream for Topical Treatment of Shingles, and approximately $3M is budgeted for general and administrative expenses.

Thereafter, we estimate that beyond the current budgetary one year period ending September 30, 2019, over the following two years for human clinical development of the Skin Cream for Topical Treatment of Shingles, we may need approximately an additional $21M. The additional funds will be needed to pay additional personnel, increased subcontract costs related to the expansion and further development of our drug pipeline, for human clinical trials, and for additional capital and operational expenditures. Further, we anticipate incurring additional capital costs over this period for further improvements at our 1 Controls Drive, Shelton, CT facility.

These anticipated additional expenses for the two-year period commencing October 1, 2019 can be summarized as follows:

1. Planned Research and Development Costs of $9,000,000: Planned costs for in vivo and in vitro studies for the eight indications in HerpeCide program, two indications in FluCide program, Eye Nanoviricide, DengueCide, and HIVCide, and Other programs (see Table 2). This includes staffing costs of approximately $3,500,000, for the scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to FDA compliance, as required for development of necessary data for filing an Investigational New Drug with the United States Food and Drug Administration.

2. Corporate overhead of $4,000,000: This amount includes budgeted office salaries, legal, accounting, investor relations, public relations, business development, and other costs expected to be incurred by being a public reporting company.

3. Capital costs of $1,000,000: This is the estimated cost for additional equipment and laboratory improvements.

4. Clinical Trial Manufactured Batch of Drug Product approximately $2,000,000 for Phase IIa for the first HerpeCide program drug candidate. [The clinical trial manufacturing batch cost for the drug product supply for Phase I, and prior to that, the drug product supply for Tox Package studies, are already accounted for in the budgeted expenditures prior to September 30, 2018.]

5. Clinical Trials Costs budgeted at $5,000,000 for the Skin Cream for Shingles and an additional $5,000,000 costs for clinical trials that are expected to extend beyond the above 24-month timeframe, as follows:

5a. When and if we initiate human clinical trials for a Topical HerpeCide, we anticipate approximately $1 million total costs for the Phase I clinical trials (which is now included in the budgeted R&D expenditures leading up to September 30, 2018), and approximately $2 million for the Phase II (study in recruited patients presenting with disease) clinical trials. In a subsequent year, if Phase I and Phase II are successful, we anticipate approximately $10 million for Phase III human clinical trials. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional costs. These estimates assume that Topical HerpeCide is highly effective and therefore would require relatively few patients in each arm of the each trial in order to establish statistically significant results.

5b. 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 one of the eight Topical HerpeCide drug candidate indications into an IND application stage. We will need to raise additional financings to support the ensuing 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 the coming year's workplan 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.

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.

Our animal efficacy studies as well as safety/toxicology studies are performed by third parties. We opt into drug developments against specific disease indications for which we have appropriate partners that can perform the necessary cell culture and animal efficacy studies.

The Company reports summaries of its studies as the data becomes available to the Company, after analyzing and verifying same, in its press releases. The studies of biological testing of materials provide information that is relatively easy to understand and therefore readily reported. In addition, we continue to engage in substantial work that is needed for the optimization of synthesis routes and for the chemical characterization of the nanoviricide drug candidates. We also continue to work on improving the drug candidates and the virus binding ligands where necessary. We continue to work on creating the information needed for the development of controlled chemical synthesis procedures that is vital for developing c-GMP manufacturing processes.

We cannot accurately project the timeline of when we would be able to take a drug candidate into clinical studies, nor can we predict when we may be able to achieve our first drug approval, if any. As such we do not provide any guidance on expected timelines. The Company has no experience in having taken a single drug through the US FDA or any international drug approval process as of now. As such, we may not be able to estimate the time or cost of these studies accurately. However, we try to do our best by using expert consultants and preparing reasonable estimates based on quotations from various contract research organizations.

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

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.

Off Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements during the year ended June 30, 2018.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Accounting for Stock Based Compensation – The Company follows the provisions of ASC 718 – Stock Compensation, which requires the measurement of compensation expense for all shared-based payment awards made to employees and non-employee directors, including employee stock options. Shared-based compensation expense is based on the grant date fair value estimated in accordance with the provisions of ASC 718 and is generally recognized as an expense over the requisite service period, net of forfeitures.

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

RECENT ACCOUNTING PRONOUNCEMENTS

Recently Issued Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for non-employee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard will be effective for the Company in the first quarter of fiscal year 2020, although early adoption is permitted (but no sooner than the adoption of Topic 606). The Company does not expect that the adoption of this ASU will have a significant impact on its financial statements.

In July 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-11. "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 revises the guidance for instruments with down round features in Subtopic 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for annual and interim periods beginning December 15, 2018, and early adoption is permitted, including adoption in an interim. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of retaining earnings in the fiscal year and interim period adoption. The Company is currently in the process of assessing the impact of this ASU on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Stock Compensation (Topic 718)", which includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The standard is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The adoption of this standard on July 1, 2017 did not have a material effect on the Company's financial position, results of operations or cash flows.

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.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d)-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the "SEC"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to our management including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitation of controls systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of June 30, 2018, an evaluation was carried out under the supervision and with the participation of our management, including our interim Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Securities Exchange Act of 1934). Based on this evaluation, our interim Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of June 30, 2018, because of material weaknesses in our internal control over financial reporting described below.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of management, including our interim Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness, as of June 30, 2018, of our internal control over financial reporting based on the framework in 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was not effective as of June 30, 2018 due as described below.

Management did not maintain effective procedures in the areas of review of the 10K, review of third party valuation reports and income taxes. These material weaknesses resulted from the lack of timely and effective review of the Company's period-end closing process and adequate personnel and resources. Specifically,

- The Company's Form 10-K and other filings need to be reviewed thoroughly by management on a timely basis. Management's responsibility is to oversee that the Company is capable of developing accurate and timely financial information. The Company must reinforce procedures to ensure that Form 10-K as well as other required filings are done on a timely and accurate basis.

- Management reviewed all information available to them from the outside consultant's valuation reports, which included all external models, however, all inputs of the consultants' model were not available to management and were not verified by the management. A more thorough review which includes all inputs of the models used by the consultants will ensure no additional journal entries need to be recorded and the financial information is accurate and free from material misstatement.

- The Company's calculation of the provision for income taxes and related deferred income tax balances were not calculated correctly in accordance with ASC 740, Income Taxes. The Company needs to gain a more precise understanding of the components of the income tax provision and deferred income taxes and monitor the differences between the income tax basis and the financial reporting basis of assets and liabilities to effectively reconcile the deferred income tax balances.

Remediation Plan

We are remediating the material weaknesses by, among other things, implementing a process of enhanced review of all financial transactions. The actions that we are taking are subject to ongoing senior management review and Audit Committee oversight.

Effective September 1, 2018, the Company has appointed Dr. Irach Taraporewala as Chief Executive Oficer, an experienced pharmaceutical industry executive, to provide additional management review of financial reporting and the period-end closing processes identified.

The Company will provide additional training and development classes for management, accounting and finance staff regarding current changes in accounting for income taxes and deferred income taxes, pursuant to ASC 740, to enhance their current skills and understanding of the components of deferred taxation and accounting for income taxes.

Management believes the foregoing efforts will effectively remediate the material weakness identified above. 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

Other than was described above, there were no material changes in our system of internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the year ended June 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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

The following table sets forth the names and ages of our current directors and executive officers, their principal offices and positions and the date each such person became a director or executive officer. Each executive officer holds the office until he/she resigns, is removed by the Board or his/her successor is appointed by the Board upon appropriate due diligence. Directors are elected biannually 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.	60	President; Chairman of the Board, Interim CEO
Stanley Glick, CPA	82	Director, Independent
Mukund S. Kulkarni, MD	71	Director, Independent
Milton Boniuk, MD (Resigned)	86	Director, Independent
Meeta Vyas	60	Chief Financial Officer

The Company's directors are elected biannually and serve until their term expires, and may be re-elected for an additional term at the annual meeting of shareholders. The executive officers that become members of the Board of Directors are elected via biennial election and serve as director through the term, and may be re-elected for an additional term at the annual meeting of shareholders.

Anil Diwan, PhD, age 60, 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. Dr. Diwan has won over 12 NIH SBIR grants. Dr. Diwan holds several issued patents, and three PCT international patent applications in various stages of prosecution in a number of countries, and also has several additional patentable discoveries. 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 82, was appointed as an independent Director and as chair of the Audit Committee of the Company on June 22, 2013. 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". 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 71, has been a Chancellor of Penn State Harrisburg since 2010 through his retirement in July 2018. Dr. Kulkarni joined Penn State University 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 held the rank of professor of finance. Dr. Kulkarni earned his bachelor's degree from Shivaji University located in Kolhapur, India and master's degrees from University of Pune located in Pune, India, and an M.B.A. from Marshall University. He also earned a Doctorate in Economics from the University of Kentucky. Dr. Kulkarni is widely published in academic journals and has presented papers at several scholarly conferences. Dr. Kulkarni is an invited lecturer and consultant to several academic institutions in the U.S. and abroad, in addition to state government and nonprofit organizations. Dr. Kulkarni is widely engaged in social and civic activities in and around the Harrisburg region. He is member of several boards of civic and nonprofit organizations including the Harrisburg Regional Chamber of Commerce, United Way of the Capital Region, Modern Transit Partnership, and Asian Indian Americans of Central Pennsylvania, among others. He has delivered lectures and provided consultations to other business schools, government agencies, and non-profit organizations, and he has valuable corporate experience in the commercial banking industry. As a result of his valuable experience in the commercial banking industry and his vast academic background in economics and finance, the Company concluded Dr. Kulkarni was qualified to serve as a member of its Board of Directors.

Milton Boniuk, MD, age 86, 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 keratoconjunctivitis (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. On July 10, 2018, Dr. Milton Boniuk resigned as a Director of the Company and as a member of all of the committees of the Board that he belonged to.

Meeta Vyas, SB, MBA, age 60, 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. We concluded that Ms. Vyas' experience and training render her qualified to serve as the Company's Chief Financial Officer.

AUDIT COMMITTEE

In June 2013, Stanley Glick, CPA was elected, as an independent member, to the Company's Board of Directors and the Chair of the Company's Audit Committee. Due to his education and extensive experience as a Certified Public Accountant, Mr. Glick meets the criteria of an independent director and an "Audit Committee Financial Expert" as provided in Release 33-8173 and 34-47235. In addition, in June 2013, Milton Boniuk and Mukund S. Kulkarni were appointed as independent directors and members of the Audit Committee. Due to the resignation of Dr. Boniuk on July 10, 2018, the Company formed a Search Committee, and is conducting interviews with potential board candidates, in order to engage an independent director to replace him.

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, 2018, 2017 and 2016:

Name and Principal Position	Year	Salary	Bonus ($)	Stock Award(s) ($)	Option Awards(#)	All Other Compensation ($)	Total ($)
Eugene Seymour, Ex-CEO, Ex-Director	2018	$ 631,250	$ 118,750	$ 121,008	250,000	$ 63,500	$ 934,508
	2017	$ 372,917	$ 75,000	$ 297,266	—	$ —	$ 745,183
	2016	$ 345,833	$ 75,000	$ 309,344	—	$ —	$ 655,177
Anil Diwan President, Director	2018	$ 397,917	$ 75,000	$ 267,143		$ —	$ 740,060
	2017	$ 372,917	$ 75,000	$ 810,250		$ —	$ 1,258,167
	2016	$ 345,833	$ 75,000	$ 309,344		$ —	$ 655,177
Meeta Vyas CFO	2018	$ 129,600	$ —	$ 75,381	—	$ —	$ 204,980
	2017	$ 129,600	$ —	$ 98,964	—	$ —	$ 228,564
	2016	$ 129,600	$ —	$ 123,656	—	$ —	$ 253,256

The following table sets forth for each named executive officer certain information concerning the outstanding equity awards as of June 30, 2018.

Name and Principal Position	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested	Market Value of Shares or Units of Stock that Have Not Vested	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested
Anil Diwan, President and Director	-	-	$ -	-	—	—	—	—
Eugene Seymour, MD	-	250,000	$ 2.00	04/08/2023	250,000	-	—	—
Milton Boniuk, MD	-	-	$ -	-	—	—	—	—
Mukund Kulkarni	-	-	$ -	-	—	—	—	—
Stanley Glick	-	-	$ -	-	—	—	—	—
Meeta Vyas	-	-	$ -	-	—	—	—	—

COMPENSATION OBJECTIVES

We believe that the compensation programs for the Company's executive officers should reflect the Company's performance and the value created for the Company's stockholders. In addition, the compensation programs should support the short-term and long-term strategic goals and values of the Company, and should reward individual contributions to the Company's success. Our compensation plans are consequently designed to link individual rewards with Company's performance by applying objective, quantitative factors including the Company's own business performance and general economic factors. We also rely upon subjective, qualitative factors such as technical expertise, leadership and management skills, when structuring executive compensation in a manner consistent with our compensation philosophy.

ELEMENTS OF COMPENSATION

BASE SALARY. All full time executives are paid a base salary. Base salaries for our executives are established based on the scope of their responsibilities, professional qualifications, academic background, and the other elements of the executive's compensation, including stock-based compensation. However, at this time current total annual compensation is not in line with comparable companies, because our philosophy was to pay modest salaries with minimum bonuses 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, 2018, under the Company's employment agreements, the Company issued 207,650 shares of the Company's Series A Preferred Stock and 71,430 of the Company's restricted Common Stock. The convertible preferred series A shares are subject to restriction on sale. The valuation applied to the shares was based upon an appraisal derived from the application of statistical calculations and based upon assumptions at the time of the appraisal that may not be realized.

DETERMINATION OF COMPENSATION

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

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, 2018, 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	9,419,170	13.62%
Anil Diwan (2) (3) 135 Wood Street West Haven, CT 06516	2,005,367	2.90%
Eugene Seymour (4) 135 Wood Street West Haven, Connecticut 06516	1,033,813	1.50%
Milton Boniuk (5) 135 Wood Street West Haven, CT 06516	7,824,466	11.31%
Mukund Kulkarni 135 Wood Street West Haven, CT 06516	46,234	0.06%
Stanley Glick 135 Wood Street West Haven, CT 06516	50,875	0.07%
Meeta Vyas (6) 135 Wood Street West Haven, CT 06516	147,021	0.21%
All Directors and Executive Officers as a Group (7 persons)	20,526,946	29.70%

(1) For each shareholder, the calculation of percentage of beneficial ownership is based upon 69,171,740 shares of Common Stock outstanding as of September 15, 2018, 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 90% of the outstanding capital stock of TheraCour. Anil Diwan has both investment and dispositive power over the NanoViricides shares held by TheraCour Pharma, Inc. Does not include 2,000,000 shares of the Company's Series A Preferred Stock (the "Series A"), held by TheraCour Pharma, Inc. which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company.

(3) Anil Diwan, President and Chairman of the Board of Directors. Does not include 16,419,170 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 996,429 shares of Series A Preferred Stock which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company.

(4) Eugene Seymour, Chief Executive Officer Emeritus, resigned effective January 27, 2018. 1,033,813 shares of NanoViricides common stock are held by Dr. Seymour. Does not include 603,571 shares of the Company's Series A Preferred Stock (the "Series A") which votes at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company or upon achieving certain trading prices of the Common Stock. Does not include warrants to purchase 250,000 shares of Common Stock which have been authorized but not yet been issued.

(5) Milton Boniuk, resigned as an Independent Member of the Board of Directors on July 10, 2018. Includes 166,286 shares of common stock owned by the reporting person, 657,142 shares of common stock owned by the reporting person and his wife Laurie Boniuk, and 7,001,037 shares of common stock owned by Milton Boniuk IRA. Does not include 2,776,793 shares of common stock and warrants to purchase 257,143 shares of common stock currently exercisable held by Boniuk Interests Ltd. Does not include 337,000 shares of Series A Preferred Stock held by Milton Boniuk IRA, which are not readily convertible. Does not include warrants to purchase 542,856 shares of common stock, held by the reporting person and his wife. Dr. Boniuk holds voting and dispositive power over Boniuk Interests Ltd. Does not include any shares held by the Boniuk Charitable Foundation since on February 3, 2017, Dr. Boniuk filed a Form 4 which indicated that Dr. Boniuk no longer holds voting and dispositive power over the shares of common stock owned by the Boniuk Charitable Foundation.

(6) Includes 26,001 shares held by Connect Capital LLC, over which Ms. Vyas holds voting and dispositive power. Does not include 156,891 shares of Series A Preferred Stock.

EMPLOYMENT AGREEMENTS

The Company and Dr. Diwan, President and Chairman of the Board of Directors, entered into an employment agreement effective July 1, 2015 for a term of three years. Dr. Diwan's compensation is $350,000 for the first year of employment, $375,000 for the second year and $400,000 for the final year. Additionally, Dr. Diwan was awarded a grant of 225,000 shares of the Company's Series A Preferred Stock. 75,000 shares vested on June 30, 2016, 2017 and 2018. The employment agreement also provided incentive bonuses of $75,000 per year payable on or before July 31, 2016, 2017 and 2018. Incentive bonuses for 2016 and 2017 have been paid according to the terms of the contract. The Company and Dr. Diwan agreed that the 2018 bonus would be earned and paid upon a filing of an IND.

The Company and Dr. Seymour, the Company's Chief Executive Officer and Director, entered into an employment agreement effective July 1, 2015, for a term of three years. Dr. Seymour's compensation would be $350,000 for the first year of employment, $375,000 for the second year and $400,000 for the final year. Additionally, Dr. Seymour was awarded a grant of 225,000 shares of the Company's Series A Preferred Stock. 75,000 shares vested on June 30, 2016, 75,000 shares vested on June 30, 2017 and 75,000 shares were scheduled to vest on June 30, 2018. The employment agreement also provided incentive bonuses of $75,000 per year payable on or before July 31, 2016, 2017 and 2018. The incentive bonuses for 2016 and 2017 have been paid according to the terms of the contract. A prorated bonus of $43,750 was paid in 2018 due to the departure of Dr. Seymour.

On January 27, 2018, Dr. Eugene Seymour resigned as the Chief Executive Officer and as a Director of the Company. On April 30, 2018, the Company and Dr. Seymour finalized a Severance Agreement. The separation agreement calls for continued payment of his salary through December 2018, the vesting of 50,000 of the 75,000 Series A Preferred shares that were originally scheduled to vest on June 30, 2018 and issuance of warrants to purchase 250,000 shares of the Company's common stock. The remainder of his unvested shares was forfeited. The warrants were valued at $53,500 and vest in three equal installments over three years with the last installment vesting on May 1, 2021. The Company reversed the compensation recorded from July 1, 2017 through January 31, 2018 related to the 75,000 shares that will no longer vest under the terms of the employment agreement and then calculated the fair value of the 50,000 shares as a result of the modification of the award as of January 27, 2018. The Company then recognized noncash compensation expense related to the issuance of the Series A Preferred Shares pursuant to the Settlement Agreement of $121,008 for the fiscal year ended June 30, 2018.

On March 3, 2010, the Company entered into an employment agreement with Dr. Jayant Tatake to serve as Vice President of Research and Development. The employment agreement provides for a term of four years with a base salary of $150,000. In addition, the Company issued 26,786 shares of Series A Preferred Stock and 35,715 shares of common stock upon entering into the agreement, and issued an additional 26,786 shares of Series A Preferred Stock and 35,715 shares of common stock on each anniversary date of the agreement. The shares of Series A Preferred Stock were issued in recognition of Dr. Tatake's work towards the achievement of several patents by the Company. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements. For the years ending June 30, 2018, 2017 and 2016, compensation under the agreement was $168,300, $168,300 and $168,300, respectively.

On March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provided for a term of four years with a base salary of $150,000. In addition, the Company issued 35,715 shares of common stock upon entering into the agreement, and issued an additional 35,715 shares of common stock on each anniversary date of the agreement. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements. For the years ending June 30, 2018, 2017 and 2016 compensation under the agreement was $168,300, $168,300 and $168,300, respectively.

On May 30, 2013, the Company entered into an Employment Agreement with Meeta Vyas to serve as its Chief Financial Officer. The employment agreement provided for a term of three years with a base salary of $9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. On January 1, 2015, her compensation was increased to $10,800 per month. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and employment agreements. For the years ending June 30, 2018, 2017 and 2016 compensation under the agreement was $129,600, $129,600 and $129,600, respectively.

COMPENSATION OF DIRECTORS

At this time, directors, who are officers of the Company, receive no remuneration for their services as directors of the Company. The Company reimburses directors for expenses incurred in their service to the Board of Directors. The Company paid accrued fees to its independent directors of $30,000 to each Director, of which half is to be paid in the Company's common stock.

COMPENSATION OF SCIENTIFIC ADVISORY BOARD

The Company anticipates holding four Scientific Advisory Board meetings per annum. As compensation, each member of the Scientific Advisory Board (SAB) will be granted 2,858 warrants each quarter to purchase the Company's common stock at 120% of the Company's closing stock quote on the day following the meeting. Should the Company not call a quarterly meeting, quarterly warrants will be granted on May 15, August 15, November 15, and February 15. The warrants have a four-year expiration date. In addition the Company will reimburse each SAB member for travel and other out-of-pocket expenses incurred in the course of performing their services. For the year ended June 30, 2018, the SAB was granted a total of 45,728 stock warrants. For the years ended June 30, 2017 and 2016, the SAB was granted a total of 57,160 and 68,592, stock warrants, respectively. The warrants are exercisable into common shares at prices from $0.64 to $1.56, $1.40 to $2.04 and $1.44 to $2.18 per share, respectively.

EMPLOYEES AND SERVICE PROVIDERS

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

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. 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-1 and HSV-2), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), and Rabies. On February 15, 2010, the Company entered into 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.

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 a specified portion of certain direct costs as a Development Fee and such development fees shall be due and payable in periodic installments as billed; (2) we will pay $2,000 or actual costs monthly, whichever is higher, for other general and administrative expenses incurred by TheraCour on our behalf; (3) make royalty payments (calculated as a percentage of net sales of the licensed drugs) of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour; (4) TheraCour retains the exclusive right to develop and manufacture the licensed drugs. TheraCour 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 (5) TheraCour may request and NanoViricides, Inc. will pay an advance payment (refundable) equal to twice the amount of the previous month's 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.

TheraCour acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, to the Company, at cost, of $30,321, $33,147, and $39,938, for the fiscal years ended June 30, 2018, 2017, and 2016, respectively.

Accounts payable to TheraCour were $107,468 and $340,695 at June 30, 2018 and 2017 respectively.

Development costs charged by and paid to TheraCour Pharma, Inc. were $3,176,977, $3,368,919 and $3,731,498, for the fiscal years ended June 30, 2018, 2017, and 2016, respectively. No royalties are due or have been paid from inception through June 30, 2018.

As of June 30, 2018, TheraCour owns 9,419,170 shares of the Company's outstanding common stock and 2,000,000 shares of Series A Preferred. Anil Diwan, the Company's President and Chairman, also serves as the CEO and Director of TheraCour and owns approximately 90% of the outstanding capital stock of TheraCour.

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 independent registered public accounting firm 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, 2018	$ 162,000	EisnerAmper LLP
June 30, 2017	$ 156,000	EisnerAmper LLP.

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, 2018	$ 0	EisnerAmper LLP
June 30, 2017	$ 5,000	EisnerAmper LLP

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, 2018	$ 0	EisnerAmper LLP
June 30, 2017	$ 0	EisnerAmper LLP

All Other Fees

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

June 30, 2018	$ 0	EisnerAmper LLP
June 30, 2017	$ 0	EisnerAmper LLP

Pre-Approval Policies

The Board of Directors, and the Audit Committee appointed by the Board, currently do not have any pre-approval policies or procedures concerning services performed by EisnerAmper LLP. All the services performed by EisnerAmper LLP 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 (1)
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
4.4	Certificate of Designation of Rights and Preferences of Series B Convertible Preferred Stock
4.5	Amended and Restated Certificate of Designation of Rights and Preferences of Series B Convertible Preferred Stock
4.6	Amendment to Certificate of Designation of Rights and Preferences of Series B Convertible Preferred Stock
4.7	Amendment to Certificate of Designation of Rights and Preferences of Series B Convertible Preferred Stock
4.8	Form of Common Stock Purchase Warrant
10.1	Share Exchange Agreement between NanoViricide, Inc. and the Registrant (2)
10.2	Employment Agreement Eugene Seymour (3)
10.3	Employment agreement Anil Diwan (3)

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
10.13	Securities Purchase Agreement dated May 11, 2010 by and between NanoViricides, Inc. and Seaside 88, LP.
10.14	Letter Agreement and Amendment with respect to Follow-On Offering pursuant to that certain Securities Purchase Agreement, dated as of May 11, 2010, by and between NanoViricides, Inc. and Seaside 88, LP
10.15	Securities Purchase Agreement dated April 18, 2011 by and between NanoViricides, Inc. and Seaside 88, LP.
10.16	Securities Purchase Agreement dated November 1, 2011 by and between NanoViricides, Inc. and Seaside 88, LP.
10.17	Securities Purchase Agreement dated June 26, 2012 by and between NanoViricides, Inc. and Seaside 88, LP.
10.18	Securities Purchase Agreement dated September 9, 2013 by and between NanoViricides, Inc. and certain purchasers
10.19	Form of Common Stock Purchase Warrant
10.20	Securities Purchase Agreement dated January 21, 2014 by and between NanoViricides, Inc. and certain purchasers
10.21	Form of Common Stock Purchase Warrant
10.22	Agreement of Purchase and Sale between NanoViricides, Inc. and Inno-Haven, LLC
10.23	Conversion and Settlement Agreement
10.24	Confidential Separation Agreement and General Release
10.25	Employment Agreement with Anil Diwan
10.26	Employment Agreement with Irach Taraporewala
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1	Certification of Chief Executive Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Schema Document.
101.CAL	XBRL Calculation Linkbase Document.
101.DEF	XBRL Definition Linkbase Document.
101.LAB	XBRL Label Linkbase Document.
101.PRE	XBRL Presentation Linkbase Document.

(1) Incorporated by reference to Exhibit A to the Company's Definitive Revised Information Statement filed with the Commission on April 23, 2009 and Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 3, 2013.

(2) Incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form 10-SB, filed with the Securities Commission on November 14, 2006, as amended.

(3) 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: October 12, 2018

NANOVIRICIDES, INC.

/s/ Anil Diwan, PhD
Name: Anil R. Diwan, PhD.
Title: President and Chairman of the Board of Directors
(Principal Executive Officer)

/s/ Meeta Vyas
Name: Meeta Vyas
Title: Chief Financial Officer
(Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

October 12, 2018 /s/ Anil Diwan, PhD
Name: Anil Diwan, PhD
Title: President and Chairman of the Board of Directors
(Principal Executive Officer)

October 12, 2018 /s/ Meeta Vyas
Name: Meeta Vyas
Title: Chief Financial Officer
(Principal Accounting Officer)

October 12, 2018 /s/ Mukund Kulkarni
Name: Mukund Kulkarni
Title: Director

October 12, 2018 /s/ Stanley Glick
Name: Stanley Glick
Title: Director

NanoViricides, Inc.

Index to the Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
NanoViricides, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NanoViricides, Inc. (the "Company") as of June 30, 2018 and 2017, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended June 30, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended June 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company’s recurring losses from operations and negative cash flows from operating activities raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2014.

EISNERAMPER LLP
Iselin, New Jersey
October 12, 2018

NanoViricides, Inc.
Balance Sheets

	June 30, 2018	June 30, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 7,081,771	$ 15,099,461
Prepaid expenses	240,257	190,166
Total Current Assets	7,322,028	15,289,627
PROPERTY AND EQUIPMENT		
Property and equipment	14,018,383	13,776,561
Accumulated depreciation	(3,177,290)	(2,505,501)
Property and equipment, net	10,841,093	11,271,060
TRADEMARK AND PATENTS		
Trademark and patents	458,954	458,954
Accumulated amortization	(84,025)	(75,756)
Trademark and patents, net	374,929	383,198
OTHER ASSETS		
Security deposits	4,647	3,515
Service agreements	3,515	55,414
Other Assets	8,162	58,929
Total Assets	$ 18,546,212	$ 27,002,814
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 223,339	$ 135,786
Accounts payable – related parties	107,468	340,695
Derivative liability – warrants	298,092	-
Debentures payable - Series C, net of discount	-	3,956,153
Derivative liability - Series C debentures	-	32,213
Accrued expenses	253,049	34,004
Deferred interest payable - current portion	-	166,667
Total Current Liabilities	881,948	4,665,518
LONG TERM LIABILITIES:		
Derivative liability - warrants	-	2,015,354
Total Liabilities	881,948	6,680,872
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A convertible preferred stock, $0.001 par value, 8,500,000 shares designated, 4,531,394 and 4,348,744 shares issued and outstanding, at June 30, 2018 and 2017, respectively	4,531	4,349
Common stock, $0.001 par value; 150,000,000 shares authorized, 69,171,740, and 63,306,774 shares issued and outstanding at June 30, 2018 and 2017, respectively	69,172	63,307
Additional paid-in capital	101,282,707	95,382,977
Accumulated deficit	(83,692,146)	(75,128,691)
Total Stockholders' Equity	17,664,264	20,321,942
Total Liabilities and Stockholders' Equity	$ 18,546,212	$ 27,002,814

See accompanying notes to the financial statements

NanoViricides, Inc.
Statements of Operations

	Year Ended June 30,		
	2018	**2017**	**2016**
OPERATING EXPENSES			
Research and development	$ 4,826,840	$ 5,531,708	$ 5,028,970
General and administrative	4,498,329	4,069,016	3,830,531
Total operating expenses	9,325,169	9,600,724	8,859,501
LOSS FROM OPERATIONS	(9,325,169)	(9,600,724)	(8,859,501)
OTHER INCOME (EXPENSE):			
Interest income	100,429	60,955	62,638
Interest expense on convertible debentures	(185,274)	(780,767)	(1,042,470)
Loss on extinguishment of debt	(1,348,247)	(332,524)	-
Discount on convertible debentures	(359,214)	(1,347,748)	(1,427,218)
Change in fair value of derivatives	2,554,020	1,696,318	541,922
Other income (expense), net	761,714	(703,766)	(1,865,128)
LOSS BEFORE INCOME TAX PROVISION	(8,563,455)	(10,304,490)	(10,724,629)
INCOME TAX PROVISION	-	-	-
NET LOSS	$ (8,563,455)	$ (10,304,490)	$ (10,724,629)
NET LOSS PER COMMON SHARE			
- Basic	$ (0.13)	$ (0.17)	$ (0.19)
- Diluted	$ (0.13)	$ (0.17)	$ (0.19)
Weighted average common shares outstanding			
- Basic	64,920,856	60,102,855	57,669,472
- Diluted	64,920,856	60,102,855	57,669,472

See accompanying notes to the financial statements.

NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the Period from July 1, 2015 through June 30, 2018

	Series A Preferred Stock: Par $0.001		Common Stock: Par $0.001		Additional		Total
	Number of Shares	Amount	Number of Shares	Amount	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balance, June 30, 2015	3,583,445	$ 3,583	57,242,070	$ 57,242	$ 85,824,614	$ (54,099,572)	$ 31,785,867
Warrants issued for Series B debenture interest	-	-	-	-	56,115	-	56,115
Series A Preferred stock issued for employee stock compensation	507,649	508	-	-	881,878	-	882,386
Common stock issued for consulting and legal services rendered	-	-	106,554	107	157,893	-	158,000
Warrants issued to Scientific Advisory Board	-	-	-	-	42,886	-	42,886
Common stock issued for employee compensation	-	-	72,725	73	142,516	-	142,589
Common stock issued upon stock option exercise	-	-	313,155	313	(313)	-	-
Common stock issued for debenture interest	-	-	415,343	416	659,584	-	660,000
Common stock issued for Directors fees	-	-	29,852	30	44,970	-	45,000
Net loss	-	-	-	-	-	(10,724,629)	(10,724,629)
Balance, June 30, 2016	4,091,094	$ 4,091	58,179,699	$ 58,181	$ 87,810,143	$ (64,824,201)	$ 23,048,214
Series A Preferred stock issued for employee stock compensation	257,650	258	-	-	1,271,852	-	1,272,110
Common stock issued for consulting and legal services rendered	-	-	164,465	164	201,149	-	201,313
Warrants issued to Scientific Advisory Board	-	-	-	-	37,948	-	37,948
Common stock issued for employee compensation	-	-	71,430	71	82,074	-	82,145
Common stock issued for Series B debentures	-	-	4,335,386	4,335	5,328,189	-	5,332,524
Common stock issued for debenture interest	-	-	521,861	522	606,656	-	607,178
Common stock issued for Directors fees	-	-	33,933	34	44,966	-	45,000
Net loss	-	-	-	-	-	(10,304,490)	(10,304,490)
Balance, June 30, 2017	4,348,744	$ 4,349	63,306,774	$ 63,307	$ 95,382,977	$ (75,128,691)	$ 20,321,942
Series A Preferred stock issued for employee stock	57,650	57	-	-	524,201	-	524,258

compensation							
Series A Preferred stock forfeited in Separation Agreement	(25,000)	(25)	-	-	25	-	-
Series A Preferred stock issued for Series C debenture	150,000	150	-	-	314,193		314,343
Common stock issued for consulting and legal services rendered	-	-	243,759	244	155,946	-	156,190
Warrants issued to Scientific Advisory Board	-	-	-	-	16,770	-	16,770
Warrants issued as severance payment	-	-	-	-	53,500	-	53,500
Common stock issued as employee compensation	-	-	71,430	71	65,645	-	65,716
Common stock issued for Series C debenture	-	-	5,500,000	5,500	4,724,500	-	4,730,000
Common stock issued for Directors fees	-	-	49,777	50	44,950	-	45,000
Net loss	-	-	-	-	-	(8,563,455)	(8,563,455)
Balance, June 30, 2018	4,531,394	$ 4,531	69,171,740	$ 69,172	$101,282,707	$ (83,692,146)	$ 17,664,264

See accompanying notes to the financial statements

NanoViricides, Inc.
Statements of Cash Flows

	Year Ended June 30,		
	2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (8,563,455)	$ (10,304,490)	$ (10,724,629)
Adjustments to reconcile net loss to net cash used in operating activities			
Preferred shares issued as compensation	524,258	1,272,110	882,386
Common shares issued as compensation and for services	266,906	328,458	345,589
Common shares issued for debenture interest	60,274	607,178	660,000
Warrants issued for Series B Interest	-	-	56,115
Warrants granted to Scientific Advisory Board	16,770	37,948	42,886
Warrants granted for severance agreement	53,500	-	-
Depreciation	671,789	654,685	651,275
Amortization	8,269	8,269	8,270
Software disposal	-	-	26,974
Change in fair value of derivative liability	(2,554,020)	(1,696,318)	(541,922)
Amortization of debt discount convertible debentures	359,214	1,347,748	1,427,218
Loss on extinguishment of debt	1,348,247	332,524	-
Changes in operating assets and liabilities:			
Prepaid expenses	(50,091)	29,292	(5,033)
Security deposit	-	-	(3,515)
Other long term assets	50,767	40,612	46,505
Accounts payable	87,553	39,262	7,007
Accounts payable - related parties	(233,227)	(426,759)	451,258
Accrued expenses	219,045	(1,598)	7,087
Deferred interest payable	(41,667)	(166,667)	(166,666)
NET CASH USED IN OPERATING ACTIVITIES	(7,775,868)	(7,897,746)	(6,829,195)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(241,822)	(164,978)	(476,368)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Repayment of Series B Debentures payable	-	(1,000,000)	-
NET CHANGE IN CASH AND CASH EQUIVALENTS	(8,017,690)	(9,062,724)	(7,305,563)
Cash and cash equivalents at beginning of period	15,099,461	24,162,185	31,467,748
Cash and cash equivalents at end of period	$ 7,081,771	$ 15,099,461	$ 24,162,185
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:			
Interest paid	$ 166,667	$ 173,589	$ 1,036,115
Income tax paid	$ -	$ -	$ -
NON CASH FINANCING AND INVESTING ACTIVITIES:			
Common stock issued for debenture payment	$ 4,605,000	$ 5,000,000	$ -
Common stock issued for deferred interest	$ 125,000	$ -	$ -
Reduction in leasehold improvements and fixtures and accumulated depreciation due to decommissioning of West Haven, CT facilities	$ -	$ -	$ 332,476
Series A Preferred stock issued for Series C debenture	$ 314,343	$ -	$ -
Common stock issued upon cashless exercise of stock options	$ -	$ -	$ 313

See accompanying notes to the financial statements

NanoViricides, Inc.
June 30, 2018, 2017 and 2016
Notes to the Financial Statements

Note 1 – Organization and Nature of Business

NanoViricides, Inc. (the Company") is a nano-biopharmaceutical research and development company specializing in the discovery, development, and commercialization of drugs to combat viral infections using its unique and novel nanomedicines technology. NanoViricides is also unique in the bio-pharma field in that it possesses its own state of the art facilities for the design, synthesis, analysis and characterization of the nanomedicines that we develop, as well as for production scale-up, and c-GMP-like production in quantities needed for human clinical trials, where our design, development, and production work is performed. The biological studies such as the effectiveness, safety, bio-distribution and Pharmacokinetics/Pharmacodynamics on our drug candidates are performed by external collaborators and contract organizations.

We are a company with several drugs in various stages of early development. In our lead antiviral program against herpes viruses, i.e. the HerpeCide™ program alone, we have drug candidates against at least five indications at different stages of development. Of these, our shingles drug candidate is expected to enter human clinical trials in the very near future. It is in advanced, IND-enabling pre-clinical studies at present, and large-scale production is being performed to supply the safety-toxicology study. In addition, our drug candidates against HSV-1 "cold sores" and HSV-2 "genital herpes" are in advanced studies and are expected to follow the shingles drug candidate into human clinical trials. Shingles in adults and chicken pox in children is caused by the same virus, namely VZV (Varicella-zoster virus, aka HHV-3 or human herpesvirus-3). Chickenpox is re-emerging as a major disease especially in European countries, with 23,500 confirmed cases in the first six months of 2018. In addition, we have drugs in development against all influenzas in our FluCide™ program, as well as drug candidates against HIV/AIDS, Dengue, Ebola/Marburg, and other viruses.

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 broad, exclusive licenses in perpetuity. The first license agreement we executed with TheraCour on September 1, 2005, gave us an exclusive, worldwide license for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus. On February 15, 2010, the Company executed an Additional License Agreement with TheraCour. Pursuant to the Additional License Agreement, the Company was granted exclusive 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. In addition, the Company is negotiating a license for VZV (shingles, chicken pox virus), and the remaining human herpes viruses from TheraCour. For this purpose, the Company has conducted a valuation for the shingles and PHN indications. The negotiation process has begun in earnest after the reporting period, with Dr. Irach Taraporewala being appointed as the new Chief Executive Officer of the Company, effective September 1, 2018. To date, TheraCour has not withheld any licenses for antiviral nanomedicines that NanoViricides has asked for, and we anticipate that the licenses to the remaining herpes viruses including VZV will be executed once the due diligence process is completed.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock and potentially outstanding shares of common stock during the period to reflect the potential dilution that could occur from common shares issuable through stock options, warrants, convertible preferred stock, and convertible debentures.

The following table shows the number of potentially outstanding dilutive common shares excluded from the diluted net loss per common share calculation, as they were anti-dilutive:

	Potentially Outstanding Dilutive Common Shares	
	For the Years Ended	
	June 30, 2018	June 30, 2017
Warrants	6,969,588	6,673,860

The following represents the basic and diluted per share calculations for loss from operations:

	For the Year Ended		
	June 30, 2018	**June 30, 2017**	**June 30, 2016**
Calculation of basic loss per share of common stock:			
Net loss attributable to common stockholders	$ (8,563,455)	$ (10,304,490)	$ (10,724,629)
Denominator for basic weighted average shares of common stock	64,920,856	60,102,855	57,669,472
Basic loss per share of common stock	$ (0.13)	$ (0.17)	$ (0.19)

Series C debentures were redeemed for Common Stock effective November 13, 2017. Series B and Series C debentures were excluded from the loss per share calculation for the years ended June 30, 2017 and 2016 because the impact is anti-dilutive.

The Company has also issued 4,531,394 shares of Series A Convertible Preferred Stock to investors and others as of June 30, 2018. 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 of the Company or the Company's intellectual property. In the absence of a Change of Control event, the Series A Convertible Preferred Stock is not convertible into common stock, and does not carry any dividend rights or any other financial effects. At June 30, 2018, the number of potentially dilutive shares of the Company's common stock into which these Series A Preferred shares can be converted into is 15,859,879 and is not included in diluted earnings per share since the shares are contingently convertible only upon a Change of Control.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheet and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, accounting for share-based compensation, accounting for derivatives and accounting for income taxes. Actual results could differ from those estimates.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value for applicable assets and liabilities, we consider the principal or most advantageous market in which we would transact and we consider assumptions market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. This guidance also establishes a fair value hierarchy to prioritize inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets and would be charged to earnings. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. The Company has not recorded an impairment charge for the years ended June 30, 2018, 2017 and 2016.

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, using the straight-line method. The Company generally assigns useful lives of thirty years for assets classified as GMP facility, fifteen years for assets classified as furniture and fixtures, ten years for assets classified as lab equipment, and five years for assets classified as office equipment. 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 the statements of operations.

Trademarks and Patents

The Company amortizes the costs of trademarks and patents on a straight-line basis over their estimated useful lives, the terms of the exclusive licenses and/or agreements, or the terms of legal lives of the patents, whichever is shorter. Upon becoming fully amortized, the related cost and accumulated amortization are removed from the accounts.

Research and Development

Research and development expenses consist primarily of costs associated with the preclinical and/ or clinical trials of drug candidates, compensation and other expenses for research and development, personnel, supplies and development materials, costs for consultants and related contract research and facility costs. Expenditures relating to research and development are expensed as incurred.

Stock-Based Compensation

The Company follows the provisions of ASC 718 – "Stock Compensation", which requires the measurement of compensation expense for all shared-based payment awards made to employees and non-employee directors, including employee stock options. Stock-based compensation expense is based on the grant date fair value estimated in accordance with the provisions of ASC 718 and is generally recognized as an expense over the requisite service period, net of forfeitures.

The fair value of common stock issued as employee compensation is the average of the open and close share price on the date the common shares are issued.

The Series A preferred shares are not traded in any market. The assumptions used to determine the fair value of the Series A preferred shares issued as employee compensation are presented in Note 8 to the financial statements.

The fair value of each option award is estimated on the date of grant using a Black-Scholes option-pricing valuation model. The ranges of assumptions for inputs are as follows:

- Expected term of share options and similar instruments: The expected term of share options and similar instruments represents the period of time the options and similar instruments are expected to be outstanding taking into consideration the contractual term of the instruments and employees' expected exercise and post-vesting employment termination behavior into the fair value of the instruments. It may be appropriate to use the simplified method, if (i) A company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded; (ii) A company significantly changes the terms of its share option grants or the types of employees that receive share option grants such that its historical exercise data may no longer provide a reasonable basis upon which to estimate expected term; or (iii) A company has or expects to have significant structural changes in its business such that its historical exercise data may no longer provide a reasonable basis upon which to estimate expected term. The Company uses the simplified method to calculate expected term of share options and similar instruments, as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

- Expected volatility of the Company's shares and the method used to estimate it: Expected volatility is based on the average historical volatility of the Company's common stock over the expected term of the option.

- Expected annual rate of quarterly dividends: The expected dividend yield is based on the Company's current dividend yield as the best estimate of projected dividend yield for periods within the expected term of the option and similar instruments.

- Risk-free rate(s): The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods within the expected term of the option and similar instruments.

The Company's policy is to recognize compensation cost for awards with only service conditions and a graded vesting schedule on a straight-line basis over the requisite service period for the entire award.

Equity Instruments Issued to Parties other than Employees for Acquiring Goods or Services

The Company follows the provisions of "ASC 505 – Equity", which accounts for equity instruments issued to parties other than employees for acquiring goods or services. Pursuant to ASC 505, all transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the performance is complete or the date at which a commitment for performance is reached. The assumptions used in determining the fair value of the Series A Preferred shares are presented in Note 8 to the financial statements.

The Company uses the average of the open and close share price of the Company's common stock at each measurement date to determine the fair value of the restricted common stock issued as compensation for goods and services.

The Company has issued securities to acquire goods or services at or after the delivery of the goods or services for which it contracted. The securities when issued are fully vested and the Company has recognized such issuances as an immediate expense.

The fair value of share options and similar instruments is estimated on the date of grant using a Black-Scholes option-pricing valuation model. The ranges of assumptions for inputs are as follows:

- Expected term of share options and similar instruments: The expected term of share options and similar instruments represents the contractual term of the instruments.

- Expected volatility of the Company's shares and the method used to estimate it. Expected volatility is based on the average historical volatility of the Company's common stock over the contractual term of the option and similar instruments.

- Expected annual rate of quarterly dividends. The expected dividend yield is based on the Company's current dividend yield as the best estimate of projected dividend yield for periods within the contractual term of the option and similar instruments.

- Risk-free rate(s). The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods within the contractual term of the option and similar instruments.

Income Tax Provision

The Company uses the asset and liability method of accounting for deferred income taxes. Deferred income taxes are measured by applying enacted statutory rates to net operating loss carryforwards and to the differences between the financial reporting and tax bases of assets and liabilities. Deferred tax assets are reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company recognizes uncertainty in income taxes in the financial statements using a recognition threshold and measurement attribute of a tax position taken or expected to be taken in a tax return. The Company applies the "more-likely-than-not" recognition threshold to all tax positions, commencing at the adoption date of the applicable accounting guidance, which resulted in no unrecognized tax benefits as of such date. Additionally, there have been no unrecognized tax benefits subsequent to adoption. The Company has opted to classify interest and penalties that would accrue, if any, according to the provisions of relevant tax law as general and administrative expenses, in the statements of operations. For the years ended June 30, 2018, 2017 and 2016 there was no such interest or penalty.

Concentrations of Risk

Financial instruments that potentially subject us to a significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured institutions in excess of federally insured limits. The Company does not believe it is exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Recently Issued Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for non-employee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The standard will be effective for the Company in the first quarter of fiscal year 2020, although early adoption is permitted (but no sooner than the adoption of Topic 606). The Company does not expect that the adoption of this ASU will have a significant impact on its financial statements.

In July 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-11. "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 revises the guidance for instruments with down round features in Subtopic 815-40, Derivatives and Hedging – Contracts in Entity's Own Equity, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An

entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for annual and interim periods beginning December 15, 2018, and early adoption is permitted, including adoption in an interim. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of retaining earnings in the fiscal year and interim period adoption. The Company is currently in the process of assessing the impact of this ASU on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, "Stock Compensation (Topic 718)", which includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The standard is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The adoption of this standard on July 1, 2017 did not have a material effect on the Company's financial position, results of operations or cash flows.

Note 3 – Liquidity and Going Concern

The Company's financial statements have been prepared assuming that it will continue as a going concern, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the normal course of business. As reflected in the financial statements, the Company has an accumulated deficit at June 30, 2018 of approximately $83.7 million and a net loss of approximately $8.6 million and net cash used in operating activities of approximately $7.8 million for the fiscal year then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of June 30, 2018, the Company had available cash and cash equivalents of approximately $7.1 million. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Management adjusted its planned expenditures, activities, and programs, in accordance with budgetary constraints and in accordance with its expectations of obtaining additional financing.

The Company has made several adjustments to its past expenditures in the ensuing annual budget, eliminating several expenses including a reduction in workforce and consultants to the extent feasible without affecting its program of drug development. In addition, the Company has focused its efforts primarily on a single lead program to minimize cost outlays, namely, taking the shingles drug candidate against VZV into human clinical trials. Management's budget indicates that these changes have freed up sufficient funds to allow for the ensuing costs of the external advanced IND-enabling studies of this drug candidate. Management has considered several options for financing the net working capital deficit as well as to obtain additional funds that will be needed for future human clinical trials. The Company is also evaluating the possibility of obtaining a mortgage on its fully owned cGMP-capable laboratory facility in Shelton, CT, in order to free up a portion of the fixed capital for usage as liquid working capital.

In addition, the Company believes that it has several important milestones that it will be achieving in the ensuing year. Management believes that as it achieves these milestones, the Company would likely experience improvement in the liquidity of the Company's stock, and would eventually improve the Company's ability to raise funds on the public markets at terms that may be favorable to the terms we are offered at present.

Management believes that as a result of the management plan, the Company's existing and planned resources and access to the capital markets will be sufficient to fund the Company's planned operations and expenditures through October 2019. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The accompanying audited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

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

Note 4 – Related Party Transactions

Related Parties

Related parties with whom the Company had transactions are:

Related Parties	Relationship
Anil R. Diwan	Chairman, President, acting CEO, significant stockholder and Director
Eugene Seymour	CEO Emeritus, significant stockholder (Retired January 27, 2018)
TheraCour Pharma, Inc. (“TheraCour”)	An entity owned and controlled by a significant stockholder
Milton Boniuk, MD	Director (retired July10, 2018) and significant stockholder

Property and Equipment

	For the Year Ended		
	June 30, 2018	June 30, 2017	June 30, 2016
During the reporting period, TheraCour acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment at cost, to the Company	$ 30,321	$ 33,147	$ 39,938

Accounts Payable Related Party

	As of	
	June 30, 2018	June 30, 2017
Pursuant to an Exclusive License Agreement we entered into with TheraCour, the Company was granted exclusive licenses in perpetuity for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. 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 certain direct costs as a development fee and such development fees shall be due and payable in periodic installments as billed, (2) we will pay $2,000 or actual costs each month, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf, (3) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour; (4) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. Accounts payable due TheraCour on the reporting date was	$ 107,468	$ 340,695

Research and Development Costs Paid to Related Parties

	For the Year Ended		
	June 30, 2018	June 30, 2017	June 30, 2016
Development fees and other costs charged by and paid to TheraCour pursuant to exclusive License Agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at June 30, 2018, 2017 and 2016	$ 3,176,977	$ 3,368,919	$ 3,731,498

Debentures Payable to a Director

	As of	
	June 30, 2018	**June 30, 2017**
Series C Convertible Debentures - Milton Boniuk	$ -	$ 5,000,000

On November 13, 2017, the Company entered into a Debenture Redemption Agreement with an entity controlled by Dr. Milton Boniuk to redeem the Series C Debenture (see Note 7). The related shares were issued on March 21, 2018.

	As of	
Debenture Interest Payable to a Director	**June 30, 2018**	**June 30, 2017**
Deferred interest payable - short-term	$ -	$ 166,667

Coupon interest expense on the Series C Debenture paid to the Milton Boniuk IRA (the "Holder") for the years ended June 30, 2018, 2017 and 2016 was $185,274, $500,000 and $500,000 respectively. The Series C Convertible Debenture was redeemed on November 13, 2017. See Note 7.

Stock and warrant interest paid in kind on Series B Convertible Debentures to Dr. Milton Boniuk and recognized at fair value was $0, $0 and $37,410 for the years ended June 30, 2018, 2017, and 2016, respectively.

Coupon interest expense on the Series B Debentures to two holders controlled by Dr. Milton Boniuk for the years ended June 30, 2018, 2017 and 2016 was $0, $187,178 and $320,000, respectively. The Series B Convertible Debenture matured on February 1, 2017. See Note 7.

Note 5 – Property and Equipment

Property and equipment, stated at cost, less accumulated depreciation consisted of the following:

	June 30, 2018	June 30, 2017
GMP Facility	$ 8,011,230	$ 7,996,402
Land	260,000	260,000
Office Equipment	57,781	48,486
Furniture and Fixtures	5,607	5,607
Lab Equipment	5,683,765	5,466,066
Total Property and Equipment	14,018,383	13,776,561
Less Accumulated Depreciation	(3,177,290)	(2,505,501)
Property and Equipment, Net	$ 10,841,093	$ 11,271,060

Depreciation expense for the years ended June 30, 2018, 2017 and 2016 was $671,789, $654,685 and $651,275, respectively.

During the year ended June 30, 2016, the Company completed the transfer of laboratories and personnel from its previous laboratory facilities at 135 Wood Street, West Haven, CT to 1 Controls Drive, Shelton, CT. The Company recorded the abandonment of fully depreciated non-removable laboratory fixtures and leasehold improvements associated with the 135 Wood Street rented facility of $332,476 as a reduction to Property and Equipment with a corresponding reduction to Accumulated Depreciation.

Note 6 – Trademark and Patents

Trademark and patents, stated at cost, less accumulated amortization consisted of the following:

	June 30, 2018	June 30, 2017
Trademarks and Patents	$ 458,954	$ 458,954
Less Accumulated Amortization	(84,025)	(75,756)
Trademarks and Patents, Net	$ 374,929	$ 383,198

Amortization expense amounted to $8,269, $8,269, and $8,270 for the years ended June 30, 2018, 2017 and 2016, respectively.

The Company amortizes our trademarks and patents over their expected original useful lives of 17 years.

Amortization expense in future years is as follows:

2019	$ 8,270
2020	8,270
2021	8,270
2022	8,270
2023	8,270
Thereafter	333,579
Total amortization	$ 374,929

Note 7 – Convertible Debentures and Derivatives

Debentures - Series B

The Company's Series B Convertible Debentures, in the amount of $6 million, matured on January 31, 2017. For the years ended June 30, 2017 and 2016, the Company paid a total of $173,589 and $320,000, respectively, of coupon interest to Holders in cash and two additional Holders of the Company's Series B Convertible Debentures elected to receive $107,178 and $160,000 respectively, of their coupon interest payment in shares of the Company's common stock.

The debt discount had been amortized to interest expense over the term of the debenture. The Company recognized amortization of this discount as an additional interest charge to "Discount on convertible debentures" for the years ended June 30, 2017 and 2016, in the amounts of $525,263 and $774,155, respectively. The debenture contained embedded derivatives that were not clearly and closely related to the host instrument. The embedded derivatives were bifurcated from the host debt instrument and treated as a liability.

On February 8, 2017, the Company entered into agreements with certain holders (the "Holders") of the Company's Series B Convertible Debentures (the "Debentures"). The Company and the Holders agreed to extinguish an aggregate of $5,027,178 of principal and interest attributable to the Company's Series B Debentures, which were payable on January 31, 2017 (the "Maturity Date") by converting into 4,359,652 newly-issued, restricted shares (the "Conversion Shares") of the Company's Common Stock. The number of shares attributable to the principal being converted was determined by dividing the $5,000,000 principal by $1.1533, the volume weighted average price ("VWAP") of the Company's stock price for the period from December 15, 2016 to January 30, 2017. The $5,000,000 of principal and $27,178 of accrued interest were converted into 4,335,386 and 24,266 shares of common stock, respectively. The principal balance of $1,000,000 not converted was paid in cash on February 8, 2017. The Company recognized a non-cash loss on extinguishment of debt of $332,524 on the extinguishment of the aforesaid principal attributable to the Series B Debentures into the Company's Common Stock. The loss on extinguishment of debt resulted from the excess of the market value of the shares issued on February 8, 2017 of $1.23 per share or $5,332,524 in the aggregate, over the $5,000,000 face value of the debt extinguished.

Debenture - Series C

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 the Milton Boniuk IRA, a trust controlled by a member of the Company's Board of Directors, (the "Holder"). The Debenture was due on June 30, 2018 (the "Maturity Date") and was 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 bore interest at the coupon rate of ten percent (10%) per annum, computed on an annual basis of a 365 day year, payable in quarterly installments on March 31, June 30, September 30 and December 31 of each calendar year until the Maturity Date. In accordance with the debenture agreement, the interest for the initial year of the debenture for a total of $500,000 was deferred, to be paid over the remainder of the term at $166,667 per year. The Holder at its option may choose to receive such coupon interest payment in shares of Common Stock calculated using the average of the open and close prices of the Company's common stock on the date such interest payment was due.

The Series C Convertible Debenture was redeemed on November 13, 2017. For the year ended June 30, 2018, the Holder elected to receive $60,274 (through November 13, 2017) of its coupon interest payment and $125,000 of deferred interest payment in common stock of the Company and $125,000 of its coupon interest payment and $41,667 of its deferred interest payment in cash. For the year ended June 30, 2017, the Holder elected to receive $375,000 of its coupon interest payment, and $125,000 of deferred interest payment in common stock of the Company and $125,000 of its coupon interest payment and $41,667 of its deferred interest payment in cash.

On July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debentures, the Company issued 187,000 shares of its Series A Convertible Preferred Stock (the "Series A") to Dr. Milton Boniuk, pursuant to the terms of the Debenture. Proceeds received in a financing transaction are allocated to the instruments issued prior to evaluating hybrid contracts for bifurcation of embedded derivatives. Since the Series A Convertible Preferred Stock is classified as equity, the proceeds allocated to the Preferred Stock are recorded at relative fair value. The fair value of the Series A was $1,645,606 at issuance and the relative fair value was calculated as $1,152,297. The remaining amount of the proceeds was allocated to the Debenture and a debt discount of $1,152,297 was recorded to offset the amount of the proceeds allocated to the Series A. Then, the embedded derivative was bifurcated at its fair value of $1,879,428 with the remaining balance allocated to the host instrument (Debenture). The total debt discount was amortized over the actual term of the Debenture using the effective interest method.

The Company recognized amortization of this discount as an additional interest charge to "Discount on convertible debentures" in the amount of $359,214, $822,485 and $653,063 for the years ended June 30, 2018, 2017 and 2016, respectively.

The Holder of the Series C Debenture and the Company agreed on November 13, 2017 that the Debenture would be redeemed for the Company's common stock, as described further below. The Holder waived all early redemption payments provided for in the Debenture in consideration for 150,000 shares of the Company's Series A Preferred shares.

The following represents the balance of the Debenture payable – Series C, net of discount at November 13, 2017 and at June 30, 2017. The debt discount has been amortized to interest expense over the actual term of the debenture.

	November 13, 2017	June 30, 2017
Proceeds	$ 5,000.000	$ 5,000,000
Debt Discount:		
Series A Preferred	(1,152,297)	(1,152,297)
Embedded derivative	(1,879,428)	(1,879,428)
	1,968,275	1,968,275
Accumulated amortization of debt discount	2,347,092	1,987,878
Debenture payable - Series C, net	**$ 4,315,367**	**$ 3,956,153**

The Company used a lattice model that valued the compound embedded derivatives of the Series C Convertible Debenture based on a probability weighted discounted cash flow model at November 13, 2017 and June 30, 2017.

The following assumptions were used for the valuation of the compound embedded derivative at November 13, 2017 and June 30, 2017:

- The balance of the Series C Convertible Debenture as of November 13, 2017 and June 30, 2017 is $5,000,000;
- The underlying stock price was used as the fair value of the common stock; The stock price decreased to $1.00 at November 13, 2017 from $1.35 at June 30, 2017, with lower projected annual volatility. The warrant value with the $6.05 exercise price decreased due to the decreasing term remaining;
- The projected annual volatility was based on the Company historical volatility:
- An event of default would occur 0% of the time, increasing 1.00% per month to a maximum of 10%;
- The Holder would automatically convert the interest if the Company was not in default and its share value was equivalent to the cash value;
- The Holder would automatically convert the debenture at maturity if the registration was effective and the Company was not in default.
- The weighted cost of capital discount rate (based on the market value of the transaction at issuance) adjusted for changes in the risk free rate is 21.99%.
- Even though the shares are restricted the underlying assumption is that any restriction on resale will be removed either through registration or the passage of time at the time of issuance.

The fair value of the compound embedded derivatives of the Series C Convertible Debenture at November 13, 2017 and June 30, 3017 was $15,449 and $32,213, respectively.

The Company's Series C Debenture in the amount of $5,000,000 was due to mature on June 30, 2018. On November 13, 2017, the Company entered into a Debenture Redemption Agreement (the "Agreement") with the Holder, to redeem (the "Redemption") its $5,000,000 Series C Convertible Debenture (the "Debenture") for an aggregate of 5,500,000 shares of the Company's $0.001 par value Common Stock ("Purchase Price") comprising 5,000,000 shares for the principal of the Debenture and 500,000 shares for unpaid coupon interest from October 1, 2017 through June 30, 2018. The unpaid interest included $60,274 of accrued interest through November 13, 2017, $314,726 in coupon interest through June 30, 2018 and $125,000 of unpaid deferred interest. The price per share was equal to the closing price of the Company's stock on Friday, November 10, 2017 of one ($1.00) dollar per share. The Holder waived all early redemption penalty payments provided for in the Debenture for consideration of 150,000 shares of the Company's $0.001 par value Series A Convertible Preferred Stock. The Company did not incur placement agent fees in redemption of the Series C Convertible Debenture. The Company recognized a non-cash loss on extinguishment of debt of $1,348,247 on the extinguishment of the aforesaid principal attributable to the Series C Debentures into the Company's common and preferred stock. The loss on extinguishment arises from, the obligation to issue 150,000 shares of the Company's Series A Preferred shares with a fair value of $364,337, as of November 13, 2017, obligation to issue 314,726 shares of the Company's $0.001 par value Common Stock with a fair value of $314,726 as of November 13, 2017, in consideration of Debenture coupon interest from the redemption date through June 30, 2018, and unamortized discount of $684,633 as of the redemption date, offset by the derivative liability of ($15,449) as of the redemption date.

Pursuant to the redemption agreement for the Company's Series C Debenture, the Company issued 5,500,000 shares of its registered Common Stock from its shelf registration and the 150,000 shares of its Series A Preferred Stock upon receiving consent to issue the shares pursuant to New York Stock Exchange ("NYSE") regulations. The Company submitted a request for authorization to issue the Common Stock and Series A Preferred Shares to the NYSE, which was authorized on March 18, 2018 and the shares were issued on March 21, 2018

On November 13, 2017, the Company recognized a liability from the obligation to issue the shares in settlement of the redemption of the Company's Series C debenture totaling $5,864,337. On March 21, 2018, when the shares were issued, the 150,000 Series A Preferred shares had a fair value of $314,343 and the common shares had a fair value of $4,730,000.

The change in the fair value of the obligation to issue registered shares is recorded in the statements of operations as "change in the fair value of derivatives". For the year ended June 30, 2018, the gain from change in fair value of the obligation to issue registered shares was $819,994.

On March 21, 2018, when the shares were issued, the liability for the obligation to issue registered shares of $4,730,000 for the common shares and $314,343 for the Series A Preferred shares was reclasssed to stockholders' equity.

The Series A Preferred Stock fair value as of March 21, 2018 is based on the greater of i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the Holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a Change of Control. The valuations of the Series A Preferred Stock at each issuance used the following inputs:

a. The common stock price was in the range $1.14 to $.92;

b. The calculated weighted average number of shares of common stock in the period;

c. A 26.63% premium over the common shares for the voting preferences;

d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 12.27% to 15.25% of the total;

e. The conversion value is based on an assumption for calculation purposes only of a Change of Control in 4 years from October 31, 2016 and a remaining restricted term of 3.00 to 2.59 years;

f. 31.69% to 30.43% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 58.33% to 52.49% volatility, 1.62% to 2.30% risk free rate) applied to the converted common.

Note 8 – Accrued expenses

Accrued expenses consisted of the following:

	June 30, 2018	June 30, 2017
Severance payment	$ 233,333	$ -
Personnel and compensation costs	19,716	29,141
Other accrued expenses	-	4,863
Accrued Expenses	$ 253,049	$ 34,004

Note 9 – Equity Transactions

Fiscal Year Ended June 30, 2016 Transactions

On January 23, 2016, the Company's Board of Directors and a majority of the holders of the Company's Series A Convertible Preferred Shares (the "Series A Shares") approved an amendment to the Certificate of Designation of the Series A Shares to increase the number of authorized Series A Shares from 4,000,000 to 8,500,000.

Unregistered Securities

On February 1, 2016, 571,433 warrants were issued for interest in accordance with the terms of the Series B debenture. The warrants are exercisable at $3.50 per warrant and will be valid for 3 years after issuance. The Company recorded an expense of $56,115 for the fair value of the warrants. The Company estimated the fair value of the warrants issued to the Holders of the Company's Series B Debentures on the date of issuance using the Black-Scholes Option-Pricing Model.

Expected life (year)	3
Expected volatility	44.18%
Expected annual rate of quarterly dividends	0.00%
Risk-free rate(s)	1.01%

For the year ended June 30, 2016, the Scientific Advisory Board was granted fully vested warrants to purchase 68,592 shares of common stock at exercise prices between $1.44- $2.18 per share expiring in the fiscal year ending June 30, 2020. These warrants were valued at $42,886 and recorded as consulting expense.

For the year ended June 30, 2016, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

Expected life (year)	4
Expected volatility	57.81% -73.40%
Expected annual rate of quarterly dividends	0.00%
Risk-free rate(s)	1.07 - 1.63%

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 57,649 shares of its Series A Convertible Preferred Stock which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of $263,698, which is the fair value at date of issuance.

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Anil Diwan, the Company's president. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 Series A preferred shares to Dr. Diwan. 75,000 shares will vest on June 30, 2016 and the remainder of the shares will vest over the three years of

the employment agreement and are subject to forfeiture. The Company recognized a noncash compensation expense related to the issuance of the Series A Preferred Shares of $309,344 for the year ended June 30, 2016. The balance of $564,410 will be recognized as the remaining shares are vested.

On July 21, 2015, the Board of Directors approved a new employment agreement with Dr. Eugene Seymour, the Company's Chief Executive Officer. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 225,000 of the Company's Series A preferred shares to Dr. Seymour. 75,000 shares will vest on June 30, 2016 and the remainder of the shares will vest over the three years of the employment agreement and are subject to forfeiture. The Company recognized a noncash compensation expense related to the issuance of the Series A Preferred Shares of $309,344 for the year ended June 30, 2016. The balance of $564,410 will be recognized as the remaining shares are vested.

The fair value of the Series A Preferred Stock at each date of issuance was as follows:

Date	Shares	Value
7/21/2015	408,839	$1,587,669
7/31/2015	2,572	10,998
8/31/2015	2,572	9,631
9/30/2015	2,572	7,220
10/31/2015	2,572	7,440
11/30/2015	2,572	7,837
12/31/2015	2,572	8,068
1/31/2016	43,732	167,677
2/29/2016	2,572	9,332
3/31/2016	2,572	15,565
4/30/2016	2,572	14,948
5/31/2016	2,572	11,332
6/30/2016	29,358	153,490
	507,649	$2,011,207

There is currently no market for the shares of Series A Preferred Stock and they can only be converted into shares of common stock upon a Change of Control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Series A Preferred Stock granted to various employees and others on the date of grant. The Series A Preferred Stock fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a Change of Control. The valuations of the Series A Preferred Stock at each issuance used the following inputs:

a. The common stock price was in the range $1.82 to $1.20;

b. The calculated weighted average number of shares of common stock in the period;

c. A 5.36% premium over the common shares for the voting preferences;

d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 4.896% to 5.046% of the total;

e. The conversion value is based on an assumption for calculation purposes only of a Change of Control in 4 years from March 1, 2013 and a remaining restricted term of 1.92 to 1.67 years;

f. 30.86% to 31.42% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 63.52% to 69.38% volatility, 0.22% to 0.26% risk free rate) applied to the converted common.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 106,554 shares of its common stock which are fully vested with a restrictive legend for consulting services. The Company recorded an expense of $158,000 which is the fair value at date of issuance.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 29,852 shares of its common stock, which are fully vested with a restrictive legend for Director services. The Company recorded an expense of $45,000 which is the fair value at date of issuance.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 72,725 shares of its common stock which are fully vested with a restricted legend for employee compensation. The Company recorded an expense of $142,589 which is the fair value at date of issuance.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 313,155 shares of its common stock for the exercise of 428,573 stock options on a cashless basis.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 101,558 shares of its common stock to holders of the Company's Series B Debentures. Two Holders of the Company's Series B Debentures elected to receive a total of $160,000 of the quarterly interest payments in restricted common stock of the Company. The Holders are entities controlled by Dr. Milton Boniuk, a director of the Company.

For the year ended June 30, 2016, the Company's Board of Directors authorized the issuance of 313,785 shares of its common stock to the Holder of the Company's Series C Debentures. The Holder of the Company's Series C Debentures elected to receive $375,000 of the quarterly interest payments and $125,000 of the deferred interest in restricted common stock of the Company. The Holder is an entity controlled by Dr. Milton Boniuk, a director of the Company.

Fiscal Year Ended June 30, 2017 Transactions

For the year ended June 30, 2017, the Scientific Advisory Board was granted fully vested warrants to purchase 57,160 shares of common stock at exercise prices between $1.40- $2.04 per share expiring in the fiscal year ending June 30, 2021. These warrants were valued at $37,948 and recorded as consulting expense.

For the year ended June 30, 2017, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

Expected life (year)	4
Expected volatility	55.57% -87.09%
Expected annual rate of quarterly dividends	0.00%
Risk-free rate(s)	1.00 - 1.79%

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 57,650 shares of its Series A Convertible Preferred Stock, which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of $164,592 which is the fair value at date of issuance.

On January 25, 2017 the Board of Directors authorized the issuance of 200,000 fully vested shares of its Series A Convertible Preferred stock to Anil Diwan. The Company recorded an expense of $512,984.

For the year ended June 30, 2017, the Company recognized a noncash compensation expense of $297,267 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Anil Diwan's employment agreement that vest over three years. The remaining balance of $267,143 will be recognized as the remaining shares are vested over the term of the contract.

For the year ended June 30, 2017, the Company recognized a noncash compensation expense of $297,267 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Eugene Seymour's employment agreement that vest over three years. The remaining balance of $267,143 will be recognized as the remaining shares are vested over the term of the contract.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 71,430 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $82,145.

The fair value of the Series A Preferred stock was the following for the dates indicated:

Date	Shares	Value
7/31/2016	2,572	$ 11,439
8/31/2016	2,572	11,978
9/30/2016	2,572	10,847
10/31/2016	2,572	9,591
11/30/2016	2,572	7,631
12/31/2016	2,572	6,583
1/25/2017	200,000	512,984
1/31/2017	2,572	6,231
2/28/2017	2,572	6,357
3/03/2017	26,786	65,630
3/31/2017	2,572	6,493
4/30/2017	2,572	6,679
5/31/2017	2,572	7,500
6/30/2017	2,572	7,633
	257,650	$ 677,576

There is currently no market for the shares of Series A Preferred Stock and they can only be converted into shares of common stock upon a Change of Control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Series A Preferred Stock granted to various employees and others on the date of grant. The Series A Preferred Stock fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a Change of Control. The valuations of the Series A Preferred Stock at each issuance used the following inputs:

a. The common stock price was in the range $1.07 to $1.74;

b. The calculated weighted average number of shares of common stock in the period;

c. A 26.63% premium over the common shares for the voting preferences;

d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 10.25% to 12.26% of the total;

e. The conversion value was based on an assumption for calculation purposes only, for the period ended September 30, 2016 of a Change of Control in 4 years from March 1, 2013 and a remaining restricted term of 1.92 to 1.67 years. For the period from October 1, 2016 to June 30, 2017, the conversion value was based on an assumption for calculation purposes only of a Change of Control in 4 years and a remaining restricted term of 4 to 3.34 years;

f. 21.76% to 38.87% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 63.58% to 85.39% volatility, 0.37% to 1.50% risk free rate) applied to the converted common.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 164,465 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $201,313, which was the fair value at date of issuance.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 33,933 fully vested shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of $45,000, which was the fair value at date of issuance.

On February 8, 2017 two Holders of the Company's Series B Debentures elected to convert $5,000,000 of the principal into restricted common stock of the Company. The Company's Board of Directors authorized the issuance of 4,335,386 of the Company's restricted common stock. One of the Holders is controlled by Dr. Milton Boniuk, a Director of the Company. The second Holder is a foundation established by him.

For the year ended June 30, 2017 two Holders of the Company's Series B Debentures elected to receive $107,178 in restricted common stock of the Company. For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 97,999 shares of the Company's restrict common stock for interest payable to the Holders. One of the Holders is controlled by Dr. Milton Boniuk, a Director of the Company. The second Holder is a foundation established by Dr. Milton Boniuk.

For the year ended June 30, 2017, the Company's Board of Directors authorized the issuance of 423,862 shares of its common stock to the Holder of the Company's Series C Debentures. The Holder of the Company's Series C Debentures elected to receive $375,000 of the quarterly interest payments and $125,000 of the deferred interest in restricted common stock of the Company. One Holder is an entity controlled by Dr. Milton Boniuk, a director of the Company. The other Holder is a charitable foundation established by Dr. Milton Boniuk.

Fiscal Year Ended June 30, 2018 Transactions

For the year ended June 30, 2018, the Scientific Advisory Board was granted fully vested warrants to purchase 45,728 shares of common stock at exercise prices between $0.64- $1.56 per share expiring in the fiscal year ending June 30, 2022. These warrants were valued at $16,770 and recorded as consulting expense.

For the year ended June 30, 2018, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

Expected life (year)	4
Expected volatility	53.56% -56.10%
Expected annual rate of quarterly dividends	0.00%
Risk-free rate(s)	1.67 – 2.84%

For the year ended June 30, 2018, Eugene Seymour was granted five year warrants (the "Warrants") to purchase 250,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock") at an exercise price of $2.00 per share, vesting in three, equal installments over three years with the last installment vesting on May 1, 2021. The fair value of these warrants was $53,500 and recorded as employee compensation expense for severance.

For the year ended June 30, 2018, the Company estimated the fair value of the warrants granted to Eugene Seymour on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

Expected life (year)	5
Expected volatility	53.56%
Expected annual rate of quarterly dividends	0.00%
Risk-free rate(s)	2.56

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 57,650 shares of its Series A Convertible Preferred Stock, which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of $136,106, which is the fair value at date of issuance.

The fair value of the Series A Preferred Stock was the following for the dates indicated:

Date	Shares	Value
7/31/2017	2,572	$ 8,242
8/31/2017	2,572	8,397
9/30/2017	2,572	8,588
10/31/2017	2,572	7,011
11/30/2017	2,572	6,313
12/31/2017	2,572	6,513
1/31/2018	2,572	5,552
2/28/2018	2,572	5,404
3/03/2018	26,786	60,725
3/31/2018	2,572	5,811
4/30/2018	2,572	5,215
5/31/2018	2,572	4,639
6/30/2018	2,572	3,696
	57,650	$ 136,106

There is currently no market for the shares of Series A Preferred Stock and they can only be converted into shares of common stock upon a Change of Control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Series A Preferred Stock granted to various employees and others on the date of grant. The Series A Preferred Stock fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a Change of Control. The valuations of the Series A Preferred Stock at each issuance used the following inputs:

a. The common stock price was in the range $.58 to $1.14;

b. The calculated weighted average number of shares of common stock in the period;

c. A 26.63% premium over the common shares for the voting preferences;

d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 10.25% to 15.50% of the total;

e. The conversion value was based on an assumption for calculation purposes only, for the period ended September 30, 2016 of a Change of Control in 4 years from March 1, 2013 and a remaining restricted term of 1.92 to 1.67 years. For the period from October 1, 2016 to June 30, 2017, the conversion value was based on an assumption for calculation purposes only of a Change of Control in 4 years and a remaining restricted term of 4 to 3.34 years;

f. 21.76% to 38.87% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 53.22% to 85.39% volatility, 0.37% to 2.10% risk free rate) applied to the converted common.

For the year ended June 30, 2018, the Company recognized a noncash compensation expense of $267,144 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Anil Diwan's employment agreement that vest over the three years ended June 30, 2018.

For the year ended June 30, 2018, the Company recognized a noncash compensation expense of $121,008 related to Series A Preferred Shares issued on July 21, 2015 in accordance with Dr. Eugene Seymour's employment agreement that vested over three years. On January 27, 2018, Dr. Eugene Seymour resigned as Chief Executive Officer and as a Director of the Company. See Note 12.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 150,000 shares of its Series A Convertible Preferred Stock, which are fully vested with a restrictive legend to the Holder of the Company's Series C Convertible

Debenture in consideration for its waiver of all early redemption payments provided for in the Debenture. See Note 7. The Company recorded an expense of $314,343, which is the fair value at date of issuance.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 71,430 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $65,716.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 243,759 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $156,190, which was the fair value at the dates of issuance.

For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 49,777 fully vested shares of its common stock with a restrictive legend for Director services. The Company recorded an expense of $45,000, which was the fair value at date of issuance.

For the year ended June 30, 2018 the Holder of the Company's Series C Debentures elected to receive 5,500,000 shares of the Company's restricted common stock in redemption for its $5,000,000 Series C Debenture, quarterly interest payments of $375,000 and deferred interest of $125,000. For the year ended June 30, 2018, the Company's Board of Directors authorized the issuance of 5,500,000 shares of the Company's restricted common stock for the redemption of the debenture payable to the Holder and quarterly and deferred interest payments. See Note 7

Note 10 – Stock Options and Warrants

The following table presents the activity of stock options issued for the period ended June 30, 2018 as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price per share ($)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($)
Outstanding and exercisable at June 30, 2015	535,715	$ 0.35	0.23	$ 749,997
Granted	-	-	-	-
Exercised	428,573	0.35	-	$ 149,999
Expired	107,142	0.35	-	$ -
Canceled	-	-	-	-
Outstanding at June 30, 2016	-	-	-	-
Granted	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding at June 30, 2017	-	-	-	-
Granted	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding at June 30, 2018	-	-	-	-

For the years ended June 30, 2018, 2017 and 2016 there was no compensation expense recorded. As of June 30, 2018 there was no unrecognized compensation cost.

Stock Warrants	Number of Shares	Weighted Average Exercise Price per share ($)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($)
Outstanding and exercisable at June 30, 2015	5,976,675	$ 5.14	3.20	$ 19,000
Granted	640,025	3.31	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding and exercisable at June 30, 2016	6,616,700	$ 4.96	2.55	$ 4,459
Granted	57,160	1.71	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding and exercisable at June 30, 2017	6,673,860	$ 4.93	1.36	$ -
Granted	295,728	1.87	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Canceled	-	-	-	-
Outstanding and exercisable at June 30, 2018	6,969,588	$ 4.80	.53	$ -

Of the above warrants; 6,548,108 expire in fiscal year ending June 30, 2019; 68,592 expire in fiscal year ending June 30, 2020; 57,160 expire in fiscal year ending June 30, 2021; 45,728 expire in fiscal year ending June 30, 2022; and 250,0000 expire in fiscal year ending June 30, 2023.

Note 11 – Fair Value Measurement

Fair value measurements

At June 30, 2018 and 2017, the fair value of derivative liabilities is estimated using a lattice model that is based on the individual characteristics of our warrants, preferred and common stock, the derivative liability on the valuation date as well as assumptions for volatility, remaining expected life, risk-free interest rate and, in some cases, credit spread. The derivative liabilities are the only Level 3 fair value measures.

At June 30, 2018 and 2017, the estimated fair values of the liabilities measured on a recurring basis are as follows:

	Fair Value Measurements at June 30, 2018:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series C debentures	$ -	-	$ -
Derivative liability – Warrants	-	-	298,092
Total derivatives	$ -	$ -	$ 298,092

	Fair Value Measurements at June 30, 2017:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability – Series C debentures	$ -	-	$ 32,213
Derivative liability – Warrants	-	-	2,015,354
Total derivatives	$ -	$ -	$ 2,047,567

In conjunction with the Company's registered direct offerings of Units, consisting of the Company's common stock and warrants, on September 12, 2013 and January 24, 2014 the Company issued 2,945,428, and 2,479,935 warrants respectively, and, of which, 2,810,071 and 2,479,935 respectively are outstanding at June 30, 2018. Additionally, the Company issued 58,910 and 76,306 warrants, respectively, to the placement agents which are also outstanding at June 30, 2018, for a total number of 5,425,222 warrants outstanding pursuant to the aforesaid registered direct offerings.

The Company accounts for stock purchase warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreements. Under applicable accounting guidance, stock warrants must be accounted for as derivative financial instruments if the warrants contain full-ratchet anti-dilution provisions, which preclude the warrants from being considered indexed to its own stock. The warrants described above contained a full-ratchet anti-dilution feature and are thus classified as a derivative liability.

The Company used a lattice model to calculate the fair value of the derivative warrants based on a probability weighted discounted cash flow model. This model is based on future projections of the various potential outcomes. The features that were analyzed and incorporated into the model included the exercise and full reset features.

The Warrants were valued as of issuance, exercise, and the annual periods with the following assumptions:

- The 5-year warrants issued on 9/12/13 and 1/24/14 included Investor and Placement Agent Warrants with an exercise price of $5.25 and $6.05 (subject to adjustments-full ratchet reset). A reset event occurred during the quarter ended September 30, 2014 adjusting the $6.05 exercise price to $5.25

- 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	
6/30/17	60%
6/30/18	56%

The primary factors driving the economic value of options are stock price; stock volatility; reset events and exercise behavior. Projections of these variables over the remaining term of the warrant are either derived or based on industry averages. Based on the above, a probability was assigned to each scenario for each future period, and the appropriate derivative value was determined for each scenario. The option value was then probability weighted and discounted to the present.

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the years ended June 30, 2016, 2017 and 2018:

		Fair Value Measurement Using Significant Unobservable Inputs		
	Obligation to issue shares	Derivative liability – Series B	Derivative liability – Series C	Derivative liability - warrant
Balance at July 1, 2015	$ -	$ 366,764	$ 476,289	$ 3,442,754
Additions during the year		-	-	-
Change in fair value	-	(163,734)	(132,616)	(245,572)
Transfer in and/or out of Level 3		-	-	-
Balance at July 1, 2016	$ -	$ 203,030	$ 343,673	$ 3,197,182
Additions during the year	-	-	-	-
Change in fair value	-	(203,030)	(311,460)	(1,181,828)
Transfer in and/or out of Level 3	-	-	-	-
Balance at July 1, 2017	$ -	$ -	$ 32,213	$ 2,015,354
Additions during the year	5,864,337	-	-	-
Change in fair value	(819,994)	-	(16,764)	(1,717,262)
Transfer in and/or out of Level 3	(5,044,343)	-	(15,449)	-
Balance at June 30, 2018	$ -	$ -	$ -	$ 298,092

Note 12 – Income Tax Provision

On December 22, 2017 the U.S. President signed the Tax Cuts and Jobs Act (the "Tax Act") into law. Effective January 1, 2018, among other changes, the Tax Act (1) reduces the U.S. federal tax rate from 35 percent to 21 percent, (2) changes the rules relating to net operating loss carryforwards and carrybacks, (3) eliminates the corporate alternative minimum tax ("AMT") and changes how existing AMT credits can be realized and (4) requires companies to pay a onetime transition tax on certain unrepatriated earnings of foreign subsidiaries.

The Tax Act did not have a material impact on our financial statements since our temporary differences in the United States are fully offset by a valuation allowance and we do not have any significant offshore earnings from which to record the mandatory transition tax.

On December 22, 2017, the SEC issued guidance under Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118") directing taxpayers to consider the impact of the Tax Act as "provisional" when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law. The changes in the Tax Act are broad and complex. The final impacts of the Tax Act may differ from the Company's estimates due to, among other things, changes in interpretations of the Tax Act, further legislation related to the Tax Act, changes in accounting standards for income taxes or realized interpretations in response to the Tax Act, or any updates to estimates the Company has utilized to calculate the impacts of the Tax Act. The SEC has issued rules that would allow for a measurement period of up to one year after the enactment date of the Tax Act to finalize the related tax impacts. The Company currently anticipates finalizing any resulting adjustments by the end of our next fiscal year ending June 30, 2019. The Company, based on current knowledge did estimate the impact of SAB 118 on its income tax provision for the year ended June 30, 2018. The impact on the Company's financial statements for the year ended June 30, 2018 is immaterial, primarily because the Company has a valuation allowance on deferred tax assets.

The Company has no current tax expense due to its losses.

The income tax expense for the years ended June 30, 2018, 2017, and 2016 differed from the amounts computed by applying the U.S. federal income tax rate of 28.1%, 34% and 34% respectively as follows:

	For the Year Ended		
	June 30, 2018	June 30, 2017	June 30, 2016
Federal Statutory Rate	-28.10%	-34.00%	-34.00%

Research and Development Credit	0.40%	-6.87%	-6.10%
State Tax Rate	-3.79%	-4.95%	-6.18%
Change in Statutory Federal Rate	62.36%	-%	-%
Valuation Allowance	-30.87%	45.82%	46.28%
Effective Tax Rate	-	-	-

The significant components of the Company's deferred tax assets and liabilities at June 30, 2018 and 2017 are as follows:

	June 30, 2018	June 30, 2017
Net operating losses	$ 24,839,394	$ 23,839,852
Research and development credit	6,198,377	6,217,612
Other	6,047,301	10,336,196
Total gross deferred tax assets	37,085,072	40,393,660
Less: valuation allowance	(37,085,072)	(40,393,660)
Net deferred tax assets	$ -	$ -

At June 30, 2018 and 2017, the Company has recorded a full valuation allowance against its net deferred tax assets of $37,085,072 and $40,393,660, respectively. The change in the valuation allowance during the year ended 2018 was $(3,308,588) and a full valuation allowance has been recorded since, in the judgment of management, these assets are not more likely than not to be realized. The Tax Cut and Jobs Act of 2017 was enacted in December 2017. Among other things, the Act reduces the U.S. federal corporate tax rate from 34% to 21% and eliminates the alternative minimum tax ("AMT") for corporations. Since the deferred tax assets are expected to reverse in a future year, it has been tax effected using the 21% federal corporate tax rate. As a result of the reduction in the corporate income tax rate, the Company wrote down approximately $5.3 million of the gross deferred tax assets and valuation allowance against the gross deferred assets for the year ended June 30, 2018, and which has no impact on the financial statements for the year ended June 30, 2018.

As of June 30, 2018, the Company has approximately $70,000,000, of gross net operating loss carryforwards. As of June 30, 2018, credit carryforwards for federal and state purposes are $6,539,647 and $372,546, respectively. The net operating loss and credit carryforwards begin to expire in 2025.

Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carry-forwards could be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carryforward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there could be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

The Company applies the elements of FASB ASC 740-10 "Income Taxes - Overall" regarding accounting for uncertainty in income taxes. This clarifies the accounting for uncertainty in income taxes recognized in financial statements and required impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. As of June 30, 2018 the Company did not have any unrecognized tax benefits and has not accrued any interest or penalties through 2018. The Company does not expect to have any unrecognized tax benefits within the next twelve months. The Company's policy is to recognize interest and penalties related to tax matters within the income tax provision.

Note 13 – Commitments and Contingencies

Legal Proceedings

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

Employment Agreements

The Company and Dr. Diwan, President and Chairman of the Board of Directors, entered into an employment agreement effective July 1, 2015 for a term of three years. Dr. Diwan's compensation would be $350,000 for the first year of employment, $375,000 for the second year and $400,000 for the final year. Additionally, Dr. Diwan was awarded a grant of 225,000 shares of the Company's Series A Preferred Stock. 75,000 shares vested on June 30, 2016, 2017 and 2018. The employment agreement also provided incentive bonuses of $75,000 per year payable on or before July 31, 2016, 2017 and 2018. The incentive bonuses for 2016 and 2017 have been paid

according to the terms of the contract. The Company and Dr. Diwan agreed that the 2018 bonus would be earned and paid upon a filing of an IND.

See Footnote 14 for Dr. Diwan's employment agreement extension.

The Company and Dr. Seymour, the Company's Chief Executive Officer and Director, entered into an employment agreement effective July 1, 2015, for a term of three years. Dr. Seymour's compensation would be $350,000 for the first year of employment, $375,000 for the second year and $400,000 for the final year. Additionally, Dr. Seymour was awarded a grant of 225,000 shares of the Company's Series A Preferred Stock. 75,000 shares vested on June 30, 2016, 75,000 shares vested on June 30, 2017 and 75,000 shares were scheduled to vest on June 30, 2018. The employment agreement also provided incentive bonuses of $75,000 per year payable on or before July 31, 2016, 2017 and 2018. The incentive bonuses for 2016 and 2017 have been paid according to the terms of the contract. A prorated bonus of $43,750 was paid in 2018 due to the retirement of Dr. Seymour on January 27, 2018.

On January 27, 2018, Dr. Eugene Seymour resigned as the Chief Executive Officer and as a Director of the Company. On April 30, 2018, the Company and Dr. Seymour finalized a Severance Agreement. The separation agreement calls for continued payment of his salary through December 2018, the vesting of 50,000 of the 75,000 Series A Preferred shares that were originally scheduled to vest on June 30, 2018 and issuance of warrants to purchase 250,000 shares of the Company's common stock. The remainder of his unvested shares was forfeited. The warrants were valued at $53,500 and vest in three equal installments over three years with the last installment vesting on May 1, 2021. The Company reversed the compensation recorded from July 1, 2017 through January 31, 2018 related to the 75,000 shares that will no longer vest under the terms of the employment agreement and then calculated the fair value of the 50,000 shares as a result of the modification of the award as of January 27, 2018. The Company then recognized noncash compensation expense related to the issuance of the Series A Preferred Shares pursuant to the Settlement Agreement of $121,008 for the fiscal year ended June 30, 2018.

On March 3, 2010, the Company entered into an employment agreement with Dr. Jayant Tatake to serve as Vice President of Research and Development. The employment agreement provides for a term of four years with a base salary of $150,000. In addition, the Company issued 26,786 shares of Series A Preferred Stock and 35,715 shares of common stock upon entering into the agreement, and issued an additional 26,786 shares of Series A Preferred Stock and 35,715 shares of common stock on each anniversary date of the agreement. The shares of Series A Preferred Stock were issued in recognition of Dr. Tatake's work towards the achievement of several patents by the Company. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements. For the years ending June 30, 2018, 2017 and 2016, compensation under the agreement was $168,300, $168,300 and $168,300, respectively.

On March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provided for a term of four years with a base salary of $150,000. In addition, the Company issued 35,715 shares of common stock upon entering into the agreement, and issued an additional 35,715 shares of common stock on each anniversary date of the agreement. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and Employment agreements. For the years ending June 30, 2018, 2017 and 2016 compensation under the agreement was $168,300, $168,300 and $168,300, respectively.

On May 30, 2013, the Company entered into an Employment Agreement with Meeta Vyas to serve as its Chief Financial Officer. The employment agreement provided for a term of three years with a base salary of $9,000 per month and 2,572 shares of Series A Preferred Stock, also on a monthly basis. On January 1, 2015, her compensation was increased to $10,800 per month. The Compensation Committee of the Board of Directors has extended the current provisions of the Employment Agreement pending its review of current industry compensation arrangements and employment agreements. For the years ending June 30, 2018, 2017 and 2016 compensation under the agreement was $129,600, $129,600 and $129,600, respectively.

License Agreements

The Company is dependent upon its license agreement with TheraCour Pharma, Inc. (See Note 4). If the Company lost the right to utilize any of the proprietary information that is the subject of the TheraCour Pharma license agreement on which it depends, the Company will incur substantial delays and costs in development of its drug candidates. There has not been any royalty payable to date. The Company has declared its intent to license VZV (shingles) and the remaining human herpes viruses from TheraCour, and has conducted a valuation for the shingles and PHN indications. The Company had previously stated its intention to complete the license negotiations under the auspices of its new Chief Executive Officer, Dr. Irach Taraporewala who was engaged on July 19, 2018 and will join the Company as its new Chief Executive Officer on September 1, 2018.

Note 14 - Subsequent Events

Management performed an evaluation of the Company's activity through the date these financials were issued to determine if they must be reported. The Company determined that there were certain reportable subsequent events to be disclosed as follows:

• On July 3, 2018, the Company received a notice from the New York Stock Exchange (the "NYSE") indicating that the Company is not in compliance with the NYSE's continued listing requirements set forth in Part 8 of the NYSE American Company Guide (the "Company Guide"). The NYSE noted that the Company is not in compliance with Section 803(B)(2)(a) of the Company Guide in that it no longer has at least three members on the audit committee, effective as of June 29, 2018 when Dr. Mukund Kulkarni advised the Company that he resigned as a member of its audit committee.

The NYSE informed the Company that, under the NYSE's rules, the Company will have until the earlier of its next annual meeting or one year from the occurrence of the event that caused the failure to comply with the audit committee and the board of directors composition requirements, provided, however, that if the annual shareholders' meeting occurs no later than 180 days following the event that caused the failure to comply with these requirements, the Company shall instead have 180 days from such event to regain compliance.

• On July 10, 2018, Dr. Milton Boniuk resigned as a Director of the Company and as a member of its audit, compensation and nominating committees.

• On July 10, 2018, Dr. Kulkarni advised the Company that he rescinded his resignation as a member of the audit committee and the Company accepted the same.

• On July 11, 2018, The Company entered into an extension of the Employment Agreement (the "Agreement") with Dr. Anil R. Diwan as President of the Company effective July 1, 2018. The Agreement provides Dr. Diwan will be paid an annual base salary of $400,000. Dr. Diwan shall be entitled to participate in all fringe benefits the Company provides for its employees generally and such other benefits as the Company provides for its senior executives. In addition, the Company shall maintain a Term Life Insurance policy for Dr. Diwan, valued at $2 million, of which $1 million shall be assigned to the Company and the remaining to Dr. Diwan's estate. In addition, as an incentive towards the ultimate success of the Company, and to provide leadership authority to Dr. Diwan, the Company granted 525,000 shares of the Company's Series A Preferred Shares to Dr. Diwan. Dr. Diwan's rights in the shares shall be vested in one-third increments on June 30, 2019, June 30, 2020 and June 30, 2021.

Dr. Diwan will be eligible to receive severance if he is terminated by the Company other than for cause in which event the Company shall pay to Dr. Diwan an amount equal to six (6) month's salary as severance compensation (without regard to compensation or benefits Dr. Diwan receives from any other source). Dr. Diwan shall be eligible for all benefits during this six (6) month period including bonuses, vesting of previously awarded stock options, health care insurance and other fringe benefits that have been ongoing. The Company may elect to pay such severance compensation in a lump sum or in equal payments over a period of not more than six (6) months.

• On July 19, 2018, the Company entered into an Employment Agreement (the "Agreement") with Dr. Irach Taraporewala as Chief Executive Officer of the Company beginning on September 1, 2018. Dr. Taraporewala shall be nominated to serve as a member of the Company's Board of Directors subject to election by the Company's shareholders at the next annual or special meeting of the Company's shareholders. The Agreement provides a term of three years during which Dr. Taraporewala will be paid an annual base salary of $360,000. Dr. Taraporewala shall be entitled to participate in all fringe benefits the Company provides for its employees generally and such other benefits as the Company provides for its senior executives, as more fully specified in the Agreement. In addition, the Company granted Dr. Taraporewala options to purchase up to 300,000 shares of the Company's common stock, par value $0.001 per share at an exercise price equal to 20% above the closing bid price of $0.41 the common stock on the effective date of the Agreement July 19, 2018, (the "Effective Date") (i.e. $0.492/share). The options shall vest in three, equal, annual installments commencing on the Effective Date. Dr. Taraporewala shall be eligible to earn certain Performance "Milestone Bonus" awards based on the Company's achievement of certain milestones, as more fully described in the Agreement, so long as he is employed by the Company on the date the milestone is achieved.

Dr. Taraporewala may receive severance of six months' salary if he is terminated by the Company other than for cause, and further, shall be eligible for all benefits during this six (6) month period including bonuses, vesting of previously awarded stock options, health care insurance and other fringe benefits that have been ongoing.

• On October 2, 2018, the Company entered into an agreement with TheraCour Pharma, Inc. for a waiver of the two month worth of prepaid balance advance of anticipated invoicing and the application of the current advance as a credit against current open invoices, Additionally, Theracour has agreed to defer $25,000 per month of development fees for six months. The agreement with Theracour results in increased working capital of approximately $700,000.