Table of Contents https://www.sec.gov/Archives/edgar/data/1379006/000141057823002146/nnvc-20230630x10k.htm

**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, 2023

Commission File Number 001-36081

# NANOVIRICIDES, INC.

(Name of Business Issuer in Its Charter)

| DELAWARE | 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 $0.00001 PER SHARE | NYSE AMERICAN |
|---|---|
| (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 ☒

On October 10, 2023 there were approximately 11,746,000 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on December 31, 2022, by non-affiliates of the registrant was approximately $12,235,000 based on the closing price of $1.11 per share, as reported on the NYSE American on December 31, 2022, 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.

**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.

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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 United States Food and Drug Administration (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.

**ITEM 1: BUSINESS**

**Organization and Nature of Business**

NanoViricides, Inc. (the "Company", "NanoViricides", "we," or "us") was incorporated in Nevada on April 1, 2005, and redomiciled to Delaware effective May 30, 2023. 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".

We are a clinical stage company with our first drug in Phase 1a/1b clinical trial and several additional drug candidates in various stages of pre-clinical development, including IND-filing stage and late stage IND-enabling non-clinical studies. We have no customers, products or revenues to date, and may never achieve revenues or profitable operations.

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 Nanoviricides Platform provides for modalities that can result in potentially cures for viruses that do not establish latent virus infection in humans.

NV-CoV-2, Our First Nanoviricide Drug that has Entered Phase 1a/1b Human Clinical Studies

NV-CoV-2, the drug we developed in response to the COVID-19 pandemic, has entered Phase 1a/1b human clinical trials sponsored by our licensee and collaborator, Karveer Meditech Private Limited ("Karveer"), in India, around June 19, 2023.

Nanoviricides Platform Has Enabled Industry-Leading Orally Available Nanomedicines And Multiple Routes of Administration

We found that unlike almost all other nanomedicine platforms, our nanoviricide NV-387, the active pharmaceutical ingredient (API) of NV-CoV-2, demonstrated strong antiviral activity when administered orally in multiple animal models. Most nanomedicines do not possess significant oral bioavailability and therefore have to be administered as injections or infusions. This oral bioavailability of our nanoviricides distinguishes our technology from almost all of the rest of the nanomedicines world.

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We developed two different oral formulations of NV-387, namely “NV-CoV-2 Oral Syrup”, and “NV-CoV-2 Oral Gummies”. The latter is a semi-solid fixed-dose form. The oral syrup enables body-weight-based dose titration as is required for pediatric cases. Both of these are in the Phase 1a/1b human clinical trial.

The oral dosage forms are expected to provide wide-spread adoption across the entire population from children to senior citizens, and special cases such as immune-compromised patients outside the hospital. The Oral Gummies fixed dosage form has the advantage that it is suitable even for patients that cannot swallow the usual hard tablets or capsules, because it slowly dissolves in the mouth as it is absorbed.

We have also developed a NV-387 formulation called “NV-CoV-2 Solution for Injection, Infusion and Inhalation”. We believe treatment of severe cases that are not yet hospitalized would be best performed by an injection. Hospitalized patients would benefit most from the 100% bio-availability of the injection route, and may be dosed with an infusion if larger quantity dosing is warranted.

Importantly, the same injectable solution can be readily delivered directly into the lungs as a fog created using standard portable battery operated nebulizer devices. This enables direct and quick action at the most important site of infection by a respiratory virus such as coronaviruses, RSV, influenzas, human meta-pneumovirus (hMPV), certain adenoviruses, and others, that can lead to severe pneumonia.

**The Nanoviricide Platform Technology in Brief**

NanoViricides, Inc. is engaged in the application of nanomedicine technologies to the complex issues of viral diseases. We are developing a class of drugs, that we call nanoviricides®, using a platform technology. This approach enables rapid development of highly effective and safe new drugs against a number of different viruses.

A nanoviricide is a “biomimetic” - it is designed to appear to the virus like the cell surface bearing the sites that the virus binds to. The nanoviricide™ technology enables direct attacks at multiple points on a virus particle.

Since the cellular binding sites for a given virus do not change despite mutations and other changes in the virus, we believe that the virus would be highly unlikely to escape our drug candidates even as a virus changes rapidly as it evolves.

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. As the nanoviricide polymeric micelle interacts with the virus particle, the nanoviricide is capable of binding to the virus at multiple points, and while doing so, wrapping itself around the virus by virtue of an effect called “lipid-lipid mixing”. In the process, the specific glycoproteins that the virus uses for binding to the cell (for example, the coronavirus “Spike” protein) are expected to be neutralized and dismantled. It is believed that such attack would lead to the virus particle becoming ineffective at infecting cells. Therefore we call this novel mechanism of action “Re-Infection Inhibition”.

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.

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.

It is important to realize that the flexible, “shape-shifting” nanoviricides nanomedicines show substantial advantages over hard sphere nanoparticles in this antiviral drug application as the nanoviricides enable lipid-lipid mixing with the viral envelope and can wrap around or merge with the virus surface. Hard sphere nanomaterials such as dendritic materials (dendrimers), nanogold shells, silica, gold or titanium nanospheres, polymeric particles (such as PLA-PLGA, others), etc., were never designed to be capable of completely enveloping and neutralizing the virus particle.

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This powerful Nanoviricides 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. While our first drug candidate, NV-CoV-2, is now in human clinical trials, and another one, NV-HHV-1, is awaiting to go into the clinic, over the years we have developed more than ten drug candidates that, we believe, can be rapidly moved into the clinical stage, from nearly forty different antiviral drug development programs. Our progress to clinic is limited by our resources. We anticipate that once our first drug goes successfully through Phase 1 and Phase 2 clinical trials thereby proving our capabilities and our Nanoviricides Platform technology, the Company, assuming it acquires the necessary financings, could enter a phase of exponential growth and rapid clinical development of additional candidates thereby transforming the way viral infections are treated.

**Nanoviricides Represent the Next Generation Development Beyond Immunotherapeutics**

Our nanoviricide technology relies on copying the human cell-surface receptor to which the virus binds, and making small chemicals that are called “ligands” that will bind to the virus in the same fashion as the attachment receptor or the cognate receptor (see below). These ligands are chemically attached to the base polymer or “nanomicelle”, to create a nanoviricide™.

A class of small molecules called entry inhibitors exists. These drugs are designed to bind to the virus to stop it from binding to cells. A very large number of these small molecules must simultaneously attack the virus particle for the particle to be fully inhibited – a task that has very low probability in vivo (“kinetic hurdle”). Additionally, similar to antibodies, entry inhibitors are also rapidly rendered ineffective as the virus changes.

In contrast to a nanoviricide that is expected to bind to the virus at multiple points, antibodies can bind a virus particle at only a maximum of two attachment points per antibody. Several antibodies are required to simultaneously bind to the virus particle to neutralize it. Additionally, the human complement system and immune systems are required to work properly to clear the resulting complex.

“Resistance is Futile” – NanoViricides Has a Unique Technology Designed So That Viruses Would Not Readily Escape Our Drugs

The Nanoviricide Platform has built into it cognitive elements that the virus recognizes and binds to, no matter how much it mutates, provided we have mimicked the virus-binding site on the attachment or cognate cellular receptor properly. This is because no matter how often a virus mutates, generating myriads of variants as it evolves, the specific binding sites to which virus attaches and gains entry into cells does not change.

In contrast, antibodies are extremely specific and therefore even minor changes in the virus tend to make them ineffective. Antibodies and vaccines are readily evaded by viruses under the evolutionary pressure in a natural process itself. This has become starkly evident in the COVID-19 pandemic.

Even as new virus variants develop that evade exiting antibodies and vaccines, the variants continue to bind to their cellular attachment receptor(s) and the cellular cognate receptor(s) at the same sites and in the same manner, despite changes in the viral glycoprotein itself. Thus if we design the ligands correctly, the nanoviricide would continue to be effective even as the virus keeps changing in the field, in stark contrast to antibodies and vaccines that readily lose effectiveness as the virus evolves.

We believe that our platform technology enables development of drugs that viruses would not escape from. In fact, we have successfully screened our COVID-19 drug candidates to be able to protect cells against infection by distinctly different coronaviruses. This broad-spectrum drug development approach was adopted to ensure that our drug candidates should remain effective even as future variants of SARS-CoV-2 evolve in the field, as was already anticipated by us at the very beginning of the pandemic.

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

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 attack is expected to 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. In contrast, a nanoviricide would complete the job of making the virus particle non-infectious, without any help from the human immune system.

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, and, in some cases, reassortment. Such viral escape from antibodies has been witnessed in almost every viral epidemic, be it HIV/AIDS, the Influenza pandemic of 2009, or the Ebola epidemic of 2014-15. In contrast, despite mutations and other changes, a virus is unlikely to escape a nanoviricides drug designed against it.

It is anticipated that when a virus comes in contact with the nanoviricide, not only would it land on the nanoviricide surface, binding to the copious number of ligands presented there, but it would also get entrapped because the nanomicelle polymer would turn around and fuse with the virus lipid envelop, harnessing a well known biophysical phenomenon called "lipid-lipid mixing". In a sense, a nanoviricide drug acts against viruses like a "venus-fly-trap" flower does against insects. Unlike antibodies that tag the virus and thereafter require the human immune system to take over and complete the task of dismantling the virus, a nanoviricide is a nanomachine that is designed to not only bind to the virus but also complete the task of rendering the virus particle ineffective.

Thus the Nanoviricide Platform technology can be viewed as the next step in evolution of antibody-based approach, taking into account and eliminating the limitations of antibodies.

Uniform Polymer Nature Enables Simplified 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, the very nature of polymer and particle making processes, particularly in the case of block-copolymers that are commonly employed, and the fact that many nanomedicines are mixtures of multiple components.

The Nanoviricide Platform technology has been designed from the ground up to enable consistent manufacture and control. Thus, the nanoviricide backbone is a "homopolymer" (i.e. it is made up of a single repeating unit or monomer), which enables a naturally uniform structure. This is unlike block-copolymers wherein there is structural heterogeneity along the polymer chain that is often difficult to control. 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 as well as to remove impurities. The final nanoviricide solutions are 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.

Formulation is Inherent in the Design Aspect of a Nanoviricide

Since developing our API NV-387 in the COVID drug development program, development of its formulations, injectable, infusion, inhalation, oral syrup, and oral gummies (semi-solid form) was relatively quick, accomplished within months, including formulation design and scale-up with cGMP manufacturing considerations. Similarly, since declaring our shingles clinical candidate, NV-HHV-1, its formulation as a skin cream for topical treatment of shingles rash, and scale-up, and cGMP-compliant manufacture was accomplished relatively rapidly, within a few months. 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.

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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.

The Nanoviricides Platform's capabilities can be harnessed in multiple modalities, and we are working on a number of drugs based on these modalities to enable cures for viral diseases.

**Nanoviricides Platform Modality #1: Broad-Spectrum Antiviral "Reinfection Inhibitors"**

There are certain classes of cellular features that a very large number of viruses commonly use to get access to cells. As a first step, the virus binds to one so called "Attachment Receptor(s)." This allows the virus to concentrate near the target cells, and enables the virus particles to latch onto more specific receptors on the cell surface itself that are termed "Cognate Receptor(s)". Some viruses can directly fuse with the cell membrane without such a cognate receptor.

The attachment receptors employed by most viruses fall into very few families. One such family is "Sulfated Proteoglycans (S-PG)", or "Glycosaminoglycans (GAGs)." We loosely include a number of sulfated proteoglycan types in this "S-PG class". They differ in exact structures but share a number of commonalities. This family includes heparan sulfate (HSPG), dermatan sulfate (DSPG), chondroitin sulfate (CSPG), and keratan sulfate (CSPG). Over 90% of known pathogenic viruses bind to one or more of these S-PG class attachment receptors. These viruses include Coronaviruses, Paramyxoviruses (RSV - Respiratory Syncytial Virus, and HMPV- human Metapneumovirus), Dengue Viruses, Herpesviruses, Human Papillomavirus (HPV), HIV, Hendra and Nipah Viruses, Ebola and Marburg Viruses, among others.

Many of these viruses have no available antivirals or have antivirals with limited applicability. Nanoviricides that mimic S-PG can be expected to be capable of attacking many of these viruses, enabling very broad-spectrum antiviral agents. This is reminiscent of the development of beta-lactam antibiotics, that have broad-spectrum antibacterial properties because they attack a common feature of a large number of bacteria; the peptidoglycan cell wall.

NV-387 was designed using our knowledge of the commonalities in this S-PG class of attachment receptors for mimicking it with small chemical ligands. Thus, NV-387 is designed as a broad-spectrum antiviral agent. After its success in attacking multiple unrelated coronaviruses, we have undertaken a program to expand the potential indications of NV-387. Effectiveness in any of these additional indications would enable direct entry into Phase II/III clinical trials for that indication after completion of the current Phase 1 clinical trials of the NV-387 containing drug NV-CoV-2.

We reported in July 2023 that NV-387 was highly effective against a lethal RSV infection in a mouse model study. In light of the recent Nipah virus cases in Kerala, India, it would be interesting to explore if NV-387 can be an effective drug against Nipah and the related Hendra viruses. Such expansion of use of NV-387 would significantly expand the market size and substantially improve the return on investments (ROI).

Another important class of attachment receptors is Sialic Acids (SA). We are working on developing broad-spectrum antivirals mimicking SA. SA is well known as the initial site of binding for Influenza viruses, as well as many of the infectious Adenoviruses and many other viruses.

It would be very difficult for a virus to become resistant to a nanoviricide that mimics the virus' attachment receptor. This is firstly because the nanoviricides based on mimicking attachment receptors are broad-spectrum in nature, capable of antiviral effect against not just a specific virus type or subtype, strain or variant, but entire *families* of viruses (as defined in the virus classification system), and secondly, because, no matter how much a virus mutates or changes, its binding to the cellular receptor does not change.

**Nanoviricides Platform Modality#2: Specific, Highly Effective, Antiviral "Reinfection Inhibitors"**

Instead of developing bio-mimetics of the broad-spectrum attachment receptors, we can also develop nanoviricides that mimic the specific cognate receptor(s) used by a virus to develop highly specific drugs against that virus.

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Our antiviral drug candidate NV-HHV-1 is based on mimicking the cognate receptor HVEM ("herpesvirus entry mediator"). It has shown strong activity against VZV (Varicella Zoster Virus). VZV causes chickenpox in children and immune-compromised persons, and its reactivation causes Shingles in adults. NV-HHV-1 has completed pre-clinical IND-enabling studies for VZV. NV-HHV-1 was also effective against HSV-1 and HSV-2. We plan on exploring its activity against other herpesviruses such as CMV and EBV as well.

Further, we have developed drug candidates in the HIVCide™ Program that mimic the cellular CD4 binding site used by HIV to gain cell entry. Another important HIV cognate receptor is CCR5. The Nanoviricides Platform enables using mimics of one or more cellular receptors attached into a single nanoviricide drug. Thus this platform has the capability of mimicking both the CD4 binding site and the CCR5 binding site of HIV on one nanoviricide, which is expected to enable the most effective drug against HIV. The only countable number of patients that have been "cured" of HIV were recipients of stem cells that possess a modified CCR5 lacking its HIV-binding region, attesting to the importance of mimicking both CD4 and CCR5 simultaneously.

*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. Some viruses use more than one receptor. 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' cognate 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.

**Nanoviricides Platform Modality #3: Nanoviricides Platform Enables Cures for Viruses that Do Not Become Latent**

To date most viral infections do not even have effective drugs, let alone cures.

Most viruses do not become latent in the human body. Such viruses have a relatively simple life cycle: After a virus is transmitted to the person and infects some cells, it replicates inside the infected cell (the replication part), thereafter the new virus copies exit the cell and then infect new cells (the "re-infection" part) thus starting the cycle over again. If both parts of the life cycle can be blocked effectively, then such a virus infection can be readily cured. The Nanoviricide Platform Modality #3 enables such cures.

In this modality, the nanoviricide technology simultaneously enables attacking the external virus particle, as well as blocking the rapid intracellular reproduction of the virus by incorporating one or more APIs within the "belly" 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.

The nanoviricides built using Modality #1 as well as Modality #2 can be employed to add the replication-inhibition capability in this manner.

NV-CoV-2-R, our other drug in development for treatment of coronaviruses contains the API NV-387-R. This API is made up of remdesivir encapsulated within the belly of the polymeric micelles of NV-387. While NV-387 is designed to directly attack the virus outside the cell, the remdesivir component is known to block the virus replication inside the cell. By blocking both of these pathways, NV-387-R would result in a cure of the viral infection. Remdesivir is a broad-spectrum antiviral agent that has been approved for COVID and has shown strong pre-clinical activity against many RNA viruses. Its clinical activity is limited by its rapid metabolism in the bloodstream. NV-387 holds remdesivir like in a bottle and releases it slowly, thus limiting the metabolism and enhancing the pharmacokinetics and thereby the effectiveness of remdesivir.

Note that Remdesivir, sponsored by Gilead, is a known antiviral drug that has received full FDA approval for treatment of COVID-19 and has received Emergency Use Authorization ("EUA") in many countries. We are developing NV-CoV-2-R on our own, independent of Gilead.

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We have also developed other drugs based on this concept of curing the viral infection.

One of these is NV-387-Rp, which contains a modified and improved form of Remdesivir. Another one is NV-387-Ribvp, which contains a prodrug of Ribavirin. Ribavirin is a highly toxic but highly effective antiviral drug. It is approved in the USA only for the treatment of RSV infection as a drug of last resort. However, it is used in the case of many viral infections for which no antivirals are known in severe hospitalized cases. NV-387-Ribvp is expected to enable cures for such viruses by combining the Re-Infection Inhibition activity of NV-387 with the Replication Inhibition activity of Ribavirin, while at the same time enabling lower doses of Ribavirin to stay well below its toxicity level.

**Nanoviricides Platform Modality #4: Nanoviricides Platform Has the Capability to Enable Cures for Viruses that Do Become Latent**

HIV and many viruses in the herpesviridae family form "latent reservoirs" in human cells making them difficult to cure. HIV and the class of lentiviruses achieve this by directly copying its genomic information into the human chromosomal DNA itself. Two of the herpes viruses, namely HHV-6A and HHV-6B, are known to copy their genetic information into the telomere region of the chromosome, shortening the number of cell divisions the modified cell can undergo, effectively a phenomenon of aging. All other herpesviruses create episomal islands in the cell's nucleus which are their own "factories" for making progeny copies. The nanoviricides technology platform can be harnessed against these viruses in another different modality that can potentially produce cures. We are working on such cures of latent viruses in our research and development ("R&D") projects.

**Broad and Expanding Pipeline Based on the Nanoviricide Platform Technology – in Brief**

We have several drugs in our pipeline, enabled by our strong and extensive nanoviricide technology platform. Of these, NV-CoV-2 is in Phase 1a/1b Clinical Trials for the COVID indication and is the farthest along in the regulatory pathway. The need for the broad-spectrum nanoviricide SARS-CoV-2 drug cannot be overstated in the current circumstances and the present status of the pandemic with continuous evolution of variants of the virus and a constant threat of the possibility that a substantially more pathogenic virus compared to the current omicron variants may readily emerge. The current set of tools available for combating the COVID-19 pandemic is not robust enough to allow a "Living with COVID" attitude.

Following completion of the Phase 1a/1b clinical trials of NV-CoV-2, we plan on moving this drug into Phase 2 Efficacy Clinical Trials. We have currently associated the treatment indication of COVID for this drug. The same API, NV-387, was also highly effective against a lethal infection of RSV in a mouse model. Thus, we plan on entering this drug into Phase 2 Efficacy Clinical Trials for the RSV indication, in addition to COVID, depending upon our financial resources.

We plan on continuing additional exploratory studies to evaluate the effectiveness of NV-387 against other viruses that use S-PG class of attachment receptors. We have also completed pre-clinical development of a nanoviricide drug showcasing Modality 2, namely NV-HHV-1. We plan on undertaking Phase 1 and further clinical development of NV-HHV-1 as and when enabled by our financial resources. NV-HHV-1 is currently formulated as a Skin Cream for the treatment of Shingles.

We also have several additional pre-clinical drug development programs including Herpes Simplex Viruses (HSV-1 that causes cold sores, and HSV-2 that causes genital ulcers), HIV/AIDS, Influenza, Dengue viruses, and Ebola/Marburg, that we plan to advance further towards clinical drug candidates as they progress further. Thus we have a strong and broad pipeline that is expected to continue to result in highly effective drug candidates against a number of viral diseases.

We are now at the stage of clinically harnessing the development of Modality #1 and Modality #2 nanoviricides drugs. To recap, Modality #1 drugs mimic Attachment Receptors and possess a very broad spectrum of antiviral activity that includes a large number of different types of viruses. Modality#2 drugs mimic Cognate Receptors and possess a very strong antiviral activity against a set of specific types of viruses. In both cases, the targeted viruses are highly unlikely to escape the drug by evolving variants. NV-387 is an example of Modality #1 nanoviricides, and NV-HHV-1 is an example of Modality #2 nanoviricides. NV-387 is now in Phase 1a/1b clinical trials with COVID as indication. We are in the process of completing the IND-enabling studies for NV-387 to enter Phase 2 clinical trials for the treatment of RSV in addition to COVID. NV-HHV-1 has completed IND-enabling studies as a Skin Cream for the treatment of Shingles.

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We have also continued R&D on Modality #3 nanoviricide drugs that promise potential cures for non-latency viruses. NV-387-Rp and NV-387-Ribvp have shown strong effectiveness against Coronaviruses and RSV in animal models respectively, and are expected to be highly active against a number of other viruses based on the known activities of the components. We plan on developing these Modality #3 potential cures of a number of viral diseases after the Modality #1 and Modality #2 drugs.

Overall, since our founding, we have worked on development of about 40 different drugs against a number of different viral diseases in a number of drug programs. In the process, we have built an extensive library of both the (i) Nanoviricides Platform know-how and (ii) the actual synthesized chemical drugs. This enabled us to rapidly respond to the COVID-19 pandemic. We were able to announce that our early COVID drug candidates demonstrated strong antiviral effectiveness in animal studies as early as May 2020. We have diligently continued to progress these drug candidates with the culmination of the start of human clinical trials of the API NV-387 (the drug products are called NV-CoV-2) recently.

Additional details of our drug pipeline can be found in the section “NanoViricides Drug Pipeline” further below.

**NanoViricides Drug Development Process**

Our drug programs begin from initial R&D to understand the virus and advance to design antiviral medical countermeasures. Then we chemically synthesize selected potential small molecules to act as the ligands that mimic the cellular receptor(s) of both Modality #1 (broad spectrum) type as well as Modality #2 (specific to the virus family) type to bind to the virus. Separately we have been engaged in evolving and optimizing various versions of the nanoviricide backbone polymer. We then choose some of the select polymers and attach the selected antiviral ligands chemically to the polymer providing a library of antiviral nanoviricides. We then evaluate these antivirals in cell cultures against the target viruses. We further evaluate selected antiviral ligands from this screen in animal model studies. We then down-select from the effective drug candidates about five to seven candidates for further development based on a number of considerations including level and spectrum of activity, any likely issues with safety/tolerability, drug stability, pharmacokinetics, pharmacodynamics, ease of manufacturing, ease of formulations, and the desired routes of administration.

Along the way, we refine the methods of preparation of these drug candidates, from chemical synthesis all the way to formulation and packaging of the final drug product, developing and implementing the Chemistry, Manufacture and Controls information for the resulting drug substances as well as the potential drug products.

The selected candidates then undergo additional studies. Typically about two of them are advanced into IND-enabling GLP Safety/Tolerability studies. One of these is then selected for further evaluation in human clinical trials.

**NanoViricides, Inc. is a Fully Integrated Pharma Company**

We have strived to minimize the risks inherent in the drug development process. One of the major risks is the manufacture of our nanoviricide drug candidates in a manner to produce consistently quality drugs.

NanoViricides c-GMP-capable Kilogram-Scale Manufacturing Facility for Drug Substance and Drug Products

Manufacturing of drug products for sale, as well as for late stage clinical trials is required to be performed in FDA-registered cGMP manufacturing facilities. Manufacture of drugs for earlier stage clinical trials as well as for IND-enabling GLP Safety/Toxicology studies needs to be performed in a c-GMP-compliant manner.

We discovered early in our development that the existing contract manufacturing operations in the pharmaceutical industry have very limited expertise that would be applicable to our kind of drugs. In order to speed up nanoviricide drug development, save on costs, and ensure quality, we have set up our own manufacturing facility that can scale from discovery qualities of a few grams to clinical trials quantities of a few kilograms.

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

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We have produced and plan to continue to produce our nanoviricide drugs for clinical trials in this facility. We have the capability to produce sufficient drugs for about 1,000 patients in a single batch of production, depending upon dosage. This production capacity is anticipated to be sufficient for the clinical trials of our anti-coronavirus drug, as well as for the anticipated clinical trials of NV-HHV-1 skin cream for the treatment of Shingles. Further, this cGMP-compliant manufacturing capacity is anticipated to be sufficient for commercialization of our RSV drug candidate subsequent to required regulatory approvals thus enabling rapid market entry and revenue generation.

Our cGMP-compliant manufacturing facility is equipped with Class 100 (ISO 5), Class 1000 (ISO 6), and Class 10000 (ISO 7) clean room suites for injectables and other manufacturing operations.

We have in-house all the capabilities necessary for formulation, filling and finishing of our drug products in the following forms: (i) oral syrup, (ii) oral gummies (semi-solid form), (iii) skin creams and (iv) ointments. We plan to employ an external Contract Manufacturing Organization (CMO) for our injectable drug products for the clinical trials as and when required.

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

NanoViricides State-of-the-Art Nanomedicines Characterization Lab Supports In-Process QC, Release Testing of Manufactured Drug Substance, Drug Products, as well as R&D

We have a state of the art nanomedicines characterization facility in-house in the same campus that has all the capabilities necessary for in-process quality control as well as release testing and quality assurance of our drug products and for supporting our manufacturing operations as well as our R&D operations. We also have a Bio-Analytical laboratory that we use for various quantitative and semi-quantitative analyses.

NanoViricides BSL2 Virology Lab for Evaluation of Drug Candidates in Cell Culture Studies

In addition to the cGMP-capable manufacturing facilities, we have also brought in-house the capability for testing of our nanoviricide drug candidates against a number of viruses in cell culture studies for early evaluation. We have built a Biological Safety Level-2 (BSL2) Virology Laboratory with attendant cell culture and biochemistry capabilities in our campus in Shelton, CT, certified by the State of Connecticut. We are able to perform drug efficacy and safety studies in cell cultures for multiple different viruses at the same time in this facility, in isolated lab rooms.

We can also study antivirals against certain BSL3 and BSL4 viruses in this facility by developing what are called “pseudovirions”. Pseudovirions are virus particles that cannot replicate, but that have the coat protein of the virus that we want to study (e.g. SARS-CoV-2, Ebola, Marburg etc.) on a viral backbone that is a BSL2 compatible virus. We only require and employ pseudovirions technology where the resulting virus particles cannot replicate. The pseudovirion systems allow evaluation of drug candidates that block the entry of the virus particle into cells, such as entry inhibitors, antibodies, and nanoviricides.

We have developed in-house cell culture screening capability for developing drug candidates against human Coronaviruses (h-CoV) including SARS-CoV-2 pseudovirions, VZV, HSV-1 and HSV-2, Influenzas, HIV, RSV, Ectromelia Mousepox Virus (a model for MPox and Smallpox viruses), and pseudovirion technology for Ebola/Marburg viruses, among others. We believe that this internal screening enables speedy evaluation of a much larger number of candidates than external collaborations allow. We believe this has significantly improved our ability to find highly effective ligands and performing structure-activity-relationship studies of the same in a short time period.

External CROs for GLP and Non-GLP Animal Model Studies, Regulatory Affairs Support, and Clinical Trials

We depend upon external collaborators and Contract Research Organizations (“CROs”) for all of our animal studies that include antiviral efficacy studies, safety and tolerability studies, in both GLP and non-GLP practices. We also depend upon external collaborators and CROs for completing our regulatory filings, designing suitable clinical protocols, as well as for conducting human clinical trials, compiling the resulting data, biostatistics evaluations, and preparation of reports for regulatory filings. We plan on bringing some of the regulatory affairs capabilities in-house in the near future in order to speed up our regulatory processes.

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NanoViricides Campus – Fully Owned Asset Group

All of the facilities described above, the land, building, construction, and equipment, are fully owned by NanoViricides, Inc. with no mortgages or liens. This forms a significant and stable part of our long term assets, accounting for over $8 million in long term assets post-depreciation and amortization. The replacement cost of this asset is estimated to exceed $25 million.

We believe NanoViricides, Inc. is one of a few innovation-led small pharma companies that has or is close to having a fully integrated pharmaceutical operation from drug discovery to drug product manufacturing. This sets us apart in the field by substantially de-risking our development programs as well as enabling time and cost savings in the new drug development process.

**Fiscal Year 2022 - 2023 in Review**

NV-CoV-2 Phase 1a/1b Clinical Trial Encompassing both Safety and Effectiveness Indications for COVID Treatment, and Interim Update on Phase 1a/1b Human Clinical Trial of NV-CoV-2

In the reported year and subsequently to date, we have been working towards the goal of conducting human clinical trials for NV-CoV-2.

The API in NV-CoV-2, namely NV-387, is a broad-spectrum antiviral designed to destroy the virus particle so it cannot infect cells. We believe that NV-387 has broad-spectrum pan-coronavirus activity, and should be effective against the deadly MERS-CoV and SARS-CoV-1 infections, as well as the SARS-CoV-2 and seasonal coronavirus infections, some of which, including hCoV-NL63 and hCoV-OC43 can be deadly.

We previously completed pre-clinical IND-enabling studies on our novel SARS-CoV-2 drug candidate NV-CoV-2 around May, 2021, and thereafter engaged in efforts to enter the drug into clinical studies.

NV-387 was found to be statistically effective in multiple unrelated coronaviruses in cell culture studies, including hCoV-229E and hCoV-NL63. It was also found to be statistically effective in blocking cell infection by pseudovirions of bearing the SARS-CoV-2 Spike protein on their surface. Further, in multiple animal studies of lethal lung infection by hCoV-NL63, NV-387 given by injection, as well as given orally was statistically effective. h-CoV-NL63 produces pathology similar to SARS-CoV-2 in humans and they both bind to the same attachment receptor(s) (S-PG class), as well as the same cognate receptor, namely ACE2. Therefore hCoV-NL63, which requires BSL2 lab, has been widely used as a surrogate for SARS-CoV-2, which requires BSL3/4 labs.

We found that NV-387 was safe, with a No-Observable-Adverse-Event-Level (NOAEL) of 1,200mg/Kg and a Maximum-Tolerated-Dose Level (MTD) of 1,500 mg/Kg in rats. In GLP Safety/Toxicology Studies, NV-387 was found to be safe and no observations (i.e. no adverse events) were reported in cardiotoxicity as well as respiratory and neurologic studies.

We have also found that NV-387 is non-immunogenic, non-mutagenic, and non-genotoxic in appropriate IND-enabling studies. There were no injection-site reactions in any of our studies. NV-387 was therefore presumed non-allergenic; accordingly, allergenicity testing was not required.

Additionally, the pharmacokinetics (PK) of NV-387 in rats as well as in a primate (i.e. human-like species) model, namely, cynomolgus monkeys, was found to produce a plateau in the blood stream in at least the 4-8hr range, after a maximum around 0.5-2 hr range. Further, the PK profile upon multiple repeated dosings over a period of several days suggested accumulation of the drug with clearance extended well beyond 24 hrs. This PK profile is unlike that of most small chemicals, and is reminiscent of sustained-drug-release approaches. This profile enables once daily dosing of NV-387.

We faced substantial difficulties in our efforts to take NV-CoV-2 into clinical trials while the pandemic was raging due to the on-going pandemic restrictions, the saturation of clinical sites, consequent unavailability of CRO's, and the clinical market dynamics. We were pursuing both US and international possibilities for starting clinical trials with our limited resources. In September 2021, we signed an agreement with Karveer to evaluate the possibility of them sponsoring our COVID drugs for clinical trials in India.

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We, in collaboration with Karveer, the Drug Sponsor in India, and PristynCR, a Clinical Research Organization ("CRO") in India, completed medical writing of the IND-enabling studies including Chemistry, Manufacture and Controls (CMC) and Pre-clinical Safety/Toxicology, Pharmacology, and Animal and Cell Culture Effectiveness Studies. We, together with our collaborators, Karveer, and PristynCR, completed developing the full-fledged Clinical Protocols rapidly and thereafter a complete Clinical Trial Application was submitted by Karveer in India around November, 2022. Karveer received a conditional regulatory approval from the Central Drugs Standard Control Organization and the Drug Controller General of India ("CDSCO/DCGI") to proceed at the end of January, 2023. The conditions pertained to local clinical trial site related arrangements and approvals. The processes for satisfying these conditions were completed around March/April, 2023.

In March 2023, we consummated a License Agreement with Karveer pursuant to which we outlicensed to Karveer the two COVID drugs namely NV-CoV-2 and NV-CoV-2-R for further development and commercialization in India, as anticipated with the September 2021 engagement. Karveer has retained a local CRO, PristynCR Solutions, Pvt. Ltd., that developed the clinical trial protocols and clinical trial applications. PristynCR is performing the clinical trials at Mahatma Gandhi Mission Medical College and Hospital in Aurangabad, India (MGM). Karveer is managing the entire clinical trial process.

Around March/April, 2023, we completed cGMP-compliant manufacture of the clinical drug products at our own facility and shipped them to Karveer. The clinical process documentation was prepared by the CRO in collaboration with Karveer and the clinical trial site, MGM. Subsequently, initial enrollment work began. On or about June 19, 2023, the first healthy volunteers were dosed in the clinical trial. The clinical trial has continued with interim data reviews and further enrollments as planned.

On June 29, 2023, we announced that the clinical trial of NV-CoV-2 Oral Syrup and Oral Gummies has started. The clinical trial is designed to assess the safety and tolerability of the two drug products in healthy volunteers as well as in PCR +ve COVID patients. The Phase 1a part is a single-ascending dose ("SAD") protocol study in healthy volunteer subjects and includes three cohorts for each of the drug products with six subjects per cohort. The Phase 1b part is a multiple ascending dose ("MAD") protocol study. Phase 1b has two subparts. The healthy volunteers subpart of Phase 1b includes three cohorts for each of the drug products with six subjects per cohort. Additionally, the COVID patient subpart of Phase 1b includes three cohorts for each of the drug products with six subjects per cohort. Karveer intends to enroll PCR positive COVID patients with mild-to-moderate disease. All enrolled subjects will be sequestered in a hospital ward set aside for this purpose for the duration of the study in that subject. Clinical observations, Blood Chemistry, and Organ Function Tests are included at different time points and at a follow-up visit post-discharge. In addition, pharmacokinetics of the drug will be studied in the healthy volunteers cohorts. In the COVID cohorts, PCR tests will be conducted to determine when the virus clears. This part is designed to provide information on effectiveness of the drug and also to provide guidance on selection of dosing regimen for Phase II/III clinical trials.

On August 21, 2023, we reported interim communication that 26 out of the target of 36 healthy volunteers in the various cohorts in the Phase 1a Single-Ascending-Dose ("SAD") have already completed the study. Additionally, 17 of the target of 36 healthy volunteers in the various cohorts in the Phase 1b Multiple-Ascending-Dose ("MAD") part of the clinical trial had already completed the study by then. As of the date of this report, 26 out of 36 healthy volunteers in the various cohorts in the Phase 1b MAD study have completed the study, and an additional 10 healthy volunteers are expected to be recruited soon. Additionally, PristynCR has requested the Ethics Committee for permission to begin enrolling COVID patients.

No adverse events or serious adverse events were found in the SAD or MAD studies to date, in either the NV-CoV-2 Oral Syrup or the NV-CoV-2 Oral Gummies administration cohorts, even at the highest doses administered. These results are consistent with our pre-clinical safety toxology studies.

Bringing Clinical Programs into FDA Regulatory Processes

While our collaborator Karveer has progressed NV-387 into Phase 1a/1b clinical trials in India, we are now working on how to bring over the results of the clinical trial to the FDA once the reports become available. This would enable us to qualify to begin Phase II or Phase II/III clinical trials of the same drug in the USA for COVID and presumably, for RSV, as well as other potential indications that NV-387 may be a good candidate for their treatment.

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Expanding Indications of NV-387: RSV, Other Viruses

Additionally, knowing that NV-387 has broad-spectrum antiviral activity, as mimic of the attachment receptor S-PG class, we began exploration of its antiviral activity against other respiratory viruses.

The first of the target respiratory viruses we chose is RSV. We chose RSV because it is an important life-threatening infection particularly for newborns and children which leads to pneumonia in infants and children, and can result in deaths.

RSV is an Acute Lower Respiratory Infection (ALRI; includes Pneumonia). RSV is a common cause of childhood ALRI and a major cause of hospital admissions in young children. Each year in the United States, an estimated 58,000–80,000 children younger than 5 years old are hospitalized due to RSV infection. Globally, in 2015, 33 million episodes of RSV-ALRI resulted in about 3.2 million hospital admissions, and 59,600 in-hospital deaths in children younger than 5 years. About 45% of hospital admissions and in-hospital deaths due to RSV-ALRI occur in children younger than 6 months.

Yet there is currently no drug for the treatment of RSV infection, which represents a multi-billion-dollar unmet medical need. GrowthPlus Reports, in June 2023, said the market size for RSV therapeutics was worth $1.8 Billion in 2022, and is expected to grow at a CAGR of 18.9%, reaching $8.73 Billion by 2031.

We reported in July 2023, that NV-387 was almost as effective against lethal RSV infection in an animal model as the only known drug active against it, namely, ribavirin, which is a highly toxic drug. More importantly, both oral dosing of NV-387 as gummies, as well as dosing as an injection were successful in combating the RSV infection. Further, the oral bioavailability of NV-387, when comparing for equivalent clinical effect, was found to be quite high, approaching 50%. If the Phase 1a/1b clinical trials of NV-CoV-2 are acceptable then we would be able to engage into Phase II/III clinical trials of NV-387 oral formulations under the RSV indication. These oral formulations, currently named NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies, are likely to be renamed because of their broad-spectrum activity beyond coronaviruses.

We are also continuing additional work on other viruses that are likely to be susceptible to NV-387, that is, viruses that are known to use S-PG class of attachment receptors for infecting cells. This is a huge list that covers many of the viruses we are already working on and many new ones.

Our IND-Ready Drug Candidate, NV-HHV-1 Skin Cream for the Treatment of Shingles

We have previously developed NV-HHV-1 and formulated it as a skin cream for the treatment of Shingles rash, NV-HHV-1 has completed IND-enabling studies. We plan on undertaking further development of NV-HHV-1 into human clinical trials once our NV-387 based drug candidates progress further in clinical trials.

**Licenses, Patents, Trademarks, Proprietary Rights: Intellectual Property**

Licenses from TheraCour

Our drug development business model was formed in May 2005 with a license to the patents and intellectual property held by TheraCour Pharma, Inc. (TheraCour) that enabled creation of drugs engineered specifically to combat viral diseases in humans. This exclusive license from TheraCour serves as a foundation for our intellectual property. We have a worldwide exclusive license to this technology for several field of application verticals with specific targeting mechanisms for the treatment of a number of human viral diseases. TheraCour owns approximately 21% of our voting capital stock and, Anil Diwan, our Founder, President and Executive Chairman, owns approximately 90% of TheraCour's capital stock.

Our drug candidates are licensed from TheraCour, and are developed by TheraCour for the Company on the basis of several patents, patent applications, provisional patent applications, and other proprietary intellectual property know-how held by TheraCour. Unlike usual pharma industry licenses that are specified for single chemical entities or for groups of similar chemical entities, our licenses are specified for the vertical application field of use, thereby providing us with a large universe of diverse development candidates under the same umbrella. Further, the licenses are held by NanoViricides for worldwide use and can be sub-licensed. The licenses can revert only in the case of a default by NanoViricides. The terms of default are such that, effectively, TheraCour would be able to take the licenses back only in the event that NanoViricides declares insolvency and inability to conduct its business.

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We have exclusive licenses from TheraCour for drug candidates derived from and based on TheraCour's technologies for several viruses. In 2005, we obtained a license from TheraCour 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. Thereafter, on February 15, 2010, we entered into an Additional License Agreement with TheraCour granting the Company the exclusive licenses 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. While herpes simplex viruses were already specified as licensed previously, the term "ocular herpes keratitis" was added to this additional license agreement at the specific request of the Company for clarity only. In addition, we completed the process of licensing the VZV (shingles, chicken pox virus) field from TheraCour in November 2019. We further completed the process of licensing antivirals for the field of human coronavirus indications in September 2021 under the COVID agreement. As in the past, as and when advised by counsel, we will seek additional licenses to verticals of antiviral fields from TheraCour. To date, TheraCour has not withheld any licenses for antiviral nanomedicines that NanoViricides has requested.

We retain worldwide exclusive rights to commercially develop, commercialize, and market the licensed products. We pay TheraCour for the R&D work asked to be performed by the Company to develop these drugs, their chemistries, formulations, and manufacturing processes, substantially at cost, with a certain fee as specified in the license agreements. We may perform initial developmental testing by ourselves and through third parties, such as academic labs, government institutions, contract research organizations, for safety and effectiveness, among other tests. The Company may perform further IND-enabling advanced pre-clinical studies using third parties, such as contract research organizations, usually on clinical drug candidates. We expect to perform human clinical trials using contract research organizations with expertise in such clinical trials. We intend to sponsor the drugs for commercialization activities and obtain the rights of commerce under various regulatory authorities for its own use.

We focus our research and clinical programs on specific anti-viral therapeutics and are seeking to add to its existing portfolio of products through our internal discovery and clinical development programs and through an in-licensing strategy. To date, we have not commercialized any product.

For all the licensed fields, we control the research and work TheraCour performs on our behalf and no costs may be incurred without the prior authorization or approval by us.

The TheraCour technologies and patents required for execution of our work in the licensed fields and licensed products are automatically licensed to us even if such technologies and patents are developed after the license agreements themselves.

Patents, Patent Applications, Proprietary Rights

Patents and other proprietary rights are essential for our operations. If our drugs are protected by 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, in conjunction with TheraCour, 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.

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A new international PCT patent application regarding coronavirus drug candidates, PCT/US21/39050, entitled "Self-Assembling Amphiphilic Polymers As Anti-Covid-19 Agents," was filed under the Patent Cooperation Treaty (PCT) on June 25, 2021. An additional international PCT patent application that builds on this application regarding coronavirus drug candidates, PCT/US22/35210, entitled "Self-Assembling Amphiphilic Polymers As Anti-Covid-19 Agents," was filed on June, 28, 2022, with a requested priority date of the 2021 application. Our anti-COVID drugs are based on polymeric micelle nanomedicine technologies developed by TheraCour and its affiliate, AllExcel, Inc. ("AllExcel"). The inventors at AllExcel have filed these two broad PCT patent applications that form the basis of our two lead drug candidates, namely, NV-CoV-2 and NV-CoV-2-R. These new patent applications cover the new technologies, compositions, formulations, processes, manufactured products, and methods of use, among other specifics.

The nominal expiry date for patents resulting from these two PCT applications would be 20 years, after filing and if issued, i.e. June 24, 2041, and could be extended in certain countries under regulatory extensions to as late as into the year 2043, providing a significant commercial runway.

We believe that our drugs by themselves may be eligible for patent protection. We, in conjunction with TheraCour, plan on filing patent applications for protecting these drugs when we have definitive results that enable clinical drug development. We believe this strategy would maximize the available commercial patent life for many of our future drugs well beyond 2043. We intend to file the patent application for HerpeCide before entering human clinical trials, as we have done for our Coronavirus program. The estimated expiry date for the HerpeCide patents, if and when issued, would be no earlier than 2044-2049.

The Company has licenses to 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 |
|---|---|---|---|---|
| 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. | Oct. 2028 (estimated) | Applications are in various prosecution stages. Fifty-two of these have been issued or validated. | TheraCour Pharma, Inc. [Exclusive License]. |
| 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]. |
| PCT/US21/39050 - SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTI-COVID-19 AGENTS | Applied: June 25, 2021 | Ca. 2043 (estimated) | PCT Application filed. | TheraCour Pharma, Inc. [Exclusive License]. |
| PCT/US22/35210 – SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTI-COVID-19 AGENTS (**) | Applied: June 28, 2022 | Ca. 2043 (estimated) | PCT Application filed, | TheraCour Pharma, Inc. [Exclusive License]. |

**:The PCT application PCT/US22/35210 was filed with request for priority of PCT/US21/39050.

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We have previously announced certain important issuances of patents on the TheraCour® technology underlying our Nanoviricides® drugs. A total of at least 61 patents have been issued globally, on the basis of the first two international PCT patent families that cover the fundamental aspects of the platform technology we license from TheraCour. 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 patent expiry 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 five years extension for regulatory delays.

We believe that the novel compositions disclosed in these patent applications, and additional proprietary intellectual property provide the necessary features that enable the development of nanoviricides. We believe 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, we have no knowledge of the extensive active internal developments at a number of companies in the targeted therapeutics area.

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

Out-Licensing to Karveer Meditech Private Limited, India

On March 27, 2023 we entered into a License Agreement with Karveer wherein we granted to Karveer a limited, non-transferable, exclusive license for the use, sale, or offer of sale in India of the two clinical test drug candidates titled as NV-CoV-2 and NV-CoV-2-R for the treatment of COVID in patients in India. Karveer has engaged in further drug development in India including sponsoring of drug candidates for human clinical trials in India and has acted as clinical trials manager for such clinical trials. Karveer shall provide NanoViricides with all reports of the clinical trials and the Company can use such reports for further advancement of the drug candidates with regulatory authorities outside India. In consideration, Karveer will be reimbursed by us for all direct and indirect costs incurred for the clinical trials and development activities with a customary clinical trials manager fee of thirty (30)% of such costs and applicable taxes. Upon commercial sales of any resulting approved drugs, Karveer will pay the Company a royalty of seventy (70)% percent of the final invoiced sales less costs to unaffiliated third parties. Diwan, our Founder, President and Executive Chairman, is a passive investor in Karveer. His ownership interest does not provide him with control or significant influence over Karveer.

**Trademarks**

The Company currently has no registered trademarks.

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**Corporate Events - Financing**

We had approximately $8.1 million cash in hand as of June 30, 2023, the end of the reporting period. We spent approximately $5.7 million in cash on operating activities in the reported year, although our expenditures are expected to increase upon commissioning of additional human clinical trials. Additionally, we have long term assets of $8.1 million post-depreciation and amortization that represent our facilities.

We believe we have sufficient financing to complete at least the initial set of human clinical trials for our most advanced drug candidate, namely, NV-CoV-2, which is anticipated to occur during the coming fiscal year.

On July 8, 2020, we entered into an underwriting agreement (the "Underwriting Agreement" or "Offering") with Kingswood Capital Markets, a Division of Benchmark Investments, Inc. ( now EF Hutton Group). The Offering was consummated on July 10, 2020, whereby we sold 1,369,863 shares of common stock and a fully exercised underwriters' over-allotment option of 205,479 additional shares at $7.30 per share. No warrants were issued in this Offering. The net proceeds to us from the Offering was approximately $10.4 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

On July 31, 2020, we entered into an At Market Issuance Sales Agreement (the "ATM Sales Agreement") with B. Riley Securities, Inc. and Kingswood Capital Markets, a division of Benchmark Investments, Inc. (now EF Hutton Securities) (each a "Sales Agent" and collectively, the "Sales Agents"), pursuant to which we may offer and sell, from time to time, through or to the Sales Agents, shares of common stock (the "Placement Shares"), having an aggregate offering price of up to $50 million (the "ATM Offering*").*

On March 2, 2021 we sold 814,242 shares of common stock at an average price of $7.83 under the ATM Sales Agreement with the Sales Agents. The net proceeds from the offering were approximately $6.1 million after deducting underwriting discounts and commissions and other offering expenses.

On May 5, 2023, we filed a registration statement on Form S-3 (File No. 333-271706) with the Securities and Exchange Commission (the "SEC"), as amended on May 8, 2023, which registration statement was declared effective by the SEC on May 22, 2023. Under this shelf registration process, we may, from time to time, sell up to $150 million in the aggregate of shares of common stock, shares of preferred stock, debt securities, warrants and units.

On or about August 1st, 2023, the ATM Sales Agreement was amended to name EF Hutton, division of Benchmark Investments, LLC as the only sales agent (the "Agent") and to remove B. Riley Securities, Inc. as a sales agent. On August 4, 2023, we filed a prospectus supplement relating to the issuance and sale of our common stock, par value $0.00001 per share, having an aggregate offering price of up to $5,713,022 from time to time through or to our Agent. These sales, if any, will be made pursuant to the terms of the amended ATM Sales Agreement between us and the Agent.

Management believes that the Company has several important milestones to be achieved in the ensuing year. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced and support our goals of obtaining approvals for our COVID-19 drug candidates, marketing, establishing additional commercial scale manufacturing, and re-engaging additional drug development programs that are currently on hold.

Our drug development strategies may be influenced by considerations regarding the ability to engage into licensing or co-development relationships with other pharmaceutical companies. 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) for potential collaborations. Such licensing or co-development relationships 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 us. We intend to develop our drugs on our own if a suitable collaboration does not occur. As and when needed, management plans to continue to raise additional funds for our continuing drug development efforts from public markets. However, there can be no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us.

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**Investor Outreach**

We have retained Tradigital, Inc. as our investor relations firm. In addition, we have presented at various investor conferences.

On December 6, 2022, Dr. Anil Diwan, presented at the RHK Capital Disruptive Growth Conference in New York City, providing an update on the NV-CoV-2 Clinical Trials Program.

On January 9, 2023, Dr. Anil Diwan, presented at Biotech Showcase in San Francisco, providing an update on the NV-CoV-2 Clinical Trials Program.

On April 4, 2023, we announced that we had out-licensed NV-CoV-2 and NV-CoV-2-R for further development and commercialization in the territory of India to Karveer and that Karveer had obtained regulatory approval in India for starting Phase 1a/1b human clinical trials of NV-CoV-2 Oral Syrup and Oral Gummies for development in India.

On June 5, 2023, Dr. Anil Diwan presented the Company's assets and current development stage at the BIO International Conference in Boston, MA.

Additionally, we have provided updates on our progress via press releases.

***NanoViricides Drug Programs***

**Our Drug Programs for Coronavirus Infections Including COVID (Table 2.A):**

We are currently developing the following drug products for the treatment of COVID-19 disease:

(i) NV-CoV-2 Oral Syrup,

(ii) NV-CoV-2 Oral Gummies, and

(iii) NV-CoV-2 Solution for Injection, Infusion and Inhalation.

We were pleasantly surprised with the strong oral bioavailability of NV-387, the API of the drug product NV-CoV-2 in our animal studies. Very rapidly we developed two oral formulations of the drug. The oral gummies are a convenient and palatable form that resembles a soft candy or gummy. This form may have an advantage in terms of acceptability, particularly with pediatric population, and possibly in terms of its absorption characteristics, as it dissolves slowly in the mouth. The oral syrup has the advantage that it can be given in amounts proportional to body weight, a requirement that arises with treatment of very young children. These oral drugs are being developed for the treatment of mild to moderate COVID-19 disease.

The injectable form of NV-CoV-2 is designed for the treatment of hospitalized patients. Initially, we plan on delivering the drug NV-CoV-2 as a 30 minute infusion for hospitalized patients with severe COVID-19.

We plan to reduce the drug administration to a simple, slow-push, I.V. injection rather than the infusion if the data suggest that such injection will be well tolerated and effective. If so, we believe the injections would be for use in non-hospitalized patients that have moderate to severe disease which may require hospitalization if not treated immediately.

The same injectable form of NV-CoV-2 can be directly introduced as a mist into lungs using a simple hand-held nebulizer device. We expect such inhalation would deliver NV-CoV-2 at high concentration directly at the site of viral injury, i.e. the respiratory tract and lungs, for the most direct protective effect on the lungs. Such inhalation, possibly in conjunction with injection or infusion, would likely result in rapid benefit to severely ill, hospitalized patients requiring oxygen assistance.

We are also developing an additional drug product for the treatment of COVID-19 disease:

(iv) NV-CoV-2-R Solution for Injection, Infusion and Inhalation.

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*NV-CoV-2-R*

In addition to NV-CoV-2 itself as a drug to combat COVID-19, we are also developing another SARS-CoV-2 drug candidate, NV-CoV-2-R, which encapsulates remdesivir inside NV-CoV-2 represents a drug of the Nanoviricides Platform Modality#3 type. While Remdesivir substantially blocks the replication of the virus inside cells, NV-CoV-2 is designed to block the virus outside cells by entrapping it and thereby not allowing it to infect the cells in the first place. Thus NV-CoV-2-R is designed to block both the intra-cellular life cycle of the virus and the extra-cellular life cycle of the virus. Blocking both lifecycles should enable complete control of the viral disease, promising a potential cure. Remdesivir, sponsored by Gilead, is a known antiviral drug that has received full FDA approved for treatment of COVID-19 and has received EUA in many countries. We are developing NV-CoV-2-R on our own, independently of Gilead.

NV-CoV-2-R was observed to provide significant advantages over its encapsulated component remdesivir in terms of substantially superior pharmacokinetics consistent with our expectation in designing this drug by encapsulating remdesivir within our lead drug candidate NV-CoV-2. This encapsulation results in the dual-acting drug candidate NV-CoV-2-R which we believe has the promise of a potential pan-coronavirus cure.

The NV-CoV-2-R infusion, and if needed, associated inhalation of the same into lungs, may provide true cure of the SARS-CoV-2 infection by mounting a strong, double-whammy attack on the entire lifecycle of the virus, with NV-387 attacking the Re-infection Cycle, and Remdesivir attacking the Replication Cycle, to shut down the virus potentially completely. Such attack would also make drug escape or resistant variant generation highly unlikely if not practically impossible.

Both Remdesivir and NV-CoV-2 have demonstrated broad-spectrum activity against coronaviruses. Thus NV-CoV-2-R is expected to continue to be active in spite of evolution of novel variants of SARS-CoV-2. In contrast, antibody drugs and vaccines which induce antibodies lose effectiveness against variants. The more the variant drifts from the original strain, the less protection is offered by vaccines, and effectiveness of antibodies also diminishes significantly. This is now known to be occurring for current vaccines and antibodies during the global COVID-19 pandemic.

NV-CoV-2-R combines (1) the power of the nanoviricides® platform attacking the virus particle outside cells with (2) the power of Remdesivir in attacking the virus reproduction inside cells. Additionally, we believe that (3) NV-CoV-2-R improves the effect of remdesivir by (a) enabling a higher effective concentration of remdesivir in the body and (b) sustaining this higher concentration for a substantially longer period of time, both compared to the standard formulation of remdesivir, as observed in this pharmacokinetic animal study.

Both NV-CoV-2 and Remdesivir are expected to retain their effectiveness against existing and emerging variants of SARS-CoV-2. NV-CoV-2 has shown effectiveness against multiple unrelated coronavirus types. Remdesivir has been demonstrated to possess antiviral activity in cell culture against a large number of RNA viruses.

The strong effectiveness of our drug candidates NV-CoV-2 and NV-CoV-2-R against two unrelated coronaviruses, namely hCoV-NL63 and hCoV-229E, and SARS-CoV-2 pseudovirions in cell culture studies indicates their strong potential for treatment of coronavirus diseases including COVID-19, irrespective of variants or coronavirus types. The broad-spectrum effectiveness of the Company's drug candidates is very important as coronavirus variants that are reported to evade antibodies, potentially causing disease in spite of vaccination, are becoming widespread as the COVID-19 global pandemic is progressing into its second year.

We believe that our broad-spectrum anti-coronavirus drugs will continue to be effective even as the virus continues to mutate developing into a number of variants of concern. Antibody protection afforded by vaccines and the effectiveness of antibody drugs have continued to decline progressively as new SARS-CoV-2 variants continue to emerge. We believe that our unique anti-viral nanomachine technology overcomes these issues.

Oral administrations of NV-CoV-2 as well as NV-CoV-2-R were also found to be highly effective in a lethal coronavirus lung infection rat model. The oral delivery requires more dosing for equivalent effect compared to injectable delivery, as is normal for all drugs except a few that directly work in gastroenteric tract itself. Additionally, the extremely strong safety of our drugs, particularly NV-CoV-2, is expected to be very important for pediatric application.

Therefore we plan to include pediatric cohorts into clinical trials at the appropriate stages.

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NV-387 (NV-CoV-2) is Safe

In a NOAEL/MTD Study in rats, there were no clinical signs of immune or allergic reactions such as itching, biting, twitching, rough coat, etc. Further, there were no observable changes in any organs including large intestine or colon on post mortem in gross histology. The only reportable changes observed were, in the highest dosage groups, loosened stools associated with the non-absorption of water, in the colon. In clinical usage, the drug candidates are not anticipated to be administered in such high levels. The objective of this study was to discover the dosage level at which such an effect may occur. Loose or very loose stools at very high dosages in such a study is an expected and acceptable side effect of the polyethylene glycol (PEG) moiety, which we believe forms the backbone of the nanoviricides drug candidates. PEG is used prior to colonoscopy in humans to promote loose stools and internal cleaning of the intestines, by causing non-absorption of water, and is also used as a stool softener to counteract constipation. The NOAEL was estimated at 1,200 mg/Kg and MTD was estimated at 1,500 mg/Kg in rats, demonstrating extremely strong safety of NV-387 in animal model in this study.

Pharmacokinetics of NV-387-Encapsulated Remdesivir Is Substantially Superior to the Standard Remdesivir/SBECD Formulation

Almost double the amount of Remdesivir remained intact in plasma when given as the encapsulated NV-CoV-2-R form, in comparison to the standard remdesivir formulation made in betadex sulfobutyl ether sodium (SBECD), during the first day of dosing in a rat pharmacokinetics study in the time profile. Additionally, remdesivir accumulation was observed on repeated dosing of NV-CoV-2-R. After the fifth dose of NV-CoV-2-R (on day 7), in comparison to the standard remdesivir dosing pattern (twice on day 1 followed by daily thereafter; on day 7), the circulating level of intact remdesivir in plasma was 75% greater in the NV-Cov-2-R group as compared to the standard remdesivir group. The data were normalized to reflect the same amount of remdesivir given to the animals per kg body weight for uniform comparison. The assays were performed using the well-established isotopic internal standard method of remdesivir estimation with LCMS detection.

The increased circulating level of intact remdesivir when given as NV-CoV-2-R encapsulated formulation without any increase in toxicity is significant. It can be expected to result in improved antiviral effectiveness of the remdesivir component in human usage of NV-CoV-2-R treatment. This is important because remdesivir is a highly effective drug in cell culture and pre-clinical studies but does not show clinical effectiveness in humans at levels that would be expected based on its cell culture efficacy due to its rapid metabolism. Additionally, there is very little margin to increase remdesivir dosing in its standard formulation because of dose limiting toxicity.

Importantly, NV-CoV-2-R was found to be less toxic than the standard remdesivir formulation in this study. At day 7, when a total of 80mg/kg remdesivir was dosed in the standard formulation, the body weight loss was approximately 9.5% in male and 9.5% in female animals. In contrast, when 80mg/kg of remdesivir was delivered as NV-CoV-2-R encapsulated formulation, at day 7, the weight loss was only approximately 3% in male animals and 1% in female animals that was the same as with the vehicle treatment reflecting injection trauma itself and no drug toxicity.

These data demonstrate that the pan-coronavirus nanoviricide drug candidate NV-CoV-2-R substantially decreases the loss of remdesivir to bodily metabolism in comparison to the standard formulation, and also minimizes toxic effects of remdesivir. We anticipate that this stabilizing effect should lead to a highly effective pan-coronavirus drug that could potentially cure most cases of COVID-19 infection.

The standard Veklury® formulation of remdesivir in betadex sulfobutyl ether sodium (SBECD) helps with suspending remdesivir in solution, but does not appear to significantly improve upon the metabolic effects. In contrast, NV-CoV-2-R is an encapsulation approach wherein remdesivir would slowly leak out into the bloodstream from the polymeric nano-micelle over time, imparting protection against metabolism and sustained effective levels of the encapsulated drug component over a longer time period.

NV-CoV-2 (API NV-387) and NV-CoV-2-R (API NV-387-R) Were Statistically Effective Against Lethal Lung Coronavirus Infection in an Animal Model

NV-CoV-2 and NV-CoV-2-R were found to be statistically effective against a totally lethal lung infection caused by coronavirus NL-63 that uses the same receptor, ACE2 as SARS-CoV-2, and exhibits similar but less severe human pathology compared to SARS-CoV-2, in rats based on multiple indicators:

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Survival: While rats in the untreated infected group succumbed to the disease in 5 to 6 days, the rats in the NV-CoV-2 treatment group survived for 14 days, and the rats in the NV-CoV-2-R treatment group survived for 16 days. In contrast, rats treated with remdesivir formulated in SBECD (comparable to the FDA-approved Veklury® formulation of remdesivir) survived for only 7.5 days. The total dose of remdesivir was 90mg/kgBW for the remdesivir treated group, and it was 80mg/kgBW when encapsulated in the NV-CoV-2-R group. Thus compared to treatment with remdesivir, treatment with the Company's drug candidate NV-CoV-2 extended the lifespan by approximately four times more days. Further, treatment with the Company's other drug candidate NV-CoV-2-R extended the lifespan by approximately five times more days.

Body Weight: Both NV-CoV-2 and NV-CoV-2-R protected the animals from body weight (BW) loss that results from the infection and immune response, in addition to the substantially increased survival, in this lethal coronavirus infection model. NV-CoV-2 group lost only about 7% BW (12.5 g/animal) at day 13, and the NV-CoV-2-R group lost as little as ~1.8% BW (3g/animal) at day 13. In contrast, the remdesivir group had already lost ~17% BW (30g/animal) by day 7 and succumbed to the disease soon thereafter.

These results clearly indicate statistically effectiveness of NV-CoV-2 as well as NV-CoV-2-R in fighting the coronavirus lung infection and its ill effects, as compared to the FDA-approved drug Remdesivir.

The (1) significant improvement in lifespan by a factor of four to five, and (2) the significant prevention of body weight loss, upon treatment with NV-CoV-2 as well as NV-CoV-2-R as compared to treatment with the FDA-approved Remdesivir are important indicators for potential human clinical success of the Company's drug candidates.

We studied the effectiveness of these drugs against the human coronaviruses h-CoV-NL63 (NL63) that uses the same ACE2 human cellular protein as receptor to gain entry into cells, as do all variants of SARS-CoV-2 and SARS-CoV-1. Additionally, the human pathology of NL63 infection closely mimics that of SARS-CoV-2, albeit with limited disease severity. NL63 is a circulating human coronavirus that can be used in BSL2 labs. NL-63 is therefore being used as a model for anti-SARS-CoV-2 drug development in various labs including ours (see Chakraborty and Diwan for a review: A. Chakraborty and A. Diwan (2020). "NL63: A Better Surrogate Virus for studying SARS- CoV-2". Integr Mol Med, 2020, vol.7, pp 1-9, doi: 10.15761/IMM.1000408).

Remdesivir (Veklury®, Gilead) has shown relatively weak effectiveness in animal and clinical studies in contrast to its strong effectiveness in cell culture studies. This has been related by scientists to the metabolism of remdesivir in the blood stream that causes loss of effectiveness. The Company has developed the drug candidate NV-CoV-2-R by encapsulating ("hiding inside") remdesivir into NV-CoV-2. The Company believes that this encapsulation should protect remdesivir from bodily metabolism and thereby significantly increase its clinical effectiveness (see below about pharmacokinetics of NV-CoV-2-R and protection of remdesivir).

The effectiveness of NV-CoV-2-R observed in this study can be understood as a combination of (a) the improvement in the effectiveness of remdesivir due to encapsulation, and (b) the effectiveness of NV-CoV-2 by itself. NV-387-R is a representative of the Nanoviricides Platform Modality 3, whereas NV-387 is representative of the Nanoviricides Platform Modality 1.

NV-CoV-2-R, we believe, is an excellent demonstration of the power of the Nanoviricides Platform technology that enables combining multiple modalities seamlessly into a single drug.

We believe that these in vivo study results support a potential synergistic improvement in the drug effect as a result of combining the two different mechanisms of attacking (i) the virus reinfection cycle and (ii) the virus replication cycle simultaneously.

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**"Long COVID" or Post-Acute Sequelae of COVID (PASC)**

The COVID-19 pandemic is rapidly evolving into an endemic wherein regular waves of variants are expected to occur a foreseeable future, with peaks of between one to three times a year. Each wave of variant makes obsolete the previously developed antibody drugs and reduces the effectiveness of vaccines and prior immunity. However, the residual immunity, which in the COVID-19 scenario has not been enduring, still has helped draw down the fatality rates per wave, although infection rates per wave have actually increased wave-over-wave so far. Additionally, catching COVID as well as in some cases the COVID vaccines have been linked to increased incidences of future heart diseases, Type I diabetes, ischemia and stroke, among other life-threatening events, even if the COVID infection itself was mild, (https://fortune.com/2022/10/06/strokes-heart-attacks-sudden-death-america-long-term-risks-catching-covid-carolyn-barber/?showAdminBar=true). A significant percentage of COVID infections result in long drawn out syndromes of pathology collectively referred to as "Long COVID" or Post-Acute Sequelae of COVID (PASC) which, according to one highly publicized recent CDC study, afflicts some 20% of COVID-19 survivors ages 18 to 64 (https://www.theatlantic.com/ideas/archive/2022/10/long-post-covid-symptoms-mild-cases/670469/?utm_source=apple_news).

We believe that control of the virus infection by an effective therapeutic would minimize such post-COVID after-effects ("Long COVID") that experts suggest may be linked to a new pro-thrombotic and pro-inflammatory physiological state that is raised in the patient. Thus there is an urgent need for a highly effective therapy for coronavirus variants infection.

We believe NV-CoV-2 will probably be one of the best tools to address the COVID-19 spectrum of diseases, based on the pre-clinical safety and strong pre-clinical efficacy data that we have accumulated of NV-CoV-2 and NV-CoV-2-R, and based on our studies of similar pre-clinical datasets and their correlation to the clinical findings of the currently approved drugs.

**Expansion of Indications for NV-387 and NV-387-based Modality #3 Drug Candidates**

As previously noted, NV-387 is based on the S-PG class of attachment receptor(s) to which over 90% of human pathogenic viruses are known to bind.

We have also developed NV-387-Rp (as an improvement over NV-387-R), and NV-387-Ribvp as drug candidates that could be potential cures for a large number of viruses based on the activities of NV-387, Remdesivir, and Ribavirin, respectively.

We have therefore engaged in exploring other virus candidates for which NV-387 or its encapsulation-derivatives based on Modality #3 could be effective therapeutics and potential cures.

**Our Drug Programs for RSV (Table 2.B):**

Our very first exploratory studies towards expanding indications of the API NV-387 have led to successful demonstration of strong effectiveness in an animal model of lethal lung infection by RSV. We believe that we will be able to declare NV-387 as a clinical drug candidate in the near future. We plan to pursue NV-387 as a treatment for RSV infection towards the goal of Phase II/III clinical trials once the Phase 1a/1b trial of NV-CoV-2 (API NV-387) are completed and the report becomes available.

Treatment of RSV Infection Remains an Unmet Medical Need

Two protective antibodies are approved for administering to infants, namely palivizumab (Synagis) and the recently approved nirsevimab (Beyfortus), but not for treatment of RSV infection. Two vaccines have recently been approved for RSV prophylaxis. Arexvy (GSK), and Abrysvo (Pfizer) were approved in May, 2023 for use in adults over 60 years of age and both reduced severity of RSV infection. There are no vaccines currently approved for infants and children.

Nevertheless, there is no drug approved for the treatment of RSV infection, other than the highly toxic Ribavirin that is indicated only as a last resort. Thus there is a significant unmet medical need for a safe and effective RSV therapeutic.

GrowthPlus Reports, in June 2023, said the market size for RSV therapeutics was worth $1.8 billion in 2022, and is expected to grow at a CAGR of 18.9%, reaching $8.73 billion by 2031.

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Injectable NV-387 was found to be statistically effective in a lethal direct-lung RSV infection in a mouse model study

In July, 2023, we reported that NV-387 was found to be statistically effective against RSV in a lethal RSV infection animal model study.

Orally administered NV-387 Injection was found to be statistically effective in the same lethal direct-lung RSV infection study

Animals treated with injection vehicle solution alone survived 7 days. Ribavirin, a toxic drug, was used as a positive control. Animals treated with injections of ribavirin survived 16 days, whereas animals treated with injectable NV-387 survived 15 days, almost matching the efficacy of ribavirin treatment.

NV-387 administered by oral gavage was also found to be statistically effective in the same lethal direct-lung RSV infection study.

Animals treated with oral drug vehicle alone survived 7 days. Orally administered Ribavirin, a toxic drug, was used only as a positive control. Animals treated with oral ribavirin survived 16 days, whereas animals treated with oral NV-387 survived 15 days, again almost matching the efficacy of Ribavirin treatment.

Unlike Ribavirin, NV-387 has been found to be safe in preclinical studies. Therefore, it would be possible to increase the dose level or frequency of NV-387 to increase its effectiveness. Thus this study demonstrated that NV-387 is an effective drug candidate for the treatment of RSV infection with significant patient benefits.

NV-387 demonstrated very high oral bioavailability in this study

The dosing of NV-387 orally given was twice as much as that given by I.V. injection to compensate for oral bioavailability. The apparent oral bioavailability of NV-387 based on efficacy parameters appears to be of the order of almost 50% in this study, a very high value.

NV-387 can advance directly into Phase II Human clinical trials for RSV treatment

It is expected that NV-387 can be advanced into Phase II studies against RSV once the current Phase I studies of NV-CoV-2 (which contains the same API, NV-387) are completed. This will significantly speed up the development of the RSV drug, save costs, and improve return on investments (ROI).

**Our Drug Programs for Varicella Zoster Virus (VZV), Cause of Shingles and Chickenpox (Table 2.C):**

NV-HHV-1 skin cream for the treatment of shingles rash

NV-HHV-1 is our lead drug candidate in the HerpeCide™ program. It has advanced as a skin cream through pre-clinical development stages and at present it is at the IND application stage, with the design of clinical protocols, clinical site selection, and preparing for clinical trials, in process. Shingles is caused by reactivation of VZV (Varicella-Zoster Virus), which causes chickenpox in children.

Several additional indications in the HerpeCide™ program, including skin creams for the treatment of “genital ulcers” (HSV-2), and for the treatment of “cold sores” (HSV-1”) are expected to follow the shingles candidate into clinical development

NV-HHV-1 is a Virus-Family-Specific drug candidate based on the Nanoviricides Platform Modality #2. The ligand used therein copies features of the HerpesVirus Entry Mediator (HVEM), which is the receptor used for cell entry by HSV-1 and HSV-2. It was not known whether VZV uses HVEM.

As part of the IND-enabling development of our topical skin cream for treatment of shingles rash, we have performed a substantial amount of safety and toxicology studies. We performed non-GLP safety toxicology studies in a rat model with two of the development stage candidates first. Both candidates were extremely well tolerated and no adverse events occurred. These safety/toxicology studies along with efficacy studies in the Human Skin Organ Culture model of Dr. Moffat, led us to identify a clinical candidate, namely, NV-HHV-1. We have performed IND-enabling non-GLP Safety Toxicology studies of this clinical candidate in multiple animal species. NV-HHV-1 was well tolerated at all dosages tested and none of the parameters tested were affected. A GLP Safety/Toxicology study of dermal treatment in mini-pigs also found that NV-HHV-1 was well tolerated as a skin cream. These safety results are in agreement with histopathological observations in the human skin organ culture model studies.

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We manufactured NV-HHV-1 in a cGMP-compliant manner at our own facility for its IND-enabling GLP Safety/Toxicology study. The drug substance, or active pharmaceutical ingredient (API) was produced at approximately 1Kg-scale. Drug products, i.e. different dose levels of the skin cream, were made at scales of 3-5kg batches.

We have conducted a Pre-IND Meeting with the FDA regarding NV-HHV-1 as treatment for Shingles rash, and received a response from the FDA in May, 2019. In particular, the Agency agreed that the Company's strategy for drug substance and drug product acceptance criteria is adequate. The Agency further agreed that the IND-enabling non-clinical studies proposed by the Company are generally adequate. The FDA also stated that the proposed design of the IND-opening human clinical studies appears reasonable at this time. The FDA made valuable suggestions in the pre-IND response. The additional non-clinical studies recommended by the Agency were generally consistent with our then-planned IND-enabling non-clinical studies. These studies have been completed subsequent to the Pre-IND Meeting.

Shingles and associated pain, post-herpetic 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.

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, 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.

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NV-HHV-1 Skin Cream is intended for topical (dermal) application directly onto the shingles rash. It is expected to be useful in mild to moderate cases with limited body coverage of the rash in non-hospitalized patients.

Importantly, NV-HHV-1 has shown broad-spectrum activity against HSV-1 (cause of "cold sores"), HSV-2 (cause of "genital ulcers"), and VZV (the varicella-zoster virus, that causes chickenpox in children and immune-compromised humans, and shingles in adults). We therefore believe that NV-HHV-1 Skin Cream may be useful as a topical treatment of HSV-1 "cold sores" and HSV-2 "genital ulcers" in addition to treatment of Shingles skin rash.

Our other HerpeCide program candidates in progress at present are mostly based on NV-HHV-1, thereby maximizing return on investments and shareholder value.

**HerpeCide™ Drug Candidates Based on HVEM, the Potential Common Cognate Entry Receptor for the Nine Human Viruses in the Orthoherpesviridae Family Enable Additional Indications (Modality #2, #3) :**

As previously noted, NV-HHV-1 is based on copying the herpesvirus binding site on the human cellular receptor HVEM. Therefore, NV-HHV-1 is likely to be a potential pan-herpesviridae nature of our anti-HSV drug candidates is expected to enable several anti-herpesviral indications. 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.

Many of the herpesvirus family infections may also warrant systemic therapeutics (oral or injectable) in addition to topical therapeutics, for greater effectiveness. As demonstrated with NV-387 oral bioavailability, we believe we have potentially orally available drug candidates in the herpesvirus drugs pipeline.

We are also developing possibly even more effective pan-herpes drugs compared to NV-HHV-1 based on Modality #3, i.e. by encapsulating replication inhibitors inside the polymeric micelle "belly" of NV-HHV-1. We have developed derivatives of the well-known anti-herpes drug acyclovir for efficient encapsulation within NV-387 for this purpose. Further, the treatment of herpes virus infections caused by acyclovir- and famciclovir- resistant mutants is currently an unmet medical need. We are developing replication-inhibitors addressing this resistance issue as well, that we plan on encapsulating within NV-HHV-1.

It is known that many of the human herpesvirus infections produce lifelong latent infections. The Modality #3 drugs we are making are expected to reduce the breakout frequency of such latent infections and may eventually cure the infection completely after repeated treatment. This is likely because it is well known that even repeated application of acyclovir-class of drugs in some patients leads to reduction in the breakout frequency or recurrence of herpe labilis ("cold sores") caused by HSV-1. We do not expect that HHV-6A or HHV-6B infection could be cured by the Modality #3 approach because these two viruses are known to integrate their genome into human cells.

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 previously anticipated. We anticipate that many of these new drugs would be variations on our current drug candidate for VZV, namely, NV-HHV-1. This should simplify drug development pathway and also maximize the Return on Investments (ROI).

We are developing drugs against three indications in the HerpeCide 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 efficient parallel development. Our parallel development of these indications maximizes return on investment and shareholder value.

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Of these, the shingles indication program has resulted in the clinical drug candidate NV-HHV-1, for which we are in the process of clinical trial design and clinical site selection, which will be a part of the IND application.

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 about eleven different drug development programs, attesting to the strength of our platform technology.

We have chosen to focus strategically on the applications of NV-387 which was developed as a pan-coronavirus drug initially, and which appears to have a much broader spectrum of activity.

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 may 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 candidate for Ocular Herpes Keratitis (HK) as well. HK 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, we expect this drug may cover almost 99% of all external eye viral pathologies.

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.

Viral Acute Retinal Necrosis (v-ARN)

We are also exploring additional indications of its anti-herpes drug candidates that are expected to 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 treatment followed with 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.

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**The FluCide™ Program**

We intend to re-engage the FluCide program once the HerpeCide drug candidates enter human clinical trials, resource permitting. Previously, we had achieved industry-leading effectiveness levels demonstrating as high as 1,000-fold viral load reduction in a lethal animal model of influenza infection with multiple strains of influenza. We were developing an injectable drug candidate for treatment of severely ill patients, and an oral drug candidate for the treatment of outpatients.

**Our DengueCide™ Program**

We intend to reengage the DengueCide program if and when non-dilutive funding such as research grants become available to us. At present we have not applied for any grants for this program.

**Our HIVCide™ Program**

We intend to re-engage the HIVCide program once the HerpeCide drug candidates enter human clinical trials, resource permitting. Previously, 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. We believe 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. We believe that substantially all HIV viruses 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, we believe that this therapy would also minimize the chances of HIV transmission. These drug candidates are effective against both the R5 and X4 subtypes of HIV-1 in cell cultures. We believe 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 for our anti-HIV drugs. 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.

**Adenoviral EKC**

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: “Disease X”, MPox, Smallpox, Acute Flaccid Myelitis (AFM, EV68), Polio, Pediatric Acute Adenoviral Hepatitis, Ebola/Marburg, Rabies and Others (Table 2.G)**

In addition, the Company also has research programs against Rabies virus, Ebola and Marburg viruses, 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. At present we have not applied for any grants for these programs.

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NV-387-Ribvp, Potential Cure, Pandemic Preparedness, Viral "Disease X" Scenario

In addition to NV-387, we have developed NV-387-Ribvp, a Nanoviricide Platform Modality#3 type drug candidate for treatment of RSV and potentially many other viral infections. NV-387-Ribvp is made up of NV-387 that encapsulates within the belly of the polymeric micelle, a pro-drug of Ribavirin which is a known active drug against many viruses. The clinical use of ribavirin is limited by its toxicity, specifically to red blood cells, that can lead to failure of kidneys, liver and spleen at high dosages. We believe that encapsulation within NV-387 may limit these toxicity concerns, as well as make Ribavirin available for a significantly longer period of time (PK improvement), enabling better effectiveness.

Ribavirin is the standard drug of choice in unknown "Viral Disease X" (i.e. unknown or novel virus) scenarios, as well as against viruses that do not have any known therapeutic, including RSV. Thus we believe that NV-387-Ribvp could qualify as a Pandemic Preparedness and Response drug and would be an ideal candidate for National Stockpiling in the USA and possibly other countries, should its development progress successfully.

Our Smallpox/MPox/Poxviruses; "Acute Flaccid Myelitis" (AFM) (EV68); Polio; and AD-71 Pediatric Hepatitis Programs

In response to the last year's MPox virus (MPXV) epidemic, we began a limited drug development program to treat MPXV patients. While this epidemic quieted down relatively rapidly with societal/behavioral changes and rapid mobilization of a smallpox vaccine as well as a smallpox drug from the US National Stockpile, experts expect that this virus will become endemic in the Western world, as it is in the African subcontinent (https://www.cdc.gov/poxvirus/monkeypox/cases-data/technical-report/report-3.html#dynamics).A vaccine against smallpox appears to have substantial effectiveness in protecting vaccinated persons from MPXV infection. The only currently available drug, tecovirimat (TPOXX®, SIGA), approved for smallpox, has a low resistance barrier for virus mutations, i.e., the virus can readily escape it by simple mutations, and has other limitations on its use.

Thus there remains an urgent need for broad-spectrum drugs that can treat MPXV, smallpox, and other poxviruses.

Additionally, in response to the ongoing pediatric "acute flaccid myelitis" (AFM, a disease that can lead to paralysis) cases that appear to be on an uptick, we initiated a limited broad-spectrum drug development program for the treatment of Enterovirus D68 (EV68), the cause of AFM, and potentially other enteroviruses including the poliovirus. Cases of polio have begun to emerge in the United States. Apparently due to loss of "herd immunity" as the poliovirus immunizations in childhood have dropped, the cases are caused by what is believed to a be a revertant of the attenuated strain of poliovirus that is used for vaccination in certain underdeveloped countries.

Another important pediatric disease is severe hepatitis that is caused by Adenovirus 71.

We intend to run the MPXV, EV68, and AD71 programs by initially evaluating the Company's existing drug candidate library for effectiveness. If effective existing drug candidates are found, we intend to undertake additional work as well as seek additional financing, preferably via non-dilutive funding sources.

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.

This year, we have further focused our programs and prioritized them with the result that our first drug candidate NV-387 is now in human clinical trials.

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

We have not attempted to evaluate the market size of coronavirus drug candidates. During the pandemic, it is clear that hundreds of billions of dollars were spent on vaccines and therapeutics for COVID-19 treatment worldwide. However, as we had expected, the overall number of cases and their severity appears to be going down with newer waves of COVID variants. Yet, novel SARS-CoV-2 variants continue to evolve and continue to improve in their transmissibility, infectiousness, as well as vaccine and antibody avoidance. SARS-CoV-2 can be considered a globally endemic coronavirus now, similar to Influenza. Additionally, our drug, NV-CoV-2 (API NV-387) is pan-coronavirus and would work against the existing seasonal coronaviruses, novel variants of SARS-CoV-2, as well as the lethal sporadic coronaviruses MERS and SARS-CoV-1, Based on these considerations, it can be expected that the market size for anti-coronavirus drugs will continue to be in several billions of dollars.

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The current market size for RSV drugs is estimated to be about $2 Billion, and expected to grow to about $8 Billion by 2030.

The current market size for drugs for the treatment of different herpes simplex infections is estimated to be approximately $2-4 billion. We believe that when an effective topical treatment is introduced, the market size is likely to expand substantially, as it has for several drugs in the antivirals, oncology, and other areas.

If a highly effective drug against HSV-1 and HSV-2 recurrences is developed, we believe the Herpesvirus Drugs market size would explode, as was seen with Hepatitis C virus.

Severe cases of shingles may lead to hospitalization in several thousand cases in the USA every year. In addition, shingles appearing on the face may reach the eye and may cause significant vision issues. In addition to the older inactivated chickenpox virus vaccine, Shingrix®, a two-dose vaccine has recently been introduced. However, due to the severe side effects in a significant percentage of persons taking this vaccine at its first dose, compliance as well as market penetration may be limited.

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.

The market size for severe cases of shingles may be approximately one billion dollars. These estimates take into account the Shingrix® vaccine as well as existing vaccines. About 500,000 to 1 million cases of shingles occur every year in the USA alone.

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 $4 billion. The current market size for anti-HIV treatments is in excess of $20 billion. Other drugs in our pipeline, taken together, are estimated to be several billion dollars in market sizes.

Our focus at present is on the coronavirus program and additional indications of the same drug, NV-387 for other viruses such as RSV. Our next priority is 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 resources become available.

About the Priority Levels for Our Drug Development Programs:

The priority levels for our drug development programs are set forth in the tables below. The priority levels of A and B are our current focus, with priority level C to be taken up next for advanced preclinical and clinical development. Priority levels D, E, F, and G are longer term than priority levels A, B, C, and we work on those projects as we have resources available.

***NanoViricides Drug Pipeline in the CoronaVirus Program: Drugs Against SARS-CoV-2 and Variants (COVID-19) (Table 2.A)***

NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies Drug Products are in Phase 1a/1b Clinical Trial with COVID indication. We plan on adding PhaseI/II clinical trials of the NV-CoV-2 Injectable Solution for moderate to severe COVID-19 disease indication as the clinical trials of the oral forms provide safety data. With the decrease in hospitalizations for COVID-19, the clinical trials for hospitalized COVID-19 patients are expected to become more complex and difficult to run, primarily due to the difficulty of recruiting patients. It is likely, given the strong effectiveness of the API NV-387 against RSV, that we would be able to pursue Treatment of RSV Infection in Phase II for Oral as well as Injectable formulations of NV-387 (currently the drug products are called NV-CoV-2) (Table 2.B).

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| Table 2. A. Broad-Spectrum Antiviral to Treat Coronavirus Infections SARS-CoV-2 and Seasonal Coronaviruses (Modality#1) | | | | |
|---|---|---|---|---|
| **No.** | **Drug** | **Indications** | **Development Stage** | **Priority** |
| 1 | NV-CoV-2 Oral Gummies | ● Mild to Moderate COVID-19<br>● Non-hospitalized<br>● Patients of all ages, pediatric to over 65; with or without co-morbidities<br>● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test)<br>● Seasonal coronavirus afflictions<br>● MERS, SARS-CoV-1 | Phase 1a/1b in Progress | A |
| 2 | NV-CoV-2 Oral Syrup | ● Mild to Moderate COVID-19<br>● Non-hospitalized<br>● Patients that require drug titration (i.e. specified mg/Kg dosing, as with younger pediatric populations); with or without co-morbidities<br>● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test)<br>● Seasonal coronavirus afflictions<br>● MERS, SARS-CoV-1 | Phase 1a/1b in Progress | A |
| 3 | NV-CoV-2 Injectable Solution for Injection, Infusion or Inhalation: Use for Injection or for Infusion | ● Moderate to Severe COVID-19<br>● Hospitalized or with Urgent Risk of Hospitalization<br>● Patients of all ages, pediatric to over 65; with or without co-morbidities<br>● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test)<br>● Seasonal coronavirus afflictions<br>● MERS, SARS-CoV-1 | IND-Preparation | B |
| 4 | NV-CoV-2 Injectable Solution for Injection, Infusion or Inhalation: Use for Inhalation and for Infusion | ● Moderate to Severe COVID-19, requiring Oxygen Support<br>● Hospitalized or with Urgent Risk of Hospitalization<br>● Patients of all ages, pediatric to over 65; with or without co-morbidities<br>● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test)<br>● Seasonal coronavirus afflictions<br>● MERS, SARS-CoV-1 | IND-Preparation | B |

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***Broad-Spectrum Antiviral NV-387 - Additional Indications : RSV (Modality #1) (Table 2.B)***

| Table 2.B. Broad-Spectrum Antiviral NV-387 - Additional Indications : RSV (Modality #1) | | | | |
|---|---|---|---|---|
| **No.** | **Drug** | **Indications** | **Development Stage** | **Priority** |
| 1 | Oral Gummies,<br>API NV-387 | ● RSV Infection<br>● Non-hospitalized<br>● Patients of all ages, pediatric to over 65; with or without co-morbidities | Phase 1 (Under COVID) | B |
| 2 | Oral Syrup,<br>API NV-387 | ● RSV Infection<br>● Non-hospitalized<br>● Patients that require drug titration (i.e. specified mg/Kg dosing, as with younger pediatric populations); with or without co-morbidities | Phase 1 (Under COVID) | B |
| 3 | Injectable Solution,<br>API NV-387<br>Use for Injection or for Infusion | ● RSV Infection<br>● Hospitalized<br>● Patients of all ages, pediatric to over 65; with or without co-morbidities | IND-Preparation | B |
| 4 | Injectable Solution ,<br>API NV-387<br>Use for Inhalation and for Infusion | ● RSV Infection<br>● Hospitalized, Severe Disease<br>● Patients of all ages, pediatric to over 65; with or without co-morbidities | IND-Preparation | B |

***VZV Program; NanoViricides Drug Products in Development (Modality #2) (Table 2.C)***

VZV (HHV-3) Nanoviricides Efficacy Evaluation at 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 was performed in the laboratory of Dr. Jennifer Moffat and included *in vitro* human cell culture and *ex* vivo human-skin model studies to explore inhibition of VZV replication by our nanoviricides drug candidates towards selection of a clinical lead drug.

VZV is restricted to human tissue and only infects and replicates in human tissue. Dr. Moffat has extensive experience in VZV infection and antiviral agent discovery. 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.

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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 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.

Based on these studies, we selected NV-HHV-1 as the clinical drug candidate.

Further IND-Enabling Development of NV-HHV-1

Since then we completed manufacturing development and scale-up of the skin cream for Shingles treatment, NV-HHV-1. We have also completed certain IND-enabling Safety/Toxicology studies of NV-HHV-1 at BASi, Indiana. We held a pre-IND meeting for NV-HHV-1 with FDA whereby we received a written response in May, 2019. Thereafter we were in the process of completing our IND package including additional required studies and establishing relationship with a CRO. In January, 2020 we began to devote our attention to developing a drug against COVID-19, and focused on the COVID-19 program after finding leads around April-May 2020.

We worked with the Moffat Lab, initially for optimization of the drug candidates and chemistries, and thereafter towards clinical drug candidate selection. We plan on re-engaging this collaboration as we advance the Shingles drug NV-HHV-1 into an IND.

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***VZV Program; NanoViricides Drug Products in Development (Modality #2) (Table 2.C)***

| Table 2.C. VZV Program; NanoViricides Drug Products in Development (Modality #2) | | | | | |
|---|---|---|---|---|---|
| **No.** | **Virus** | **Drug** | **Indications** | **Development Stage** | **Priority** |
| 1 | | NV-HHV-1<br>Dermal Topical (“Skin Cream”) | • Mild to Moderate Shingles with Limited Body Coverage<br>• Non-hospitalized | IND-Preparation (Phase I/II). Pre-IND Meeting with FDA Conducted. | C |
| 2 | **Varicella-Zoster Virus (VZV)** | NV-HHV-1<br>Oral Gummies | • Mild to Moderate Shingles with More Extensive Body Coverage<br>• Mild to Moderate Chickenpox<br>• Non-hospitalized | Pre-Clinical | C |
| 3 | Causes Chickenpox in children and immuno-compromised persons.<br><br>Causes Shingles in adults. | Oral Syrup | • Mild to Moderate Shingles<br>• Mild to Moderate Chickenpox<br>• Non-hospitalized<br>• Patients that require drug titration (i.e. specified mg/Kg dosing, as with younger pediatric populations); with or without co-morbidities | Pre-Clinical | D |
| 4 | Causes Post-herpetic Neuralgia (long lasting pain after obvious shingles ulcers have healed). | Injectable Solution, for Injection or Infusion | • Moderate to Severe Shingles<br>• Moderate to Severe Chickenpox<br>• Hospitalized or with Urgent Risk of Hospitalization | Pre-Clinical | D |
| 5 | | NV-HHV-1<br>Oral Gummies | • Post-Herpetic Neuralgia (PHN)<br>• Non-hospitalized | Pre-Clinical | E |
| 6 | | Oral Syrup | • Post-Herpetic Neuralgia (PHN)<br>• Non-hospitalized<br>• Patients that require drug titration | Pre-Clinical | E |
| 7 | | Injectable Solution, for Injection or Infusion | • Post-Herpetic Neuralgia (PHN)<br>• Hospitalized or with Urgent Risk of Hospitalization | Pre-Clinical | E |

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***HSV-1 Program; NanoViricides Drug Products in Development (Modalities #2, #3) (Table 2.D)***

**Table 2.D. HSV-1 Program; NanoViricides Drug Products in Development (Modalities #2, #3)**

| No. | Virus | Drug | Indications | Development Stage | Priority |
|---|---|---|---|---|---|
| 1 | **Herpes Simplex Virus -1 (HSV-1)** | Dermal Topical ("Skin Cream") | • Mild to Moderate "Cold Sores" with Limited Body Coverage<br>• Non-hospitalized | Pre-Clinical | D |
| 2 | Causes Orolabial ulcers ("Cold Sores"); Recurrent Herpes Labialis (RHL) | Oral Gummies | • Mild to Moderate "Cold Sores" with More Extensive Body Coverage<br>• Non-hospitalized<br>• Recurrent Herpes Labialis | Pre-Clinical | D |
| 3 | Causes Ocular Herpes Keratitis (HK)<br><br>Causes viral Acute Retinal Necrosis (vARN) | Oral Syrup | • Mild to Moderate "Cold Sores" with More Extensive Body Coverage<br>• Non-hospitalized<br>• Recurrent Herpes Labialis<br>• Patients that require drug titration (i.e. specified mg/Kg dosing, as with younger pediatric populations); with or without co-morbidities | Pre-Clinical | E |
| 4 | Also Linked to Alzheimer's Disease (ALZD) | Injectable Solution, for Injection or Infusion | • Moderate to Severe HSV-1 Lesions<br>• Hospitalized or with Urgent Risk of Hospitalization | Pre-Clinical | E |

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***HSV-2 Program; NanoViricides Drug Products in Development (Modalities #2, #3) (Table 2.E)***

**Table 2.E. HSV-2 Program; NanoViricides Drug Products in Development (Modalities #2, #3)**

| No. | Virus | Drug | Indications | Development Stage | Priority |
|---|---|---|---|---|---|
| 1 | **Herpes Simplex Virus -2 (HSV-2)** | Dermal Topical ("Skin Cream") | ● Mild to Moderate Genital Ulcers with Limited Body Coverage<br>● Non-hospitalized | Pre-Clinical | D |
| 2 | Causes genital ulcers; Recurrent Herpes Genitalis (RHG) | Oral Gummies | ● Mild to Moderate Genital Ulcers with More Extensive Body Coverage<br>● Non-hospitalized<br>● Recurrent Herpes Genitalis | Pre-Clinical | D |
| 3 | Causes Ocular Herpes Keratitis (HK) | Oral Syrup | ● Mild to Moderate Genital Ulcers with More Extensive Body Coverage<br>● Non-hospitalized<br>● Recurrent Herpes Genitalis<br>● Patients that require drug titration (i.e. specified mg/Kg dosing, as with younger pediatric populations); with or without co-morbidities | Pre-Clinical | E |
| 4 | Causes viral Acute Retinal Necrosis (vARN) | Injectable Solution, for Injection or Infusion | ● Moderate to Severe HSV-2 Lesions<br>● Hospitalized or with Urgent Risk of Hospitalization | Pre-Clinical | E |

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***Eye Diseases Caused by Herpesviruses (HSV-1, HSV-2, VZV); (Modalities #2, #3) (Table 2.F)***

**Table 2.F. Eye Diseases Caused by Herpesviruses (HSV-1, HSV-2, VZV); (Modalities #2, #3)**

| No. | Disease | Drug | Indications | Development Stage | Priority |
|---|---|---|---|---|---|
| 1 | **Herpes Keratitis (HK)** Generally Caused by HSV-1 or HSV-2 | Ocular Solution | • Mild to Moderate Herpes Keratitis<br>• Non-hospitalized | Pre-Clinical | F |
| 2 | | Oral Gummies | • Mild to Moderate Herpes Keratitis<br>• Non-hospitalized | Pre-Clinical | F |
| 3 | | Oral Syrup | • Mild to Moderate Herpes Keratitis<br>• Non-hospitalized<br>• Patients that require drug titration (i.e. specified mg/Kg dosing, as with younger pediatric populations); with or without co-morbidities | Pre-Clinical | F |
| 4 | | Injectable Solution | • Moderate to Severe Herpes Keratitis | Pre-Clinical | F |
| 5 | **viral Acute Retinal Necrosis (v-ARN)** Generally Caused by HSV-1, HSV-2, or VZV. | Injectable Solution (for Intra-Ocular Injection) | • Moderate to Severe viral Acute Retinal Necrosis (v-ARN) | Pre-Clinical | F |

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***All Other Programs; "Disease X" (Novel Pandemic Preparedness); MPox, Smallpox; AFM, Polio (Enteroviruses); Adenoviral Pediatric Hepatitis; Herpesviruses Expansion; HIV; Influenza; Dengue; Ebola/Marburg; Rabies; and R&D for Cures of Persistent Viruses (Table 2.G)***

**Table 2.G. All Other Programs; NanoViricides Drug Products in Development**

| | Program | Virus | Indications | Development Stage | Priority |
|---|---|---|---|---|---|
| 1 | "Disease X", | Unknown or Novel Virus | Treatment | NV-387-Rp,<br>NV-387-Ribvp, Others (Modality #3) | TBD |
| 2 | Mpox Treatment | Mpox Virus, Smallpox, Poxviruses | Poxvirus family viral infection | Screening Existing Drugs in Our Pipeline (Modality #1, #2, #3)) | TBD |
| 3 | Enterovirus 68 Treatment | Enterovirus 68 or Related Viruses | Acute Flaccid Myelitis (AFM) | Screening Existing Drugs in Our Pipeline (Modality #1, #2, #3)) | TBD |
| 3 | Adenovirus 71 Treatment | Adenovirus 71 or Related Viruses | Severe Pediatric Hepatitis Caused by Adenovirus 71 | Screening Existing Drugs in Our Pipeline (Modality #1, #2, #3)) | TBD |
| 4 | HerpeCide™ Program Expansion Drug Projects | EBV, HCMV, HHV-6A, HHV-6B, HHV7, KSHV | Broad-Spectrum nanoviricides against different herpes viruses for different indications | Screening Existing Drugs in Our Pipeline (Modality #1, #2, #3)) | E |
| 5 | HIVCide ™ | HIV/AIDS | Escape-resistant<br>Anti-HIV nanoviricide | Preclinical<br>(Modality #2) | E |
| 6 | HIVCide ™ | HIV/AIDS | Escape-resistant<br>Anti-HIV nanoviricide - towards a Potential Cure | R&D<br>(Modality #3, #4) | E |
| 7 | FluCide™ Broad-Spectrum Anti-Influenza nanoviricide | All Influenza A | Injectable FluCide™ for hospitalized patients | Preclinical<br>(Modality #2) | F |
| | | All Influenza A | Oral Flucide™ for outpatients | Preclinical<br>(Modality #2) | F |
| 8 | Nanoviricide Eye Drops | Adenoviruses, HSV-1 | Viral Diseases of the External Eye | Preclinical | F |
| 9 | DengueCide™ | Dengue viruses, all types | Broad-Spectrum nanoviricide against all types of Dengue viruses | Preclinical (Modality #1, #3) | F |
| 10 | Other Nanoviricides Drug Projects | Ebola/Marburg, Rabies, Others | Broad-Spectrum nanoviricide drugs against different viruses and indications | R&D<br>Various Modalities. | G |
| 11 | Long Term Projects | Various Persistent Viruses | Technologies for Cures for Persistent (Latent) Viral Diseases | R&D<br>Various Modalities. | G |

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***Broad and Expanding Drug Pipeline Enabled by the NanoViricides Platform Technology***

As can be seen from these extensive lists of drug development programs and targets, we have been making tremendous progress year-over-year in bringing highly effective anti-viral drugs based on our novel technology platform into human clinical studies.

We believe that with the human clinical trials in our coronavirus program, we will be able to accumulate the evidence of human safety and effectiveness that would help us achieve meaningful partnerships with Big Pharma. We are also working on obtaining non-dilutive funding for various programs and projects in our pipeline. At present, we have sufficient funding to take us through the ongoing Phase 1a/1b clinical trials for our COVID-19 drug candidate, NV-CoV-2. We believe that as we achieve proof of principle in human studies, we will be able to attract substantially greater market valuation and investor funding for further progress of these drugs towards approval and commercialization. We believe that once we have revenues from commercialization of our first drug or from partnership, we will be able to engage in further speeding up the development of programs in Tables 2.C through 2.G.

Management's beliefs are based on results of pre-clinical cell culture studies, *ex vivo* tissue-based studies (e.g. human skin patch or a culture model), and *in vivo* animal studies using small animals.

**Drug Development Plan**

We intend to perform the regulatory filings and own all the regulatory licenses for the drugs we are currently developing. We will develop these drugs in part via subcontracts to TheraCour, the exclusive source for these nanomaterials. With sourcing of materials from TheraCour, we prefer to manufacture these drugs in our own facility. However, we may manufacture these drugs under subcontract arrangements with external manufacturers that carry the appropriate regulatory licenses and have appropriate capabilities. We intend to distribute these drugs via subcontracts with distributor companies or in partnership arrangements. We plan to market these drugs either on its own or in conjunction with marketing partners. We also plan to actively pursue co-development, as well as other licensing agreements with other pharmaceutical companies, both in the USA as well as internationally. 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 us. Such licensing and/or co-development agreements may shape the manufacturing and development options that we may pursue.

**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 some 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 some of 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;

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- insurance and other reimbursement coverage;
- distribution;
- marketing; and
- adaptability to various modes of dosing.

Several companies have advanced drug candidates for the management of COVID-19. Remdesivir, an antiviral drug, has received full approval, but requires repeated infusions and has limited clinical effectiveness. Oral Molnupiravir (Merck and Ridgeback) has received EUA but it has very poor effectiveness and well-known risks of mutagenicity, and is not widely used. Oral Paxlovid (a combination of nirmatrelvir and ritonavir tablets taken together, Pfizer) has received full approval but was only effective in the population at high risk of hospitalizations such as persons with co-morbidities and over age 65. Its use in persons not listed is considered off-label, and recent clinical report has shown that it has no benefits relative to placebo treatment in these groups. Also in a certain percentage of cases Paxlovid has been shown to cause viral resurgence after achieving COVID-negative status upon treatment. Several antibodies had received EUAs, but all of these have been revoked due to loss of efficacy as new variants emerged. None of the available drugs attack the external circulating virus particles or block the re-infection cycle as NV-CoV-2 is designed to do. Thus, their mode is complementary to NV-CoV-2 and combination therapy with one of these drugs and NV-CoV-2 may yield substantial benefits. We also note that none of these drugs in development attack the complete lifecycle of the virus as NV-387-Rp is designed to do, to the best of our knowledge.

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 was in clinical development against VZV, but these clinical developments appear to have been abandoned. 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 because VZV has an ineffective vTK enzyme, as opposed to HSV-1 and HSV-2, that is required for activating these drugs. 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.

We are aware of 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 have generally become ineffective because of 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 (baloxivir), developed by Shionogi Pharma (Japan) is approved in Japan and 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. Importantly, the resistance barrier for all of these drugs is rather low, and resistant mutants have arisen in the field. Thus there is an unmet medical need for an effective and safe pan-Influenza drug that the virus is unlikely to escape.

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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.

Some antibody drugs have become available for Ebola/Marburg viruses, but are generally expensive, require infusion, and have poor acceptance. There are no drugs available for the treatment of Dengue viruses, Hendra/Nipah Viruses, and many others that are considered potential pandemic threats.

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.

Vaccines are in development for many of these viral diseases. Many vaccines have significant side effects. According to the Western Australian Vaccine Safety Surveillance – Annual Report 2021, the rates of serious adverse events with COVID-19 vaccines were at 260-300 per 100,000 whereas the rates for all other vaccines were about 11 per 100,000. The rate of myocarditis/myopericarditis was 0.4 per 100,000 doses of Vaxzevria (Astra-Zenecka), 4.5 per 100,000 doses of Comirnaty (Pfizer), and 7.3 per 100,000 doses of Spikevax (Moderna). The mRNA vaccines appear to have greater numbers of serious adverse events while overall COVID vaccines had thirty-times more events than the other vaccines in general use. (https://www.health.wa.gov.au).

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 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.

Regulation by governmental authorities in the United States and other countries is a significant factor in our research and development and will be a significant factor in the manufacture and marketing of our proposed products. The nature and extent to which such regulation applies to us will vary depending on the nature of any products we may develop. Governmental authorities, including the FDA and comparable regulatory authorities in other countries, regulate the design, development, testing, manufacturing, safety, efficacy, labeling, storage, record-keeping, advertising, promotion and marketing of pharmaceutical products, including drugs and biologics, under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations, and, for biologics, under the Public Health Service Act, or PHSA, and its implementing regulations. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, import restrictions, injunctive actions and criminal prosecutions of both companies and individuals. In addition, administrative remedies can involve requests to recall violative products; the refusal of the government to enter into supply contracts; or the refusal to approve pending product approval applications until manufacturing or other alleged deficiencies are brought into compliance. The FDA also has the authority to cause the withdrawal of approval of a marketed product or to impose labeling restrictions. The process of obtaining approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

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**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 (ICH stands for The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use). 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

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- Completion of preclinical testing of new pharmaceutical or biological products, generally conducted in the laboratory and in animal studies in accordance with GLP standard, and applicable requirements for the humane use of laboratory animals or other applicable regulations to evaluate the potential efficacy and safety of the product candidate;
- Submission of the results of these studies to the FDA as part of an Investigational New Drug application, which must become effective before clinical testing in humans can begin;
- Manufacturing of investigational medicine under cGMP standard;
- Performance of adequate and well-controlled human clinical trials according to GCPs and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the product candidate for its intended use;
- Submission to the FDA of a new drug application, or NDA, for any new chemical entity drug we seek to market that includes substantive evidence of safety, purity, and potency, or safety and effectiveness from results of nonclinical testing and clinical trials;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced, packaged and distributed, to assess compliance with cGMPs, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- Potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

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 a time-consuming and costly three-phase process 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 1. 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 2. 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.

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- Phase 3. If a compound appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 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 2 clinical trials to fail in the more rigorous and reliable Phase 3 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, or will be acceptable to the appropriate regulatory agency (e.g. CDSCO/DCGI in India) or FDA without further work. 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.

*United States Review and Approval Process*

After the completion of clinical trials of a product candidate, FDA approval of a NDA must be obtained before commercial marketing of the product. The NDA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information as well as a significant user fee. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the NDA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. Once the submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is safe and effective for its intended use, and in each case, whether the product is being manufactured in accordance with cGMP or GTP, if applicable. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve a NDA without a REMS, if required.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA does not satisfy its regulatory criteria for approval and deny approval via a letter detailing such deficiencies. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the FDA denies an application, the applicant may either resubmit the NDA, addressing all of the deficiencies identified by the FDA, or withdraw the application.

***Expedited FDA Review Programs***

The FDA has four expedited program designations -Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review - to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions.

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The Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that treat a serious condition and fill an unmet medical need. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. In Fast Track, the FDA may consider for "rolling review" of sections of the IND on a rolling basis before the complete application is submitted. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

The FDA may also accelerate the approval of a designated drug through the Breakthrough Therapy designation by expediting the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on one or more clinically significant endpoints. If the FDA designates a drug as a breakthrough therapy, the drug is eligible for all Fast Track designation features, intensive guidance on an efficient drug development program, potentially beginning at Phase 1 and organizational commitment involving senior managers regarding the development of the drug to ensure that the development program and the design of the clinical trials is as efficient as practicable.

The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit.

The Priority Review designation means that the FDA's goal is to take action on the application within six months, compared to ten months under standard review.

Fast Track designation, Priority Review, Accelerated Approval and Breakthrough Therapy designations do not change the standards for approval but may expedite the development or approval process.

*Orphan Drug Designation*

The Orphan Drug Act provides granting special status to drugs or biological products for rare diseases and conditions affecting fewer than 200,000 persons. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven-year exclusive marketing period in the United States for that product where the FDA will not approve another version of the same product. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. In addition, if the holder of the orphan drug designation cannot assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients, the FDA could also grant approval to another product.

*United States Post-Approval Requirements*

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. We rely, and expect to continue to rely, on third parties for the production of some, or all, clinical and commercial quantities of our products in accordance with cGMP and GTP regulations, as applicable. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, GTP and other laws.

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The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

*Regulatory Review and Approval Process in India*

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. The Drug Controller General of India (DCGI) heads CDSCO. The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made thereunder for ensuring the safety, rights and well being of the patients by regulating the drugs and cosmetics. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

The regulatory process in India operates under ICH guidelines. After submission of a Clinical trial Application, the Office of DCGI reviews the application, and usually holds a briefing meeting with the Drug Sponsor. If satisfactory, the DCGI would approve the clinical trial application, generally with conditions that have to be satisfied prior to actually beginning dosing. There are requirements for interim reports as well as there are provisions for unannounced inspections. After completion of a given phase of clinical trial, the drug sponsor would then prepare a report and file for the next phase of clinical trials. In case of a health emergency, applications may be processed in an expedited timeframe and approvals for commercial use of the drug may be provided at the end of Phase 2 with requirements for further data collection. Normally, the new drug approval application would be submitted after completion of a Phase 3 clinical trial. Thereafter, the CDSCO and expert committees organized by the CDSCO will review the application for approval or denial.

*Other Foreign Regulatory Review and Approval*

Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities in other countries will be necessary prior to commencement of marketing the product in such countries. The regulatory authorities in each country may impose their own requirements and may refuse to grant an approval, or may require additional data before granting it, even though the relevant product has been approved by the FDA or another authority. As with the FDA, the regulatory authorities in the European Union, China and other developed countries have lengthy approval processes for pharmaceutical products. The process for gaining approval in particular countries varies, but generally follows a similar sequence to that described for FDA approval.

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.

We must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of such product in those countries. The requirements and processes governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In addition, we, and our partners, may be subject to foreign laws and regulations and other compliance requirements, including, without limitation, anti-kickback laws, false claims laws and other fraud and abuse laws, as well as laws and regulations requiring transparency of pricing and marketing information and governing the privacy and security of personal information. If we, or our partners, fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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*Other Health Care Laws*

In the event any of proposed products are ever approved for marketing, we may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and privacy and security laws and regulations.

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.

**Time Schedules, Milestones and Development Costs**

In the ensuing fiscal year, we hope to meet several important milestones towards establishing human proof-of-concept for the Nanoviricides Platform:

- Phase 1a/1b studies for the coronavirus clinical drug candidate API NV-387, as drug products NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies.
- File an IND for RSV treatment for Phase I and Phase II human clinical trials with the appropriate NV-387 based drug product, and resources permitting, begin human clinical trials for RSV treatment indication.

After the Coronavirus and RSV programs clinical trials are in progress, we plan on completing an effective clinical trial plan for our Shingles drug candidate to reengage human clinical trials for the shingles treatment program.

All of these studies are dependent on external collaborators providing available time slots for us. Thus, there can be delays in achieving the milestones that are beyond our control.

Management believes it has sufficient financing to pursue its COVID-19 drug candidate NV-COV-2 through the current Phase 1a/1b human clinical trials based on currently available finances. There is no assurance we will be successful in obtaining sufficient financing on terms acceptable to us to fund complete drug development through approval. We cannot provide assurance that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. We have estimated approximately $600,000 for the Phase 1a/1b clinical trials. We have estimated approximately $1,500,000 for the Phase II clinical trials for RSV indication. The total cost of these Phase I and Phase II trials could be significantly more. If so, we may need to raise additional funds to support continued program development through Phase II and Phase III studies at least and revenue realization.

**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, and our projected timeline of drug development.

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The work-plan we have developed for the next twelve months is expected to enable us to complete the Phase 1a/1b clinical trials in the coronavirus drug program and, provided that our clinical plan is approved by the regulatory agency, to begin Phase 2 human clinical trials for coronavirus or RSV indications or both, resources permitting. Given our dependence on external collaborators for the regulatory affairs, IND-enabling studies and study reports, Clinical Trial CROs and other services providers, we cannot provide time estimates. Our work-plan is extremely dependent on external factors, collaborations, and unanticipated delays can occur. We are experiencing extreme staffing constraints as well as facility and resources constraints. We note as a risk factor that these resource constraints may cause further delays in our estimated timelines.

We have taken on the most important risk in nanomedicines, that of enabling cGMP manufacture, with consistent product from batch to batch, "head on" so to speak. Having established critical quality parameters in our manufacturing processes and having accomplished cGMP-compliant scale-up of manufacturing from starting materials to API to formulation to fill-finish-packaged-labeled drug products, we believe that we have minimized the risk related to manufacturing capabilities.

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 minimize the risk for further drug development towards IND or regulatory filings by making available backup drug candidates with different PK-PD profiles.

This work-plan is expected to reduce certain risks of drug development. We have completed the work plan in the last year leading us to successfully completing IND-enabling Non-GLP and GLP Safety/Toxicology and Pharmacology studies that have established excellent safety and efficacy of our anti-coronavirus drug candidates in animal models, preparing and filing of investigator’s brochure and clinical trial applications with our collaborators, and have achieved regulatory approvals. We believe these data will also enable us to file appropriate IND application(s) to the FDA for coronavirus as well as RSV indications. We believe that in the ensuing fiscal year we will be able to complete Phase 1a/1b human clinical trials of our pan-coronavirus drug products and obtain valuable information on the safety and tolerability of our anti-coronavirus clinical drug candidate in humans. If our human clinical studies in COVID-19 program are not successful, we will have to develop additional drug candidates and perform further studies, or further advance our other programs, for example RSV, VZV, HSV-1 or HSV-2 drug candidates, into human clinical trials. If our studies are successful, we would be more confident in further developing our Coronavirus, RSV, HerpeCide as well as other program drug candidates and may be in a position to re-engage our highly valuable drug programs including HIVCide and FluCide.

Based on our pre-clinical study data, and based on our own studies of approved drugs in the COVID-19 space, we believe that we have a very high probability that NV-CoV-2 would be demonstrated to be a highly effective and safe drug for the treatment of most if not all Coronavirus infections including SARS-CoV-2 (COVID-19) as well as seasonal coronaviruses, in most if not all segments of the human population including pediatric, geriatric, immune-compromised, and other high risk as well as low risk populations.

Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies for further development of NV-CoV-2 and other drugs in our pipeline. 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. There can be no assurance that we will be able to obtain the additional financial resources necessary to fund our anticipated obligations over the next year.

We are a clinical stage company and will continue in this drug development stage until generating revenues from the sales of our 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.

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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, we provide scientific input regarding certain modifications to their protocols as may be needed. The Laboratory returns the results and data to us. The Laboratory is allowed to publish the results after allowing time for us to protect intellectual property (IP) as needed. We send 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 us. 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.

We try 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 us. In addition, we try to work with more than one laboratory for the evaluation of an antiviral agent developed by us. We also try 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. Further, we try 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 GLP and 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.

**Related Parties**

**TheraCour Pharma, Inc.**

Pursuant to an exclusive license agreement we entered into with TheraCour, the Company was granted exclusive licenses 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 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.

On November 1, 2019, the Company entered into an Agreement with TheraCour for an exclusive, worldwide license to use, promote, offer for sale, import, export, sell and distribute products for the treatment of VZV derived indications. The Company was not required to make any upfront payments to TheraCour and agreed to milestone payments to TheraCour.

TheraCour has not denied any licenses sought by the Company in the past.

On September 9, 2021 the Company entered into a License Agreement with TheraCour for an exclusive, worldwide license to use, promote, offer for sale, import, export, sell and distribute products for the field comprising anti-viral treatments for coronavirus derived human infections (the “CoV Agreement”). The licensed field includes antiviral drugs to treat SARS-CoV-2 and its variants that cause the COVID-19 disease resulting in a global pandemic that continues to rage through the world, wave after wave, as new variants develop and take hold. There was no upfront cash payment for the license and the compensation terms were generally consistent with prior licenses, and are summarized below.

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Under the CoV Agreement, we have obtained a world-wide, exclusive, sub-licensable, license to use, promote, offer for sale, import, export, sell and distribute antiviral drugs that treat human Coronavirus infections using TheraCour's proprietary as well as patented technology and intellectual property, including the new patent application cited above. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. We will not make any upfront cash payments to TheraCour and we have agreed to the following milestone payments to TheraCour: 100,000 shares of the Company's Series A Convertible Preferred Stock, par value $0.00001 per share (the "Series A Preferred Stock") upon the execution of the Agreement; 50,000 shares of Series A Preferred Stock after the grant of the approval of Licensee's Investigational New Drug (IND) Application, or its equivalent; cash payments of $1,500,000 after the initiation of Phase I clinical trials or its equivalent; $2,000,000 after the completion of Phase 1 Clinical Trials or its equivalent for at least one product within twelve (12) months from the date of the acceptance of the IND; $2,500,000 no later than six (6) months after the completion of Phase 2A Clinical Trials or its equivalent for at least one product within twenty (24) months from the date of the completion of Phase 1 or its equivalent; 100,000 shares of Series A Preferred Stock after the initiation of Phase 3 clinical trials or its equivalent; and, at TheraCour's option, $5,000,000 in cash or 500,000 shares of Series A Preferred Stock, no later than six (6) months after the completion of Phase 3 Clinical Trials or its equivalent for at least one product within thirty-six (36) months from the completion of Phase 2 Clinical Trials or its equivalent. In addition, we agreed to pay to TheraCour fifteen percent (15%) of net sales of licensed products and any income from sublicensed products, consistent with previous agreements. Under the CoV Agreement, TheraCour retains the exclusive right to develop and manufacture the Licensed Products. The Agreement contemplates that the parties will enter into a separate Manufacturing and Supply Agreement for the commercial manufacture and supply of the drug products if and when we intend to engage into commercialization of the drugs. The CoV Agreement provides that the Manufacturing and Supply agreement would be on customary and reasonable terms, on a cost-plus basis, using a market rate based on then-current industry standards, and include customary backup manufacturing rights, as with prior agreements. The Series A Convertible Preferred Shares are only convertible upon a "change of control" of the Company as defined in its full specification, are non-transferrable and have no trading market. Each Series A share carries 9 votes, and is convertible only upon a change of control into 3.5 shares of the Company's common stock.

To assist in the analysis of the terms of the CoV Agreement, we commissioned research reports on Coronavirus drug market sizes for the Coronavirus antiviral field from an independent consulting agency, Nanotech Plus, LLC. Additionally, we obtained business analysis and valuation reports for potential licensing terms for a coronavirus drug from an independent consultant. NanoViricides was represented by McCarter & English, LLP while TheraCour was represented by DuaneMorris LLP.

In consideration for the CoV Agreement the Company issued 100,000 shares of the Company's Series A preferred shares upon execution of the agreement in 2021. The Company also issued 50,000 shares of the Company's Series A preferred shares upon the grant of an IND to perform clinical trials which are being sponsored by our licensee and collaborator Karveer in India, in April 2023. On June 19, 2023, the Company was notified that the Company's licensee, Karveer had commenced volunteer recruitments for Phase 1a/1b clinical trials of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies. Pursuant to the CoV Agreement a third Milestone payment of $1,500,000 became due 5 days after the start of Phase 1a/1b clinical trials. The Company issued a Convertible Promissory Note to TheraCour in lieu of a cash payment of $1,500,000 on July 19, 2023 for the third milestone payment. The Note bears simple interest at the rate of 12% per annum and matures on January 19, 2025. The principle of the Note is convertible, at TheraCour's option, into shares of the Company's Series A preferred stock, par value $0.00001 at the conversion price specified in the terms and conditions contained within the Note. No payments are due under this Note until maturity.

Development costs and other costs charged by TheraCour for the years ended June 30, 2023 and 2022 were approximately $2,536,000 and $2,369,000, respectively. At June 30, 2023, approximately $233,000 was due to TheraCour.

No royalties are due TheraCour from the Company's inception through June 30, 2023.

TheraCour is affiliated with the Company through Dr. Anil Diwan, our Founder, President, and Executive Chairman, who owns approximately 90% of the capital stock of TheraCour which itself owns 470,959 shares of the Company's outstanding common stock and 350,000 shares of the Company's Series A preferred stock at June 30, 2023.

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**Karveer Meditech, Private Limited.**

On March 27, 2023 the Company entered into a License Agreement with Karveer, wherein the Company granted to Karveer a limited, non-transferable, exclusive license for the use, sale, or offer of sale in India of the Company's two clinical test drug candidates titled as NV-CoV-2 and NV-CoV-2-R for the treatment of COVID-19 in patients in India ("Karveer COVID License"). Karveer has engaged in further drug development in India including sponsoring of drug candidates for human clinical trials in India and is acting as clinical trials manager for such clinical trials. Karveer is in the process of establishing a manufacturing plant for some of those medicines. Karveer shall provide NanoViricides with all reports of the clinical trials and the Company has the rights to use such reports for further advancement of the drug candidates with regulatory authorities outside India. In consideration, Karveer will be reimbursed by the Company for all direct and indirect costs incurred for the clinical trials and development activities with a customary clinical trials manager fee of thirty (30%) of such costs and applicable taxes. Upon commercial sales of any resulting approved drugs, Karveer will pay the Company a royalty of seventy percent (70%) of the final invoiced sales less the cost of sales and goods sold to unaffiliated third parties. The Company has not received any invoices from Karveer, but has received a budget that the Company has incorporated in its cash budget projections. After review of the existing status and progress of the clinical trials, the Company has estimated and accrued $100,000, as of June 30, 2023, as an expense for research and development. On June 19, 2023 Karveer commenced the equivalent of Phase 1 clinical trials in India.

Karveer is owned by the Diwan family, consisting of four siblings and their immediate families. Dr. Diwan has an undivided share in the Diwan family interest in Karveer. The number of shares is not currently available. Consequent to and subsequent to the Karveer COVID License, Karveer is deemed to be a related party.

**Meeta Vyas.**

Meeta Vyas is the Company's Chief Financial Officer and is married to Dr. Anil Diwan. Due to her marriage to Dr. Anil Diwan, Meeta Vyas is deemed to be a related party,

**Employees**

As of June 30, 2023 the Company had approximately 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. The Company has subcontracted its animal studies to various contract research organizations, government institutes, academic labs, and private institutions. In the future, the Company anticipates having additional service providers. We believe that we have good relations with our employees and subcontractors.

**Reports to Security Holders**

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 (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 is listed on the NYSE-American. The NYSE-American Exchange requires additional corporate governance, financial and reporting requirements.

The Company is fully compliant with the requirements of the NYSE-American regarding requirements for independent board members and board committee compositions.

**Website**

Our website address is www.nanoviricides.com. Information on our website is not incorporated by reference herein.

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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.

**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, and not subject to any mortgage or debt.

We subcontract the laboratory research and development work to TheraCour, pursuant to the License Agreement with TheraCour. The work is performed in our own laboratory facility in Shelton, CT. Management believes that the space is sufficient for the Company to monitor the developmental progress at its subcontractors.

**Legal Proceedings**

From time to time, we are subject to various legal proceedings arising in the ordinary course of business, including proceedings for which we have insurance coverage. 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 that we believe will have a material adverse effect to our business, financial position, results of operations, or liquidity.

**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.

**Summary of Risk Factors**

Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. Some of the principal risk factors that make an investment in the Company speculative or risky are summarized as follows:

- Our company is in the developmental stage and has no products approved for commercial sale, no generated revenue, and may never achieve profitability.
- The Company will need to raise substantial additional capital in the future to fund operations.
- Due to the nature of the process involved in the development process of pharmaceuticals, the Company can provide no assurance of the successful and timely development of new drugs.
- The Company must comply with significant and complex government regulations, which may delay or prevent the commercialization of drug candidates.

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- The Company can provide no assurance that drug candidates will obtain regulatory approval or that the results of clinical studies will be favorable.
- In the event that regulatory approvals are obtained, drug candidates will be subject to regulatory review. Failing to comply with U.S. and foreign regulations could result in loss of approvals to market such drugs and would harm the business.
- Development of drug candidates requires significant research and development, which will lead to significant research and development costs.
- The Company will be unable to proceed with its business plan without obtaining additional financing.
- The Company has limited experience in conducting or supervising clinical trials and must outsource clinical trials. Additionally, we lack suitable facilities for clinical testing which leads to a reliance on third parties.
- The Company may be unable to attract or retain and motivate skilled personnel which will delay product development programs and research and development efforts.
- The Company has no sales or marketing personnel.
- The Company's collaborative relationships with third parties could cause the Company to expend significant resources and incur substantial business risk with no assurance of financial return.
- The Company may be liable for damages caused by biological and hazardous material.
- The Company depends on senior management and their loss or unavailability could put the Company at a competitive disadvantage.
- There exist conflicts of interest among officers, directors and stockholders.
- Risks relating to dependence on U.S. government contracts.
- Company common stock may be considered "penny stock".
- Management of the Company has identified a material weakness in internal controls that if not remediated could result in material misstatements in our financial statements.

These and other material risks we face are described more fully herein which investors should carefully review prior to making an investment decision with respect to the Company or its securities.

**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. 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;

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- 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 clinical drug development stage company with a limited operating history, making it difficult for you to evaluate our business and your investment. 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;
- 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, 2023, we had a cash and cash equivalent balance of $8,149,808. Also, we have incurred significant operating losses since its inception, resulting in an accumulated deficit of $131,080,749 at June 30, 2023. Such losses are expected to continue for the foreseeable future.

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***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 have sufficient cash to be able to take our NV-CoV-2 drug candidates, into initial human clinical trials, we currently do not have sufficient resources to complete the development, clinical trials, and commercialization of any of our proposed products. Management is actively exploring additional required funding through non-dilutive grants and contracts, partnering, debt or equity financing pursuant to its plan. There is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us to fund continuing operations. Management believes that as a result of the management plan, our existing resources and access to the capital markets will permit us to fund planned operations and expenditures. However, we 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.

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.***

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;

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- 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 clinical and pre-clinical developmental stages. 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 several 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 have limited manufacturing expertise and we may have to rely on external manufacturers.***

We believe that the technology we use to manufacture our products and compounds is proprietary, although some of the generalities are patented or patent-pending. 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.

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***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.

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- 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 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.

***Preclinical and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from preclinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed.***

We have no products on the market and except NV-CoV-2 (NV-387) which is in Phase 1a/1b clinical trials, all of our other product candidates are in preclinical development. In particular, none of our product candidates, other than NV-CoV-2 (NV-387), have ever been tested in a human subject. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, purity and potency of our product candidates.

The success of our product candidates will depend on several factors, including the following:

- successfully designing preclinical studies which may be predictive of clinical outcomes;
- successful results from preclinical and clinical studies;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection for future product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and
- successfully commercializing our products, if and when approved, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete the development or commercialization of our product candidates, which would materially harm our business.

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***Because the results of preclinical testing are not necessarily predictive of future results, our products may not have favorable results in our planned clinical trials.***

Even if we have positive results from our preclinical testing of our products, this may not necessarily be predictive of the results from our planned clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. If we fail to produce positive results in our clinical trials, the development timeline and regulatory approval and commercialization prospects for our products, and, correspondingly, our business and financial prospects, would be materially adversely affected.

***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.***

Our R&D cost estimates and budgets are based on discussions with industry professionals and service providers. These may not take into account all of the activities involved for the development. Additionally, regulatory requirements may change from time to time and may dictate additional activities that lead to increased expenditures beyond budgeted.

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; and

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- maintenance of our relationship with our licensing partner TheraCour and our rights and obligations under the license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy payment obligations under such agreement, our ability to develop and commercialize the affected product candidate may be adversely affected. Any loss of our rights under our license agreements could delay or completely terminate our product development efforts for the affected product candidate.

***We will be unable to proceed with our business plan without obtaining additional financing to support our budgeted Clinical Development, Pre-Clinical Research and Development and other costs.***

We believe we have sufficient funds on hand to take one drug candidate into initial human clinical trials.

We have estimated a total cash expenditure budget of approximately $7.1 million for the period of July 2023 through October 2024 of which approximately $4.1 million is expected to be spent on research and development for our drug candidates, including the human clinical trials of our lead drug candidate NV-CoV-2 for treatment of coronavirus diseases, an IND filing for RSV indication, and approximately $3 million is budgeted for general and administrative expenses.

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 hope 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., a clinical trial fails 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 an 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.

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***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 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 plan to continue to 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

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***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 for which we have entered into licensing agreements. We have exclusive licenses from TheraCour 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. 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 technology we license 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 possible 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 TheraCour's 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.

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***We are dependent upon TheraCour for the rights to develop the products we intend to sell and our license agreements with TheraCour require that TheraCour is the sole developer and supplier of our licensed products.***

Our ability to develop, manufacture and sell the products the Company plans to develop is derived from our licensing agreements with TheraCour. 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. In addition, TheraCour is the sole developer of our licensed products and we are required to pay TheraCour fees for indirect and direct costs incurred by TheraCour for its licensed products. Therefore, we are dependent upon TheraCour for all of our product development needs. 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.

***The expiration or loss of patent protection may adversely affect our future revenues and operating earnings.***

We rely on patent, trademark, trade secret and other intellectual property protection in the discovery, research and of our product candidates. In particular, patent protection is important in the development and eventual commercialization of our products and product candidates. Patents covering our products and product candidates normally provide market exclusivity, which is important in order for our products and product candidates to become profitable.

Certain of the patents, which comprise the intellectual property that we license, expire between 2026 and 2028. While we believe the patent holders may seek additional patent coverage that may protect the technology underlying these patents, there can be no assurances that such additional patent protection will be granted, or if granted, that these patents will not be infringed upon or otherwise held enforceable. Even if we are successful in obtaining a patent, patents have a limited lifespan and we currently do not have any products for sale. In the United States, the natural expiration of a utility patent typically is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and product candidates, we may be open to competition from generic versions of such methods and devices.

***We lack suitable facilities for clinical testing; and rely 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 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. If this were to occur, then we would 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, increase our costs, or otherwise impair our competitive position.

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

We have not previously 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 own facilities that we use to manufacture clinical quantities of any products that might be developed by us. 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.

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***We may be unable to attract, retain, and motivate skilled personnel which will delay our product development programs and our research and development efforts.***

Our success depends on our continued ability to attract, retain, and motivate highly qualified scientific personnel who must undergo extensive training to assist in our research programs. Competition for skilled and qualified personnel and academic and other research collaborations is intense. If we lose the services of personnel with the necessary skills, or if there are extensive delays in training such personnel, it could significantly impede the achievement of our research and development objectives. We are currently experiencing extreme staffing constraints as well as financing constraints that have already caused substantial delays 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. There can be no assurance that we will be able to raise sufficient funding or that even if we are able to raise funding on terms favorable to the Company, that we will be able to hire and retain such qualified employees, The inability to hire and retain these employees will significantly delay our objectives including filing an IND with the FDA.

***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, and have not secured sales and marketing staff at this early stage of operations. We cannot generate sales without a sales or marketing staff and we cannot guarantee we will be successful in developing one. 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.

***Since we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates.***

We cannot commercialize any of our product candidates to generate revenue until the appropriate regulatory authorities have reviewed and approved the marketing applications for the product candidates. We cannot ensure that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate that we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Regulatory approval processes outside the United States include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

***We license our core technology from TheraCour 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***

We have entered into Material License Agreements with TheraCour. 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. We control the research and work TheraCour performs on our behalf and no costs may be incurred without our prior authorization or approval.

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.

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***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 such 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.

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We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***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 $7,000,000 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 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 Dr. Anil Diwan, our President and Executive Chairman is 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 this key officer 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.***

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, Dr. Anil Diwan owns approximately 90% of the capital stock of TheraCour, which as of June 30, 2023, owned 4.0% of our common stock, and 350,000 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 to date, Dr. Diwan may have conflicting fiduciary duties between the Company and TheraCour, for which he must recuse himself from certain decision-making processes of the Company.

The Company does not allow a conflicted shareholder, director, or executive officer to vote on matters wherein a conflict may be perceived. The conflicted person or 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.

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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.

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***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.

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.***

While we have not yet received U.S. government funding, 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.

***Failure to remediate a material weakness in internal accounting controls could result in material misstatements in our financial statements.***

Our management has identified a material weakness in our internal control over financial reporting and has concluded that, due to such material weakness, our disclosure controls and procedures were not effective as of June 30, 2023. The material weakness in internal control over financial reporting resulted from the lack of timely review of the Company's 10-K. The material weakness had not been remediated as of June 30, 2023. If not remediated, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and the trading price of our common stock. We have implemented a remediation plan to remediate this material weakness.

**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 Coronavirus drug candidates would compete with the already approved therapies (either EUA or full approvals).

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Our RSV drug does not have any direct competition at present but there are two protective antibodies as well as two vaccines for RSV, although there are no approved treatments other than the highly toxic last-resort drug, ribavirin.

Our shingles drug candidate would compete with Valtrex®, an approved drug (valacyclovir), and other acyclovir-related nucleoside analogs, and new drugs in the pipeline. 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. 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 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, USA, and most of the world by Genetech/Roche. 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 novel H1N1/2009 vaccines are also in development worldwide. Several companies are developing anti-influenza drugs and vaccines.

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 of which have greater market presence and resources than we do. 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 hope 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.

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***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**

***General securities market uncertainties resulting from international turmoil.***

International securities markets have become highly unstable in the aftermath of extensive spending by the governments to combat COVID-19, the rise in energy prices resulting from the Russian war in Ukraine, the political, social and economic effects of this war, changes in governments leading to changes in monetary and fiscal policies, inflation, and other external factors. As a result, the markets may not be available to us for purposes of raising required capital at the time we need it. Should we not be able to obtain financing when required, in the amounts necessary to execute on our plans in full, or on terms which are economically feasible we may be unable to sustain the level of spending required to pursue our strategic plan and may have to reduce the planned future growth and scope of our operations.

***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.***

Our common stock is 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," fail to meet stockholders equity requirements, 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 a non-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;

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- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

***Our Company is subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (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 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 and the common stock does not fall within any exemption, 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;

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- 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.

***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, 2023, shareholders of the Company held 1,492,542 shares of restricted common stock, or approximately 12.8% 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. The 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.

The Company is authorized to issue up to 150,000,000 shares of common stock without additional approval by shareholders. As of June 30, 2023, we had 11,698,497 shares of common stock outstanding, 8,004 warrants convertible to 8,004 shares of common stock, and 547,674 shares of Series A preferred stock convertible into 1,916,859 shares of common stock only in the event of a change in control.

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

As of June 30, 2023, 1,492,542 of 11,698,497 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 547,674 shares of Series A preferred stock are restricted and convertible into 1,916,859 shares of common stock only upon of a change of control of the Company.

Approximately 862,576 shares of our restricted shares of common stock are held by non-affiliates who may avail themselves of the public information requirements and sell their shares in accordance with Rule 144. As a result, some or all of these shares may be sold in accordance with Rule 144 potentially causing the price of the Company's shares to decline.

In general, under Rule 144, a person (or persons whose shares are aggregated) who has satisfied a six month holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitation, by a person who is not an Affiliate, as such term is defined in Rule 144(a)(1), of the Company and who has satisfied a 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 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 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. We subcontract the laboratory research and development work to TheraCour under the License Agreement with TheraCour. Management believes that the space is sufficient for the Company to monitor the developmental progress at its subcontractors.

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**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 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.

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**PART II**

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

Our Common Stock is listed on the NYSE-American under the symbol "NNVC".

Number of Shareholders.

As of June 30, 2023, a total of 11,698,497 shares of the Company's common stock are outstanding and held by 152 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, 10,205,955 shares are unrestricted, of which 0 shares are held by affiliates, 862,576 shares are restricted securities held by non-affiliates, and the remaining 629,966 shares are restricted securities held by affiliates. These shares may only be sold in accordance with Rule 144.

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.

**ITEM 6: [RESERVED]**

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

The following discussion should be read in conjunction with the information contained in the 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, 2023. 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 Delaware 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 that enabled creation of drugs engineered specifically to combat viral diseases in humans. This exclusive license from TheraCour serves as a foundation for our intellectual property. The Company was granted a worldwide exclusive license to this technology for several drugs with specific targeting mechanisms 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 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. The Company completed a license agreement for the field of VZV indications in November 2019 from TheraCour. The Company completed a license agreement for the field of human Coronavirus indications in September 2021 from TheraCour. TheraCour has not denied any licenses sought by the Company in the past.

The Company may seek to add additional virus types to its drug pipeline as the Company progresses further. The Company would then need to negotiate with TheraCour or an unrelated party appropriate license agreements to include those of such additional viruses that the Company determines it wants to follow for further development. Historically, the Company initiates negotiations for additional licenses when initial exploratory research determines that a viable drug candidate for the targeted field is possible. 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.

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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") 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. Seeking these regulatory approvals would only occur when and if one or more of our drugs have significantly advanced through the 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 for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour, 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.

Although we have been able to develop nanoviricide drug candidates for multiple indications that are safe and effective in pre-clinical studies there can be no assurance that we will have sufficient resources to be able to successfully obtain regulatory approvals, 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.

In summary, we are developing and sourcing compounds and preparing nano-materials; performing experiments involving preclinical studies using cell cultures and animal models of efficacy and safety, advancing drug candidates against different indications into IND-enabling safety/toxicology studies, and we have advanced our first drug candidate for treatment of COVID into Phase 1a/1b clinical studies. 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. 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.

**Results of Operations**

The Company is a biopharmaceutical company and does not have any revenue for the years ended June 30, 2023 and June 30, 2022.

***Comparison of the Year End June 30, 2023 to the Year Ended June 30, 2022***

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

***Operating Expenses*** - Research and development expenses for the year ended June 30, 2023 increased approximately $608,000, to approximately $6,392,000 from approximately $5,785,000 for the year ended June 30, 2022. This year-to-year increase is generally attributable to the increase in license fees. General and administrative expenses increased approximately $222,000 to approximately $2,551,000 for the year ended June 30, 2023 from approximately $2,329,000 for the year ended June 30, 2022. The increase in general and administrative expenses is generally attributable to an increase in legal and professional expenses and investor relations expenses.

***Interest Income*** - Interest income was approximately $356,000 and approximately $12,000 for the years ended June 30, 2023 and 2022, respectively. Interest income increased due to higher interest rates for the majority of the year ended June 30, 2023 offset by lower cash balances.

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***Interest Expense***- The Company has incurred interest expense of approximately $900 and $5,000 for the years ended June 30, 2023 and June 30, 2022 respectively. The decrease results from the repayment of an insurance loan in October 2022.

***Income Taxes*** - There is no provision for income taxes due to ongoing operating losses. As of June 30, 2023, we had estimated cumulative tax benefits and development tax credits and other deferred tax credits resulting in a deferred tax asset of approximately $37,391,000. This amount has been offset by a full valuation allowance.

***Net Loss*** - For the year ended June 30, 2023, the Company had a net loss of approximately $8,589,000, or a basic and fully diluted loss per share of $0.74 compared to a net loss of approximately $8,107,000, or a basic and fully diluted loss per share of $0.70 for the year ended June 30, 2022. The increase in the Company's net loss for the year ended June 30, 2023 from the year ended June 30, 2022 of $482,000 is generally attributable to increased license milestone expenses incurred in the year ended June 30, 2023.

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

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

**R&D Cost Allocations**

| | | Year Ended | |
|---|---|---|---|
| | Program | June 30, 2023 | June 30, 2022 |
| 1 | **Pan-Coronavirus Drug Program (Including COVID)** | $ 6,092,414 | $ 5,684,862 |
| 2 | **RSV** | 200,000 | 0 |
| 3 | **HerpeCide™ Program. Herpes Simplex virus infections (HSV-1, HSV-2) and VZV Indications: Cold Sores, Genital Ulcers, Shingles and ARN** | 100,000 | 100,000 |
| | **Total** | **$ 6,392,414** | **$ 5,784,862** |

Our Shingles Skin Cream, has completed IND-enabling studies, and we intend to file an IND for this drug after the pan-coronavirus program and RSV program drugs are into clinical trials. We have completed scale-up as well as c-GMP-compliant manufacture of NV-387, the drug substance (API) in NV-CoV-2, and the drug products NV-CoV-2 Orals Syrup and NV-CoV-2 Oral Gummies clinical batches. As these drug candidates are advancing into the clinic, we believe that our additional drug candidates, including two or more drug candidates in the HerpeCide program will also enter into IND-enabling studies. We intend to further re-engage our FluCide and HIVCide drug development programs once we have established our platform technology with the Coronavirus and HerpeCide program drug candidates.

**Financings**

On May 5, 2023, we filed a registration statement on Form S-3 (File No. 333-271706) with the Securities and Exchange Commission (the "SEC"), as amended on May 8, 2023, which registration statement was declared effective by the SEC on May 22, 2023. Under this shelf registration process, we may, from time to time, sell up to $150 million in the aggregate of shares of common stock, shares of preferred stock, debt securities, warrants and units. The entire amount of $150 million remains available for sale as of the date of this filing.

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On or about August 1st, 2023, the ATM Sales Agreement was amended to name EF Hutton, division of Benchmark Investments, LLC as the only sales agent (the "Agent") and to remove B. Riley Securities, Inc. as a sales agent. On August 4, 2023, we filed a prospectus supplement relating to the issuance and sale of our common stock, par value $0.00001 per share, having an aggregate offering price of up to $5,713,022, from time to time through or to our sole sales agent, EF Hutton, a division of Benchmark Investments, LLC (the "Agent"). These sales, if any, will be made pursuant to the terms of an At Market Issuance Sales Agreement, or the sales agreement, between us and the Agent.

***Liquidity and Capital Reserves***

As of June 30, 2023, the end of the reporting period, we had approximately $8,150,000 in cash and cash equivalents, prepaid expenses of approximately $295,000 and approximately $8,107,000 of property and equipment, net of accumulated depreciation. Our liabilities at June 30, 2023 are approximately $2,034,000, including accounts payable of approximately $157,000 payable to third parties, accounts payable to TheraCour of approximately $233,000, accrued expenses approximately $144,000, and a non-current liability of $1,500,000 payable to TheraCour. Stockholders' equity was approximately $14,866,000 at June 30, 2023. In comparison, as of June 30, 2022, we had approximately $14,066,000 in cash and cash equivalents, prepaid expenses of approximately $350,000 and property and equipment of approximately $8,694,000, net of accumulated depreciation. Our liabilities at June 30, 2022 were approximately $413,000, including accounts payable of approximately $58,000 payable to third parties, accounts payable to TheraCour of approximately $214,000, a loan payable of approximately $95,000, and accrued expenses of approximately $46,000. Stockholders' equity was approximately $23,082,000 at June 30, 2022.

The Company has an accumulated deficit at June 30, 2023 of approximately $131,081,000 and a net loss of approximately $8,589,000 and net cash used in operating activities of approximately $5,670,000 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. 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's ability to raise additional funds in the public markets would be enhanced. There can be no assurance that the Company will be able to raise the necessary capital or that it will be on acceptable terms.

Management believes that the Company's cash and cash equivalents balance of approximately $8,150,000 will be sufficient to fund the Company's planned operations and expenditures through October 2024. 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.

Our Shingles Skin Cream, has completed IND-enabling studies, and we intend to file an IND for this drug after the pan-coronavirus program and RSV program drugs are into clinical trials. We have completed scale-up as well as c-GMP-compliant manufacture of NV-387, the drug substance (API) in NV-CoV-2, and the drug products NV-CoV-2 Orals Syrup and NV-CoV-2 Oral Gummies clinical batches. As these drug candidates are advancing into the clinic, we believe that our additional drug candidates, including two or more drug candidates in the HerpeCide program will also enter into IND-enabling studies. We intend to further re-engage our FluCide and HIVCide drug development programs once we have established our platform technology with the Coronavirus and HerpeCide program drug candidates.

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**Requirement for Additional Capital**

We have ended the year with sufficient cash on hand by controlling costs and expenditures. We project that our current capital resources are sufficient for accomplishing the goal of completing the Phase 1a/1b human clinical trials of our lead drug candidate, NV-CoV-2, and for filing an IND for the same drug for the RSV indication. We will need additional financing to complete human clinical trials of our drug candidates into drug approval.

The Company estimates that it will need additional funding to continue further development of its drug candidates through later stages of 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.

These anticipated expenses for the subsequent period commencing on July 1, 2023 can be summarized as follows:

1. Planned costs for the Phase 1a/1b human clinical trials of NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies (expected recruitment of 36 healthy volunteers in Phase 1a, 36 healthy volunteers in the healthy part of Phase 1b, and 36 COVID patients in the COVID part of Phase 1b).

2. Planned costs for the Bioanalytical studies and reports for the Phase 1a/1b clinical trials.

3. Staffing costs 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 IND with the FDA for Phase II clinical trials based on the data of the Phase 1a/1b clinical trials, which we believe we can do for the RSV indication.

4. Additional R&D Expenditures for RSV Project.

5. Drug Substance and Drug Product Manufacturing costs, and

6. Corporate overhead. This 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.

As our programs mature and as we are able to move additional drug candidates into human clinical trials we will continue to require additional funding for such activities. As a rule of thumb, we estimate that, for each drug candidate that goes into clinical trials, we estimate approximately $1.5 million for Phase I clinical trials in the United States, approximately $5 million for Phase II and approximately $10 million for Phase III, assuming each of the prior phase studies are successful. After completing these clinical trials we would be able to file a New Drug Application (NDA) with the FDA for obtaining marketing approval. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional costs. These estimates assume that our drug candidates are highly effective and therefore would require relatively few patients in each arm of each trial in order to establish statistically significant results.

We believe that as our programs mature towards FDA approval, the Company's market capitalization should improve substantially, based on market capitalizations of comparable public companies in clinical stages. We believe that our coronavirus program is maturing rapidly through human clinical trials. We believe that assuming that we can take the same drug (NV-387) forward successfully as a treatment for RSV indication, we may be able to get a "Fast Track" designation with the FDA for this unmet medical need; we would be able to go directly into a Phase II/III efficacy evaluation study; and may be able to get accelerated approval treatment and early access to revenues.

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We believe we have sufficient funding to take our Coronavirus drug candidate through Phase 1a/1b clinical trials, and for filing an IND towards Phase II clinical trials for the treatment of RSV infection. We will need to raise additional funds to take NV-HHV-1 and additional topical HerpeCide drug candidate indications into IND filing and clinical trials. There is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us to fund these programs. Management believes that as a result of the management plan, our existing resources and access to the capital markets will permit us to fund planned operations and expenditures for at least one year from the filing of the 10-K. However, we cannot provide assurance that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate.

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 work plan will lead us to obtain certain information about the safety and efficacy of our coronavirus drug candidate NV-CoV-2 in human clinical trials. 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 and further human clinical studies, expanding into Phase 2, and Phase 3 human clinical trials of our drug candidates.

Our strategy is to minimize capital expenditure. We therefore rely on third party collaborations for the testing of our drug candidates. We continue to engage with our previous collaborators.

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.

We report summaries of the study results as the data becomes available to us, after analyzing and verifying the same, in our press releases. The studies of biological testing of materials provide information that is relatively easy to understand and therefore readily reported. In addition, we continue to engage in substantial work that is needed for the optimization of synthesis routes and for the chemical characterization of the nanoviricide drug candidates. We also continue to work on improving the drug candidates and the virus binding ligands where necessary. We continue to work on creating the information needed for the development of controlled chemical synthesis procedures that is vital for developing c-GMP manufacturing processes. We have also begun to publish what we believe are our extraordinary achievements in the COVID-19 space in peer reviewed journals.

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. We have no experience in having taken a single drug through the 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.

We plan on seeking non-dilutive financing, grants and contracts, as well as pharmaceutical partnerships, as our first nanoviricide platform technology drug, namely NV-CoV-2, matures into human clinical trials. Management further intends to use capital and debt financing, as required, to fund the Company's operations. There can be no assurance that we will be able to obtain the additional capital resources, non-dilutive financings, grants and contracts, or pharmaceutical partnerships.

We are considered to be a clinical drug development stage company and will continue in the clinical drug development stage until we can get regulatory approvals and thereafter generate revenues from the sales of our products or services.

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**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, non-employee directors, and non-employees 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.

**RECENT ACCOUNTING PRONOUNCEMENTS**

*Recently Issued Accounting Pronouncements*

The Company considers the applicability and Impact of all Accounting Standard Updates ("ASU's"). ASU's not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's financial statements. There have been certain changes in ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) - Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. While the Company is currently evaluating the adoption impact of this ASU on its financial statements, the preliminary assessment is that the adoption of this standard is not expected to have a material effect on the Company's financial statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company as defined by 17 C.F.R. 229 (10)(f)(i) and are not required to provide information under this item.

**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.

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As of June 30, 2023, an evaluation was carried out under the supervision and with the participation of our management, 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 Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are not effective as of June 30, 2023.

**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 Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness, as of June 30, 2023, 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, 2023 due to the material weakness described below:

Management did not maintain effective procedures pertaining to the timely review of the Form 10-K. Specifically, the Company has not established procedures for thorough review by management, on a timely basis, of the Form 10-K. Management's responsibility is to oversee that the Company is capable of developing accurate and timely financial information. The Company must continue to reinforce additional procedures ensuring that Form 10-K is prepared and reviewed on a timely and accurate basis.

**Changes in Internal Controls over Financial Reporting**

Other than what was described below, 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 three months ended June 30, 2023 that has materially affected, or is likely to materially affect, our internal control over financial reporting. During the year ended June 30, 2023, as noted below, we have implemented changes in our internal control over financial reporting to address the material weakness described above, however the material weakness was not fully remediated as of June 30, 2023.

**Remediation Plan**

The Company has established a financial reporting controls committee comprised of members of senior management and a member of the Audit Committee of the Board of Directors. The committee provides oversight to the Company's efforts for ensuring appropriate internal control over financial reporting including, but not limited to, remediation of the aforesaid material weakness and identifying and testing for potential internal control weakness in the financial reporting process to assure reliability and accuracy. While the Company has implemented additional layers of review of its Form 10-K through the establishment of the financial reporting controls committee, it was not able to fully remediate the material weakness with respect to the timeliness component. The Company will continue to work to improve its timeliness in review and issuance of its future annual filings.

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**ITEM 9B. OTHER INFORMATION**

On October 9, 2013, NanoViricides, Inc. consummated an Extension Agreement (the "Extension") of the Employment Agreement with Dr. Anil Diwan entered into on July 1, 2018 (the "Employment Agreement") to continue to serve as the President of the Company, effective July 1, 2023 under the same general terms and conditions. The Extension provides that Dr. Diwan will continue to serve as the Company's President until June 30, 2024 at a base 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 balance 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 10,204 shares of the Company's Series A preferred stock, par value $0.00001 per share to Dr. Diwan. Dr. Diwan's rights in the shares shall vest in equal, quarterly installments commencing on September 30, 2023 and fully vest on June 30, 2024. The Company will recognize non-cash compensation expense related to the issuance of the Series A preferred stock of $42,232 during the year ended June 30, 2024. 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 the six month period. A copy of the Extension Agreement is attached to this Annual Report as Exhibit 10.25 and is incorporated by reference.

On October 9, 2013, NanoViricides, Inc. consummated an Extension to CFO Agreement with its Chief Financial Officer Meeta Vyas effective July 1, 2023 (the "CFO Agreement Extension") of the agreement originally entered into on May 30, 2013. The agreement is renewable on an annual basis. The original agreement provided for a term of three years with a base compensation of $9,000 per month and 129 shares of Series A preferred stock, also on a monthly basis. On January 1, 2015, her cash compensation was increased to $10,800 per month. The CFO Agreement Extension is for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms as the prior CFO Agreement with amendments to provide that the CFO shall be reimbursed up to 50% of all costs of Health Insurance including any Medical, Dental, and any and all parts and subparts of Medicare Insurance that she subscribes to, not to exceed $2,500 per month. A copy of the CFO Agreement Extension is attached to this Annual Report as Exhibit 10.26 and is incorporated by reference.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.**

Not applicable

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

The following table sets forth the names and ages of our current directors and executive officers, their principal offices and positions. 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. | 64 | President and Executive Chairman of the Board |
| Makarand "Mak" Jawadekar | 72 | Director, Independent |
| Theodore Edward ("Todd") Rokita | 53 | Director, Independent |
| Brian Zucker | 61 | Director, Independent |
| Meeta Vyas | 64 | Chief Financial Officer |

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***Anil Diwan, PhD, age 64,*** 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.

***Makarand "Mak" Jawadekar, 72,*** was appointed as an Independent Member of the Board of Directors, and serves as a member of the Company's Audit, Compensation and Nominating Committees. Dr. Jawadekar has over 35 years of experience in the pharma industry spanning both business and research activities. Dr. Jawadekar has extensive experience in joint ventures, alliance management, contracting, outsourcing, benchmarking, performance metrics, pharmaceutical research and development, drug delivery technologies, formulations, clinical supply manufacturing and packaging, clinical trial materials, pharmaceutics, and pharmaceutical sciences. He also has deep knowledge and global experience working across the United States, Europe, India, and other parts of Asia, including Japan and China. He has helped create several pharma R&D partnerships, joint ventures, and collaborations during his career. Dr. Jawadekar serves as a strategic advisor to pharmaceutical and biotechnology companies through his independent consultancy, founded in 2010, after retiring from Pfizer, Inc., as Director, Portfolio Management & Analytics, and as Vice President, Asia Colleague Resource Group, in Pfizer Global R&D division. From 1982 to 2010, Dr. Jawadekar held roles of increasing responsibility in technical, management, and business development positions at Pfizer, in the areas of Drug Delivery Technology Assessment, Strategic External Alliance Management, Strategic CMC, Pharma R&D, Clinical Manufacturing, Manufacturing Technology Transfer and Scale-up, beginning as a research scientist in formulations development. Dr. Jawadekar serves on the boards of two public companies, namely: Preveceutical Medical Inc. (CSE: PREV), and Cardax, Inc. (OTC: CDXI), as an independent board member. He also serves on the Strategic and Scientific Advisory Boards of several companies, including Actinium Pharma (NYSE-Amer.: ATNM), Saama Technologies, Inc., and Diant Pharma, Inc., as well as Tonino Lamborghini SpA, Italy. He also serves as a member of the Board of Directors at Abilities Inc., a New York based, non-profit organization. Mak holds a Ph.D. in Pharmaceutics from the University of Minnesota, and was honored with an honorary D.Sc. degree by DYP Mumbai University, recommended by the President of India. The Company believes Dr. Jawadekar's long history as a pharmaceutical and biotech professional, particularly in alliance development and management, in business strategy, and in pharmaceutical sciences and CMC in drug delivery, render him well qualified to serve as an independent member of the Board of Directors.

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***Theodore Edward ("Todd") Rokita, 53, Director.*** Mr. Rokita was appointed as an Independent Member of the Board of Directors, and serves as a member of the Company's Audit, Compensation and Nominating Committees. Mr. Rokita currently serves as the Attorney General of the State of Indiana, an elected office. Prior to that, he was co-owner and General Counsel and Vice President of External Affairs, Apex Benefits Group, Inc. where he served as a member of the executive team and the corporate board. He was responsible for legal strategies, including litigation, acquisitions and other matters, primarily involving ERISA and employment laws, and is responsible for the regulatory compliance of Apex's clients. In his role, he served as the public face of the company and was responsible for external messaging, events, and other outreach functions. Mr. Rokita was elected to the United States Congress as a Representative from the State of Indiana, serving four terms from 2011 to 2019. As a member of the US Congress, he served as the Chairman, House Subcommittee on Early Childhood, Elementary, and Secondary Education, as the Vice Chairman, House Committee on the Budget, as a Member, House Committee on Education and the Workforce (Health, Employment, Labor and Pensions subcommittee), as a Member, House Committee on Transportation and Infrastructure, (aviation, railroad, and pipeline subcommittees), as a Member, Committee on House Administration (2011-2014), as a Member, Steering Committee (2011-2012) (elected by peers to make their committee assignments), and also as a Director, Republican Study Committee (2014- 2019) (group affecting policy direction and tactics). Prior thereto Mr. Rokita served as the Secretary of State, Indiana, from 2003 to 2011) and as Chief Operating Officer and General Counsel, Office of Indiana Secretary of State from 2000-2002. Mr. Rokita serves or has served as a Member of the Board of Directors on a number of commercial and charitable institutions, among them: Aircraft Owners and Pilots Association Foundation, (2014-Present); Achieve International, Indianapolis, IN (helping troubled teens), (2012-2018); Saint Vincent Hospital Foundation, (2011-2013); Indiana Council for Economic Education, (2004-2010). Mr. Rokita also serves or has served as an Advisory Board Member for several institutions, among them: Merchandise Warehouse, Inc. Indianapolis, IN, (2019-Present); WishBone Medical, Inc., Warsaw, IN, (2019-Present); and Acel 360, Inc., Reston, VA (2019-Present). Mr. Rokita has also served as a Member, Board of Trustees of Saint Joseph's College, Rensselaer, IN, (2007-2017). In addition to his public service, Mr. Rokita is involved as a Volunteer for the Veterans Airlift Command and Angel Flight, Volunteer (2011- Present), actively flying missions for Veterans Airlift Command and other similar non-profits dedicated to providing free air transportation to children and post-9/11 combat wounded veterans and their families for medical and other compassionate purposes. Mr. Rokita holds a Bachelor of Arts degree from Wabash College in Crawfordsville, Indiana, where he was an Eli Lilly Fellow and a Juris Doctor from IUPUI's Indiana University Robert H. McKinney School of Law. The Company believes Mr. Rokita's long history as an executive and as a board member of a number of institutions and his long record of public service, uniquely qualifies him to serve as a member of the Company's Board of Directors.

***Brian Zucker, 61, Director.*** Since October 2011, Mr. Zucker has been a Partner at CFO Financial Partners, LLC, a firm that provides outsourced CFO (Chief Financial Officer), Controller and Financial Operations services as well as back office reporting and bookkeeping services for public and private companies, broker dealers, hedge funds, and family offices and high net worth individuals, among others. Mr. Zucker also serves as the CFO and Financial Operations Principal for numerous broker dealers and hedge funds. In addition to and simultaneously therewith, Mr. Zucker has served as a Partner at RRBB Accountants & Advisors, (aka Rosenberg Rich Baker Berman & Co.), a full-service accounting, advisory and consulting firm located in Central New Jersey. Mr. Zucker has over thirty years of experience as a CPA specializing in the securities industry. From 1983 through 1986, Mr. Zucker was a Senior Consultant at Deloitte Haskins and Sells and at Price Waterhouse from January 1987 through September 1989. He has previously served as the President and Chairman of Atlantis Business Development Corp. (ABDV), CFO of Natcore Solar Technology, Inc. (NTCXF) and as a Managing Director of American Frontier Financial Corp. (EVIS). He is on the Board of Directors of National Investment Banking Association (NIBA). Mr. Zucker obtained a B.S. in Public Accounting from Pace University. The Company believes Mr. Zucker's extensive career as a public accountant and experience providing sophisticated accounting services to public companies and broker dealers, render him well qualified to serve as an independent member of the Board of Directors, as well as its Audit, Compensation, Nominating and Governance Committees. Mr. Zucker was appointed as a director in 2020 and as Chair of the Audit Committee in 2022

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***Meeta Vyas, SB, MBA, 64***, 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. Meeta Vyas has been the Company's Chief Financial Officer since 2013.

AUDIT COMMITTEE

On November 13, 2020 Brian Zucker was appointed as independent director and member of the Audit Committee. Due to his education and extensive experience as a Certified Public Accountant, Mr. Zucker meets the criteria of an independent director and an "Audit Committee Financial Expert" as provided in Release 33-8173 and 34-47235. In 2022 Brian Zucker was appointed Chairman of the Audit Committee.

CODE OF ETHICS

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

**ITEM 11. EXECUTIVE COMPENSATION**

The following table reflects all forms of compensation for the years ended June 30, 2023, and 2022.

| Name and Principal Position | Year | Salary | Bonus ($) | Stock Award(s) ($) | Option Awards(#) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| Anil Diwan | 2023 | $ 400,000 | $ — | $ 43,721 | | $ — | $ 443,721 |
| CEO, President, Director | 2022 | $ 400,000 | $ — | $ 108,982 | | $ — | $ 508,982 |
| Meeta Vyas | 2023 | $ 129,600 | $ — | $ 7,748 | — | $ — | $ 137,348 |
| CFO | 2022 | $ 129,600 | $ — | $ 18,129 | — | $ — | $ 147,729 |

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The following table sets forth for each named executive officer certain information concerning equity awards as of June 30, 2022.

| 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, Director, and CEO | — | — | $ — | — | — | — | — | — |
| Meeta Vyas Chief Financial Officer | — | — | $ — | — | — | — | — | — |

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. 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.

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.

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**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS, MANAGEMENT, AND RELATED STOCKHOLDERS MATTERS.**

The following table sets forth, as of October 10, 2023, certain information regarding the beneficial ownership of the Company's Common Stock and Series A Convertible Preferred Stock outstanding by (i) each person known to us to own or control 5% or more of our Common Stock, (ii) each of our directors, (iii) each of our "Named Executive Officers" (as defined in Item 402(a)(3) of Regulation S-K) and (iv) our current Named Executive Officers and directors as a group. Unless otherwise indicated, each person named in the table below has sole voting and investment power with respect to the shares beneficially owned.

| | Common Stock | | Series A Convertible Preferred Stock[1] | | |
|---|---|---|---|---|---|
| Name and Address of Beneficial Owner | Amount and Nature of Beneficial Owner[2] | Percent of Class[2] | Amount and Nature of Beneficial Owner[2] | Percent of Class[2] | Percent of Voting Power[3] |
| TheraCour Pharma, Inc.[4] | 470,959 | 4.0 % | 350,000 | 62.7 % | 21.6 % |
| Anil Diwan[4][5] | — | — | 116,683 | 20.9 % | 6.3 % |
| Meeta Vyas[6] | 7,129 | — | 15,979 | 2.9 % | 0.9 % |
| Makarand Jawadekar | 22,542 | 0.2 % | — | — | 0.1 % |
| Theodore Rokita | 22,015 | 0.2 % | — | — | 0.1 % |
| Brian Zucker | 20,792 | 0.2 % | — | — | 0.1 % |
| All Directors and Executive Officers as a Group (6 persons) | 543,437 | 4.6 % | 482,662 | 86.5 % | 29.1 % |

(1) The Series A Convertible Preferred Shares (the "Series A") vote 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.

(2) For each shareholder, the calculation of percentage of beneficial ownership is based upon 11,745,544 shares of Common Stock and 558,265 shares of Series A Preferred Stock outstanding, 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.

(3) Amount stated reflects the number of votes held on all matters submitted to a vote of our stockholders.

(4) 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.

(5) Does not include 470,959 shares of common stock nor the 350,000 shares of Series A preferred stock owned by TheraCour Pharma, Inc. which votes at the rate of 3 and one-half shares of common stock for each Share of Series A preferred stock (the "Series A preferred stock"), over which Anil Diwan holds voting and dispositive power. Does not include the beneficial ownership of the securities held by Meeta Vyas, the wife of Anil Diwan, and Armstoo Irrevocable Trust over which Dr. Diwan disclaims beneficial ownership and voting and dispositive control.

(6) Includes 1,072 shares held by Connect Capital LLC, over which Ms. Vyas holds voting and dispositive power. Does not include the beneficial ownership of the securities held by Anil Diwan, the husband of Ms. Vyas, TheraCour, nor 94,471 common shares held by Armstoo Irrevocable Trust over which Ms. Vyas disclaims beneficial ownership and voting and dispositive control.

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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. Diwan entered into an extension of employment agreement effective July 1, 2018 for a term of three years. Dr. Diwan's will be paid an annual base salary of $400,000. Additionally, Dr. Diwan was awarded a grant of 26,250 shares of the Company's Series A preferred stock. 8,750 shares vest equally on June 30, 2019, 2020 and 2021. Any unvested shares are subject to forfeiture. On September 24, 2021, the Company and Dr. Diwan entered into extension of the employment agreement for a period of one year from July 1, 2021 through June 30, 2022 under the same general terms and conditions. The Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A Preferred Stock. The shares will be deemed partially vested in quarterly installments following the grant date and fully vested on June 30, 2022. The employment agreement is renewable annually with approval by the Board of Directors. On October 6, 2022, the Company agreed to the extension of the employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares will be deemed partially vested in quarterly installments following the grant date and fully vested on June 30, 2023. As of July 1, 2023, the Company agreed to the extension of the employment agreement for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares will be deemed partially vested in quarterly installments following the grant date and fully vested on June 30, 2024.

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 1,340 shares of Series A preferred stock and 1,786 shares of common stock upon entering into the agreement, and will issue an additional 1,340 shares of Series A preferred stock and 1,786 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.

On May 30, 2013, the Company entered into an agreement with Meeta Vyas, to serve as its Chief Financial Officer. Ms. Vyas incidentally is married to our President and Chairman of the Board, Anil Diwan. The CFO agreement provided for a term of three years with a base compensation of $9,000 per month and 129 shares of Series A preferred stock, also on a monthly basis. On January 1, 2015, her cash compensation was increased to $10,800 per month. The agreement is renewable on an annual basis. As of July 1, 2023, the Company agreed to the extension of the CFO agreement for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms as the prior CFO Agreement with amendment to provide that the CFO shall be reimbursed up to 50% of all costs of Health Insurance including any Medical, Dental, and any and all parts and subparts of Medicare Insurance that she subscribes to, not to exceed $2,500 per month.

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 fees to its independent directors of $45,000 to each Director, of which $11,250 is to be paid in the Company's common stock commensurate with their contracts.

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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 286 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, 2023, and 2022, the SAB was granted a total of 1,144 and 2,288 of stock warrants, respectively. The warrants are exercisable into common shares at prices from $1.39 to $3.40, and $1.46 to $5.92 per share, respectively.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE**

NanoViricides, Inc, the Company, has adopted a "Code of Conduct and Ethics" in its corporate governance as well as policies and procedures regarding related party transactions.

Management, under the direction of the Board of Directors, follows the policies and procedures regarding related party transactions.

On May 13, 2013, Meeta Vyas was appointed as the Company's Chief Financial Officer. During the term of Ms. Vyas' service, she was being compensated on the basis of $9,000 per month and 129 shares of Series A Preferred Stock, also on a monthly basis. Ms. Vyas is married to Anil Diwan, the President and Chairman of the Company. On January 1, 2015, her compensation was increased to $10,800 per month.

As of July 1, 2023 the Company agreed to reimburse up to 50% of all costs of Health Insurance including any Medical, Dental, and any and all parts and subparts of Medicare Insurance that Meeta Vyas subscribes to, not to exceed $2,500 per month.

**TheraCour Pharma, Inc.**

TheraCour currently holds 470,959 shares of the Company's common stock and 350,000 shares of the Company's Series A preferred stock.

On May 12, 2005, we entered into a material license agreement, amended as of January 8, 2007 (the "License") with TheraCour Pharma, Inc. ("TheraCour"). Anil Diwan, our founder, President and Chairman, owns approximately 90% of TheraCour's capital stock. We were 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, we entered into an Additional License Agreement with TheraCour. Pursuant to the exclusive Additional License Agreement, in consideration for the issuance of 100,000 shares of our Series A Preferred Stock, (the "Series A Preferred"), we were 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 the greater $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 us, and unless such license is terminated, will not manufacture such product for its own sake or for others; and (5) TheraCour may request and we 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.

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On November 1, 2019, the Company entered into a License Agreement (the "Agreement") with TheraCour for an exclusive, worldwide license to use, promote, offer for sale, import, export, sell and distribute products for the treatment of Varicella Zoster Virus derived indications. The Company was not required to make any upfront payments to TheraCour and agreed to the following milestone payments to TheraCour; the issuance of 75,000 shares of Series A Convertible Preferred Stock upon the grant of an IND Application; $1,500,000 in cash upon completion of Phase I Clinical Trials; $2,500,000 in cash upon completion of Phase II clinical trials; and $5,000,000 in cash upon completion of Phase III clinical trials. In addition, the Company is required to pay to TheraCour fifteen percent (15%) of net sales of licensed products, and any income from sublicensed products. Under the Agreement, TheraCour retains the exclusive right to develop and manufacture the Licensed Products. As in previous licensing agreements with TheraCour, the Company agreed to pay the following amounts to TheraCour to the extent not previously paid under existing licensing agreements: (1) costs (direct and indirect) plus 30%, subject to certain specified exclusions, as a Development Fee and such development fees shall be due and payable in periodic installments as billed and (2) a deposit equal to estimated development costs for two months (refundable), such estimates to be reconciled quarterly. Payments not made within 90 days after due date will be charged an interest at the rate of 1% per month. TheraCour and the Company have agreed to enter into a manufacture and supply agreement, under which TheraCour would manufacture the licensed products exclusively for the Company, and the Company would also have customary backup manufacture rights, as specified in the Agreement. TheraCour may terminate the license upon a material breach by the Company as specified in the agreement. However, the Company may avoid such termination if the breach is cured within 90 days of receipt of such termination.

On December 17, 2019, the Company entered into a Deferred Expense Exchange Agreement with TheraCour whereby TheraCour agreed to exchange $250,000 of deferred development fees owed to TheraCour into 100,000 Series A preferred stock with a fair value of $392,669 for $250,000 previously deferred development fees owed to TheraCour, and recognized a loss on the exchange of $142,669. The Company paid the deferred payments on May 2, 2022.

On September 9, 2021, the Company entered into a license agreement for the field comprising anti-viral treatments for coronavirus derived human infections with TheraCour (the "CoV Agreement"). Previously, on June 9, 2020, we had announced signing of a Memorandum of Understanding ("CoV MoU") with respect to anti-viral treatments for coronavirus derived human infections (the "Field") with TheraCour Pharma, Inc., which is now perfected into this licensing Agreement. The licensed field includes antiviral drugs to treat SARS-CoV-2 and its variants that cause the COVID-19 disease resulting in a global pandemic that continues to rage through the world, wave after wave, as new variants develop and take hold. There was no upfront cash payment for the license and the compensation terms were generally consistent with prior licenses, and are summarized below.

Under the CoV Agreement, the Company obtained a world-wide, exclusive, sub-licensable, license to use, promote, offer for sale, import, export, sell and distribute antiviral drugs that treat human Coronavirus infections using TheraCour's proprietary as well as patented technology and intellectual property, including the new patent application cited above. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. We will not make any upfront cash payments to TheraCour and we have agreed to the following milestone payments to TheraCour: 100,000 shares of the Company's Series A Preferred Stock, par value $0.00001 per share (the "Series A Preferred Stock") upon the execution of the Agreement; 50,000 shares of Series A Preferred Stock after the grant of the approval of Licensee's Investigational New Drug (IND) Application, or its equivalent; cash payments of $1,500,000 after the initiation of Phase I clinical trials or its equivalent; $2,000,000 after the completion of Phase 1 Clinical Trials or its equivalent for at least one product within twelve (12) months from the date of the acceptance of the IND; $2,500,000 no later than six (6) months after the completion of Phase 2A Clinical Trials or its equivalent for at least one product within twenty (24) months from the date of the completion of Phase 1 or its equivalent; 100,000 shares of Series A Preferred Stock after the initiation of Phase 3 clinical trials or its equivalent; and, at TheraCour's option, $5,000,000 in cash or 500,000 shares of Series A Preferred Stock, no later than six (6) months after the completion of Phase 3 Clinical Trials or its equivalent for at least one product within thirty-six (36) months from the completion of Phase 2 Clinical Trials or its equivalent. In addition, we agreed to pay to TheraCour fifteen percent (15%) of net sales of licensed products and any income from sublicensed products, consistent with previous agreements. Under the CoV Agreement, TheraCour retains the exclusive right to develop and manufacture the Licensed Products. The Agreement contemplates that the parties will enter into a separate Manufacturing and Supply Agreement for the commercial manufacture and supply of the drug products if and when we intend to engage into commercialization of the drugs. The CoV Agreement provides that the Manufacturing and Supply agreement would be on customary and reasonable terms, on a cost-plus basis, using a market rate based on then-current industry standards, and include customary backup manufacturing rights, as with prior agreements. The Series A Preferred Shares are only convertible upon a "change of control" of the Company as defined in its full specification, are non-transferrable and have no trading market. Each Series A share carries 9 votes, and is convertible only upon a change of control into 3.5 shares of the Company's common stock.

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On April 20, 2023, the Company was notified that the Company's licensee, Karveer, was authorized to enter into Phase 1a/1b clinical trials of its COVID, NV-CoV-2 Oral Syrup and its NV-CoV-2 Oral Gummies after satisfying the conditions of a conditional authorization received on or about January 27, 2023. Pursuant to the TheraCour – Nanoviricides Covid License Agreement a milestone payment of 50,000 shares of the Company's Series A preferred shares was issued to Theracour Pharma, Inc. On June 14, 2023, the Company was notified that the Company's licensee, Karveer, has commenced volunteer recruitments for Phase 1a/1b clinical trials of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies. Pursuant to the TheraCour–Nanoviricides Covid License Agreement a milestone payment of $1,500,000 became due and has been recorded as a non-current liability on the accompanying balance sheet.

Pursuant to a Licensing Agreement dated September 7, 2021 (the "License Agreement") between the Company and TheraCour, the Company is obligated to make certain milestone payments to TheraCour upon achieving certain milestones. TheraCour had achieved the milestone regarding the "Initiation of Phase 1 Clinical Trials or Equivalent" within 3 months from regulatory approval. Upon achieving this milestone, the Company was obligated to pay TheraCour a cash milestone payment in the amount of $1,500,000. In lieu of this cash payment, TheraCour agreed to accept a Convertible Promissory Note in the principal amount of $1,500,000 effective July 19, 2023 (the "Note"). The Note accrues interest at the rate of twelve percent (12%) per annum and is due and payable on January 19, 2025. The Note is convertible, at TheraCour's option, into shares of the Company's Series A preferred stock, par value $0.00001 (the "Series A Shares") at the conversion price specified in the terms and conditions contained within the Note. Dr. Diwan recused himself from voting on any action of the Registrant's Board of Directors in connection with the License Agreement and the Note (as that term is defined herein), and any discussions related thereto.

COVID-19 Related Drugs: Patent Coverage and Lifetime

Two new International PCT patent applications have been filed relating to the application of the TheraCour polymeric micelle technology to drug development for Coronavirus antiviral drugs including ones for the treatment of COVID-19; PCT/US21/39050 was filed on June 25, 2021. Additionally, PCT/US22/35210 was filed on June 28, 2022, with a request for the same priority date as that of the prior PCT/US21/39050 application. These new broad patents cover new compositions of matter, methods of making them (processes), drug formulations, and uses of the articles of manufacture. The patents resulting from these are expected to have expiry dates extending at least into the year 2043, with additional specific extensions possible in various countries based on regulatory extensions for pharmaceutical products. All ensuing patents will be automatically exclusively licensed to NanoViricides for anti-coronavirus drugs pursuant to the "CoV License Agreement". The nominal expiry date for these PCT applications would be 20 years, after filing and if issued, i.e. June 24, 2041, and could be extended in certain countries under regulatory extensions to as late as into the year 2043, providing a significant commercial runway.

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, in the approximate amounts of $32,000 and $183,000 for the fiscal years ended June 30, 2023 and 2022 respectively.

Accounts payable to TheraCour were approximately $233,000, and $215,000 at June 30, 2023 and June 30, 2022, respectively.

Development costs charged by TheraCour were approximately $2,536,000 and $2,369,000 for the years ended June 30, 2023 and 2022, respectively. No royalties are due or have been paid from inception through June 30, 2023

As of June 30, 2023 TheraCour owned 470,959 shares of the Company's outstanding common stock and 350,000 shares of Series A preferred stock, which votes at the rate of nine shares of common stock per each share of Series A preferred stock and is convertible into three and one half shares of common stock upon a change in control of the Company. Dr. Diwan, also serves as the CEO and Director of TheraCour and owns approximately 90% of the outstanding capital stock of TheraCour.

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**Karveer Meditech, Private, Limited**

On March 27, 2023 the Company entered into a License Agreement with Karveer, wherein the Company granted to Karveer a limited, non-transferable, exclusive license for the use, sale, or offer of sale in India of the Company's two clinical test drug candidates titled as NV-CoV-2 and NV-CoV-2-R for the treatment of COVID in patients in India. Karveer has engaged in further drug development in India including sponsoring of drug candidates for human clinical trials in India and has acted as clinical trials manager for such clinical trials. Karveer shall provide NanoViricides with all reports of the clinical trials and the Company can use such reports for further advancement of the drug candidates with regulatory authorities outside India. In consideration, Karveer will be reimbursed by the Company for all direct and indirect costs incurred for the clinical trials and development activities with a customary clinical trials manager fee of thirty (30)% of such costs and applicable taxes. Upon commercial sales of any resulting approved drugs, Karveer will pay the Company a royalty of seventy (70)% percent of the final invoiced sales to unaffiliated third parties.

On April 20, 2023, the Company was notified that the Company's licensee, Karveer,) was authorized to enter into Phase 1a/1b clinical trials of its COVID, NV-CoV-2 Oral Syrup and its NV-CoV-2 Oral Gummies after satisfying the conditions of a conditional authorization received on or about January 27, 2023.

On June 14, 2023, the Company was notified that the Company's licensee, Karveer had commenced volunteer recruitments for Phase 1a/1b clinical trials of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Audit Fees

The aggregate fees for each of the last two years for professional services rendered by EisnerAmper, our 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, 2023 | $ | 248,010 |
| June 30, 2022 | $ | 218,700 |

No other fees were paid to EisnerAmper for the last two years.

Pre-Approval Policies

The Board of Directors, and the Audit Committee appointed by the Board, currently does 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.

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**ITEM 15. EXHIBITS**

| Exhibits | Description | Filed / furnished / incorporated by reference from | Incorporated by reference from exhibit | Date filed |
|---|---|---|---|---|
| 3.1 | Certificate of Incorporation | Schedule 14C | A | April 23, 2009 |
| 2 | Amended and Restated Bylaws | Form 10-Q | 3.1 | February 22, 2010 |
| 3.3 | Plan of Conversion of NanoViricides, Inc. into NanoViricides, Inc. dated May 22, 2023 | Form 8-K | 2.1 | May 25, 2023 |
| 4.1 | Specimen Common Stock Certificate of the Registrant | Form 10-SB | 4.1 | November 14, 2006 |
| 10.1 | Form of Scientific Advisory Board Agreement | Form 10-SB | 10.5 | November 14, 2006 |
| 10.2 | Amended License Agreement with TheraCour Pharma, Inc. | Form 10-SB | 10.6 | November 14, 2006 |
| 10.3 | Amendment to License Agreement with TheraCour Pharma, Inc. | Form 10-SB | 10.11 | January 17, 2007 |
| 10.4 | Employment Agreement with M Vyas | Form S-1 | 10.7 | November 29, 2019 |
| 10.5 | Agreement of Purchase and Sale between the Registrant and Inno-Haven, LLC | Form 8-K | 10.1 | January 7, 2015 |
| 10.6 | Conversion and Settlement Agreement | Form 8-K | 10.1 | February 13, 2017 |
| 10.7 | Employment Agreement with Anil Diwan | Form 8-K | 10.1 | July 23, 2018 |
| 10.8 | Underwriting with Aegis Capital Corp. dated January 21, 2020 | Form 8-K | 10.1 | January 27, 2020 |
| 10.9 | Form of Settlement Agreement and Mutual Release | Form 8-K | 10.1 | January 28, 2020 |
| 10.10 | Form of Exchange Agreement | Form 8-K | 10.2 | January 28, 2020 |
| 10.11 | Form of Common Stock Purchase Warrant | Form 8-K | 10.3 | January 28, 2020 |
| 10.12 | Director Retainer Agreement between NanoViricides, Inc. and Makarand Jawadekar | Form 8-K | 10.1 | February 11, 2020 |
| 10.13 | Director Retainer Agreement, dated as of May 15, 2020, between NanoViricides, Inc. and Todd Rokita | Form 8-K | 10.1 | May 19, 2020 |
| 10.14 | Form of Securities Purchase Agreement dated May 21, 2020 by and between NanoViricides, Inc. and certain purchasers | Form 8-K | 10.1 | May 22, 2020 |
| 10.15 | Placement Agent Agreement, dated May 21, 2020 by and between among NanoViricides, Inc. Maxim Group LLC and Kingswood Capital Markets, a division of Benchmark Investments, Inc. | Form 8-K | 10.2 | May 22, 2020 |
| 10.16 | Underwriting Agreement with Kingswood Capital Markets, a Division of Benchmark Investments, Inc. dated July 8, 2020. | Form 8-K | 10.1 | July 13, 2020 |
| 10.17 | At Market Issuance Sales Agreement by and between NanoViricides, Inc., B. Riley Securities, Inc. and Kingswood Capital Markets, a division of Benchmark Investments, Inc., dated July 31, 2020 | Form 8-K | 1.1 | August 3, 2020 |
| 10.18 | Director Retainer Agreement dated November 13, 2020 between NanoViricides, Inc. and Brian Zucker | Form 8-K | 10.1 | November 13, 2020 |
| 10.19 | License Agreement dated September 7, 2021 between NanoViricides, Inc. and TheraCour Pharma, Inc. | Form 8-K | 10.1 | September 9, 2021 |
| 10.20 | Extension to Employment Agreement with A. Diwan | Form 8-K | 10.2 | September 9, 2021 |
| 10.21 | Extension to Employment Agreement with A. Diwan | Form 8-K | 10.2 | October 11, 2022 |
| 10.22 | License Agreement with Karveer Meditech Private Limited | Form 8-K | 10.1 | March 27, 2023 |

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| | | | | |
|---|---|---|---|---|
| 10.23 | Deferred Expense Exchange Agreement between NanoViricides, Inc. and TheraCour Pharma, Inc. | Form 8-K | 10.2 | August 29, 2023 |
| 10.24 | Convertible Promissory Note between NanoViricides, Inc and TheraCour Pharma, Inc., effective July 19, 2023 | Form 8-K | 10.3 | August 29, 2023 |
| 10.25 | Extension to Employment Agreement with A. Diwan effective July 1, 2023 * | | | |
| 10.26 | Extension to CFO Agreement with Meeta Vyas effective July 1, 2023 * | | | |
| 14.1 | Code of Ethics | Form 10-SB | 10.10 | November 14, 2006 |
| 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 | Inline XBRL Instance Document. | | | |
| 101.SCH | Inline XBRL Schema Document. | | | |
| 101.CAL | Inline XBRL Calculation Linkbase Document. | | | |
| 101.DEF | Inline XBRL Definition Linkbase Document. | | | |
| 101.LAB | Inline XBRL Label Linkbase Document. | | | |
| 101.PRE | Inline XBRL Presentation Linkbase Document. | | | |
| 104 | Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit) | | | |

* Filed herewith

**ITEM 16. FORM 10-K SUMMARY**

None.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: October 13, 2023

**NANOVIRICIDES, INC.**

*/s/ Anil Diwan, PhD*
Name: Anil Diwan, PhD.
Title: President and Executive 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 13, 2023

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

October 13, 2023

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

October 13, 2023

*/s/ Brian Zucker*
Name: Brian Zucker
Title: Director

October 13, 2023

*/s/ Makarand Jawadekar*
Name: Makarand Jawadekar
Title: Director

October 13, 2023

*/s/ Theodore Rokita*
Name: Theodore Rokita
Title: Director

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NanoViricides, Inc.
Index to the Financial Statements

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**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, 2023 and 2022, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years then ended, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

***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.

***Critical Audit Matter***

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

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*Related Party Transactions*

As discussed in Note 4 to the financial statements, the Company enters into certain agreements with related parties which (i) grant exclusive licenses for technologies developed by a related party to the Company for various virus types and (ii) grant exclusive licenses for development and commercialization rights to a related party for certain of the Company's drug candidates. As part of these agreements, the Company is required to pay certain costs charged by the related parties. These costs include research and development costs resulting from their research and development activities which include the performance of preclinical and/or clinical studies and a clinical trial management fee, compensation and other expenses for research and development personnel, supplies and development material. The Company recorded accounts payable – related party and accrued expense for research and development activities of approximately $233,000 and $100,000, respectively, as of June 30, 2023 and research and development costs incurred with related party of approximately $2,600,000, included in research and development expenses for the year ended June 30, 2023. In addition, upon achievement of two milestones during the year ended June 30, 2023 under its license agreement with a related party, the Company recorded approximately $1,600,000 of research and development expenses for the year ended June 30, 2023 and a non-current liability of $1,500,000 as of June 30, 2023.

We identified the accounting for related party transactions as a critical audit matter due to the materiality of the related party transactions occurring throughout the year and the significant judgment by management to ensure costs being charged are accurate, complete, and properly disclosed. This is turn led to a high degree of auditor judgement, subjectivity, and significant audit effort in applying procedures related to those transactions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of the controls related to the Company's process for identifying related parties and the approval and disclosure of related party transactions. We performed procedures to test the completeness of related party liabilities at the balance sheet date and expenses for the year then ended. Our procedures included, among others, (i) reading agreements and subsequent amendments; (ii) testing invoices on a sample basis to ensure purchases, expenses and milestones are properly recorded in accordance with the agreements and that appropriate approval from management and the audit committee was received; (iii) confirming the accounts payable – related party balance, equipment purchases made on behalf of the Company and the research and development costs paid to the related parties; and (iv) obtaining agreements, budgets and patient enrollment data related to the clinical trial to support amounts accrued as of the balance sheet date. We also made direct inquiries of management and viewed public filings, minutes, and agreements for evidence of related parties, the nature of the relationship and that related party transactions were accounted for and disclosed properly.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
October 13, 2023

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NanoViricides, Inc.
Balance Sheets

| | June 30, 2023 | June 30, 2022 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 8,149,808 | $ 14,066,359 |
| Prepaid expenses | 295,486 | 350,021 |
| Total current assets | 8,445,294 | 14,416,380 |
| Property and equipment, net | 8,106,647 | 8,694,194 |
| Intangible assets, net | 333,578 | 341,848 |
| OTHER ASSETS | | |
| Service agreements | 14,361 | 38,925 |
| Security deposits | — | 3,515 |
| Total other assets | 14,361 | 42,440 |
| Total assets | $ 16,899,880 | $ 23,494,862 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | $ 157,056 | $ 57,960 |
| Accounts payable – related party | 233,434 | 214,397 |
| Loan payable | — | 94,788 |
| Accrued expenses | 143,760 | 45,692 |
| Total current liabilities | 534,250 | 412,837 |
| Other non-current liability – related party | 1,500,000 | — |
| Total liabilities | 2,034,250 | 412,837 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY: | | |
| Series A convertible preferred stock, $0.00001 par value, 10,000,000 shares designated, 547,674 and 484,582 shares issued and outstanding, at June 30, 2023 and 2022, respectively. (Note 9) | 5 | 5 |
| Common stock, $0.00001 par value; 150,000,000 shares authorized, 11,698,497 and 11,592,173 shares issued and outstanding at June 30, 2023 and 2022, respectively. (Note 9) | 116 | 116 |
| Additional paid-in capital | 145,946,258 | 145,574,080 |
| Accumulated deficit | (131,080,749) | (122,492,176) |
| Total stockholders' equity | 14,865,630 | 23,082,025 |
| Total liabilities and stockholders' equity | $ 16,899,880 | $ 23,494,862 |

*See accompanying notes to the financial statements*

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NanoViricides, Inc.
Statements of Operations

| | Year Ended June 30, | |
|---|---|---|
| | 2023 | 2022 |
| OPERATING EXPENSES | | |
| Research and development | $ 6,392,414 | $ 5,784,862 |
| General and administrative | 2,551,054 | 2,328,737 |
| Total operating expenses | 8,943,468 | 8,113,599 |
| LOSS FROM OPERATIONS | (8,943,468) | (8,113,599) |
| OTHER INCOME (EXPENSE): | | |
| Interest income | 355,833 | 11,859 |
| Interest expense | (938) | (5,123) |
| Other income, net | 354,895 | 6,736 |
| NET LOSS | $ (8,588,573) | $ (8,106,863) |
| Net loss per common share- basic and diluted | $ (0.74) | $ (0.70) |
| Weighted average common shares – basic and diluted | 11,626,220 | 11,534,698 |

*See accompanying notes to the financial statements.*

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NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the period from July 1, 2021 through June 30, 2023

| | Series A Preferred Stock: Par $0.00001 | | Common Stock: Par $0.00001 | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Number of Shares | Amount | Number of Shares | Amount | | | |
| Balance, July 1, 2021 | 371,490 | $ 4 * | 11,515,170 | $ 115 * | $ 144,296,361 * | $ (114,385,313) | $ 29,911,167 |
| Series A preferred stock issued for employee stock compensation | 13,092 | — * | — | — | 135,400 * | — | 135,400 |
| Series A preferred stock issued for license agreement | 100,000 | 1 * | — | — | 935,087 * | — | 935,088 |
| Common stock issued for consulting and legal services rendered | — | — | 38,863 | 1 * | 107,999 * | — | 108,000 |
| Warrants issued to Scientific Advisory Board | — | — | — | — | 4,215 | — | 4,215 |
| Common stock issued for employee compensation | — | — | 3,572 | — * | 6,768 * | — | 6,768 |
| Common stock issued for Directors fees | — | — | 17,705 | — * | 52,500 * | — | 52,500 |
| Common stock issued for professional services | — | — | 16,863 | — * | 35,750 * | — | 35,750 |
| Net loss | — | — | — | — | — | (8,106,863) | (8,106,863) |
| Balance, June 30, 2022 | 484,582 | 5 * | 11,592,173 | 116 * | 145,574,080 * | (122,492,176) | 23,082,025 |
| Series A preferred stock issued for employee stock compensation | 13,092 | — | — | — | 56,357 | — | 56,357 |
| Series A preferred stock issued for license agreement | 50,000 | — | — | — | 156,987 | — | 156,987 |
| Common stock issued for consulting and legal services rendered | — | — | 72,668 | 1 | 107,999 | — | 108,000 |
| Warrants issued to Scientific Advisory Board | — | — | — | — | 1,012 | — | 1,012 |
| Common stock issued for employee compensation | — | — | 3,572 | — | 4,822 | — | 4,822 |
| Common stock issued for Directors fees | — | — | 30,084 | — | 45,000 | — | 45,000 |
| Net loss | — | — | — | — | — | (8,588,573) | (8,588,573) |
| Balance, June 30, 2023 | 547,674 | $ 5 | 11,698,497 | $ 117 | $ 145,946,257 | $ (131,080,749) | $ 14,865,630 |

* *Restated to reflect change in par value upon redomicile (see Note 9)*

*See accompanying notes to the financial statements*

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NanoViricides, Inc.
Statements of Cash Flows

| | Year Ended June 30, | |
|---|---|---|
| | 2023 | 2022 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (8,588,573) | $ (8,106,863) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Preferred shares issued as compensation | 56,357 | 135,400 |
| Preferred shares issued pursuant to license agreement | 156,987 | 935,088 |
| Common shares issued as compensation and for services | 157,822 | 203,018 |
| Warrants granted to Scientific Advisory Board | 1,012 | 4,215 |
| Depreciation | 739,259 | 715,055 |
| Amortization | 8,270 | 8,270 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses | 54,535 | 191,279 |
| Other assets | 28,079 | (38,925) |
| Accounts payable | 99,096 | (142,056) |
| Accounts payable - related parties | 19,037 | 182,858 |
| Accrued expenses | 98,068 | 21,407 |
| Other non-current liability-related party | 1,500,000 | — |
| NET CASH USED IN OPERATING ACTIVITIES | (5,670,051) | (5,891,254) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchase of property and equipment | (151,712) | (324,348) |
| NET CASH USED IN INVESTING ACTIVITIES | (151,712) | (324,348) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Payment of loan payable | (94,788) | (234,716) |
| NET CASH USED IN FINANCING ACTIVITIES | (94,788) | (234,716) |
| NET CHANGE IN CASH AND CASH EQUIVALENTS | (5,916,551) | (6,450,318) |
| Cash and cash equivalents at beginning of period | 14,066,359 | 20,516,677 |
| Cash and cash equivalents at end of period | $ 8,149,808 | $ 14,066,359 |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION: | | |
| Interest paid | $ 938 | $ 5,123 |
| Income tax paid | $ — | $ — |
| NON CASH FINANCING AND INVESTING ACTIVITIES: | | |
| Directors and Officers Insurance financed through loan | $ — | $ 234,198 |

*See accompanying notes to the financial statements*

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NanoViricides, Inc.
June 30, 2023, and 2022
Notes to the Financial Statements

**Note 1 – Organization and Nature of Business**

NanoViricides, Inc. (the "Company") is a clinical stage nano-biopharmaceutical company specializing in the discovery, development, and commercialization of drugs to combat viral infections using its unique and novel nanomedicines technology. NanoViricides possesses its own state of the art facility that supports research and development and drug discovery, drug candidate optimization, cGMP-compliant drug substance manufacturing, cGMP-compliant manufacturing and packaging of drug products for human clinical trials, and early commercialization. The Company has several drugs in various stages of development. The Company's lead drug candidate for the treatment of COVID, NV-CoV-2, is in Phase1a/1b human clinical trials sponsored by our licensee and collaborator in India, Karveer Meditech Private Limited (Karveer) It has shown effectiveness and safety in pre-clinical studies. NV-CoV-2 mechanism of action is orthogonal and complementary to that of the existing therapeutics, enabling combination therapy with the existing drugs in the market.

Additionally, the Company has previously developed a clinical drug candidate, NV-HHV-1 formulated as skin cream, for the treatment of Shingles. The Company plans on taking NV-HHV-1 into human clinical trials, and further develop the HerpeCide™ program after clinical trials of NV-CoV-2 (NV-387) that are expected to move rapidly from current Phase 1a/1b to Phase 2 and possibly for multiple indications. In the HerpeCide program alone, the Company has drug candidates against at least five indications at different stages of development. The Company's drug candidates against HSV-1 "cold sores" and HSV-2 "genital herpes" are in advanced pre-clinical studies and are expected to follow the shingles drug candidate into human clinical trials. In addition, the Company has drugs in development against all influenzas in its FluCide™ program, as well as drug candidates against HIV/AIDS, Dengue, Ebola/Marburg, and other viruses.

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 broad, exclusive licenses. The licenses are to entire fields and not to specific compounds. In all, the Company has exclusive, worldwide licenses 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-1 and HSV-2), Influenza and Asian Bird Flu Virus, Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis virus, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes (restated), Varicella Zoster Virus ("VZV") infections (i.e. Shingles and Chickenpox), and SARS-CoV-2 infections. In all cases, the discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour, a related party substantially owned by Dr. Anil Diwan, under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour. Milestone payments were made or are specified in certain of the license agreements, details of which have been disclosed at the time the agreements were entered into. The Company negotiates and licenses specific verticals of therapeutic applications from TheraCour if promising drug candidates are found in early research and development against a virus target. TheraCour has not denied any such licenses when requested.

The Company's business plan is based on developing the drug candidates into regulatory approvals, and partnering and sub-licensing for commercialization of the drugs whenever possible.

The Company has out-licensed NV-CoV-2 and NV-CoV-2-R for further clinical drug development and commercialization in the territory of India to Karveer, a company of which Dr. Anil Diwan is a passive investor and advisor. Karveer has sponsored NV-CoV-2 for human clinical trials and has obtained regulatory approvals in India. Karveer has retained a local clinical research organization (CRO) to conduct the clinical trials. NV-CoV-2, Phase1a/1b human clinical trials in India, sponsored by Karveer began on June 17, 2023. The clinical trial drug products, NV-CoV-2 Oral Syrup, and NV-CoV-2 Oral Gummies, were manufactured at the Company's Shelton campus, and then shipped to and received by Karveer. Under the agreement with Karveer, the Company will pay for the expenses of the clinical trials, and in return will benefit from having the data and reports made available for regulatory filings in other territories of the world. Upon commercialization, the Company will receive royalties from Karveer equal to 70% of sales to unaffiliated third parties.

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**Note 2 – Liquidity**

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, 2023 of approximately $131 million and a net loss of approximately $8.6 million and net cash used in operating activities of approximately $5.7 million for the 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 is in the regulatory drug development phase. It 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, 2023, the Company had available cash and cash equivalents of approximately $8.1 million.

Since the onset of the COVID-19 pandemic, the Company has focused its efforts primarily on a single lead program to minimize cost outlays, namely, taking the COVID drug candidate against SARS-CoV-2 into human clinical trials. The same drug candidate, NV-387 (the API), demonstrated effectiveness against RSV, indicating that its broad-spectrum antiviral activity is not limited to coronaviruses. The prior lead program for a shingles drug will follow the regulatory development of the NV-387 drug program.

The Company believes that it has several important milestones, including Phase 1a/1b human clinical trials for the Company's broad-spectrum, pan-coronavirus drug NV-CoV-2, that is now in progress. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced. However, there is no guarantee that the Company will be able to raise funds on terms acceptable to it, or at all.

Management believes that the Company's cash and cash equivalents as of June 30, 2023 will be sufficient to fund the Company's planned operations and expenditures for at least 12 months from the date of the filing of this Form 10-K. 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 Company will need to raise additional capital to fund its long-term operations and research and development plans including human clinical trials for its various drug candidates until it generates revenue that reaches a level sufficient to provide self-sustaining cash flows. There can be no assurance that the Copany will be able to raise the necessary capital or that it will be on acceptable terms. The accompanying financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

**Note 3 – 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 warrants, and convertible preferred stock.

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

| | Potentially Outstanding Dilutive Common Shares For the Years Ended | |
|---|---|---|
| | June 30, 2023 | June 30, 2022 |
| Warrants | 8,004 | 9,146 |

The Company has 547,674 and 484,582 shares of Series A preferred stock outstanding as of June 30, 2023 and 2022, respectively. 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 preferred stock is not convertible into common stock, and does not carry any dividend rights or any other financial effects. At June 30, 2023 and 2022 the number of potentially dilutive shares of the Company's common stock into which these Series A preferred shares can be converted into is 1,916,859 and 1,696,037, respectively, 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 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, the Company considers 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, 2023 and 2022.

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*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.

*Intangible Assets*

NanoViricides, Inc.'s intangible assets include acquired licenses and capitalized patent costs representing legal fees associated with filing patent applications. Intangible assets with finite lives, licenses and patent costs, are amortized using the straight- line method over the estimated economic lives of the assets, which range from seventeen to twenty years. The Company's intangible assets with finite lives are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Intangible assets determined to have indefinite useful lives, primarily patent costs, are not amortized but are tested for impairment during the fourth quarter, or more frequently if events or changes in circumstances indicate the asset may be impaired. The Company accounts for patent costs in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") ASC 350-30, *General Intangibles Other than Goodwill*. The Company will begin amortizing the patent costs when they are brought to the market or otherwise commercialized. In accordance with ASC 350, each year the Company may assess qualitative factors to determine whether it is more likely than not that the fair value of each license is less than its carrying amount as a basis for determining whether it is necessary to complete quantitative impairment assessments.

*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, non-employee directors, and non-employees, including employee stock options and grants of warrants to non-employees. 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 and non-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 and non-employee compensation are presented in Note 9 to the financial statements.

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The fair value of each option or warrant 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 warrants: 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. 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.

*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, which resulted in no unrecognized tax benefits as of June 30, 2023 and 2022. 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, 2023 and 2022 the Company paid interest to the state of Connecticut of $-0- and $1,258, respectively.

*Concentrations of Risk*

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in FDIC or SIPC insured institutions in excess of federally insured limits under the FDIC. Although the Company currently believes that the financial institutions with whom it does business will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so. The Company has not experienced any credit losses associated with its balances in such accounts for the fiscal years ended June 30, 2023 and 2022.

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*Recently Issued Accounting Pronouncements*

The Company considers the applicability and Impact of all Accounting Standard Updates ("ASU's"). ASU's not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's financial statements. There have been certain changes in ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) - Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under GAAP. The ASU also removes certain settlement conditions that are required for equity-linked contracts to qualify for the derivative scope exception, and it also simplifies the diluted earnings per share calculation in certain areas. While the Company is currently evaluating the adoption impact of this ASU on its financial statements, the preliminary assessment is that the adoption of this standard is not expected to have a material effect on the Company's financial statements.

**Note 4 – Related Party Transactions**

*Related Parties*

Related parties with whom the Company had transactions are:

| Related Parties | Relationship |
|---|---|
| Dr. Anil Diwan | Chairman, President, CEO, significant stockholder through his ownership of TheraCour, and Director |
| TheraCour Pharma, Inc. ("TheraCour") | An entity owned and controlled by Dr. Anil Diwan |
| Karveer Meditech Private Limited ("Karveer") | An entity where Dr. Anil Diwan is a passive investor and advisor without operating control |

*Property and Equipment*

| | For the Year Ended | |
|---|---|---|
| | June 30, 2023 | June 30, 2022 |
| During the reporting period, TheraCour acquired property and equipment on behalf of the Company from third party vendors and transferred such property and equipment, at cost, to the Company | $ 31,936 | $ 183,428 |

*Accounts Payable- Related Party*

| | As of | |
|---|---|---|
| | June 30, 2023 | June 30, 2022 |
| Pursuant to an Exclusive License Agreement entered into with TheraCour, the Company was granted exclusive licenses for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. On November 1, 2019, the Company entered into the VZV Licensing Agreement with TheraCour. In consideration for obtaining these exclusive licenses it was 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) the Company will pay $2,000 or actual costs each month, whichever is higher for other general and administrative expenses incurred by TheraCour on the Company's behalf, (3) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour and; (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 at June 30, 2023 was $733,434 which was offset by a two month advance (see above) of $500,000. Accounts payable due TheraCour at June 30, 2022 was $679,397 which was offset by a two month advance (see above) of $465,000. | $ 233,434 | $ 214,397 |

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*Research and Development Costs - Related Party*

| | For the Year Ended | |
|---|---|---|
| | June 30, 2023 | June 30, 2022 |
| Development fees and other costs charged by TheraCour pursuant to the 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, 2023 and 2022. | $ 2,535,862 | $ 2,369,022 |

*Clinical Trial Costs Accrued - Related Party*

| | For the Year Ended | |
|---|---|---|
| | June 30, 2023 | June 30, 2022 |
| Clinical trial related and other costs were accrued by Company pursuant to the license agreement between the Company and Karveer for the clinical trial related costs that have been incurred but not yet invoiced to the Company for Phase 1a/1b clinical trials in India. The amount has been recorded within accrued expenses in the accompanying balance sheet. | $ 100,000 | $ — |

*License Milestone Fee – Related Party*

On September 9, 2021, the Company entered into a COVID-19 License Agreement ( the " TheraCour –Nanoviricides COVID License Agreement") to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. Pursuant to such license agreement, the Board of Directors authorized the issuance of 100,000 fully vested shares of the Company's Series A preferred stock as a license milestone payment and recorded an expense to Research and Development of $935,088 for the year ended June 30, 2022. On April 20, 2023, the Company was notified that the Company's licensee, Karveer was authorized to enter into Phase 1a/1b clinical trials of its COVID, NV-CoV-2 Oral Syrup and its NV-CoV-2 Oral Gummies after satisfying the conditions of a conditional authorization received on or about January 27, 2023. Pursuant to the TheraCour – Nanoviricides COVID License Agreement a milestone payment of 50,000 shares fully vested shares of the Company's Series A preferred stock was issue as a license milestone payment and recorded as an expense to research and development of approximately $157,000 for the year ended June 30, 2023 representing the fair value of the shares on the date of grant. On June 19, 2023, the Company was notified that the Company's licensee, Karveer had commenced volunteer recruitments for Phase 1a/1b clinical trials of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies. Pursuant to the TheraCour–Nanoviricides COVID License Agreement a milestone payment of $1,500,000 became due 5 days thereafter and was recorded as a non-current liability and research and development expense. As of July 19, 2023, the Company entered into an agreement with TheraCour, to accept the Company's unsecured convertible promissory note (the "Note") in payment of the milestone award. The Note bears simple interest at the rate of 12% per annum and matures on January 19, 2025.

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**Note 5 – Property and Equipment**

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

| | June 30, 2023 | June 30, 2022 |
|---|---|---|
| GMP Facility | $ 8,168,045 | $ 8,149,416 |
| Land | 260,000 | 260,000 |
| Office Equipment | 60,347 | 57,781 |
| Furniture and Fixtures | 5,607 | 5,607 |
| Lab Equipment | 6,315,727 | 6,185,210 |
| Total Property and Equipment | 14,809,726 | 14,658,014 |
| Less Accumulated Depreciation | (6,703,079) | (5,963,820) |
| Property and Equipment, Net | $ 8,106,647 | $ 8,694,194 |

Depreciation expense for the years ended June 30, 2023 and 2022 was $739,259 and $715,055 respectively.

**Note 6 – Intangible Assets**

Intangible assets, net consists of the following:

| | June 30, 2023 | | | June 30, 2022 | | |
|---|---|---|---|---|---|---|
| | Finite Lived Intangible Assets | Indefinite Lived Intangible Assets | Total | Finite Lived Intangible Assets | Indefinite Lived Intangible Assets | Total |
| Intangible Assets | $ 153,393 | $ 305,561 | $ 458,954 | $ 153,393 | $ 305,561 | $ 458,954 |
| Less Accumulated Amortization | (125,376) | — | (125,376) | (117,106) | — | (117,106) |
| Intangible Assets, Net | $ 28,017 | $ 305,561 | $ 333,578 | $ 36,287 | $ 305,561 | $ 341,848 |

Amortization expense amounted to $8,270 and $8,270 for the years ended June 30, 2023 and 2022, respectively.

NanoViricides, Inc.'s intangible assets include acquired licenses and capitalized patent costs representing legal fees associated with filing patent applications.

**Note 7 – Accrued expenses**

Accrued expenses consisted of the following:

| | June 30, 2023 | June 30, 2022 |
|---|---|---|
| Personnel and compensation costs | $ 39,060 | $ 38,676 |
| Consultant | 4,700 | 7,016 |
| Clinical trial costs due to Karveer | 100,000 | — |
| | $ 143,760 | $ 45,692 |

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**Note 8 – Loan Payable**

The Company financed its Directors and Officers liability insurance policies through BankDirect for the period January 1, 2022 to December 31, 2022. The original loan balances as of January 1, 2022 was $234,198, payable at the rate of $23,932 monthly including interest at an annual rate of 4.74% respectively, through October of each year. At June 30, 2022, the loan balance was $94,788. For the year ended June 30, 2022 the Company incurred interest expense of $5,123. For the period January 1, 2023 to December 31, 2023 the Company did not finance its Directors and Officers liability insurance policies.

**Note 9 – Equity Transactions**

*Fiscal Year Ended June 30, 2023 Transactions*

On February 7, 2023, the Board of Directors and a majority of the shareholders of the Company approved the redomiciling of the Company wherein the Company would redomicile from a Nevada corporation to a Delaware corporation. The redomicile became effective on May 30, 2023 pursuant to Section 265 of the Delaware General Corporation Law and Sections 92A.120 and 92A.250 of the Nevada Revised Statutes. The redomicile occurred according to the Plan of Conversion whereby each share of the Company's $0.001 par value common stock was converted into one share of $0.00001 par value common stock, and each share of the Company's $0.001 par value preferred stock was converted into one share of $0.00001 par value preferred stock. The effect of the conversion decreased the total par value of common stock as reported on the Company's Balance Sheet at June 30, 2022 from $11,592 to $116, and decreased the total par value of preferred stock as reported on the Company's June 30, 2022 balance sheet from $485 to $5, and increased additional paid in capital as reported on the Company's balance sheet at June 30, 2022 by $11,596.

On April 20, 2023, the Company was notified that the Company's licensee, Karveer was authorized to enter into Phase 1a/1b clinical trials of its COVID, NV-CoV-2 Oral Syrup and its NV-CoV-2 Oral Gummies after satisfying the conditions of a conditional authorization received on or about January 27, 2023. Pursuant to the TheraCour – Nanoviricides COVID License Agreement, the Board authorized 50,000 shares of the Company's Series A preferred shares to be issued to Theracour as a license milestone payment and recorded an expense to research and development of approximately $157,000 which was the fair value on the date the milestone was met for the year ended June 30, 2023.

On October 6, 2022, the Board of Directors and Dr. Anil Diwan, President and Chairman of the Board agreed to the extension of Dr. Diwan's employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares vested in quarterly installments of 2,551 shares on September 30, 2022, December 31, 2022, March 31, 2023 and June 30, 2023. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of approximately $44,000 during the year ended June 30, 2023, which is the fair value on the date of issuance.

For the year ended June 30, 2023, the Scientific Advisory Board was granted fully vested warrants to purchase 1,144 shares of common stock at exercise prices between $1.39- $3.40 per share expiring in the fiscal year ending June 30, 2027. The fair value of the warrants was $1,012 for the year ended June 30, 2023 and recorded as consulting expense.

For the year ended June 30, 2023, 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 assumptions:

| | |
|---|---|
| Expected life (year) | 4 |
| Expected volatility | 51.39-85.12 % |
| Expected annual rate of quarterly dividends | 0.00 % |
| Risk-free rate(s) | 3.025-4.195 % |

For the year ended June 30, 2023, the Company's Board of Directors authorized the issuance of 2,888 shares of its Series A preferred stock, which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of approximately $12,000 during the year ended June 30, 2023, which is the fair value on the date of issuance.

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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 fair value of the Series A Convertible preferred stock at each issuance was estimated based upon the price of the Company's common stock after an application for a reasonable discount for lack of marketability.

For the year ended June 30, 2023, the Company's Board of Directors authorized the issuance of 3,572 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $4,822 which was the fair value on the date of issuance.

For the year ended June 30, 2023, the Company's Board of Directors authorized the issuance of 72,668 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $108,000, which was the fair value at the dates of issuance.

For the year ended June 30, 2023, the Company's Board of Directors authorized the issuance of 30,084 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.

*Fiscal Year Ended June 30, 2022 Transactions*

For the year ended June 30, 2022, the Scientific Advisory Board was granted fully vested warrants to purchase 2,288 shares of common stock at exercise prices between $1.46- $5.92 per share expiring in the fiscal year ending June 30, 2026. The fair value of the warrants was $4,215 for the year ended June 30, 2022 and recorded as consulting expense.

For the year ended June 30, 2022, 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 assumptions:

| | |
|---|---|
| Expected life (year) | 4 |
| Expected volatility | 86.00-91.00 % |
| Expected annual rate of quarterly dividends | 0.00 % |
| Risk-free rate(s) | 0.62-2.84 % |

On September 9, 2021, the Company entered into a COVID-19 License Agreement to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. Pursuant to such license agreement, the Board of Directors authorized the issuance of 100,000 fully vested shares of the Company's Series A preferred stock as a license milestone payment and recorded an expense of $935,088, which is the fair value at the date of issuance.

On September 14, 2021, the Board of Directors and Dr. Anil Diwan, President and Chairman of the Board agreed to the extension of Dr. Diwan's employment agreement for a period of one year from July 1, 2021 through June 30, 2022 under the same general terms and conditions. The Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares vested in quarterly installments of 2,551 shares on September 30, 2021, December 31, 2021, March 31, 2022 and June 30, 2022. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of approximately $109,000 during the year ended June 30, 2022, which is the fair value on the date of issuance.

For the year ended June 30, 2022, the Company's Board of Directors authorized the issuance of 2,888 shares of its Series A preferred stock, which are fully vested with a restrictive legend for employee compensation. The Company recorded an expense of $26,418 during the year ended June 30, 2022, which is the fair value on the date of issuance.

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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 fair value of the Series A Convertible preferred stock at each issuance was estimated based upon the price of the Company's common stock after an application for a reasonable discount for lack of marketability.

For the year ended June 30, 2022, the Company's Board of Directors authorized the issuance of 3,572 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $6,768 which was the fair value on the date of issuance.

For the year ended June 30, 2022, the Company's Board of Directors authorized the issuance of 38,863 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $108,000, which was the fair value at the dates of issuance.

For the year ended June 30, 2022, the Company's Board of Directors authorized the issuance of 17,705 fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of $52,500, which was the fair value at date of issuance.

For the year ended June 30, 2022, the Company's Board of Directors authorized the issuance of 16,863 fully vested shares of its common stock with a restrictive legend to satisfy open accounts payable of $35,750 for consulting services. The number of shares issued to settle the accounts payable was calculated using the market price of the common stock on the settlement date.

**Note 10 – Common Stock Warrants**

Stock Warrants

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual | Aggregate Intrinsic |
|---|---|---|---|---|
| Outstanding and exercisable at July 1, 2021 | 9,146 | $ 10.80 | 2.00 | $ 1,943 |
| Granted | 2,288 | 3.68 | 3.50 | — |
| Exercised | — | — | — | — |
| Expired | 2,288 | 22.63 | — | — |
| Canceled | — | — | — | — |
| Outstanding and exercisable at June 30, 2022 | 9,146 | $ 6.06 | 2.00 | $ 238 |
| Granted | 1,144 | 2.17 | 3.50 | — |
| Exercised | — | — | — | — |
| Expired | 2,286 | 7.98 | — | — |
| Canceled | — | — | — | — |
| Outstanding and exercisable at June 30, 2023 | 8,004 | $ 4.96 | 1.79 | $ — |

Of the above warrants; 2,286 expire in fiscal year ending June 30, 2024; 2,286 expire in fiscal year ending June 30, 2025; 2,288 expire in fiscal year ending June 30, 2026 and 1,144 expire in fiscal year ending June 30, 2027.

**Note 11 – Income Tax Provision**

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

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The income tax expense for the years ended June 30, 2023 and 2022 differed from the amounts computed by applying the U.S. federal income tax rate of 21% and 21% respectively as follows:

| | For the Year Ended | |
|---|---|---|
| | June 30, 2023 | June 30, 2022 |
| Federal statutory rate | (21.00)% | (21.00)% |
| Research and development credit | 1.10 % | 8.90 % |
| State tax rate | (5.93)% | (5.93)% |
| Stock based compensation | — % | — % |
| Other | (0.65)% | 2.73 % |
| Valuation allowance | 26.48 % | 15.30 % |
| Effective tax rate | — | — |

The significant components of the Company's deferred tax assets at June 30, 2023 and 2022 are as follows:

| | June 30, 2023 | June 30, 2022 |
|---|---|---|
| Net operating loss | $ 27,960,157 | $ 27,127,620 |
| Research and development credit | 7,868,816 | 7,774,567 |
| IRC Sec.174 R&E capitalization | 1,536,679 | — |
| Other | 25,194 | 1,604,592 |
| Total gross deferred tax assets | 37,390,846 | 36,506,779 |
| Less: valuation allowance | (37,390,846) | (36,506,779) |
| Net deferred tax asset | $ — | $ — |

At June 30, 2023 and 2022, the Company has recorded a full valuation allowance against its net deferred tax assets of $37,390,846 and $36,506,779, respectively, since in the judgment of management, these assets are not more than likely than not to be realized. The increase in the valuation allowance during the years ended June 30, 2023 and 2022 were $884,067 and $1,240,080, respectively.

As of June 30, 2023, the Company has approximately $104 million of gross net operating loss carryforwards available to reduce future taxable income, if any for federal and state tax purposes. Aggregate federal net operating losses generated after June 30, 2018 of approximately $35 million can be carried forward indefinitely. Net operating losses incurred in tax years beginning prior to June 30, 2018, of approximately $69 million, is limited to 80% of annual taxable income. Net operating losses generated in years ended June 30, 2018 and prior have a 20-year carryforward and will begin expiring in 2025. As of June 30, 2023 and 2022, research and development credit carryforwards for federal and state purposes are $7,868,816, and $7,774,567, respectively. The state 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 does not have any uncertain tax positions at December 31, 2023 and December 31, 2022 that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of unrecognized tax benefits over the next twelve months. Because the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available. If and when applicable, the Company will recognize interest and penalties as part of income tax expense.

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**Note 12 – Commitments and Contingencies**

Legal Proceedings

From time to time, we are subject to various legal proceedings arising in the ordinary course of business, including proceedings for which we have insurance coverage. 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 that we believe will have a material adverse effect to our business, financial position, results of operations, or liquidity.

*Employment Agreements*

As of July 1, 2023, NanoViricides, Inc. entered into an Extension Agreement (the "Extension") of the Employment Agreement with Dr. Anil Diwan entered into on July 1, 2018 (the "Employment Agreement") to continue to serve as the President of the Company, effective July 1, 2023 under the same general terms and conditions. The Extension provides that Dr. Diwan will continue to serve as the Company's President until June 30, 2024 at a base 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 balance 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 10,204 shares of the Company's Series A preferred stock, par value $0.00001 per share to Dr. Diwan. Dr. Diwan's rights in the shares shall vest in equal, quarterly installments commencing on September 30, 2023 and fully vest on June 30, 2024. The Company will recognize non-cash compensation expense related to the issuance of the Series A preferred stock of $42,232 during the year ended June 30, 2024. 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 the six month period.

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 1,340 shares of Series A preferred stock and 1,786 shares of common stock upon entering into the agreement, and will issue an additional 1,340 shares of Series A preferred stock and 1,786 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.

On May 30, 2013, the Company entered into an agreement with Meeta Vyas, wife of our President and Chairman of the Board, to serve as its Chief Financial Officer. The agreement provided for a term of three years with a base compensation of $9,000 per month and 129 shares of Series A preferred stock, also on a monthly basis. On January 1, 2015, her cash compensation was increased to $10,800 per month. The agreement is renewable on an annual basis. The Compensation Committee of the Board of Directors has extended the current provisions of the agreement pending its review of current industry compensation arrangements and employment agreements. As of July 1, 2023 the Company's Board of Directors approved the extension of the agreement with Meeta Vyas, Chief Financial Officer of the Company. The Company and Meeta Vyas signed an extension of the agreement for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms and conditions as the current agreement, except that she will be additionally compensated for up to 50% of all medical insurance costs, not to exceed $2,500 per month.

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*License Agreements*

The Company is dependent upon its license agreements with TheraCour (See Notes 1 and 4). If the Company lost the right to utilize any of the proprietary information that is the subject of the TheraCour license agreement on which it depends, the Company will incur substantial delays and costs in development of its drug candidates. On November 1, 2019, the Company entered into a Licensing Agreement (the "Agreement") with TheraCour for an exclusive license for the Company to use, promote, offer for sale, import, export, sell and distribute products for the treatment of VZV derived indications. Process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement. The Company was not required to make any upfront payments to TheraCour and agreed to the following milestone payments to TheraCour; the issuance of 75,000 shares of the Company's Series A preferred stock upon the grant of an IND Application; $1,500,000 in cash upon completion of Phase I clinical trials; $2,500,000 in cash upon completion of Phase II clinical trials; and $5,000,000 in cash upon completion of Phase III clinical trials.

On September 9, 2021, the Company entered into a world-wide, exclusive, sub-licensable, license ("COVID-19 License Agreement") to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. The Company was not required to make any upfront cash payments to TheraCour and agreed to the following milestone payments to TheraCour: (i) the issuance of 100,000 shares of the Company's Series A preferred stock within 30 days upon execution of this agreement; (ii) the issuance of 50,000 shares of the Company's Series A preferred stock upon the approval of the Company's Investigational New Drug (IND) Application or its equivalent by a competent regulatory authority; (iii) $1,500,000 upon initiation of Phase I clinical trials, or its equivalent, for at least one Licensed Product within the field on, or before, three (3) months from the date of the Authority's acceptance of the IND, or its equivalent; (iv) $2,000,000 in cash upon completion of Phase 1 clinical trials; (v) $2,500,000 in cash upon completion of Phase IIA clinical trials, or, its equivalent; (vi) the issuance of 100,000 shares of the Company's Series A preferred stock upon the initiation of Phase 3 clinical trials, or, its equivalent, for at least one Licensed Product within the field; and (vii) $5,000,000 in cash, or 500,000 shares of the Company's Series A preferred stock upon completion of Phase III clinical trials, or its equivalent. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement.

On March 27, 2023 the Company entered into a license agreement with Karveer wherein the Company granted to Karveer a limited, non-transferable, exclusive license for the use, sale, or offer of sale in India of the Company's two clinical test drug candidates titled as NV-CoV-2 and NV-CoV-2-R for the treatment of COVID in patients in India. Karveer has engaged in further drug development in India including sponsoring of drug candidates for human clinical trials in India and has acted as clinical trials manager for such clinical trials. Karveer shall provide NanoViricides with all reports of the clinical trials and the Company can use such reports for further advancement of the drug candidates with regulatory authorities outside India. In consideration, Karveer will be reimbursed by the Company for all direct and indirect costs incurred for the clinical trials and development activities with a customary clinical trials manager fee of thirty percent (30%) of such costs and applicable taxes. Upon commercial sales of any resulting approved drugs, Karveer will pay the Company a royalty of seventy (70)% percent of the final invoiced sales to unaffiliated third parties.

**Note 13 - Subsequent Events**

Pursuant to the COVID-19 License Agreement dated September 7, 2021 between the Company and TheraCour, the Company is obligated to make certain milestone payments to TheraCour upon achieving certain milestones. As of June 19, 2023 TheraCour achieved the milestone regarding the "Initiation of Phase 1 Clinical Trials or Equivalent" within 3 months from Regulatory Approval. Upon achieving this milestone, the Company was obligated to pay TheraCour a cash milestone payment in the amount of $1,500,000. In lieu of this cash payment, the Company offered and TheraCour agreed to accept a Convertible Promissory Note in the principal amount of $1,500,000 effective July 19, 2023 (the "Note"). The Note accrues interest at the rate of twelve percent (12%) per annum and is due and payable on January 19, 2025. The principle of the Note is convertible, at TheraCour's option, into shares of the Company's Series A preferred stock, par value $0.00001 at the conversion price specified in the terms and conditions contained within the Note.

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