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

FORM 10-K

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

FOR THE FISCAL YEAR ENDED JUNE 30, 2025

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 has filed a report on an attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 726(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

Yes ☐ No ☒

On September 27, 2025 there were approximately 17,431,000 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on December 31, 2024, by non-affiliates of the registrant was approximately $21,530,000 based on the closing price of $1.43 per share, as reported on the NYSE American on December 31, 2024, 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 REGARDING FORWARD-LOOKING STATEMENTS

This Report contains forward-looking statements within the meaning of the federal securities laws. 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 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,” “Company believes,” “management believes” and similar language. These forward-looking statements can be identified by the use of words such as “believes,” “estimates,” “could,” “possibly,” “probably,” “anticipates,” “projects,” “expects,” “may,” “will,” or “should,” or other variations or similar words. No assurances can be given that the future results anticipated by the forward-looking statements will be achieved. Forward-looking statements reflect management’s current expectations and are inherently uncertain. The forward-looking statements are based on the current expectations of NanoViricides, Inc. and are inherently 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. Our actual results may differ materially from results anticipated in these forward-looking statements.

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.

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.

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 ready to enter Phase II human clinical efficacy trial, having successfully completed Phase Ia/Ib human clinical safety and tolerability trial. Based on our nanoviricides™ platform technology, we also have 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.

We are engaged in developing a class of drugs, that we call nanoviricides™, using a platform technology based on the application of nanomedicine technologies to the complex issues of viral diseases. This approach enables rapid development of effective new drugs against a number of different viruses, that the viruses are highly unlikely to escape even as they evolve rapidly in the field, solving an important problem in attacking viruses. The virus evolution is known to generate viruses that escape the traditional antiviral approaches vaccines, antibodies and small chemical drugs.

NanoViricides Technology Platform Target Product Profile in Brief

We are a clinical stage company developing (a) host-mimetic, and (b) direct-acting, nanomachines capable of dismantling a targeted virus, (c) without assistance from the human immune system.

a. Virus Escape Unlikely. As a host-mimetic, viruses cannot escape a nanoviricide drug by generating mutants and variants in the field, because all variants still require the same signature host features that our drugs mimic. In contrast, vaccines, antibodies and small chemical drugs are readily escaped by viruses as mutations occur, rendering these medical countermeasures ineffective.

b. Direct Antivirals Expected to Provide Significant Safety and Tolerability Benefits. As a direct-acting antiviral, a nanoviricide drug is not expected to interfere with human bodily systems or enzymes, which is expected to result in significant levels of safety, unlike most of the antiviral drugs that interfere with cellular processes.

c. Applicable for All Patient Population. As a complete nanomachine that is designed to bind, engulf, and destroy virus particles without dependence on the patient's physiology, a nanoviricide is expected to provide antiviral effect for all patients, from infants, pediatrics, adults, to seniors.

d. Does Not Require Healthy Immune System. Any viral infection that causes significant pathology does so by virtue of host immune system disrepair, either pre-existing, or caused by the virus itself. Therefore, nanoviricides can be expected to be superior to approaches such as vaccines and antibodies that require a good functional host immune system for antiviral response.

These distinctive features that set nanoviricides apart from the entire world of current antiviral approaches are made possible by our novel nanoviricide chemical nanomachine design. After decades of development, this novel nanoviricide technology has now successfully reached clinical stage and regulatory processes towards approval of drugs for commercialization.

NV-387, Phase II-Ready Broad-Spectrum Nanoviricide Drug Development Against Multiple Viruses

Our first clinical stage drug candidate, NV-387, has completed Phase Ia/Ib human clinical trial for the evaluation of safety and tolerability in healthy subjects. NV-387 is the active ingredient in the two drug product formulations labeled "NV-CoV-2 Oral Syrup" and "NV-CoV-2 Oral Gummies" that we developed for the treatment for COVID infection. In this clinical trial for safety and tolerability in healthy human adult subjects: (a) there were no drop-outs, (b) there were no reported adverse events, and (c) the drugs were well-tolerated even at the highest level of dosing given multiple times. These results are indicative of safety and tolerability that have been successfully achieved for NV-387. The Clinical Study Report, a final document resulting from this clinical trial is in draft stages nearing completion. We anticipate its submission to the regulatory agency in India soon.

NV-387 is a uniquely broad-spectrum antiviral drug that has demonstrated strong activity in lethal lung infection animal model studies of Coronavirus, RSV, Influenza and even an Orthopoxvirus model for Smallpox and MPox, and most recently, even in a humanized mice model for Measles. These distinct types of viruses share a common feature; that they all utilize heparan sulfate proteoglycan (HSPG) or related Sulfated Proteoglycans (S-PG) as the first "attachment receptor" to which they bind and thereby prepare to attack the cells and cause infection. Each of these viruses then differ in the specific receptor(s) on the cell that the virus uses for attacking the cell, called the "cognate receptor(s)", and thereby fuse with the cell and enter the cell initiating infection.

NV-387 is designed to mimic the essential, invariant, feature of S-PG onto which the virus lands first as it infects a human cell. Thus, NV-387 is designed to interfere at the earliest possible step before the virus can even infect a cell. Over 90% of human pathogenic viruses are known to use sulfated proteoglycans ("S-PG") such as heparan sulfate proteoglycans (HSPG), dermatan sulfate, chondroitin sulfate, and others. This enables an extremely broad potential range of viruses that NV-387 could effectively address as an antiviral drug.

This extremely broad antiviral spectrum of NV-387 is reminiscent of the broad antibacterial spectrum of antibiotics such as penicillin and we believe NV-387 could revolutionize the treatment of viral infections the same way that penicillin revolutionized the treatment of bacterial infections.

Antibiotics such as penicillin directly attack the bacterial surface and thereby kill the bacteria. Similarly, NV-387 is designed to directly attack the viral surface and destroy the virus particle. Similar to antibiotics that possess a broad-spectrum to treat bacterial infections, NV-387 could be a much needed, ultra-broad-spectrum, direct acting, antiviral agent to treat multiple different viral infections.

We believe that a safe and effective antiviral drug, when approved, with an extensive broad-spectrum activity across multiple, distinct, virus families is an unmet medical need. Currently available broad-spectrum antivirals such as Remdesivir, Ribavirin, Cidofovir, etc. suffer from extensive and varied dose-limiting toxicities, and thereby present limitations on eligible patient populations as well as on clinical effectiveness.

NV-HHV-1, Clinical-Ready Drug Candidate and the HerpeCide™ Program

We are also developing several other virus-family-specific drug candidates, by mimicking the common cellular cognate receptors of viruses.

NV-HHV-1 is designed to attack all herpesviruses that use the cognate receptor on cells called the "Herpesvirus Entry Mediator" (HVEM, also called CD270 and TNFRSF14) for cell entry.

NV-HHV-1, developed as a skin cream for the treatment of Shingles rash, has completed non-clinical safety/pharmacology studies required for a U.S. Food and Drug Administration ("FDA") Investigational New Drug ("IND") submission. We believe that the NV-HHV-1 skin cream, when approved, can also be additionally indicated to treat HSV-1 "cold sores" and HSV-2 "genital ulcers" based on successful animal studies.

Additionally, we are developing an oral drug for the systemic treatment of most of the herpesvirus family related infections, including HSV-1 "cold sores" and HSV-2 "genital herpes" that is based on the same active ingredient as NV-HHV-1.

HSV-1 infection is known to be associated with and possibly a cause of the neurodegenerative disease, Alzheimer's disease (AD). Current therapies for HSV are limited in effectiveness and most of them target the DNA replication part of the virus. NV-HHV-1, with a mechanism orthogonal to the current therapies, could lead to a substantial improvement in the overall anti-HSV effectiveness and thereby could provide an option for blocking further neurodegeneration in AD.

NV-HIV-1, A Novel Mechanism Anti-HIV Drug Candidate and the HIVCide™ Program

We developed NV-HHV-1 to attack HIV by mimicking the conserved binding of HIV to the CD4 cell surface cognate receptor. This drug has shown remarkable effectiveness in animal studies in SCID-Hu-Thy-Liv implanted humanized mouse model for HIV. Given that Delta-CCR5- subjects are HIV-resistant, and that bone marrow transplant from such patients has led to effective cure of HIV, we believe it is possible that NV-HIV-1 itself or a further modified form to include mimicking the CCR5 portion, could lead to a drug that is close to a cure for HIV infection.

Other Drug Development Programs in the Pipeline

We have several other drug candidates at different preclinical drug development stages in our pipeline for the treatment of other viral infections including Dengue viruses, Ebola viruses, etc.

NanoViricides Owns Facilities with Fully Integrated Development and Manufacturing Capabilities

NanoViricides is one of a few pharmaceutical drug developers with its own facilities that support the entire drug development process from design and discovery, to chemical synthesis, to initial antiviral evaluation (in cell culture models), to scale-up of drug candidates, to set-up and cGMP-compatible manufacture drug substances. Our facility also supports cGMP-compatible formulation, filling, labeling and finished packaging of drug products. In addition, we also have well-equipped analytical laboratories that support both R&D development and cGLP compatible analytical testing and characterization of drug substances and drug products in the same facility. The facility is located at 1 Controls Drive, Shelton, CT.

Having such integrated facility available enabled us to develop the NV-CoV-2 COVID drug (that contains the active pharmaceutical ingredient NV-387) from concept to completion of safety/pharmacology studies required for clinical trials within a matter of just one year.

The Phase Ia/Ib human clinical trial began in June 2023 and the healthy subjects treatment and observation part was completed as of the end of December 2023. The clinical trial drug products, NV-CoV-2 Oral Syrup, and NV- CoV-2 Oral Gummies which are two oral formulations of the active ingredient NV-387, were manufactured at our Shelton, CT campus, and then shipped to and received by Karveer Meditech Pvt. Ltd. ("KMPL") our collaborator. Under the agreement with KMPL, we will pay for the expenses of the clinical trials, and in return we will benefit from having the data and reports made available for regulatory filings in other territories of the world. Upon commercialization by KMPL in India, we will receive royalties from KMPL equal to 70% of sales net of costs to unaffiliated third parties.

We have already manufactured the clinical drug substance NV-387 for the first Phase II clinical trial at this facility. The clinical drug product for this Phase II clinical trial is also planned for production at our own cGMP-compatible facility. A pilot run was completed recently, subsequent to the reporting period of this annual report.

We depend upon external parties, that may be collaborators, consultants, and sub-contractors, for the regulatory development of drug candidates including animal efficacy studies, non-clinical safety/pharmacology studies, regulatory requirements assessments, and regulatory affairs such as advice on regulatory strategy, regulatory documentation, design of clinical trials, preparation of clinical trial applications, as well as conducting clinical trials and preparing required reports.

Strong Intellectual Property and Collaborative Relationships

Our "nanoviricide" platform-based drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. ("TheraCour"), to which we have broad, exclusive licenses. The licenses are to entire fields and not to specific compounds. In all, we have 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). In all cases, the discovery of ligands and polymer materials, formulations, chemistry and chemical characterization, as well as process development and related work (the "Development Activities") will be performed by TheraCour, a related party substantially owned by Dr. Anil Diwan, under the same compensation terms across various agreements between the parties, with no duplication of costs allowed. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, although these licenses do not specify the terms of milestone payments during clinical development that are customary in the pharmaceutical industry. In addition, we have perfected a license for the field of Varicella Zoster Virus ("VZV License") infections i.e. Shingles and Chickenpox (the "Shingles License"), and another one for the field of treatment of SARS-CoV-2 infections (the "COVID License Agreement"); both of which specify the same terms for the Development Activities as the prior agreements, and further specify certain milestone payment terms specifically for the individual fields, details of which have been disclosed at the time the agreements were entered into. We have later amended the COVID License on February 12, 2024, so that any cash milestone payments that remained un-earned or unpaid by that date would not be payable in cash until the Company receives sufficient revenue from its commercialization activities including out-licensing, collaborations, co-development agreements, and commercialization, as more fully described in the amendment to the COVID License Agreement ("Amendment to the COVID License Agreement"). Certain milestone payments were made under the VZV License as well as under the COVID License Agreement prior to the Amendment to the COVID License Agreement, details of which have been disclosed. We negotiate and license 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.

We executed a Memorandum of Understanding ("MOU") with TheraCour on September 23, 2024, subsequent to the reported period, whereby we have obtained a right of first refusal for all antiviral drug developments including unlicensed developments that occur during the course of the Development Activities as specified in our license agreements, and have set out the process of development of drugs for unlicensed viral indications towards completion of appropriate license agreements. The Company and TheraCour have also agreed in this MOU that any cash milestone payments related to development activities, that are awardable, will become payable only upon NanoViricides having sufficient revenue, as defined in and more fully described in the Amendment to the COVID License Agreement referred to above, thereby including the provisions previously incorporated in the Amendment to the COVID License Agreement, to all present and future license agreements.

We have out-licensed NV-CoV-2 and NV-CoV-2-R for further clinical drug development and commercialization in the territory of India to KMPL, a company of which Dr. Anil Diwan is a passive investor and advisor, enabling KMPL to sponsor our drug products originally developed for COVID treatment, namely NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies into Phase I human clinical trial.

Our Plan for Regulatory Development and Commercialization of Our Drugs

Our most advanced drug candidate at present is the broad-spectrum antiviral drug NV-387.

NV-387's Broad Antiviral Spectrum Cuts Across Virus Families

NV-387 is the active pharmaceutical ingredient of both the oral formulations, namely NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies drug products. In various animal models of lethal virus infection challenge, NV-387 was found to lead to substantial increase in survival, compared to even approved drugs where available, indicating potential for successful clinical regulatory development as a treatment for a number of viruses. Additional criteria studied in these animal models also further bolstered these expectations of potentially successful regulatory development. The viruses we have tested and found to support expectations of potentially successful regulatory development include RSV and Influenza in addition to Coronaviruses, covering the so-called "tripledemic" viruses with a single drug to treat them. In addition, similar strong results were found for treatment with NV-387 of orthopoxvirus infection in animal models, both by dermal route, as well as by direct lung infection route. Additionally, strong results were found for treatment with NV-387 of lethal Measles virus lung infection in a humanized hCD150-knock-in mouse model. In the animal model studies, the dermal infection route models MPox infection, whereas the lung infection route models potential bioterrorist attack with Smallpox virus.

The above mentioned broad-spectrum antiviral effect of NV-387 as found in animal models of lethal virus challenge infection suggests that NV-387 is eligible for regulatory clinical development as a potential treatment for RSV, Influenza, MPox and Smallpox, as well as Measles, in addition to Coronaviruses, based on the current data at hand. It is possible that NV-387 may have similar antiviral effect against many other viruses, something that we plan on continuing to evaluate as our programs advance. This expectation is based on the mechanism of NV-387 in that it mimics sulfated proteoglycan structures associated with host cells that are used by over 90% of human pathogenic viruses as attachment receptors.

The viruses we have tested NV-387 against cut across different virus types, including RNA viruses as well as DNA viruses of different kinds. We are not aware of any other antiviral drug in development that has such a broad spectrum of activity, and safety/tolerability in humans that would potentially allow use across the entire human population.

We have developed a regulatory strategy for NV-387 that we believe would take NV-387 into commercialization stage in the most cost-effective manner and in the most rapid manner. To this end, we are devising Phase II clinical trials for NV-387 against MPox, an "Orphan" disease in the USA, as well as an innovative "basket-type" clinical trial to assess effectiveness of NV-387 against a range of viruses in a single clinical trial.

Phase II Clinical Trial for Evaluating NV-387 for the Treatment of MPox

We are working on initiating a Phase II clinical trial for NV-387 as a treatment for MPox disease caused by the MPXV virus in the Democratic Republic of Congo (DRC). We have obtained a preliminary approval from the Ethics Committee of the regulatory agency in charge for the African region, namely ACOREP, for this clinical trial. We have signed up a Clinical Trial Research Organization (CRO) to help develop the clinical protocol and conduct the clinical trial. With the CRO, we have identified sites for the clinical trial and have engaged one site in particular, which we believe will be able to provide all of the patients recruitment as needed for the Phase II clinical trial. We are now in the process of developing a clinical trial application.

In addition to the Phase II clinical trial to evaluate the safety and effectiveness of NV-387 treatment in MPox patients, we are also planning another Phase II clinical trial to evaluate the potential of NV-387 as an emperic antiviral therapeutic for acute and severe-acute viral respiratory infections (Viral ARI and SARI).

Phase II Clinical Trial for Assessing the Potential of NV-387 as a Revolutionary "Emperic" Antiviral Therapeutic

NV-387 is likely to become an "emperic therapy" for respiratory viral infections, similar to how amoxicillin has become the go-to empiric therapy for respiratory bacterial infections, if its activity that was observed in numerous animal model studies against respiratory infections holds up in the human clinical setting. This is very important for viral diseases, because the first 48 hours are crucial for successful treatment of such viral infections, as seen from notations in the product labels for a number of anti-influenza drugs such as oseltamivir (Tamiflu®, Roche), Zanamivir, and others. Regrettably, at present, antivirals are prescribed only after testing and determination of the causative agent, because the drugs are specific to the virus. This results in the loss of the window of opportunity

for best impact, not accounting for the fact that patient already suffers for a couple of days hoping for recovery before seeking physician's help.

In contrast to the current one-drug-one-bug antiviral agents, we believe that NV-387 could be prescribed when a patient presents with respiratory symptoms consistent with a viral infection without testing for specific virus, analogous to how antibiotics for respiratory bacterial infections are prescribed, i.e. as an emperic, first-line therapy. This will become possible if NV-387 demonstrates effectiveness in a properly designed clinical trial against a majority of viral respiratory infections. To this end, we are designing a so called "basket-type", adaptive, clinical trial to evaluate the effectiveness of NV-387 administered in respiratory viral infections regardless of what the causative virus is. This Phase II clinical trial will enable us to obtain definitive data regarding effectiveness of NV-387 against at least two of the most prevalent viruses during the clinical trial at the trial sites, with substantially indicative data against many others.

We are therefore planning an adaptive, "basket-type", Phase II clinical trial for the evaluation of NV-387 as a treatment for Viral Acute or Severe Acute Respiratory Infections (Viral-ARI or Viral-SARI). We believe we will obtain definitive data against Influenza, RSV, and Coronaviruses, or at least two of these three viruses, as well as substantially indicative data against the adenoviruses, echoviruses, picornaviruses, rhinoviruses (generally regarded as common cold viruses), and many others that infect by the respiratory route, in this single clinical trial. This would substantially save on costs of conducting clinical trials, and would open up the path for confirmatory Phase III clinical trials to potentially enable a variety of antiviral indications if successful.

NV-387 Has Been Formulated for Several Routes of Administration

We found that NV-387 is effective when orally administered in animal studies, unlike other known nanomedicines that are limited to injectable routes. We developed a soft solid "Oral Gummies" formulation of NV-387. This formulation has the advantage that it dissolves by itself in the mouth, eliminating the need to swallow a hard tablet. This is important for many of the diseases we are targeting. Sore throat from respiratory viral infections, Mouth Ulcers, in the case of MPox, or even old age or very young age, makes tablet swallowing difficult. Our gummies formulation can be readily administered to such patients.

We have also developed an injectable formulation primarily for use in severe cases that do not require hospitalization, an I.V. infusion formulation, that would be preferred for hospitalized patients with I.V. central line, as well as a solution for direct lung inhalation using an off-the-shelf nebulizer, which would provide most concentrated drug action at the site of the most severe infection, namely in the lungs. We plan on performing clinical trials for these cases after the two Phase II studies above are completed.

Benefits of Our Regulatory Approach for NV-387 – Orthopoxviruses – MPox, Smallpox, Biodefense

The Phase II MPox clinical trial in DRC is expected to provide first evidence of efficacy of NV-387 in a viral disease in humans.

MPox was declared as a global Public Health Emergency of International Concern ("PHEIC") by the World Health Organization (WHO) around May 2022 that was canceled about a year later. This PHEIC was caused by spill-over of the MPox Clade II virus from Africa into European countries and into the USA.

The MPox Clade II continues to cause cases in the USA even in 2025 and is an "Orphan" disease in the USA. It is less severe and less lethal than its cousin, MPox Clade I, that is endemic in regions of Africa including DRC. A new variant of Clade I, namely I.b, caused a severe epidemic leading to a Public Health Emergency of Continental Security by the Africa CDC on August 13, 2024, followed by a new PHEIC declaration by the WHO on the following day. The WHO has rescinded the PHEIC declaration on September 5, 2025, citing decrease in cases in DRC and nearby regions previously affected, whereas the Africa CDC has voted to continue the PHECS designation on September 3, 2025, due to continued spread of the MPox virus into new countries in the region, as well as rise in cases in several regions neighboring to the previous hot zones.

Smallpox is designated as an important bioterrorism target in the USA and other countries. There are two drugs currently approved for smallpox in the USA. Tecovirimat (TPOXX®, SIGA) was approved earlier, with substantial US Government funding during development, and is stockpiled in the US Strategic National Stockpile (SNS). Replenishment orders have amounted to hundreds of millions of dollars per year. Brincidofovir (TEMBREXA, previously Chimerix, now Emergent Bio) was approved more recently for Smallpox and is also now in the SNS. Both tecovirimat and brincidofovir were developed using the US FDA "Animal Rule" pathway, since clinical trials with human volunteers for Smallpox are considered unethical.

Tecovirimat inhibits the release of the virus from infected cells after replication, whereas brincidofovir inhibits the synthesis of the viral DNA. A single point mutation in the virus protein VP-37 is known to cause resistance to tecovirimat. Brincidofovir is said to have a higher bar of resistance to mutation in viruses. Brincidofovir, according to its prescribing information,[1] (i) carries a "Black Box Warning" due to observed increase in mortality in an unrelated disease clinical trial upon extended use; (ii) was found to cause diarrhea in 40% of patients, with 5% discontinuations; (iii) was found to cause elevations in hepatic (i.e. liver) transaminases and bilirubin; (iv) is considered a human carcinogen; (v) may cause embryonic or fetal harm; and (vi) may irreversibly impair fertility. Tecovirimat was tried in a clinical trial called PALM007 for treatment of MPox and the results announced by the US NIH stated that while it was found to be safe and well tolerated, it was not superior to the placebo, in August 2024[2]. In a separate international Phase III clinical trial called UNITY, tecovirimat failed to demonstrate improvement over placebo as reported on July 17, 2025[3]. Brincidofovir has entered a clinical trial called MOSA for treatment of MPox in January 2025, and interim results were anticipated in Q1 2025, according to the press release by Africa CDC[4]. The current status of this brincidofovir for MPox clinical trial is not publicly known.

At present, there is no drug approved for the treatment of MPox.

Thus, clearly there is a need for a safe and effective drug against Smallpox that would be of interest to the US Government as well as other international agencies. There is potential for drug development funding by the US Government as well as potential for revenues in several hundred million dollar range for a successful drug upon approval for biodefense stockpiling. Additionally, the market size for a successful treatment for MPox in the developed world is expected to be significant, and together with the rest of the world, globally, it would be a significant opportunity.

We are seeking non-dilutive funding for progressing NV-387 towards regulatory approval for treatment of Smallpox under the US FDA "Animal Rule". We believe that positive data, if the Phase II of NV-387 for treating MPox is successful, would go a long way towards the goal of approval of NV-387 for Smallpox as well, because MPox is an orthopoxvirus closely related to the Variola virus that causes Smallpox.

We believe our animal model study results for the lethal orthopoxvirus infection via the dermal infection route as well as via direct inhalation of viral particles into lungs are sufficiently robust to generate confidence to anticipate positive outcome from the proposed Phase II clinical trial of NV-387 for the treatment of MPox.

We plan on applying for an "Orphan Drug Designation" from the US FDA for the use of NV-387 for the treatment of MPox. We also plan on applying for an "Orphan Drug Designation" from the US FDA for the use of NV-387 for the treatment of Smallpox.

The Orphan drug designation has several advantages, including waiver of certain PDUFA FDA fees, tax credit for research and development, as well as a seven year exclusivity after approval. The Orphan designation is also expected to enable important FDA engagement and potentially rapid reviews.

We plan on filing IND with the US FDA for the use of NV-387 for the treatment of MPox as well as Smallpox, which are both Orthopoxviruses. As of now, we have not formally engaged with the US FDA for these initiatives.

Benefits of Our Regulatory Approach for NV-387 – Viral-ARI, Viral-SARI

As stated above, the Phase II clinical trial to evaluate NV-387 as a treatment for viral respiratory infections is expected to provide substantial data on safety and effectiveness of NV-387 against a large number of viral targets. Importantly, we anticipate that it will provide data on the effectiveness of NV-387 in Influenza, RSV as well as Coronaviruses.

[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214460s000,214461s000lbl.pdf.
[2] https://www.nih.gov/news-events/news-releases/antiviral-tecovirimat-safe-did-not-improve-clade-i-mpox-resolution-democratic-republic-congo.
[3] https://mpx-response.eu/large-international-trial-unity-reports-no-clinical-benefit-from-tecovirimat-for-mpox-resolution/
[4] https://africacdc.org/news-item/enrollment-starts-in-africa-cdc-led-mpox-therapeutic-study-mosa/.

Influenza is a multi-billion dollar market, and it is also an important initiative for the US Agency known as BARDA. Currently available treatments, namely oseltamivir (Tamiflu® , Roche), peramivir (Rapivab®, BioCryst), baloxavir (Xofluza®, Shionogi, Roche) and others are all known to be susceptible to virus escape by simple mutations. Thus there is an unmet medical need for an Influenza treatment that the virus cannot escape from. We note that in lethal lung infection animal model of Influenza, NV-387 was found to be substantially superior to each of the three approved drugs listed above. This leads us to believe that NV-387 would be able to go through regulatory clinical trials for Influenza viruses successfully and would be able to receive regulatory approvals.

There is no drug approved for the treatment of RSV infection, other than ribavirin which is only used in extreme cases due to its severe toxicity. We note that in lethal lung infection animal model of RSV, NV-387 was found to completely cure treated animal. This leads us to believe that NV-387 would be able to go through regulatory clinical trials for RSV successfully and would be able to receive regulatory approvals.

We therefore plan on further developing NV-387 in a regulatory process towards treatment of pediatric patients with RSV infection, an unmet medical need.

Having a single drug with broad applications enables us to minimize the regulatory development workload, minimize costs, as well as develop rapid timelines due to common or overlapping workload across the various indications. We believe this would lead to significantly robust commercial footing as well as significantly improved returns on investments if and when NV-387 reaches commercialization resulting in revenues.

NV-387 for Measles Treatment

Measles outbreaks are increasing globally. In particular, USA has seen over 1400 confirmed cases in 2025 with three fatalities[5]. Measles was declared eliminated in the USA as of 2000, with only travel-related cases occurring sporadically. Additionally, Canada has seen an increase of over 20x in measles cases since 2024, with more than 4,200 cases reported by the end of July 2025[6]. In 2024, measles cases in Europe rose to over 32,000 from slightly less than 4,000 cases in 2023[7]. There were approximately 360,000 confirmed cases of measles globally in 2024 according to WHO[8]. Measles continues to be an important disease for children despite a highly effective vaccine.

Measles virus is perhaps the most contagious virus known. Because of this, 95% of population vaccination level is required to ensure population immunity (“herd immunity”). This number has become increasingly difficult to achieve for several reasons. There is an increasing population of immune-compromised persons, as well as persons with auto-immune conditions, that may not benefit from the vaccine. There is also vaccine hesitancy that has increased significantly worldwide since the COVID-19 pandemic. Erosion of population’s trust in public health agencies and officials has substantially increased as well.

Additionally, the current measles virus vaccine is a live attenuated vaccine that dates back to 1968. The measles virus has evolved substantially since then, although this vaccine continues to remain effective, and vaccine breakthrough is estimated to be about 5% of cases. Nevertheless, there are data suggesting that vaccine breakthrough is increasing and in some episodes could be substantially greater than 5%[9], indicating a partial virus escape.

Measles infection can lead to what is known as “immune amnesia” in some patients. Since measles virus attacks the immune cells responsible for creating and maintaining immunity against infectious agents, a severe bout of measles can lead to the wipe-out of the very memory immune cells that provide protection from previously experienced infectious agents, making the subject fully vulnerable again. This is why, even though measles itself has low fatality rates (estimated at 0.1% to 0.3%), it is important to keep this virus at bay from public health perspective.

[5] https://www.cdc.gov/measles/data-research/index.html.
[6] https://health-infobase.canada.ca/measles-rubella/.
[7] https://www.ecdc.europa.eu/en/news-events/measles-rise-again-europe-time-check-your-vaccination-status.
[8] https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fimmunizationdata.who.int%2Fdocs%2F librariesprovider21%2Fmeasles-and-rubella%2Fglobal-mr-update.pptx%3Fsfvrsn%3D3547ebab_9&wdOrigin=BROWSELINK
[9] https://pmc.ncbi.nlm.nih.gov/articles/PMC11209263/.

A treatment for measles is therefore an important unmet medical need, as more of the global population becomes vulnerable to measles, and as the measles virus is likely on the cusp of escaping, at least partially, the current measles vaccine.

There is no approved treatment for measles. Vitamin supplementation was found to be beneficial in setting of nutritional deficiencies. Ribavirin, a highly toxic drug, is recommended by CDC for severe hospitalized cases but is not approved.

We performed a humanized animal model study to evaluate the effectiveness of NV-387 in lethal respiratory infection by measles virus. In this study, we found that NV-387 was able to increase the survival lifespan of the lethally infected mice significantly. We believe that this data provides sufficient rationale for a physician to use NV-387 for the treatment of a case of measles under a FDA pathway called the Physician-Initiated IND. We plan on providing the supporting datasets to enable such Physician-Initiated IND process.

With the small number of cases globally, development of drug specifically for measles is not economically viable to undertake. However, an indication for the use of NV-387 for the treatment of measles is viable in the context of a FDA rare disease pathway.

NV-387 for treatment of measles would be eligible for an Orphan Drug Designation with attendant benefits in the USA.

Other Drug Programs

In addition, we have a strong and wide drug pipeline developed over a number of years. NV-HHV-1, our drug candidate formulated as a skin cream for the treatment of Shingles, has completed regulatory required safety-pharmacology studies towards filing a US FDA IND for this drug. NV-HHV-1 skin cream could be further developed for the indications of HSV-1 cold sores treatment and HSV-2 genital ulcers treatment. In addition, we are developing a single systemic drug that would potentially be indicated for the treatment of HSV-1, HSV-2 as well as Shingles and Chickenpox viruses.

NV-HIV-1 has demonstrated anti-HIV activity in the standard SCID-Hu-Thy-Liv mouse model of HIV infection that we believe is strong enough to warrant further regulatory development of this drug candidate. In all, we have been working on over forty different viral disease indications with the purpose of developing drug candidates that are well-differentiated from existing drugs if any against these indications as described further down in this report.

Our other drug candidates are at earlier pre-clinical development stages.

Our Commercialization Strategy

The drug development process is long and expensive. As of the date of this report, we do not have any approved drugs on the market. We have no customers, products or revenues to date, and may never achieve revenues or profitable operations. We continue to add to our existing portfolio of products through our robust internal discovery and clinical development programs.

We believe we have developed several assets worthy of partnering for further regulatory development and commercialization. We seek to partner and out-license our drug candidates for these purposes. Such partnering may potentially involve initial license fees, milestone payments, and royalty payments to us that could result in an early revenue stream prior to commercial product sales.

Our business plan is based on developing the drug candidates into regulatory approvals, and partnering and sub-licensing for commercialization of the drugs whenever possible. We have begun the process of actively seeking partnerships by retaining a consulting firm, Aagami, Inc., based in Illinois. Aagami specializes in developing pharma collaborations primarily with Indian and Japanese big pharma companies, and also world-wide. We anticipate adding business development efforts in the western countries as we further develop NV-387 into a Phase II clinical trial. A Phase II clinical trial is designed for the evaluation of effectiveness of a drug for its indication and is considered a “proof-of-concept” in humans that the drug is likely to succeed in regulatory approvals. Prior to entering clinical trials, we have developed substantial “proof-of-concept” information regarding our drug candidates in relevant animal models.

We plan on seeking non-dilutive grants and contracts funding for our drug candidates that are responsive to bio-defense and pandemic-preparedness objectives, in particular, the drug development of NV-387 for Smallpox under the US FDA Animal Rule. However, there can be no assurance that we will be able to obtain grants or funding for these projects or that it will be on terms favorable to us.

There is no guarantee that we will be successful in partnering our drug candidates or obtaining non-dilutive funding for furtherance of our drug development programs. We plan on continuing drug development on our own all the way through regulatory approvals if successful collaborations are not established. We plan on continuing to finance our efforts using equity-based financing, at least until an appropriate collaboration with a suitable pharma company for one or more indications of our drug candidates takes place.

To date, we have financed our drug development programs using equity-based financing from the sale of our shares in private and public offerings including registered direct offerings as well as "At the Market" (ATM) offerings.

The Nanoviricide Platform Technology in Brief

"Resistance is Futile": NanoViricide Platform Promises Antiviral Drugs That The Virus Is Unlikely To Escape Even As It Evolves

The greatest "pain" or intractable problem in antivirals development has been that viruses rapidly evolve to evade the vaccines, antibodies, and small therapeutics that are the traditional antiviral approaches. Small changes in enzymes attacked by the small chemical antivirals lead to antiviral drug resistance. Small changes in the virus "antigens" lead to resistance to vaccines and antibodies, because these antiviral approaches are highly specific to the antigens that they are designed against. 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.

We believe this is now common knowledge after the COVID pandemic.

In contrast, novel nanoviricide™ platform technology enables a host-mimetic, direct-acting, antiviral nanomachine drug which the virus cannot escape even as it evolves.

Our novel nanoviricide class of drug candidates are designed to specifically attack and dismantle enveloped virus particles, by mimicking the host-side features that the virus particle lands on as it infects a host cell. In spite of even relatively large changes in a specific virus's surface glycoproteins as it evolves, the viral glycoprotein continues to retain, and often enhances, its ability to attach to specific host-side "attachment" receptors, and thereafter by transferring to a more specific "cognate receptor" on the cell to gain cell entry and cause infection. For example, Influenza viruses use Heparan Sulfate Proteoglycan (HSPG) as "Attachment Receptor" and Sialic Acid (or sialylated glycoproteins) as the "Cognate Receptor."

Nanoviricides mimic either the attachment receptors or the cognate receptors and present a large number of viral binding sites on each nanoviricide polymeric micelle. Further, the nanoviricide polymeric micelle is designed to "look like" a cell to the virus.

Even as new virus variants develop that evade existing 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.

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 host-side or cell-side 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.

Therefore, we believe that our unique host-mimetic approach would result in a nanoviricide drug that a virus cannot escape even as it changes in the field, because it will continue to use the same host-side landing site features (attachment receptors and/or cognate receptors) despite all the changes in its own glycoproteins that bind to those features, if the virus-binding ligands we design for the nanoviricide drug perform as designed.

As described further below, the Nanoviricides Platform provides for modalities that can result in potential cures for viruses that do not establish latent virus infection in humans.

A NanoViricide is a Nanomachine that Does Not Require Competent Immune System and Completes the Task of Dismantling Virus Particles Without Host Machinery Involvement

There are two principal parts to a virus's lifecycle. The first is to infect a new cell, called "Re-Infection" in virology (the very first virus acquisition, from an external source, is called the "Primary Infection"). The second is to replicate in the infected cell, make new virus particles and then egress into bodily fluids outside the cell, called "Replication." Most small chemical drugs are designed to affect the replication part, and must go into cells, raising toxicity concerns or reduced safety margins as they interfere with the cellular machinery. Thus, almost all currently existing nucleoside/nucleotide drugs are toxic by their very nature to varying extents.

Vaccines and antibodies have been regarded as the standard pillars of antiviral medical countermeasures. Vaccines generate antibodies, and antibodies (from vaccine or externally applied drug), block the virus by directly binding to it, but these countermeasures are (a) highly specific and thus readily escaped by viruses, and (b) require the human immune system to be in good shape. Vaccines depend upon the patient's immune system to generate new antibodies, whereas antibodies depend upon the patient's immune system for proper destruction of the virus particle that the antibody "tells" the immune system to "take care of this enemy."

Nanoviricides, in contrast, do not require the patient to have a functionally good immune system because a nanoviricide is designed as a complete nanomachine that completes the task of dismantling the virus particle. This is important because most persons with good immune systems, when infected with a virus, experience only mild infections, and may not even notice symptoms. Persons with an immune system that is not sufficiently active are the ones that would suffer severe viral infections. Additionally, viruses have evolved to block various steps in the human immune system response, thus derailing the immune system once the infection takes hold.

NanoViricide Drugs Are Designed To Act By A Novel Mechanism of Action, "Re-Infection Inhibition", To Reduce Viremia

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 a well-known physical chemistry effect called "lipid-lipid mixing." In the process, the specific glycoproteins that the virus uses for binding to the cell (for example, the HIV gp120, RSV-G protein, Influenza H and N proteins, Coronavirus S or "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 of nanoviricide by the name "Re-Infection Inhibition."

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-Engulf-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.

NanoViricides Platform is Designed for Safety

We create the polymer that makes the nanoviricide micelle by using naturally metabolizable and safe components. Additionally, the antiviral ligands that we attach to the base polymer are designed using molecular modeling (or "in-silico" design) while using generally safe component chemicals and chemistries.

The nanoviricide polymer structure is designed to directly attack the virus particles outside the cell. Therefore, we believe that interference from such nanoviricide drug with cellular machinery is likely to be minimal, thereby resulting in improved safety over drugs that must enter cells and interfere with cellular processes such as most available small chemical antivirals.

We believe that our approach for improved drug safety is validated by the demonstration of strong relevant results in animal studies of NV-387 for safety and tolerability. In a safety/toxicity evaluation of single injection in rats, NV-387 was found to have a No-Observed-Adverse-Effect-Level (NOAEL) of 1,200 mg/Kg/dose, and a Maximum Tolerated Dose (MTD) of 1,500 mg/Kg/dose, which are considered to be relatively high numbers. A drug with higher values of NOAEL and MTD is safer than one with a lower values.

Further, in the non-clinical GLP safety/toxicology studies in relevant animal models, NV-387 was found to lead to no reportable observations (i.e. no adverse events) in respiratory and neurological studies in rats and cardiotoxicity studies in a non-human primate model (cynomolgus monkey). Intravenous infusion of NV-387 did not have any toxicologic effects on cardiac rhythm or ECG morphology in cynomolgus monkeys. Intravenous infusion of NV-387 did not affect respiratory function and no significant neuropharmacological or behavioral effects were observed in rats. Body temperature was not affected by the drug treatment in either the rat or the NHP animal model study. All of these results are indicators that the drug NV-387 was well-tolerated in these animal models and thereby enabled us to obtain regulatory approvals to begin Phase Ia/Ib human safety/tolerability studies in healthy subjects.

NV-387 was found to be non-immunogenic, non-allergenic, non-mutagenic, and non-genotoxic. As such carcinogenicity studies are not required.

Consistent with the above non-clinical data, in a Phase Ia/Ib clinical trial evaluating the safety and tolerability of NV-387 treatment in healthy adult human subjects, there were no discontinuations, there were no adverse events reported, and there were no serious adverse events reported, even at the highest dosage levels in both single dosing and multiple dosing protocols.

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 activity when administered orally in multiple animal models. Most nanomedicines do not possess significant oral bioavailability and therefore they 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.

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 needed for pediatric treatments. Both of these formulations have been evaluated in the Phase Ia/Ib human clinical trial of NV-387.

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-387 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 of 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.

Thus, the unique versatility of the Nanoviricide Platform has enabled creation of a drug NV-387 in multiple formulations that allow usage across all segments of the population from children to healthy adults to geriatric patients, as well as administration across all levels of disease severity from at-home mild to moderate cases (oral syrup and oral gummies) and out-patient moderate-to-severe cases (injections), to in-patient severe cases (injections and infusions), to in-patient severe-to-morbid cases (infusions and inhalations).

Nanoviricides Represent the Next Generation Development Beyond Classical Immunotherapeutics (Antibodies and Vaccines)

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 host side attachment receptor or the cognate receptor (see below). These ligands are chemically attached to the base polymer or “nanomicelle,” to create a nanoviricide.

When a nanoviricide nanomicelle “sees” a virus particle, several of these ligands associated with the nanomicelle are expected to bind to the virus particle. 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, in a “nano-Velcro” effect. This attack is expected to result in loss of the viral glycoproteins that the virus uses to bind to cell and to fuse with the cell membrane, thus rendering the virus particle non-infectious.

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”). Also, for small molecules to possess sufficient affinity to the virus particle, they must be designed to be very specific to the viral glycoprotein structures. Therefore, entry inhibitors can be rapidly rendered ineffective as the virus changes.

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, in contrast to a nanoviricide that is expected to bind to the virus at multiple points.

For an antibody to be successful as an antiviral drug, as many as ten to fifteen antibodies must bind to saturate the virus surface. Therefore successful antiviral antibodies are highly specific to the virus glycoproteins and rapidly become ineffective as the virus changes.

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, the Ebola epidemic of 2014-15, or the COVID epidemic that is continuing now as a perennial phenomenon. 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 on the nanomicelle, 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.

Drug Manufacturing and Quality Control Considerations Are Inherent in the Design of a Nanoviricide

Uniform Polymer Nature Of The Nanoviricide Polymer Enables Simplified Nanomedicine Manufacturing Quality Assurance

A major problem in the field of nanomedicines as well as lipid-nanoparticles (LNPs) has been that most nanomedicines and LNPs 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 and particularly LNPs 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 generally difficult to control and characterize. 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 characterized 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.

Formulation is Inherent in the Design Aspect of a Nanoviricide

Since developing our lead clinical drug candidate API NV-387, 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-compliance 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.

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 during drug development.

In contrast, formulation development for novel drugs in normal pharmaceutical paradigm often takes years. In particular, formulation development with nanomedicines or LNPs generally takes longer than that for small chemical drugs, due to inherent complexities discussed earlier.

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.

NanoViricide Platform Enables Drugs That Can Be Designed To Block the Complete Virus Lifecycle, Thus Enabling Potential Cure for Non-Latency Viruses

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 platform 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.

We are implementing the nanoviricides platform in different modalities leading to different types of drugs to meet the different challenges of different viruses and 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 proteoglycans that have attached onto them heparan sulfate (HSPG), dermatan sulfate (DSPG), chondroitin sulfate (CSPG), or 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.

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

NV-387, our clinical drug candidate, is the first example, to our knowledge, of such a broad-spectrum antiviral agent. NV-387 was designed using our knowledge of the commonalities in this S-PG class of attachment receptors for mimicking the host-side S-PG common motif that is used by viruses for attachment. A developed small chemical ligands that embody the characteristics of this common motif, and attached them to the base nanomicelle polymer to create NV-387. 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 now that a Phase I clinical trial of NV-387 has been completed, after the final clinical trial report for this clinical trial becomes available.

In July 2023, we reported that NV-387 was found to demonstrate increase in survival upon treatment with NV-387 indicating antiviral effectiveness against a lethal RSV infection in a mouse model study. Subsequently, in May 2024, we reported that in a subsequent study with improved dosing regimen, NV-387 was able to lead to complete survival of the animals lethally infected with RSV, and that the lungs of the NV-387 treated animals did not show lung damage caused by the RSV. In contrast, ribavirin treatment did not protect the lungs of the RSV infected animals leading to their death with a small increase in survival over the untreated animals.

In June 2024, we reported that NV-387 treatment was found to demonstrate increase in survival, substantially surpassing the increase that occurred upon treatment with three of well-known approved anti-influenza drugs, a parameter used for indicating antiviral effectiveness, in a lethal Influenza A/H3N2 lung infection mouse model study. We believe that these results suggest that NV-387 promises to be effective against the “bird flu” influenza virus H5N1 (and other similar H5Nx viruses) as well. In fact, it is well-known that the highly pathogenic avian influenza (HPAI) viruses carry a “polybasic site” that possesses HSPG binding capability. Therefore, HPAI viruses can be expected to be susceptible to NV-387.

In the reported year, we have also reported on the antiviral activity of NV-387 in animal models relevant to Smallpox/Mpox (orthopoxvirus) infections, measured by increase in survival in relevant lethal virus-challenge animal models. MPox has caused sporadic epidemics in the Western world, and a more pathogenic strain, MPOX CladeI/Ib is currently causing an epidemic in certain parts of Central Africa, which has led the WHO to declare it a “public health emergency of international concern” (PHEIC). Smallpox is considered a bioterrorism threat. Of note, tecovirimat, approved for Smallpox treatment in the USA, has failed to show effectiveness in an NIH co-sponsored international clinical trial for the treatment of MPOX Clade 1 infections (https://www.nih.gov/news-events/news-releases/antiviral-tecovirimat-safe-did-not-improve-clade-i-mpox-resolution-democratic-republic-congo). Therefore, we believe it would be of interest to assess whether NV-387 has effectiveness in MPOX infected patients.

We intend, subject to financing, to further explore the effectiveness of NV-387 against many other important human pathogenic viruses that are known to utilize S-PG attachment receptors. For example, Nipah virus causes sporadic lethal outbreaks in India and Bangladesh in particular. We would like to explore if NV-387 can be an effective drug against Nipah and the related Hendra viruses (henipaviruses). Additionally, Ebola and Marburg viruses (filoviruses) are also known to utilize HSPG attachment factor. We would like to explore if NV-387 can be an effective drug against filoviruses. Filoviruses are important for the US Department of Defense as well as from Biodefense perspective. Currently there is no approved treatment for filoviruses or for henipaviruses. Such expansion of use of NV-387 would significantly expand the market size, provide much needed medical countermeasures for public health protection globally, 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 host-side receptor(s) does not change.

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

Choosing a specific antiviral ligand that mimics the cognate receptor on the host cell that is used by the virus would lead to specific nanoviricide agents that would attack the viruses that use that particular cognate receptor. This technique is what we call Modality 2.

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

Our antiviral drug candidate NV-HHV-1 is based on mimicking the cognate receptor HVEM ("herpesvirus entry mediator") that is known to be used by HSV-1 and HSV-2. We found that NV-HHV-1 demonstrated antiviral activity against VZV (Varicella Zoster Virus) in human skin patch infection model studies, although it was not then known whether VZV uses HVEM as the cognate receptor. 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 as a skin cream for the treatment of VZV Shingles. During the development of NV-HHV-1, nanoviricides made with the same or related ligands as the one used in NV-HHV-1 were found to have demonstrated antiviral activity against HSV-1 in cell culture studies as well as in lethal infection animal model studies. Since HSV-2 also uses HVEM as entry receptor, we believe NV-HHV-1 should be effective against HSV-2 as well. In addition to developing NV-HHV-1 for the indications involving infection by VZV, HSV-1, and HSV-2, we further plan to explore the activity of NV-HHV-1 against other herpesviruses such as CMV and EBV as well.

Additionally, 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-19 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.

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.

We have also developed other drugs based on this concept of curing the viral infection. One such drug is NV-387-Rp, which contains a modified and improved form of Remdesivir. Another drug 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

Our 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-387, 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, for 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 I and Phase II 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.

We have several drugs in our pipeline, enabled by our strong and extensive nanoviricide technology platform. Of these, NV-387 has completed a Phase Ia/Ib Clinical Trial in healthy subjects with no adverse events reported in both the single-dose and multiple-dose portions of the clinical trial, and we have now received a draft Phase I report that is in quality review from the CRO and the clinical trial manager, KMPL. Absence of any reportable adverse events is considered an excellent indication that the drug is safe and well tolerated in the Phase Ia/Ib clinical trial.

Presently, our focus is on the two separate Phase II clinical trials for NV-387 for the treatment of (i) MPox Virus Infection, and (ii) Viral Acute and Severe-Acute Respiratory Infections (Viral ARI and SARI). We are preparing the clinical trial application for the Phase II MPox trial and we have already obtained preliminary approval from the regulatory ethics committee for the clinical protocol in the Democratic Republic of Congo (DRC). In addition, we have already developed a draft clinical protocol for the Phase II Viral ARI and SARI clinical trial that is now in planning stage.

We plan on further commercial development of NV-387 as a pediatric RSV treatment once additional resources to support the RSV clinical program become available. We plan on re-engaging our HerpeCide program and our HIV program when sufficient resources become available.

We also plan on further developing NV-387 for the treatment of Smallpox as a biodefense application, via the US FDA "Animal Rule". Our work in developing NV-387 for MPox is providing enabling datasets towards approval of NV-387 as a treatment for smallpox because both of these are orthopoxviruses. We are seeking non-dilutive funding for the development of NV-387 for smallpox, a bioterrorism threat.

Additionally, we believe that NV-387 may have effectiveness against many other viruses including viruses that do not have current treatments such as Henipaviruses (Hendra and Nipa viruses), filoviruses (Ebola and Marburg viruses), other hemorrhagic viruses of interest to the Department of Defense, among others. NV-387 mimics Sulfated Proteoglycans that more than 90% of human pathogenic viruses utilize as the first landing site in causing an infection. We plan on seeking collaborations with labs that can broadly test our drugs against multiple viruses as well as non-dilutive funding for such developments.

We also have several additional pre-clinical drug development programs including NV-HHV-1 and related candidates for Herpes Simplex Viruses (HSV-1 that causes cold sores, and HSV-2 that causes genital ulcers), NV-HIV-1 and related candidates for HIV/AIDS, other candidates for Influenza viruses and Dengue viruses, that we plan to advance further towards clinical drug candidates as they progress further when financial resources become available. 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 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, a Phase II-ready clinical stage drug candidate, is an example of Modality 1 nanoviricides,whereas NV-HHV-1 and NV+HHV-2 are examples of Modality 2 nanoviricides.NV-HHV-1 has completed IND-enabling studies as a Skin Cream for the treatment of Shingles.

We have also continued R&D on Modality 3 nanoviricide drugs that promise potential cures for non-latency viruses. As examples of this technology, 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 their 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 approximately 40 different indications of different viral diseases in a number of drug development 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.

Additional details of our drug pipeline can be found in this Annual Report 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 to create 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 the level (or potency) 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 quantities 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, as well as the completely finished and packaged clinical drug product batches.

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 Phase II clinical trials of NV-387 for MPox, for Viral ARI/SARI, as well as for RSV. In general, the manufacturing capacity is sufficient for all of the anticipated clinical trials of our drug candidates in the near future. Further, this cGMP-compliant manufacturing capacity is anticipated to be sufficient for commercialization of NV-387 for treatment of pediatric RSV subsequent to required regulatory approvals thus enabling rapid market entry and future revenue generation.

Our cGMP-compliant manufacturing facility is equipped with Class 100 (ISO 5), Class 1,000 (ISO 6), and Class 10,000 (ISO 7) clean room suites for injectables and other manufacturing operations as appropriate.

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 either employ an external Contract Manufacturing Organization (CMO) for our injectable drug products for clinical trials, or develop in-house injectables manufacturing capabilities utilizing our existing Class 10,000 (ISO 7) clean room suites with Class 100 (ISO 5) enclosures housed inside them, 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 surface glycoprotein of the virus that we want to study (e.g. H5 for H5Nx Bird Flu, GP for Ebola, Marburg, S for SARS-CoV-2, 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.

NanoViricides Campus – Fully Owned Asset Group

All of the facilities described above, the land, building, improvements, and equipment, are fully owned by NanoViricides, Inc. This forms a significant and stable part of our long term assets, accounting for over $6.8 million in long term assets post-depreciation and amortization as of June 30, 2025. The replacement cost of these assets was estimated, in April 2024, at $18 million by a third party consultant, which we believe is a low-end estimate.

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 2025 in Review

In the fiscal year 2025, we have achieved a substantial level of accomplishments. We have focused on evaluating the broad spectrum of antiviral activity of NV-387. We have been able to significantly expand the potential indications of viral infections wherein NV-387 could be a drug candidate worthy of pursuing into clinical trials, to include the respiratory viral infections RSV and Influenza, in addition to the coronaviruses, as well as Smallpox/Mpox, and now to include Measles virus.

During this year, we have focused on developing a cost-effective regulatory strategy for NV-387. We have reprioritized our development plans based on our resources.

We have engaged in a number of activities necessary for initiating our very first Phase II clinical trial(s) of NV-387, which is for the evaluation of NV-387 as a treatment of MPox. We are developing the Clinical Trial Application at present, and we have already obtained a preliminary approval for our clinical trial protocol for this clinical trial from the regulatory agency in charge, namely ACOREP in DRC.

We have also developed a clinical trial protocol for a novel, adaptive, “basket-type” Phase II clinical trial for the evaluation of NV-387 as a treatment of viral acute and severe-acute respiratory infections. We are now planning this clinical trial. In this single clinical trial, we anticipate generating data on the effectiveness and safety in patients of NV-387 against a number of different respiratory viruses, including Influenza viruses, RSV, Coronaviruses, human MetaPneumovirus (hMPV), and many others. In particular, we believe the data in adult subjects will enable a Phase II clinical trial of NV-387 in pediatric population (children).

We have improved the manufacturing process of NV-387. In doing so, we have approximately doubled the production scale of the drug substance NV-387 resulting in a batch size producing approximately 6kg of the purified drug substance with a 10kg scale feasible.

We have developed and validated improved methods for the quantitation of drug substance related impurities.

We have developed and validated a new and improved method for analysis of NV-387 in biological samples such as animal and human plasma, which is required for pharmacokinetic studies.

We have improved the process of manufacturing the drug product NV-387 Oral Gummies, which we plan to take into the first Phase II clinical trials. We have improved the NV-387 Oral Gummies formulation for organoleptic properties, by improving its color, flavor, taste, and mouthfeel.

We have engaged a CRO, identified and engaged a clinical trial site, and obtained initial permission from the Ethics Committee for the proposed Phase II clinical trial for evaluation of NV-387 for the treatment of MPox in DRC.

We have also performed preliminary work and developed a clinical trial protocol for a first-of-a-kind, innovative, adaptive, “basket-type” Phase II clinical trial for the simultaneous evaluation of NV-387 for effectiveness against a number of respiratory viruses in a single clinical trial.

We have engaged in efforts to obtain non-dilutive funding for several of the developments related to NV-387 that would be of interest to various governmental agencies.

NV-387 Phase Ia/Ib Human Clinical Trial

NV-387 was developed during the COVID pandemic in a very rapid timeframe. In just about a year, we went from design and synthesis to completing the required non-clinical GLP safety pharmacology studies in animals by January 2021. The progress slowed down primarily due to lack of internal regulatory expertise and dependence on external consultants that became unavailable. We successfully completed a Clinical Trial Application for the simultaneous evaluation of two oral drug products containing the same API NV-387, namely NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies, sponsored by our licensee, collaborator, and clinical trial manager, Karveer Meditech Pvt. Ltd. (KMPL) who sponsored the drug in India, with a local CRO, around September 2022, and KMPL obtained regulatory permission for the clinical trial towards the end of January 2023.

The Phase Ia/Ib clinical trial began with the first human dosing in June 2023. The healthy subjects part of the clinical trial, comprising both Phase Ia – Single Ascending Dose – Healthy Subjects, and Phase Ib – Multiple Ascending Dose – Healthy Subjects was completed with discharge of the last subject around December 2023. There were no dropouts and no reported adverse events. These results are generally taken as indicators that a drug is well-tolerated under the conditions of treatment in a clinical trial.

The results of this Phase Ia/Ib healthy subjects part of the clinical trial are consistent with the results of the non-clinical studies in multiple animal models in which good tolerability was observed and no respiratory, cardiological, or neurophysiological effects were found.

The clinical trial application for this clinical trial was submitted during the COVID-19 pandemic and for expediency towards use of the drug in the pandemic, a separate part of the clinical trial for the treatment of COVID-19 patients with NV-387 was also proposed. Upon completion of the Healthy Subjects part, the Sponsor and the CRO went through tremendous efforts and obtained regulatory permission to add another site where a COVID-19 wave was going on during January 2024. However, by the time all of the approvals required to start enrollment were completed, the COVID-19 wave was completely gone. After performing a large number of RT-PCR tests on potential subjects with respiratory symptoms, with all tests turning up negative results for SARS-CoV-2, this second part of the clinical trials was canceled due to the inability to find patients to enroll in spite of adding a second site. The second site was subsequently closed around April/May 2024.

Concurrently data upload and crosschecking activities for the healthy subjects Phase Ia/Ib part were completed. After appropriate external audits, the drug sponsor is now getting ready to close the first clinical trial site where the healthy subjects part was executed. Thereafter, subsequent to database lock, statistical analysis of the observations of the subjects will be performed. These include a number of parameters including clinical observations, blood chemistry, and specific organ-related blood chemistry parameters, among others.

A draft Clinical Study Report (CSR) for this clinical trial comprising all of the studies has been compiled recently by the CRO and it is undergoing quality reviews as of the date of submission of this Annual Report. We anticipate completion of this process within a few weeks and submission of the final CSR to the Indian regulatory body, namely, The Central Drugs Standard Control Organisation of India (CDSCO).

Evaluating the Broad Antiviral Activity Spectrum of NV-387 Against Multiple Different Types of Viruses

As the Phase Ia/Ib clinical trial in India for evaluation of safety and tolerability of NV-387 in healthy subjects got under way, we embarked on determining whether NV-387 could be sufficiently active to be chosen as a clinical drug candidate against many different types of viruses other than coronaviruses. This work has spanned several years, and is cited here because it is important to understand the effectiveness of NV-387 in animal models in order to understand our development program for NV-387.

NV-387 was designed as a Sulfated Proteoglycan (S-PG) Mimetic. Over 90% of human pathogenic viruses are known to use heparan sulfate proteoglycan (HSPG) in particular as an attachment receptor to enable them to infect cells. NV-387 mimics the critical feature that the viruses look for in not just HSPG but other related S-PGs such as Chondroitin Sulfate (used by the Chikengunya virus), Dermatan Sulfate (used by Human Papilloma Viruses - HPV), among others. HSPG is used by almost all respiratory viruses. We therefore focused on viruses that use HSPG for our first studies. In particular, we studied activity of NV-387 in animal models of lethal lung infections by the respiratory viruses RSV and Influenza. Since orthopoxviruses are known to bind to HSPG, we also evaluated activity of NV-387 against lethal infection by the model mousepox virus (Ectromelia) that is used as a part of the US FDA Animal Rule for the development and approval of Smallpox therapeutics.

Activity of NV-387 in Lethal Lung RSV Infection in Mice – NV-387 Oral Treatment Appears to Have Cured Lethal Lung RSV Infection Based on Complete Survival and No Lung Damage

In the first animal trial, we compared the effect of NV-387 given as both injectable and as oral treatment in mice infected lethally into the lungs with RSV A2 virus. We found that NV-387 demonstrated excellent anti-RSV activity, almost matching the activity of ribavirin

as shown in the table below. Ribavirin is the only drug currently approved for treatment of RSV infection. However it is used only as a last resort drug because of its significant toxicities, including hematological and nephrological (kidney) adverse effects.

Survival Lifespan of Lethally Infected Mice - Lung Infection with RSV A2			
Treatment	**Survival, Days**	**Increase in Survival, Days**	**Increase in Survival, %**
NV-387, Injection	**15**	**8**	**115%**
Ribavirin, Injection	**16**	**9**	**129%**
Vehicle for Injection	**7**	**0**	**-**
NV-387, Oral	**15**	**8**	**115%**
Ribavirin, Oral	**16**	**9**	**129%**
Vehicle for Oral	**7**	**0**	**-**

Treatment of lethally infected mice in this study with NV-387 or ribavirin led to statistically equivalent positive effect on the outcome of the disease. Since ribavirin is highly toxic, the activity of NV-387 demonstrated in this study is of great significance.

Importantly, NV-387 given orally at approximately twice the total dose of NV-387 given as an injection produced equivalent results in terms of effect on animal survival. Thus, the oral bioavailability of NV-387 can be estimated, in terms of actual biological effects, to be approximately 50% based on this animal study. We believe that this level of effective bioavailability is excellent and it would permit development of NV-387 as an oral drug for treatment of RSV infection.

We reported on this study in a press release dated July 11, 2023.

Encouraged by the results of this animal trial, we initiated a new trial with oral dosing of NV-387 extended to ten days with two doses on first day for a total of eleven doses. We also increased the dosing of ribavirin in this second animal trial. The results of this trial are shown in the table below.

Survival Lifespan and Lung Microhistopathology of Lethally Infected Mice - Lung Infection with RSV A2				
Treatment	**Survival, Days**	**Increase in Survival, Days**	**Increase in Survival, %**	**Lung histopathology**
NV-387, Oral	**Complete**	**Cured**	**Cured**	**No Lung Damage**
Ribavirin, Oral	**14**	**6**	**75%**	**Immune Infiltration, Pneumonia**
Vehicle, Oral	**8**	**0**	**0%**	**Immune Infiltration, Pneumonia**

We were pleasantly surprised to find that the increased oral dosing of NV-387 led to complete survival of all of the lethally lung-RSV-infected mice, well beyond the 21 day study length, and they remained healthy until final sacrifice as per protocol at 30 days. The performance of oral ribavirin was similar to its performance in the previous trial, and possibly slightly worse, indicating that the dosing level of ribavirin in this trial might be close to evidencing its toxicity.

We reported on these results in a press release on May 14, 2024.

Further analysis of gross histology as well as micro- histopathology of lungs from the animals treated with NV-387 compared to ribavirin was also conducted.

The lethally RSV-infected animals in the NV-387-treated group showed no lung damage in lung histo-pathology study at all-time points during the study, including at the end of the study. This demonstrates that the NV-387 oral treatment completely protected the animals from the lethal effect of RSV infection. These results are consistent with the complete and healthy survival of the animals.

In contrast, lethally infected animals in the ribavirin oral treatment group showed progressive lung pathology, demonstrating progressive inflammation in the lung tissue which resulted in moderate levels of inflammation as well as infected cells in the inflammatory infiltrate on day 10, increasing to severely infected lungs with alveolitis and severe pneumonia by day 13. All animals in the ribavirin-treated RSV infected group died by 14 days as shown in the table.

These lung histo-pathology results in conjunction with the complete survival of NV-387 orally treated animals support our belief that NV-387 oral treatment led to complete cure of the lethal RSV infection in mice in this animal trial.

We reported on these results in a press release on May 20, 2024.

Based on these results, we have determined to seek regulatory approval for a Phase II human clinical trial for the evaluation of efficacy of oral NV-387 treatment in RSV infection.

Activity of NV-387 in Lethal Lung Influenza Infection in Mice - NV-387 Treatment Resulted in Significantly Greater Survival Improvement Compared to Three Approved Influenza Drugs, and Significantly Increased Protection of Lungs from Virally Induced Damage

We evaluated the activity of NV-387 given orally (twice on first day then once daily, 8 days, total 9 doses) in comparison with the three approved drugs, oseltamivir (Tamiflu®, Roche) given orally (twice daily for 8 days), baloxavir (Xofluza®, Shionogi, Roche) given orally as a single dose, and peramivir (Rapivab®, Biocryst) given by tail-vein injection once daily for 8 days. The survival lifespan results are shown in the table below.

Survival Lifespan of Lethally Infected Mice - Lung Infection with Influenza A/H3N2			
Treatment	**Survival, Days**	**Increase in Survival, Days**	**Increase in Survival, %**
NV-387, Oral	**15**	**7**	**88%**
Oseltamivir (Tamiflu), Oral	**10**	**2**	**25%**
Peramivir (Rapivab), Injection	**11**	**3**	**38%**
Baloxavir (Xofluza), Oral	**11**	**3**	**38%**
Vehicle, Oral	**8**	**0**	**-**

We were pleasantly surprised to find that the NV-387 oral treatment led to nearly 2.5 to 3 three times more increased survival compared to the three approved drugs, by 7 days, whereas the three approved drugs led to a survival of only 2 to 3 days over vehicle-treated animals that survived 8 days.

We reported on these results in a press release dated May 6, 2024.

We also studied the effect of NV-387 treatment on the lung mucus index, as well as lung immune cell infiltration in this animal trial. Lung mucus index is a parameter that measures the lung congestion and relates to pneumonia symptoms. Lung immune cell infiltration relates to virally induced lung damage that is actually caused by the cytotoxic cells of the immune system that kill infected cells. The results are shown in the table below.

NV-387 Oral Treatment Significantly Protected Lungs of Balb-c Mice Lethally Infected with Influenza A/H3N2 Virus		
Treatment	**Lung Mucus Index**	**% Immune Cell Infiltration**
NV-387, Oral	53	31%
Untreated Infected Control	138	68%

We found that NV-387 significantly reduced lung mucus index, as well as cell-killing immune cell infiltration into the lungs. The results indicate that NV-387 oral treatment resulted in significant reduction in lung infiltration and lung cell death. Lungs of infected animals treated with NV-387, orally, showed very limited presence of infiltrating cell-killing immune cells that are known to be an important cause of lung damage, in addition to the direct lung damage from infected cell death caused by the virus itself. Further, the overall lung damage was found to be significantly reduced upon NV-387 treatment.

The results further indicated that NV-387 treatment resulted in significant reduction in mucus load in the lungs. The extent of mucus in the lung tissue was substantially reduced in the case of NV-387 treatment a positive finding. The mucus index value in the case of NV-387 oral treatment was about 53, as compared to the infected untreated animals that had a mucus index value of 138. Mucus is secreted by secretory cells in response to viral infection in an attempt to clear the virus, but it results in reduced lung capacity and eventually can lead to pneumonia. Thus, reduction in mucus load is an important sign that the progress of the viral infection is arrested.

These results indicate that NV-387 treatment led to a significant level of protection of lungs in Balb-c mice lethally infected with Influenza A H3N2 virus.

We reported on these results in a press release on June 20, 2024.

Given the broad range of activity of NV-387 against different types of viruses, we believe that these results of activity of NV-387 against Influenza A/H3N2 lead us to believe that NV-387 likely possesses significant activity against other influenza viruses as well, including high path avian influenza (HPAI; H5Nx Bird Flu).

It is important to note that resistance against small chemical influenza drugs has emerged. The amantadine class of drugs is now largely ineffective. Oseltamivir resistant mutants are known. Peramivir is not used very much for various reasons. In a Phase III clinical trial of baloxavir, over 10% of the patients were found to have the virus evolved into resistant mutants.

Thus NV-387 with its broad spectrum and unlikely escape of virus is expected to become an important weapon in the treatment of influenza virus infections.

Activity of Oral NV-387 in Lethal Intra-digital Poxvirus Infection in Mice Matched that of Approved Drug Tecovirimat; Activity of Combination of NV-387 and Tecovirimat was Significantly Better than Either Drug Alone

We conducted evaluation of activity of NV-387 compared to the approved drug tecovirimat (TPOXX®, SIGA) in a lethal model of mousepox (ectromelia) virus intra-digital footpad infection in mice. This model emulates the virus infection by transfer of virus via skin

abrasion, a mode of infection that has been found to be the dominant mode in Mpox virus epidemics in the West. The results are shown in the table below.

Survival Lifespan of Lethally Infected Mice – Intra-digital Footpad Infection with Ectromelia Virus			
Treatment	**Survival, Days**	**Increase in Survival, Days**	**Increase in Survival, %**
NV-387, Oral	**14**	**6**	**75%**
Tecovirimat (TPOXX), Oral	**14**	**6**	**75%**
NV-387-m-T, Oral	**17**	**9**	**112%**
Vehicle, Oral	**8**	**0**	**-**

In this trial, we found that the activity of NV-387 matched that of tecovirimat, the approved drug for smallpox which was used in the recent MPox epidemics in the West. Both drugs led to approximately 75% increase in survival of the animals. Moreover, treatment with an oral co-formulation of NV-387 and tecovirimat together developed by us (that we call NV-387-m-T, "m" for "mixed-in"), led to a significantly increased survival improvement of about 112% compared to either drug given alone.

We reported on these results in a press release dated November 14, 2023.

Activity of Oral NV-387 in Lethal Lung Poxvirus Infection in Mice Matched that of Approved Drug Tecovirimat; Activity of Combination of NV-387 and Tecovirimat was Significantly Better than Either Drug Alone

We also conducted evaluation of activity of NV-387 compared to the approved drug tecovirimat (TPOXX®, SIGA) in a lethal model of mousepox (ectromelia) virus lung infection in mice. This model emulates the virus infection that would be caused in the case of aerosolized virus, a mode of infection likely in a potential bio-terrorism attack, and that was also observed in natural smallpox epidemics. The results are shown in the table below.

Survival Lifespan of Lethally Infected Mice – Lethal Lung Infection with Ectromelia Virus			
Treatment	**Survival, Days**	**Increase in Survival, Days**	**Increase in Survival, %**
NV-387, Oral	**15**	**7**	**88%**
Tecovirimat (TPOXX), Oral	**16**	**8**	**100%**
NV-387-m-T, Oral	**19**	**11**	**138%**
Vehicle, Oral	**8**	**0**	**-**

In this trial, we found that the activity of NV-387 substantially matched that of tecovirimat, the approved drug for smallpox which was used in the recent MPox epidemics in the West. Both drugs led to approximately 85-100% increase in survival of the animals. Moreover,

treatment with an oral co-formulation of NV-387 and tecovirimat together developed by us (that we call NV-387-m-T, “m” for “mixed-in”), led to a significantly increased survival improvement of about 138% compared to either drug given alone.

We reported on these results in a press release dated May 8, 2024.

Activity of Oral NV-387 in Lethal Lung Infection by Measles virus in humanized CD150-knock-in Mice Indicates NV-387 Would be a Drug Candidate for Treatment of Measles for Regulatory Development

We performed a study to evaluate the potential effectiveness of NV-387 in a lethal lung viral infection caused by measles virus in humanized hCD150+ (knock-in) mice. Measles requires the human CD150 cognate receptor to be expressed on the immune cells to cause productive infection. Therefore, it was necessary to use humanized mice.

We hypothesized that NV-387 could be an effective candidate because measles virus first binds to the HSPG as attachment receptor, concentrating next to cells to mount an attack by binding to the CD150.

In this lethal humanized animal model of respiratory infection with measles virus, NV-387 increased survival of animals to 17 days on average compared to 7.4 days in untreated animals, an increase of 130%. There were no signs of toxicity from the drug NV-387. Additionally, dose-dependent increase in survival was observed. These data demonstrate that NV-387 could be an effective drug for the treatment of measles.

We published these data in a press release on July 21, 2025.

Development Program for NV-387

With this broad-spectrum activity of NV-387 against a large number of substantially different types of viruses, we have now developed a cost-effective strategy for further development of NV-387 towards commercialization that would potentially enable non-dilutive funding, rapid approval pathways, and early revenues.

Smallpox, Biodefense, and the US FDA Animal Rule

Tecovirimat (“TPOXX®”, SIGA Pharmaceuticals) is an approved smallpox therapeutic. It was mobilized from the US Government stockpile for the treatment of Mpox infection during the recent MPox epidemic. Additional therapeutics that work with Tecovirimat such as NV-387 may reduce the required dosage and dosing period enabling rapid patient recovery.

Smallpox-causing Variola virus is considered a significant biodefense threat. While smallpox vaccines are available, their general public health usage has stopped after Smallpox was declared eradicated in 1980, leaving persons under the age of about 45 vulnerable.

Tecovirimat is stockpiled by the Biomedical Advanced Research and Development Authority (BARDA) under Project BioShield. BARDA awarded an original development and procurement contract worth approximately $435 million to SIGA in 2011, followed by another procurement contract in 2018 upon regulatory approval worth approximately $629 million. SIGA announced in July 2023 that it has received new procurement orders of approximately $138 million for TPOXX from the U.S. Government. SIGA booked approximately $85 million in sales in the first 6 months of 2025 and disclosed additional awards of $27 million to support further development and manufacturing of tecovirimat according to their press release in August, 2025. These numbers clearly indicate the revenue potential for a smallpox treatment.

There is significant interest in the development of a smallpox therapeutic drug that works well by itself, as well as in combination with the known drug, tecovirimat. Tecovirimat has a low barrier of virus escape - a single mutation in one protein can enable the virus to escape this drug, adding to the significance of additional smallpox drug development.

Since human clinical trials are not feasible for the deadly Variola virus, infection of the related animal viruses in their native species is used for evaluation of drug effectiveness under the FDA “Animal Rule.” Variola (Humans), Mpox (Monkeys), Ectromelia (Mice), and Rabbitpox (Rabbits) are some of the closely related pathogenic viruses belonging to the Orthopoxvirus genus (with their native hosts listed in parentheses).

The animal-rule based efficacy studies conducted under GLP conditions substitute for the usual Phase II/III human clinical efficacy trials for regulatory approval under the Animal Rule. Additional human safety clinical studies are expected to be required.

The Animal Rule pathway is expected to enable rapid regulatory development of NV-387 as a smallpox therapeutic towards approval. In addition, the data from our Phase II clinical trial evaluating NV-387 as a treatment of MPox, assuming positive results, should enable approval of NV-387 for treatment of smallpox as well, since both are orthopoxviruses.

MPox is a Potential Global Pandemic Threat and There is No Effective Treatment – An Unmet Medical Need

MPox is the disease caused by infection by the virus called MPXV (Monkeypox virus). A first declaration of Public Health Emergency of International Concern (PHEIC) for MPox Clade II was made by the WHO in July 2022, and it continued for approximately one year thereafter. Spread of MPXV Clade II from African countries into the Western World led to this declaration, which is short of a declaration of a pandemic. MPXV Clade II is contagious but requires sustained bruising skin contact. It has remained limited, driven primarily by sexual contact, in the MSM and associated population in the Western World, including the USA. This ongoing outbreak of Clade 2 MPox has spread to 122 countries and is now considered endemic, including in the Western World.

MPox Clade Ia is endemic in many African countries including the DRC. A rapid increase in cases of MPox prompted the Africa CDC to declare a regional Public Health Emergency of Continental Security (PHECS) on August 10, 2024. Children were the majority of cases associated with this new outbreak, caused MPox Clade Ib, a new variant of Clade I, unlike previous outbreaks that primarily affected adults. WHO followed with a new PHEIC declaration on August 14, 2024. The virus continued to rage through DRC and spread through neighboring countries. Initial scattershot vaccination effort in DRC using Jynneos did not control the spread of the virus. The PHEIC was ended by the WHO on September 5, 2025, but the Africa CDC has continued the regional PHECS declaration citing new surges emerging in Ghana, Liberia, Kenya, Zambia, and Tanzania, with fresh introductions of the virus reported in Malawi, Ethiopia, Senegal, Togo, The Gambia, and Mozambique (https://africacdc.org/news-item/mpox-still-a-continental-emergency-africa-cdc-advisory-group-recommends/).

The MPox virus circulating in DRC and neighboring regions is of Clade Ia and Clade Ib subtypes, with the latter predominant. Clade Ib is more transmissible of the two, which is why it has resulted in a sustained epidemic. The MPox Clade Ia case fatality rate (CFR) is about 3%-11%whereas the CFR for Clade Ib is about 1%. The MPox Clade IIb is the virus causing continuing cases in the Western world, which causes a much less severe disease than Clade Ia/Ib and has a very low CFR, according to CDC. Sporadic cases of Clade I in the Western World continue to occur. Six separate travel-related MPox Clade I cases were reported in the USA that did not result in any further spread, since November 2024, according to the CDC (https://www.cdc.gov/mpox/situation-summary/index.html).

MPox Clade II primarily causes localized rash that is very painful and persists for several days or months. MPox Clade I generally causes rash all over the body, and also inside the oral cavity, which is very painful and also affects the ability of the patient to swallow, causing food intake issues and leading to hospitalization.

A 2-dose vaccine called Jynneos (Bavarian Nordic), originally developed for smallpox (caused by the Variola virus) has been approved for MPox. Jynneos is a live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus.

While vaccination has started in DRC, overall, the uptake of available vaccines has remained lower than anticipated due to logistical, operational, and financial barriers, according to the report of the International Health Regulations (2005) (IHR) Emergency Committee for MPox of the WHO on June 5, 2025.

There is no treatment for MPXV Clade II or for Clade I, and this remains an unmet need. Tecorimat, approved for smallpox under the US FDA Animal Rule, failed in clinical trial to demonstrate efficacy. Brincidofovir entered a clinical trial for evaluation as a treatment for Mpox in January 2025, and was expected to have topline results available by March 2025. The status of this clinical trial is unknown. Brincidofovir is not applicable across all population because of several side effects and a black box warning as described in its prescribing information.

NV-387 was found to have strong activity against an animal model of orthopoxvirus infection which is a standard model used for both Smallpox and MPox therapeutics developments. NV-387 activity in the dermal infection model as well as the direct lung infection model was at least equivalent to that of tecovirimat. Based on the broad spectrum of activity of NV-387, this drug is not expected to carry the

liability of virus escape by a single point mutation that is known to be possible upon treatment with tecovirimat. NV-387 treatment did not result in any reportable adverse events in a Phase I clinical trial in healthy subjects, indicating excellent safety, unlike the black-box-warning and adverse event liabilities described in the brincidofovir prescribing information.

Thus we believe that NV-387 has a high likelihood of success as a treatment for MPox in the Phase II clinical trial. If successful, the dataset generated would also help towards approval of NV-387 as a treatment for smallpox.

NV-387 Has a High Likelihood of Success as a Treatment of Smallpox – Biodefense Application

Further, we believe that NV-387 is a strong potential candidate for approval as a treatment for smallpox under the US FDA Animal Rule, based the animal study data. If approved, there is potential of significant revenues in hundreds of millions of dollars as well as help with manufacturing and further advanced development of NV-387 from US Government agencies.

The Importance of Treatment for RSV Infection in Pediatric Population – An Unmet Medical Need

Each year in the United States, an estimated 58,000–80,000 children younger than five years old are hospitalized due to RSV infection. Globally, RSV is a common cause of childhood Acute Lower Respiratory Infection (ALRI, which includes pneumonia) and a major cause of hospital admissions in young children. 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 five years. About 45% of hospital admissions and in-hospital deaths due to RSV-ALRI occur in children younger than six months old.

There are No Effective Treatments for RSV

Three 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. Mresvia (Moderna), an mRNA vaccine, was approved for medical use in the United States in May 2024. Abrysvo also received approval for use by pregnant women at 32-36 weeks of pregnancy in order to confer protective antibodies against RSV to the fetus for protection of infant when born despite concerns regarding premature childbirths. There are no RSV vaccines currently approved for infants and children.

However, there are no effective therapeutics for RSV to date. Ribavirin is conditionally approved only for patients with high risk of progressively severe RSV disease, due to significant side effects including hemolytic anemia and kidney failure. Synagis (palivizumab), an antibody, is approved only as a prophylactic in children and infants at high risk of severe RSV infection, but it is not approved for treatment of RSV infection. Nirsevimab (Beyfortus, AstraZenecka), another antiviral monoclonal antibody, has been approved for the prevention of RSV lower respiratory tract disease in newborns and infants during their first RSV season that requires a single dose to confer season-long protection from RSV infection. None of these drugs are approved for treatment of RSV infection after it occurs.

Market Size of RSV Therapeutics is Expected to Hit $8.73 Billion by 2031

In June 2023, GrowthPlus Reports reported that 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 (https://www.growthplusreports.com/report/respiratory-syncytial-virus-rsv-therapeutics-market/8519).

NV-387 for the Treatment of Influenza Infections

The market size for Influenza and Bird Flu is estimated at $4.6 billion in 2024, growing to an estimated $5.9 billion in three years, at a rate of 8.5% as reported by DelveInSight (https://www.delveinsight.com/report-store/influenza-a-infections-market?utm_source=cision&utm_medium=pressrelease&utm_campaign=spr). In case a pandemic occurs, reality may outrun such projections by magnitudes, as was seen with the COVID pandemic.

NV-387 Phase II for Viral Acute and Sever-Acute Respiratory Infections (Viral ARI and SARI)

We are planning a novel, adaptive “basket-type” clinical trial of NV-387 for the treatment of viral respiratory infections. In a single clinical trial, we will be able to generate data regarding the effectiveness and tolerability of NV-387 in patients affected by a number of different viral infections that include Influenza viruses, RSV, Coronaviruses (including SARS-CoV-2 that caused COVID-19 pandemic),

hMPV, as well as certain other viruses. We can then utilize the data to strategize further development for specific indications as well as for further development as an emperic antiviral therapy. In particular, we plan on utilizing the data from adult RSV patients to further the development of NV-387 as a treatment for pediatric RSV patients.

Strong Market Potential of NV-387

Thus, we believe NV-387 alone may propel NanoViricides towards great success in a near-term horizon. We plan to license or co-develop our various drug candidates against multiple viral diseases to other pharma companies. In addition, we plan to seek non-dilutive funding for the development of drugs that are of interest for biodefense.

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.

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 TheraCour-Nanoviricides Additional License Agreement ("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.

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.				

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 (KMPL)

On March 27, 2023 we entered into a license agreement with KMPL wherein we granted to KMPL 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. KMPL 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. KMPL 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, KMPL 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, KMPL will pay the Company a royalty of seventy (70%) percent of the final invoiced sales less costs to unaffiliated third parties. Dr. Anil Diwan, our Founder, President and Executive Chairman, is a passive investor in KMPL. His ownership interest does not provide him with control or significant influence over KMPL.

Trademarks

The Company currently has no registered trademarks.

Corporate Events - Financing

We had approximately $1.6 million cash in hand as of June 30, 2025, the end of the reporting period. In addition, in February 2024, we obtained a $2 million financing in the form of a line of credit from Dr. Anil Diwan, our founder, President and Executive Chairman. On September 26, 2024, this credit line was increased to $3 million, and extended to cover the period ending March 31, 2026, with no other changes in the terms. On July 1, 2025 the maturity date of the line of credit was extended from March 31, 2026 to March 31, 2027.

We spent approximately $8.5 million in cash on operating activities during the year ended June 30, 2025, an increase of approximately $2.2 over the $6.3 million in cash expenditures in the prior year ending June 30, 2024; the increase was primarily due to clinical trial expenditures and investor outreach expenses.

Additionally, we have long term assets of $6.8 million post-depreciation and amortization that represent our facilities.

We believe we have sufficient financing to close the Phase Ia/Ib clinical trial of NV-387 with completion of a final clinical study report, and additionally to perform the necessary regulatory activities in preparation of initiating a Phase II clinical trial for the evaluation of efficacy of NV-387 for the treatment of MPox infection.

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 1, 2023, our 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.

On April 5, 2024 we entered into a new sales agreement ("Sales Agreement") with EF Hutton LLC (now D. Boral Capital), the Sales Agent, pursuant to which we may offer and sell, from time to time, through or to the Sales Agent, shares of common stock having an aggregate offering price of up to $50 million (the "ATM Offering"). As of June 30, 2024 we sold 1,308,651 shares of our $0.00001 par value common stock at an average price of $2.47 under the Sales Agreement. The net proceeds from the offering were approximately $3,120,000 after deducting underwriting discounts and other offering expenses.

From July 1, 2024 through June 30, 2025 we sold 3,351,096 shares of our $0.00001 par value common stock at an average price of approximately $1.64 under the Sales Agreement. The net proceeds from the offering to the Company were approximately $5,296,000 after deducting underwriting discounts and other offering expenses.

We believe that we have several important milestones, including data from and final reports from the Phase Ia/Ib human clinical trial for our broad-spectrum drug NV-387. Additional milestones include filing of aclinical trial application for Phase II clinical trial of NV-387 for MPox indication. Anticipated approval of the CTA, and initiation of the Phase II clinical trial for MPox. Interim Datasets regarding the Safety and Effectiveness of NV-387 for the treatment of MPox, and the completion of the Phase II Clinical Trial for MPox. as Additional anticipated milestones are filing of clinical trial application for Phase II clinical trial of NV-387 for viral-ARI/SARI indication. We anticipate approval of this clinical trial application, and the initiation of the Phase II clinical trial.We also anticipate interim datasets regarding the safety and effectiveness of NV-387 for the treatment of multiple respiratory viral infections.

Additional milestones we look forward to include: orphan drug designation filing to the US FDA for NV-387 for the treatment of MPox, Orphan drug designation filing to the US FDA for NV-387 for the treatment of Smallpox, orphan drug designation filing to the US FDA for NV-387 for the treatment of Measles, Pre-IND Application filing to the US FDA for Smallpox/MPox/Orthopoxviruses, and an IND filing to the US FDA, possibly for NV-387 for the treatment of smallpox under the FDA "Animal Rule".

We plan on initiating the Phase II clinical trial to evaluate NV-387 for the treatment of MPox as soon as feasible.

We believe that as we achieve these milestones, our 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.

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. Our current plan is focused on developing NV-387 for MPox indication and for Respiratory Viruses including Influenza and RSV to the necessary stage(s) for potential collaborations, followed by similarly developing NV-HHV-1 for shingles and the follow on systemic anti-herpesviruses drug candidate in the HerpeCide program to the necessary stage(s) for fruitful 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.

Investor Outreach

We have presented at various investor and partnership conferences.

On October 28, 2024, Dr. Anil Diwan presented a talk on the Opportunities Created by the Nanoviricides Platform Technology to Enable Oral Delivery of Otherwise Injectable Drugs at the PODD Conference in Boston, MA. The PODD Conference is focused on Partnership Opportunities in Drug Delivery.

On November 04, 2024, Dr. Anil Diwan gave an Investor Presentation at the Spartan Capital Conference in New York City, NY.

On December 12, 2024, Dr. Anil Diwan gave a short Investor Presentation at the Landmark Virtual Forum.

On January 14, 2025, Dr. Anil Diwan gave a presentation focused on the Phase II-Ready Revolutionary Host-Mimetic Broad-Spectrum Antiviral Treatment, NV-387, at the Biotech ShowCase Conference in San Francisco, CA.

On January 29, 2025, Dr. Anil Diwan gave an Investor Presentation at the Micro-Cap Conference-2025 in Atlantic City, NJ.

On May 14, 2025, Dr. Anil Diwan attended and met with several investors at the networking event, D. Boral Capital Inaugural Conference, in New York City, NY.

On June 5, 2025, Dr. Anil Diwan attended the first event in the By-Invitation-Only FDA meeting "CEO Forums An FDA Listening Tour to Engage Pharma CEOs," in Silver Spring MD, where concerns of innovative small pharma developers, particularly in the rare/orphan disease space, and FDA strategies for incentivizing and speeding up such drug development were discussed by the FDA Commissioner Dr. Marty Makary and his FDA team. Dr. Makary discussed the newly unveiled FDA Commissioner's Priority Review Voucher (CNPV) program as well.

On June 16, 2025, Dr. Anil Diwan gave a Presentation on the "A Revolutionary Strategy for Viral Infections - Emperic Treatment with NV-387 is Possible (Just Like Emperic Treatment of Bacterial Infections Became Possible with Penicillin)" at the BIO International Convention 2025 in Boston, MA.

Subsequent to the reporting period:

On July 22, 2025, Dr. Anil Diwan attended the Bipartisan Commission on Biodefense Meeting in Washington DC. The Bipartisan Commission on Biodefense was established in 2014 to conduct a comprehensive assessment of the state of U.S. biodefense efforts, and to issue recommendations to foster change.

On July 23, 2025, Dr. Anil Diwan gave a Selected Presentation on "NV-387, a Broad-Spectrum, Oral, Prophylactic and Treatment of Viral Threats to Warfighter" at the CWMD/MCDC 2025 Annual Membership Meeting in Baltimore, MD. MCDC is the Medical CBRN (Chemical Biological Radiation and Nuclear) Defense Consortium. CWMD is the Countering Weapons of Mass Destruction Consortium (https://www.medcbrn.org).

On August 26 and 27, 2025, NanoViricides gave a Poster Presentation at RRPV-BioMAP Annual Meeting, Hyatt Crystal City, Washington DC. RRPV is Rapid Response Partnership Vehicle, managed and operated for the US Biodefense Agency BARDA by Advanced Technologies, Inc. Dr. Anil Diwan also had an invitational meeting and discussions with certain BARDA officials regarding the role NV-387 could play in the US National Biodefense Preparedness and Response. (https://www.rrpv.org/).

On September 17, 2025, Dr. Anil Diwan gave a Presentation on the NanoViricides Platform technology at the Life Sciences Exchange ("LSX") World Congress-2025 in the Biotech Showcase stream (https://informaconnect.com/lsx-world-congress-usa/).

On October 6-8, 2025, Dr. Anil Diwan will be attending the Greenwich Economic Forum-2025, by invitation (https://www.thegeforum.com).

Additionally, we routinely provide updates on our progress via press releases.

Business Development

As NV-387 matures past Phase I human clinical trials and towards Phase II efficacy evaluation "human proof-of-concept" stage, we believe that it should be of interest to potential collaborators for co-development and other opportunities. We have recently retained Aagami, Inc., for business development, specifically to seek licensing and partnering opportunities for our assets and platform technology. Aagami, Inc. is a life sciences consulting firm based in the suburbs of Chicago which offers strategic consulting services, business development support in regions where the client is unable to reach out due to bandwidth, technology licensing services, and business research & market intelligence services. To date, Aagami has arranged and we have conducted meetings with several potential collaborators interested in licensing and partnering opportunities for our assets and platform technology. Non-disclosure Agreements have been signed with some of the parties.

We plan on further enhancing our business development efforts in the coming year. We believe that as NV-387 advances into Phase II clinical trials, which are considered the human proof-of-concept for any pharmaceutical agent, the interest in our assets and technologies should increase.

NanoViricides Drug Programs

We are currently focused on developing NV-387 for multiple antiviral indications that include MPox, and Measles as Orphan Drugs, Smallpox for Biodefense, as well as Viral Acute Respiratory Infections (ARI and SARI), Influenza including H5N1 Bird Flu, RSV, and Coronaviruses.

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 plan on continuing evaluation of activity of NV-387 against additional viruses of interest in order to better define and harness its broad-spectrum antiviral potential.

Our Drug Programs

We have re-prioritized our drug development programs consistent with our resources.

To this end, we are focusing on advancing NV-387 into Phase II clinical trials as a treatment for MPox. The information from this clinical trial is expected to help with the development of NV-387 for the treatment of Smallpox, which we believe is an important biodefense need, based on conversations with experts in the field. We plan to pursue Smallpox drug development if non-dilutive funding becomes available.

Additionally, we are focusing on a world-first, novel, adaptive "basket-type" Phase II clinical trial for NV-387 as a treatment for viral upper respiratory infections, agnostic of the disease agent, as well as a treatment for viral lower respiratory infections, agnostic of the disease agent, in our newly developed ARI and SARI programs. The information from this clinical trial is expected to help with the development of NV-387 for the treatment of a number of respiratory viral diseases of importance, including Influenza (and Bird Flu H5N1), RSV, Coronaviruses, human-MetaPneumoVirus (hMPV), to name a few.

We plan on making NV-387 Oral Gummies available for the treatment of Measles cases under the Physician-Initiated IND Application(s) program of the US FDA. We plan on investigating the appropriate route for approval of NV-387 to treat Measles since the cases are very few and a robust clinical trial program is not feasible.

We plan to pursue NV-387 as a treatment for RSV infection towards the goal of regulatory approval for the treatment of pediatric RSV infections once we have sufficient resources to advance this important drug development program. We believe our Phase II ARI and SARI clinical trials will provide substantial information for pursuing the RSV programs forward.

We plan to pursue NV-387 as a treatment for Influenza infections once we have sufficient resources to advance this important drug development program. We believe our Phase II ARI and SARI clinical trials will provide substantial information for pursuing the Influenza and Bird Flu H5N1 programs forward.

Our high priority drug programs and approximate qualitative priority levels are described in brief in the Table 2 below.

Table 2.A. Broad-Spectrum Antiviral NV-387 - Additional Indications: MPox (Modality#1)

No.	Drug	Indications	Development Stage	Priority
1	Oral Gummies, API NV-387	• MPXV Infection (Clade Ia/b, Clade IIa/b) • Non-hospitalized • Hospitalized • Patients of all ages, pediatric to over 65; with or without co-morbidities	Phase II	A

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

No.	Drug	Indications	Development Stage	Priority
1	Oral Gummies, API NV-387	• Measles Virus Infection • Non-hospitalized • Hospitalized • Patients of all ages, pediatric to over 65; with or without co-morbidities	Ready for Physician Initiated IND, Pre-IND to file.	B

Table 2.C. Broad-Spectrum Antiviral NV-387 - Additional Indications: Smallpox (Modality#1)

No.	Drug	Indications	Development Stage	Priority
1	Oral Gummies, API NV-387	• Smallpox virus Infection • Non-hospitalized • Patients of all ages, pediatric to over 65; with or without co-morbidities	Pre-IND to file, IND-Preparation	B
2	Injectable Solution, API NV-387 Use for Injection or for Infusion	• Smallpox virus Infection • Hospitalized • Patients of all ages, pediatric to over 65; with or without co-morbidities	Pre-IND to file, IND-Preparation	C
3	Injectable Solution, API NV-387 Use for Inhalation and for Infusion	• Smallpox virus Infection • Hospitalized, Severe Disease • Patients of all ages, pediatric to over 65; with or without co-morbidities	Pre-IND to file, IND-Preparation	C

Table 2.D. Broad-Spectrum Antiviral NV-387 - Additional Indications : ARI and SARI (Modality#1)				
No.	**Drug**	**Indications**	**Development Stage**	**Priority**
1	Oral Gummies, API NV-387	● Viral Acute Respiratory Infection (ARI) ● Non-hospitalized ● Patients of all ages, pediatric to over 65; with or without co-morbidities	Phase II ready	B
2	Oral Gummies, API NV-387	● Viral Severe Acute Respiratory Infection (SARI) ● Hospitalized Patients ● Patients of all ages, pediatric to over 65; with or without co-morbidities of all ages, pediatric to over 65; with or without co-morbidities	Phase II ready	B
3	Injectable Solution, API NV-387 Use for Injection or for Infusion	● Viral Severe Acute Respiratory Infection ● Hospitalized Patients ● Patients of all ages, pediatric to over 65; with or without co-morbidities of all ages, pediatric to over 65; with or without co-morbidities	IND-Preparation	D
4	Injectable Solution, API NV-387 Use for Inhalation and for Infusion	● Viral Severe Acute Respiratory Infection ● Hospitalized Patients, Severe Disease ● Patients of all ages, pediatric to over 65; with or without co-morbidities of all ages, pediatric to over 65; with or without co-morbidities	IND-Preparation	D

Table 2.E. Broad-Spectrum Antiviral NV-387 - Additional Indications : RSV (Modality#1)				
No.	**Drug**	**Indications**	**Development Stage**	**Priority**
1	Oral Gummies, API NV-387	● RSV Infection ● Non-hospitalized ● Patients of all ages, pediatric to over 65; with or without co-morbidities	Phase II ready	C
2	Injectable Solution, API NV-387 Use for Injection or for Infusion	● RSV Infection ● Hospitalized ● Patients of all ages, pediatric to over 65; with or without co-morbidities	IND-Preparation	E
3	Injectable Solution, API NV-387 Use for Inhalation and for Infusion	● RSV Infection ● Hospitalized, Severe Disease ● Patients of all ages, pediatric to over 65; with or without co-morbidities	IND-Preparation	E

a: The RSV program priority is lowered from prior annual report because of the current fiscal limitations of the Company. This program will be brought to high priority if sufficient funding for the clinical trials becomes available.

Table 2.F. Broad-Spectrum Antiviral NV-387 - Additional Indications : Influenzas (Modality#1)				
No.	**Drug**	**Indications**	**Development Stage**	**Priority**
1	Oral Gummies, API NV-387	● Influenza virus Infection ● Non-hospitalized ● Patients of all ages, pediatric to over 65; with or without co-morbidities	Phase II ready	C
2	Injectable Solution, API NV-387 Use for Injection or for Infusion	● Influenza virus Infection ● Hospitalized ● Patients of all ages, pediatric to over 65; with or without co-morbidities	IND-Preparation	E
3	Injectable Solution, API NV-387 Use for Inhalation and for Infusion	● Influenza virus Infection ● Hospitalized, Severe Disease ● Patients of all ages, pediatric to over 65; with or without co-morbidities	IND-Preparation	E

Our Drug Programs for Varicella Zoster Virus (VZV), Cause of Shingles and Chickenpox:

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.

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 FDA agreed that the Company's strategy for drug substance and drug product acceptance criteria is adequate. The FDA 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 aged 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.

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

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-herpes viral 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 herpes 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.

We believe that our parallel development of these indications maximizes return on investment and shareholder value.

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. We believe that such expansions would enable maximization of ROI and maximization of shareholder value.

Including the HerpeCide program explained above, we currently have about 11 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.

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.

Eye Diseases Caused by Herpesviruses (HSV-1, HSV-2, VZV), Ocular Herpes Keratitis, viral Acute Retinal Necrosis

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.

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

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.

Large Market Sizes –Targeting an Overall Anti-Viral Drug Market Size that Exceeds $40 Billion

Biodefense-related purchases in the Smallpox program, assuming NV-387 becomes an approved drug for treatment of smallpox, could reach $200 to $500 million for initial acquisitions and $100 to $300 million for supplemental requisitions thereafter, in the USA alone, based on historical data. Also, we believe it is possible to obtain non-dilutive funding for the development of NV-387 as a treatment for Smallpox infection. Our MPox program is expected to provide enabling data for the Smallpox initiative.

The current market size for RSV drugs in the USA alone is estimated to be about $2.6 billion in 2024, and expected to grow to about $8 billion by 2030 at an estimated 18+% CAGR.

The market size for Influenza drugs is estimated at ~$4.6 billion in 2024 growing to ~$5.9 billion in 2027, 8.35+% CAGR, estimated for the USA Market only. The market is expected to exceed $10 billion if and when an anticipated Bird Flu Pandemic hits.

The market size for a single drug that is effective against the triple-demic viruses, namely RSV, Influenza, and Coronaviruses, could easily exceed the sum of the market sizes above, and could be over $14 billion by 2030. Our Ari/SARI clinical trials program is designed towards the development of NV-387 as a revolutionary, virus-agnostic, empiric antiviral therapeutic.

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 U.S. 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 U.S. 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.

Presently, our focus is on the Phase II clinical trial for evaluation of NV-387 as a treatment of MPox infections. Once this clinical trial is under way, we plan to focus on the Phase II clinical trial of NV-387 for the treatment of Viral ARI/SARI. This latter clinical trial will help us with further development of NV-387 for treatment of RSV infections and other viral infections. We plan on re-engaging our HerpeCide and HIV programs when sufficient resources become available.

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 successful anti-viral drugs based on our novel technology platform into human clinical studies, as permitted by available financing.

We believe that with the human clinical trials of NV-387, we will be able to accumulate the evidence of antiviral effectiveness in human infections, in addition to 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 believe we have the ability to generate sufficient funding to complete the Phase II clinical trial of NV-387 for the treatment of MPox, and to initiate the

Phase II clinical trial of NV-387 for the treatment of Viral ARI and Viral SARI diseases. 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 our other programs.

Our 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), *in vivo* animal studies using small animals, and Phase I human clinical trials.

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 our 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 US and 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;
- 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 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 a 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-387 is designed to do. Thus, their mode is complementary to NV-387 (NV-CoV-2) and combination therapy with one of these drugs and NV-387 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, was in development by Chimerix, but certain clinical trials involving brincidofovir have failed to meet the desired end points and have actually shown a greater fatality rate in brincidofovir treated subjects compared to placebo. 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 currently not aware of any 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. A viral endonuclease inhibitor, baloxavir (Xofluza, Shionogi/Roche) has recently been introduced as a single dose treatment. In its Phase III clinical trial, as many as 10% of patients were found to have drug-resistant virus mutants. 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. Importantly, the resistance barrier for all of these drugs is rather low, and resistant mutants have arisen in the field. Thus, we believe that there is an unmet medical need for an effective and safe pan-Influenza drug that the virus is unlikely to escape.

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.

Two drugs, namely tecovirimat (TPOXX®, SIGA), and brincidofovir (Emergent Bio) have received approval as treatment for Smallpox under the US FDA "Animal Rule" and are currently acquired in the US Government Strategic National Stockpile for biodefense purposes. Tecovirimat has a low threshold of viral escape, resulting from a single point mutation in the viral VP-37 protein. Brincidofovir has a black box warning, with diarrhea and other gastrointestinal adverse events, as well as elevation of hepatic transaminases and bilirubin, limiting the use and applicability of the drug in the general population. Thus there is an unmet need for a broad-spectrum antiviral that the virus is unlikely to escape, and that can be taken by substantially all of the population, with minimal if any adverse effects. We believe NV-387 fits this need and we plan on exploring its development along these lines.

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.

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

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

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

- In case of drugs where large scale clinical trials are not feasible, it is possible that the FDA can grant approval on the basis of robust Phase I and Phase II datasets.

If we believe that the data from the Phase III 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. FDA in USA, CDSCO/DCGI in India, ACOREP in DRC, TGA in Australia, MHRA in UK, PMDA in Japan, EMA and various National agencies in Europe, and others) 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.

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 I 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.

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 Organization (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 II with requirements for further data collection. Normally, the new drug approval application would be submitted after completion of a Phase III 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.

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

- Completion and Submission of the final report of the Phase Ia/Ib clinical trial of the API NV-387, as drug products NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies.
- Filing of the Clinical Trial Application for the Evaluation of NV-387 as a Treatment for MPox to ACOREP in DRC
- Initiation of the Phase II NV-387-MPox Clinical Trial
- Top-line Effectiveness' and Safety/Tolerability in Patients Data from the Phase II NV-387-MPox Clinical Trial
- Completion of the In-Hospital Treatment Part of the Phase II NV-387-MPox Clinical Trial
- Closing of the Phase II NV-387-MPox Clinical Trial, Data Analysis and Initial Reports
- Filing of the Clinical Trial Application for the Evaluation of NV-387 as a Treatment for Viral ARI and Viral SARI in India
- Initiation of the Phase II NV-387-ARI/SARI Clinical Trial
- Top-line effectiveness and Safety/Tolerability in Patients Data from the Phase II NV-387-ARI/SARI Clinical Trial
- Potentially, Completion of the In-Hospital Treatment Part of the Phase II NV-387-MPox Clinical Trial
- Filing of Orphan Drug Designation for NV-387 as a Treatment for MPox in the USA
- Filing of Orphan Drug Designation for NV-387 as a Treatment for Smallpox in the USA
- Filing of Orphan Drug Designation for NV-387 as a Treatment for Measles in the USA
- Pre-IND Application for NV-387 as a Treatment for MPox in the USA
- Pre-IND Application for NV-387 as a Treatment for Smallpox in the USA

- Pre-IND Application for NV-387 as a Treatment for Measles in the USA

- We also plan on filing a Pre-IND application for RSV treatment for Phase II human clinical trials for NV-387 as a treatment of RSV infection, in the USA, in the context of the Phase II ARI/SARI in India, to evaluate how the data can be brought into the USA FDA IND application.

After the RSV program 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.

We believe we have sufficient financing to complete the Phase Ia/Ib human clinical trial of API NV-387 and submission of the full clinical trial report. We believe we have sufficient financing to complete the Phase II human clinical trial of API NV-387 for the treatment of MPox based on the budgets we have received and planned for. 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 $1,000,000 for the Phase II clinical trial of NV-387 for MPox indication. The total cost of the Phase II trial could be significantly more. We have not received a budget for the proposed Phase II Clinical Trial of NV-387 for the Treatment of ARI/SARI as of now. 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.

The work-plan we have developed for the next twelve months is expected to enable us to complete the Phase II clinical trial of API NV-387 for the treatment of MPox and to begin Phase II human clinical trial of NV-387 for the treatment of Viral ARI/SARI, which will include patients with Influenza, RSV, Coronavirus, hMPV, and several other human respiratory viral infections in different enrolment numbers. 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 obtaining financing, and on external factors such as collaborations, and may be affected by unanticipated delays. We are experiencing extreme staffing constraints as well as financial constraints at present. We plan on applying for grants and contracts in order to obtain non-dilutive financing for some of our programs that we consider are eligible for governmental support. We plan on raising financing via sale of equity and public and private placements of our stock to finance our workplan. We have accesss to a line of credit of up to $3 million provided by our founder and President, Anil R. Diwan; we have not drawn on this credit line at present. We note as a risk factor that these resource constraints may cause further delays in our estimated timelines.

We believe we have overcome the most important risk in nanomedicines, that of enabling cGMP manufacture, to achieve consistent product from batch to batch, and scaleability challenges of nanomedicines. 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.

Our work-plan is expected to reduce certain risks of drug development. We believe that the data we have collected particularly for the manufacture of NV-387 drug substance and drug products, and the non-clinical and clinical studies of NV-387, will enable us to file appropriate IND application(s) to the FDA for various indications. We believe that in the ensuing fiscal year we will be able to obtain valuable information on the effectiveness of NV-387 viral infections in humans in Phase II clinical trials. If our studies are successful, we believe we would be able to raise the financing needed for further developing our RSV, FluCide, HerpeCide as well as other program drug candidates and we may be in a position to re-engage our highly valuable drug programs including HIVCide.

Based on our pre-clinical study data, we believe that we have a very high probability that NV-387 would be demonstrated to be a highly effective and safe drug for the treatment of MPox in the Phase II clinical trial, and also for the treatment of RSV, Influenza, Coronaviruses, hMPV, and other respiratory viruses in the ensuing Phase II Viral ARI/SARI clinical trial.

We further believe NV-387 could be a revolutionary drug for the treatment of pediatric RSV infections, based on our data that NV-387 treatment appears to have cured mice of lethal lung RSV infection, with no lung damage.

We intend 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-387 and other drugs in our pipeline. We intend to use equity-based and debt financing, as required, to fund the operations and to raise additional capital for conducting human clinical trials as we advance our pipeline further towards regulatory approvals. 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.

All of our agreements provide for the evaluation of nanoviricides substances created and provided by us 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, we have engaged in GLP and non-GLP Efficacy and Safety evaluations in both in vitro (cell culture models, pseudovirion models) and in vivo (animal models) of our different nanoviricide research materials and drug candidates at different laboratories. NV-387 has progressed into clinical stage and we expect to submit the final report of the successful Phase Ia/Ib human clinical trial evaluating safety and tolerability of oral formulations of NV-387 in healthy subjects soon.

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 7, 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 "COVID License 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 COVID License 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 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 I 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 IIA clinical trials or its equivalent for at least one product within twenty (24) months from the date of the completion of Phase I or its equivalent; 100,000 shares of Series A preferred stock after the initiation of Phase III 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 III clinical trials or its equivalent for at least one product within thirty-six (36) months from the completion of Phase II clinical trials or its equivalent. In addition, we agreed to pay to TheraCour fifteen percent (15%) of income from licensed products and any income from sublicensed products, consistent with previous agreements. Under the COVID License 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 COVID License 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 Stock 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 share of Series A preferred stock votes at the rate of 9 votes per share, 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 COVID License 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 COVID License Agreement, the Company issued 100,000 shares of the Company's Series A Preferred Stock upon execution of the agreement in 2021. The Company also issued 50,000 shares of the Company's Series A preferred stock upon the grant of an IND to perform clinical trials which are being sponsored by our licensee and collaborator KMPL in India, in April 2023. On June 19, 2023, the Company was notified that the Company's licensee, KMPL had commenced volunteer recruitments for Phase Ia/Ib clinical trials of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies. Pursuant to the COVID License Agreement a third milestone payment of $1,500,000 became due 5 days after the start of Phase Ia/Ib clinical trials.

On 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 accrued simple interest at the rate of 12% per annum and was due and payable on January 19, 2025, the maturity date. The principal of the Note is convertible, at TheraCour's option, into 331,859 shares of the Company's Series A Preferred Stock, par value $0.00001 at the conversion price, specified as the fair value of the Series A shares on July 19, 2023 in the terms and conditions contained within the Note. On October 27, 2023, TheraCour exercised its right to convert the principal of the July 19, 2023 Note into 331,859 shares of the Company's Series A Preferred Stock. Furthermore, TheraCour cancelled all of the accrued interest on the Note totaling $49,808 which has been reported as a capital transaction credit to additional paid in capital on the accompanying statements of changes in stockholders' equity. Total interest incurred under the Note for the year ended June 30, 2024 was $49,808.

On February 12, 2024, the Company entered into an Amendment to the COVID License Agreement with TheraCour dated September 7, 2021, whereby any further cash milestone payments that would be earned upon milestone event would only become payable upon the Company having sufficient revenues, with only a portion of revenues to be used for satisfying such milestone payments.

On September 23, 2024, the Company entered into a "Memorandum of Understanding for All Antivirals Drug Development" (the "MOU") with TheraCour that granted to the Company, a limited, non-assignable, non-sublicensable, exclusive right of first refusal to License to any antiviral drugs in development or to be developed by TheraCour for research and development purposes only, for all as-yet unlicensed viral infection treatment indications. The MOU also clarified the roles and responsibilities of the Parties and essentially codified the process that the Parties have adopted since inception. The MOU further codified the treatment of all future milestone payments arising from any current or future license agreements to TheraCour to be consistent with the principles adopted in the February 12, 2024 Amendment to the COVID License Agreement.

Development fees and other costs charged by TheraCour for the years ended June 30, 2025 and 2024 were approximately $2,490,000 and $2,550,000, respectively. At June 30, 2025, approximately $584,000, was due to TheraCour.

No royalties are due TheraCour from the Company's inception through June 30, 2025.

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 470,961 shares of the Company's outstanding common stock and 681,859 shares of the Company's Series A preferred stock as of June 30, 2025.

Line of Credit - Related Party – Anil Diwan

On November 13, 2023, the Company's President and CEO, Dr. Anil Diwan, entered into a Line of Credit Agreement whereby Dr. Diwan agreed to provide a standby Line of Credit to the Company in the maximum amount of $2,000,000. All amounts outstanding under the Line of Credit, including principal, accrued interest and other fees and charges, will be due and payable on December 31, 2024. Amounts drawn down under the Line of Credit shall bear interest at a fixed rate of 12%. Advancements under the Line of Credit will be collateralized by an Open End Mortgage Deed on the Company's real property at 1 Controls Drive, Shelton, Connecticut and a Chattel Mortgage (U.C.C - 1 filing) against the Company's equipment and fixtures. Any draw down under the Line of Credit requires the approval of the Company's Board of Directors. On February 12, 2024, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Extension Agreement which extended the maturity of the Company's Line of Credit from December 31, 2024 to December 31, 2025. There were no other amendments to the original Line of Credit. On September 23, 2024 the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Amendment Agreement which increased the available line of credit from $2 million to $3 million, and extended the maturity of the Company's Line of Credit from December 31, 2025 to March 31, 2026. As of July 1, 2025 the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Amendment Agreement extending the maturity of the Company's Line of Credit from March 31, 2026 to March 31, 2027.

The Company has not drawn against the Line of Credit facility as of June 30, 2025.

Karveer Meditech, Private Limited (KMPL)

On March 27, 2023 the Company entered into a License Agreement with KMPL, wherein the Company granted to KMPL 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 ("KMPL COVID License"). KMPL 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. KMPL is in the process of establishing a manufacturing plant for some of those medicines. KMPL 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, KMPL 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, KMPL 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. On June 19, 2023, KMPL commenced the equivalent of Phase I clinical trials in India. The Company has incurred clinical trial costs to KMPL of approximately $10,000 and $443,000 for the years ended June 30, 2025 and 2024, respectively. At June 30, 2025, approximately $237,000, was due to KMPL for Phase 1 clinical trial related services performed in India. As of June 30, 2024 approximately $227,000 of such costs were accrued by the Company pursuant to the license agreement between the Company and KMPL and which was subsequently invoiced to the Company in the following year. Dr. Anil Diwan is a passive investor and advisor without operating control at KMPL.

KMPL 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 KMPL. The number of shares is not currently available. Consequent to and subsequent to the KMPL COVID License, KMPL 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, 2025, 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 website at www.nanoviricides.com. Information included on the website 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.

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 (voicemail). 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.
- 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".

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;
- 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;
- 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, 2025, we had a cash and cash equivalent balance of approximately $1.6 million. Also, we have incurred significant operating losses since its inception, resulting in an accumulated deficit of approximately $149 million at June 30, 2025. Such losses are expected to continue for the foreseeable future.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

Management believes that the Company's cash and cash equivalents balance of approximately $1.6 million, additional capital raised of approximately $1.25 million, by ATM sales of our common stock from July 1, 2025 through September 24, 2025, and the Company's existing resources, including availability under its $3 million line of credit will not 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. As a result, substantial doubt exists about the Company's ability to continue as a going concern. 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.

We cannot provide assurance that the Company's 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;
- 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.

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

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

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

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

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

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

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

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

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

The 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 Ia/Ib 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.

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

- 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 complete the remaining tasks of the Phase I clinical trial and obtain a completed clinical study report, and to develop and file a Phase II clinical trial application to evaluate use of NV-387 for the treatment of RSV infection.

We have estimated a total cash expenditure budget of approximately $11 million for the period of July 2025 through October 2026 of which approximately $7.0 million is expected to be spent on research and development for our drug candidates, including completion and reporting of the Phase I clinical trial. $1 million has been budgeted toward execution of the Phase II clinical trial of our lead drug candidate NV-387 for treatment of MPox, 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 believe that our drug candidates under development and in clinical trials address major markets and unmet medical needs 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.

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

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.

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.

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.

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.

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, 2025, owned 2.8% of our common stock, and 681,859 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.
  In any of these cases:
- Our executive officers or directors may have a conflict between our current interests and their personal financial and other interests in another business venture.
- Our executive officers or directors may have conflicting fiduciary duties to us and the other entity.
- The terms of transactions with the other entity may not be subject to arm's length negotiations and therefore may be on terms less favorable to us than those that could be procured through arm's length negotiations.

We anticipate entering into contracts with various U.S. government agencies. In contracting with government agencies, we will be subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy.

We may enter into contracts with various U.S. government agencies which have special contracting requirements that give the government agency various rights or impose on the other party various obligations that can make the contracts less favorable to the non- government party. Consequently, if a large portion of our revenue is attributable to these contracts, our business may be adversely affected should the governmental parties exercise any of these additional rights or impose any of these additional obligations.

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

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

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

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

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

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

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

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.

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 Smallpox drug candidate would compete with the already approved therapies.

Our MPox drug candidate at present does not have any known competition, but at least one drug is currently in a clinical trial.

Our Measles drug candidate at present does not have any known competition. However, the potential market size does not support us committing to regulatory drug development for this purpose without non-dilutive funding from other sources.

Our Coronavirus drug candidates would compete with the already approved therapies (either EUA or full approvals) and are subject to the COVID pandemic dissipating.

Our RSV drug does not have any direct competition at present but there are two protective antibodies as well as three 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 Influenza drug candidate would compete with already approved therapies. 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., and licensed by Roche, has been approved in Japan, USA, and most of the world. 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. A new long-acting biologic drug, CD388 (Cidara) is in late clinical trials for use as an influenza prophylactic (i.e. protection before infection, like vaccines), but not as a therapeutic (i.e. treatment after infection and disease). 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.

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 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;

- 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 ability to reach 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;

- 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, 2025, shareholders of the Company held 1,692,259 shares of restricted common stock, or approximately 10.2% 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, 2025, we had 16,606,832 shares of common stock outstanding, 5,720 warrants convertible to 5,720 shares of common stock, and 905,717 shares of Series A preferred stock convertible into 3,170,010 shares of common stock only in the event of a change in control.

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

As of June 30, 2025, 1,692,259 of 16,606,832 issued and outstanding shares of the Company's common stock are 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 905,717 shares of Series A preferred stock are restricted and convertible into 3,170,010 shares of common stock only upon of a change of control of the Company.

Approximately 1,092,000 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 1C: CYBERSECURITY

Cybersecurity Risk Management and Strategy

We are a clinical stage biotechnology company focused on developing and commercializing new treatments for viral diseases. We and our third-party service providers, collect, process, transmit, and store sensitive data on our systems, including intellectual property, proprietary or confidential business information, and a variety of personal data.

We rely on third parties, including cloud vendors, for various business functions. We select key third-party service providers based on several factors, including the type of data processed and the nature of services offered, and we oversee such key third-party service

providers by conducting vendor diligence upon onboarding and ongoing monitoring, including a review of SOC-1 reports on an annual basis, where applicable.

We have adopted processes designed to identify, assess and manage material risks from cybersecurity threats. Those processes include response to and an assessment of internal and external threats to the security, confidentiality, integrity and availability of our data and information systems, along with other material risks to our operations. In addition, we have implemented procedures over certain areas such as access on/offboarding and account management to help govern the processes put in place by management designed to protect our IT assets, data, and services from threats and vulnerabilities.

Governance

Management is responsible for the day-to-day management of the risks we face, while our board of directors has responsibility for the oversight of risk management, including risks from cybersecurity threats. The audit committee has primary responsibility for oversight of cybersecurity and is briefed on cybersecurity risks at least once a year and following any material cybersecurity incidents. Our board of directors receives periodic updates from our audit committee regarding matters of cybersecurity. Our board members also engage in ad hoc conversations with management on cybersecurity-related news events and discuss any significant updates to our cybersecurity risk management and initiatives.

As of the date of this Annual Report on Form 10-K, we have not experienced a cybersecurity incident that resulted in a material effect on our business strategy, results of operations, or financial condition.

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 with no outstanding debt or mortgage.

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.

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, 2025, a total of 16,606,832 shares of the Company's common stock are outstanding and held by 143 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 14,914,573 shares are unrestricted, of which 0 shares are held by affiliates, 1,091,838 shares are restricted securities held by non-affiliates, and the remaining 600,421 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]

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, 2025. 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 has the right of first refusal for any antiviral drugs with TheraCour.

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.

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. We have successfully completed Phase Ia/Ib clinical trial for human safety and tolerability of our first drug candidate, NV-387, a broad-spectrum antiviral with multiple virus indications. We are now advancing NV-387 towards multiple indications with different regulatory pathways in a highly cost-effective strategy. We plan on seeking non-dilutive funding for some of the initiatives. 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, 2025 and June 30, 2024.

Comparison of the Year End June 30, 2025 to the Year Ended June 30, 2024

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

Research and Development Expenses - Research and development expenses for the year ended June 30, 2025 increased approximately $112,000, to approximately $5,549,000 from approximately $5,437,000 for the year ended June 30, 2024. This year-to-year increase is generally attributable to an increase in outside lab fees related to preparation of the Company's Phase II clinical trial applications.

General and Administration Expenses - General and administrative expenses increased approximately $964,000 to approximately $4,043,000 for the year ended June 30, 2025 from approximately $3,079,000 for the year ended June 30, 2024. The increase in general and administrative expenses is generally attributable to an increase in professional services including, legal, accounting, and investor outreach expenditures.

Interest Income - Interest income was approximately $125,000 and approximately $272,000 for the years ended June 30, 2025 and 2024, respectively. Interest income decreased due to lower cash balances.

Interest Expense- The Company has incurred interest expense of approximately $149 and $50,000 for the years ended June 30, 2025 and June 30, 2024 respectively. The decrease in interest expense for the year ended June 30, 2025 is a result of the milestone payment interest expense charged pursuant to the milestone payment note with TheraCour for the year ended June 30, 2024.

Income Taxes - There is no provision for income taxes due to ongoing operating losses. As of June 30, 2025, we had estimated cumulative tax benefits and development tax credits and other deferred tax credits resulting in a deferred tax asset of approximately $42,492,000. This amount has been offset by a full valuation allowance.

Net Loss - For the year ended June 30, 2025, the Company had a net loss of approximately $9,467,000, or a basic and fully diluted loss per share of $0.63 compared to a net loss of approximately $8,294,000, or a basic and fully diluted loss per share of $0.70 for the year ended June 30, 2024. The increase in the Company's net loss for the year ended June 30, 2025 from the year ended June 30, 2024 of $1,173,000 is generally attributable to the items discussed above.

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.

Table : R&D Costs Allocation

	Program	Year Ended June 30, 2025	Year Ended June 30, 2024
1	NV-387 Manufacture, Clinical Trials, R&D	$ 4,449,000	$ 3,437,000
2	Smallpox/Mpox	$ 400,000	$ 150,000
3	Measles	$ 300,000	$ —
4	RSV	$ 150,000	$ 250,000
5	Influenza	$ 150,000	$ 100,000
3	HerpeCide™ Program. Herpes Simplex virus infections (HSV-1, HSV-2) and VZV Indications: Cold Sores, Genital Ulcers, Shingles and ARN	$ 100,000	$ —
	Total	**$ 5,549,000**	**$ 5,437,000**

As many of our programs share a substantial amount of materials as well as laboratory work, we do not maintain project-based accounting of costs at present. The table above represents estimated cost allocations for specific activities in the different programs, with the bulk of common activities reported under the "NV-387 Manufacture, Clinical Trials, R&D" heading.

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. Approximately $140 million remains available for sale as of the date of this filing.

On or about August 1, 2023, the ATM Sales Agreement that we previously had with EF Hutton, division of Benchmark Investments, LLC and B. Riley Securities, Inc., taken together as the Sales Agent, was amended to name EF Hutton as the only sales agent (the "Agent") and to remove B. Riley 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. These sales, if any, would have been made pursuant to the terms of the August 1, 2023 ATM Sales Agreement.

On April 5, 2024, the Company entered into a new ATM sales agreement with. E.F. Hutton (now D. Boral Capital), the sales agent, replacing the prior August 1, 2023 sales agreement, pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agents, shares of common stock having an aggregate offering price of up to $50 million (each such offering an "At-the-Market" or ATM Offering). As of June 30, 2024, the Company sold 1,308,651 shares of common stock at an average price of approximately $2.47 per share. The shares were issued pursuant to a prospectus supplement dated May 5, 2023 and filed with the Securities and Exchange Commission on May 5, 2023 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-271706), which became effective on May 22, 2023. The net proceeds to the Company from the offering was approximately $3,120,000 after placement agent fees and other estimated offering expenses.

From July 1, 2024 through June 30, 2025, the Company sold 3,351,096 shares of common stock at an average price of approximately $1.65 per share. The shares were issued pursuant to a prospectus supplement dated May 5, 2023 and filed with the Securities and Exchange Commission on May 5, 2023 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-271706), which became effective on May 22, 2023. The net proceeds to the Company from the offering was approximately $5,296,000 after placement agent fees and other estimated offering expenses.

From July 1, 2025 through September 24, 2025 subsequent to the Company's fiscal year end, the Company sold 824,535 shares of common stock at an average price of approximately $1.57 per share. The net proceeds to the Company from the offering was approximately $1.25 million after placement agent fees and other estimated offering expenses.

Liquidity and Capital Reserves

As of June 30, 2025, we had approximately $1.6 million in cash and cash equivalents. Our liabilities as of June 30, 2025 are approximately $1.3 million, including accounts payable of approximately $459 thousand payable to third parties, accounts payable to related parties of approximately $821 thousand, and accrued expenses approximately $26 thousand.

The Company has an accumulated deficit at June 30, 2025 of approximately $148,842,000 and net cash used in operating activities of approximately $8,479,000 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.

Management believes that the Company's cash and cash equivalents balance of approximately $1.6 million at June 30, 2025, and additional capital raised of approximately $1.25 million by ATM sales of our common stock from July 1, 2025 through September 24, 2025 and the Company's existing resources, including availability under its $3 million line of credit will not 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. As a result substantial doubt exists about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

The Company believes that it has have several important milestones, including data from and final reports from the Phase Ia/Ib human clinical trial for our broad-spectrum drug NV-387 that is now in progress. Additional milestones include filing of clinical trial application for Phase II clinical trial of NV-387 for MPox indication, anticipated approval of the application, initiation of the Phase II Clinical Trial, Interim Datasets regarding the Safety and Effectiveness of NV-387 for the treatment of MPox, Completion of the Phase II Clinical Trial for MPox, as well as filing of clinical trial application for Phase II clinical trial of NV-387 for Viral-ARI/SARI indication, anticipated approval of the application, initiation of the Phase II Clinical Trial, interim datasets regarding the safety and effectiveness of NV-387 for the treatment of a multitude of respiratory viral infections, completion of the Phase II Clinical Trial and data analysis with data regarding efficacy of NV-387 in the treatment of Influenza, RSV, Coronavirus, and possibly other respiratory viruses.

Additional milestones we look forward to include: orphan drug designation filing to the US FDA for NV-387 for the treatment of MPox, smallpox and Measles, Pre-IND Application filing to the US FDA for Smallpox/MPox/Orthopoxviruses, and an IND filing to the US FDA, possibly for NV-387 for the treatment of smallpox under the FDA “Animal Rule”.

As these milestones are achieved, the Company would likely experience improvement in the liquidity of the Company’s stock, and such improvement, if any, would enhance the Company’s ability to raise funds on the public markets at terms that may be favorable to the terms offered at present.

Management believes that it has on-going access to the capital markets including the “At-The-Market” (ATM) agreement with D. Boral Capital, the Sales Agent, that became active around April 5, 2024. However, we cannot provide assurance that the Company’s plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates.

Requirement for Additional Capital

As of June 30, 2025 we have a cash balance of approximately $1.6 million and raised an approximate additional $1.25 million through September 24, 2025 through ATM sales of our common stock.

We believe we will need additional funding to continue further development of our drug candidates through later stages of human clinical trials into regulatory approvals if we do 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, 2025 can be summarized as follows:

1. Planned costs for remaining activities in the Phase 1a/1b human clinical trial of NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies, including bioanalytical activities and reports.

2. Planned costs for Phase II clinical trial of evaluation of NV-387 for MPox. These costs include staffing costs for the scientific staff and consulting firms to assist with regulatory compliance, as well as material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to regulatory compliance, as required for development of necessary data.

3. Similarly, planned costs for Phase II clinical trial of evaluation of NV-387 for Viral ARI/SARI. We plan on preparing the Clinical Trial Application (CTA) for this trial after regulatory submission of the MPox CTA in DRC. We believe we may be able to initiate the Phase II NV-387-Viral-ARI/SARI clinical trial towards the FY2026 third quarter, but majority of the clinical trial is expected to be conducted during the early part of FY2027.

4. Additional Non-clinical Safety Toxicology Studies of NV-387 to enable treatment of children with NV-387.

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. The estimates assume that our drug candidates demonstrate effectiveness in humans that is consistent with the activity observed in animal studies, 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. 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.

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.

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.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Accounting for Research and Devlopment Costs

The Company accounts for research and development cost in accordance with Accounting Standards Codification subtopic 730-10, Research and Development ("ASC 730-10"). ASC 730-10, requires research and development costs to be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and developments costs are expensed when the contracted work has been performed or as milestone results have been achieved. For the years ended June 30, 2025 and 2024, we incurred approximately $5,549,000 and $5,437,000 respectively for research and development expense which are included in the statements of operations.

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.

ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires public business entities (PBEs) to disclose, in interim and annual reporting periods, additional information about certain expenses in the notes to financial statements. The requirements of ASU 2024-03 apply to all public business entities. The ASU requires disaggregated disclosure of income statement expenses for public business entities (PBEs). The ASU does not change the expense captions an entity presents on the face of the income statement; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the footnotes to the financial statements. ASU 2024-03 is effective for all PBEs for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning

after December 15, 2027. Early adoption is permitted. 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 and the Company's disclosures.

ASU 2023-09 Income Taxes (Topic 740) Improvements to Income Tax Disclosures. The amendments in this Update require that public business entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income (or loss) by the applicable statutory income tax rate). Additionally, the ASU requires all entities to disclose the amount of income taxes paid disaggregated by federal, state, and foreign taxes, as well as individual jurisdictions where income taxes paid are equal to or greater than 5 percent of total income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 31, 2025. Early adoption is permitted and this ASU should be applied on a prospective basis. 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 and the Company's disclosures.

Recently Adopted Accounting Standards

Segment and Geographic Information

The Company adopted Accounting Standard Update ("ASU") 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, as of January 1, 2024. This ASU requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"), an amount for other segment items by a reportable segment and a description of its composition, and disclosure of the title and position of the CODM.

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the CODM, or decision making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment: life science. The life science segment consists of the development of clinical and preclinical product candidates for the development of the Company's proprietary anti-viral therapies. The Company's CODM is the President and Executive Chairman of the Board of Directors.

Segment revenue, profit or loss, significant segment expenses and other segment items - The accounting policies of the Company's single operating and reportable segment are the same as those described in this Summary of Significant Accounting Policies. The Company's method for measuring segment profitability includes net income (loss), which the CODM uses to assess performance and make decisions for resource allocation, consistent with the measurement principals for net income (loss) as reported on the Company's statement of operations. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company's statement of operations, and expenses are not regularly reviewed on a more disaggregated basis for purposes of assessing segment performance and deciding how to allocate resources.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval.

The adoption of these disclosure requirements did not have a material impact on its financial statements and related disclosures.

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.

As of June 30, 2025, 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 effective as of June 30, 2025.

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, 2025, 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 effective as of June 30, 2025.

Changes in Internal Controls over Financial Reporting

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, 2025 that has materially affected, or is likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Effective as of July 1, 2025, NanoViricides, Inc. entered into an Extension Agreement (the "Extension") of the 2024 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, 2025 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, 2026 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, 2025 and fully vest on June 30, 2026. The Company will recognize non-cash compensation expense related to the issuance of the Series A preferred stock of $39,928 during the year ended June 30, 2026. 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.

Effective as of July 1, 2025, NanoViricides, Inc. consummated an Extension to the CFO Agreement with its Chief Financial Officer Meeta Vyas effective July 1, 2025 (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, 2025 through June 30, 2026 under the same general terms as the prior CFO Agreement.

On September 23, 2024, the Company and its President and CEO, Dr. Anil R. Diwan, entered into an Amendment to Line of Credit Agreement whereby Dr. Diwan agreed to amend certain provisions of the standby Line of Credit with the Company to increase the maximum loan amount from $2,000,000 to $3,000,000 and to extend the maturity date for all amounts outstanding under the under the Line of Credit, including principal, accrued interest and other fees and charges, to March 31, 2026. Amounts drawn down under the Line of Credit shall bear interest at a fixed rate of 12%. Advancements under the Line of Credit are collateralized by an Open End Mortgage Deed on the Company's real property at 1 Controls Drive, Shelton, Connecticut and a Chattel Mortgage (U.C.C-1 filing) against the Company's equipment and fixtures. Any draw down under the Line of Credit requires the approval of the Company's Board of Directors. The Amendment to the Line of Credit Agreement became effective as of September 22, 2024.

Effective as of July 1, 2025, subsequent to the reporting period, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil R. Diwan, signed an Amendment Agreement which extended the maturity of the Company's Line of Credit from March 31, 2026 to March 31, 2027. There were no other amendments to the original Line of Credit. The Company has not drawn against the Line of Credit facility as of June 30, 2025.

On September 23, 2024, the Company entered into a "Memorandum of Understanding for All Antivirals Drug Development" (the "MOU") with TheraCour that granted to the Company, a limited, non-assignable, non-sublicensable, exclusive right of first refusal to license to any antiviral drugs in development or to be developed by TheraCour for research and development purposes only, for all as-yet unlicensed viral infection treatment indications. The MOU also clarified the roles and responsibilities of the parties and essentially codified the process that the parties have adopted since inception. The MOU further codified the treatment of all future milestone payments arising from any current or future license agreements to TheraCour to be consistent with the principles adopted in the February 12, 2024 Amendment to the COVID License Agreement.

(a) None.

(b) Corporate Governance

During the period covered by this Annual Report on Form 10-K, there were no changes to the procedures by which security holders may recommend nominees to the Company's Board of Directors.

(c) Insider Trading Arrangements and Policies

During the three months ended June 30, 2025, no director or officer of the Company "adopted" or "terminated" a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" as each term is defined in Item 408 of Regulation S-K.

The Company has adopted insider trading policies and procedures governing the purchase, sale and other disposition of its securities by directors, officers and employees that management believes are reasonably designed to promote compliance with insider trading laws, rules, and regulations, and any listing standards applicable to the company. A copy of the Company's insider trading policy is attached as Exhibit 19.1 hereto.

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.	66	President and Executive Chairman of the Board
Makarand “Mak” Jawadekar	74	Director, Independent
Theodore Edward (“Todd”) Rokita	55	Director, Independent
Brian Zucker	63	Director, Independent
Meeta Vyas	66	Chief Financial Officer

Anil Diwan, PhD, age 66, 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, 74, 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.

Theodore Edward ("Todd") Rokita, 55, 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, 63, 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.

Meeta Vyas, SB, MBA, 66, 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.

INSIDER TRADING POLICY

We have adopted an Insider Trading Policy that provides guidance to employees (including officers) and directors with respect to transactions in the Company's securities. The Insider Trading Policy is designed to promote compliance with insider trading laws, rules and regulations and any listing standards applicable to the Company. The policy also prohibits directors, officers and other employees from purchasing financial instruments (including prepaid variable forward contracts, equity swaps, collars, and exchange funds), or otherwise engaging in transactions, that hedge or offset, or are designed to hedge or offset, any decrease in the market value of our equity securities without our prior approval.

A copy of the Company's Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The following table reflects all forms of compensation for the years ended June 30, 2025 and 2024.

Name and Principal Position	Year	Salary	Bonus ($)	Stock Award(s) ($)	Option Awards	All Other Compensation ($)	Total ($)
Anil Diwan	2025	$ 400,000	$ —	$ 49,834		$ —	$ 449,834
CEO, President, Director	2024	$ 400,000	$ —	$ 32,498		$ —	$ 432,498
Meeta Vyas	2025	$ 129,600	$ —	$ 6,322	—	$ —	$ 135,922
CFO	2024	$ 129,600	$ —	$ 5,907	—	$ —	$ 135,507

The following table sets forth for each named executive officer certain information concerning equity awards as of June 30, 2025.

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.

ERRONEOUS COMPENSATION RECOVERY POLICY

The Company adopted an Erroneous Compensation Recovery Policy in order to comply with NYSE Rule 811 and Rule 10D-1 under the Exchange Act. In the event the Company is required to prepare an accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, subject to the terms of the policy, the Company must recover reasonably promptly from its current and former executive officers the amount of any erroneously awarded incentive based compensation received on or after October 2, 2023 and during the three (3) years preceding the date that the Company is required to prepare such accounting restatement. The Erroneous Compensation Recovery Policy has been filed as Exhibit 97.1 of this Annual Report.

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

The following table sets forth, as of June 30, 2025, 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]	470,961	2.8 %	681,859	75.3 %	26.7 %
Anil Diwan[4][5]	—	—	126,887	14.0 %	4.6 %
Meeta Vyas[6]	7,129	0.1 %	18,688	2.1 %	0.7 %
Makarand Jawadekar	41,536	0.3 %	—	—	0.2 %
Theodore Rokita	41,009	0.2 %	—	—	0.2 %
Brian Zucker	39,786	0.2 %	—	—	0.2 %
All Directors and Executive Officers as a Group (6 persons)	600,421	3.6 %	827,434	91.4 %	32.5 %

(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 16,606,832 shares of common stock and 905,717 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 470,961 shares of common stock nor the 681,859 shares of Series A preferred stock owned by TheraCour Pharma, Inc. which votes at the rate of nine 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.

EMPLOYMENT AGREEMENTS

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. As of July 1, 2024, the Company agreed to the extension of the employment agreement for a period of one year from July 1, 2024 through June 30, 2025 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, 2025. As of July 1, 2025, the Company agreed to the extension of the employment agreement for a period of one year from July 1, 2025 through June 30, 2026 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, 2026.

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. As of July 1, 2024, the Company agreed to the extension of the CFO agreement for a period of one year from July 1, 2024 through June 30, 2025 under the same general terms as the prior CFO Agreement. As of July 1, 2025, the Company agreed to the extension of the CFO agreement for a period of one year from July 1, 2025 through June 30, 2026 under the same general terms as the prior CFO Agreement.

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.

COMPENSATION OF SCIENTIFIC ADVISORY BOARD

The Company anticipates holding four Scientific Advisory Board (SAB) meetings per annum. As compensation, each member of the Scientific Advisory Board 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 years ended June 30, 2025 and 2024, the SAB was granted a total of 1,144 and 1,144 of stock warrants, respectively. The warrants are exercisable into common shares at prices from $1.55 to $2.35 and $1.43 to $2.43, 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.

TheraCour Pharma, Inc.

TheraCour currently holds 470,961 shares of the Company's common stock and 681,859 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.

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 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 September 7, 2021, the Company entered into a license agreement for the field comprising anti-viral treatments for coronavirus derived human infections with TheraCour (the "COVID License 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 COVID License 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 I 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 IIA clinical trials or its equivalent for at least one product within twenty (24) months from the date of the completion of Phase I or its equivalent; 100,000 shares of Series A preferred stock after the initiation of Phase III 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 III clinical trials or its equivalent for at least one product within thirty-six (36) months from the completion of Phase II 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 COVID License 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 COVID License 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 stock is 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.

On April 20, 2023, the Company was notified that the Company's licensee, KMPL, was authorized to enter into Phase Ia/Ib 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, KMPL, has commenced volunteer recruitments for Phase Ia/Ib 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 COVID 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. TheraCour had achieved the milestone regarding the "Initiation of Phase I 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. On October 27, 2023 TheraCour exercised its right to convert the principal of the July 19, 2023 Note into 331,859 shares of the Company's Series A preferred stock. Furthermore, TheraCour cancelled all of the accrued interest on the Note totaling approximately $49,800 which has been reported as a capital transaction credit to additional paid in capital on the accompanying statements of changes in stockholders' equity.

On February 12, 2024 the Company requested and TheraCour agreed to suspend the existing license requirement to maintain an advance with TheraCour equal to two months of projected TheraCour invoices which is recalculated quarterly. The suspension will remain in effect until such time as the Company is able to raise sufficient capital. The existing available advance will be applied towards payment of TheraCour invoices.

On February 13, 2024, the Company and TheraCour amended the COVID License Agreement (the "Amendment"). The Amendment provides that the as yet unearned and unremitted cash awards specified in the COVID License Agreement for milestone payments shall not be due and payable until the Company achieves a revenue event which shall mean, but not be limited to, the receipt of revenue by the Company generated from, but not limited to, sources such as (1) research and development grants, government contracts, non-profit organizations and other sources to the extent that the amount of recognized revenue (as defined in the Amendment) is only considered to be the profit portion of revenue event, if any; (2) licensing of third-party development partnerships to the extent recognized revenue is considered to include only the profit or retained earnings portion received from such deals (and exclude any at-cost-reimbursements); (3) drug commercialization wherein recognized revenue shall be the amount of gross profit (i.e., net sales less cost of net sales); or (4) other sources of revenue such as gross profits from private contract work. Additionally, the Amendment provides that no more than 50% of the recognized revenue shall be applied for remitting such consideration at the time of payment. Further the Amendment clarifies that financing raised by the Company from sale of equity, mortgage or debt transactions, and such other instruments shall not be regarded as recognized revenue.

On September 23, 2024, the Company entered into a "Memorandum of Understanding for All Antivirals Drug Development" (the "MOU") with TheraCour that granted to the Company, a limited, non-assignable, non-sublicensable, exclusive right of first refusal to license to any antiviral drugs in development or to be developed by TheraCour for research and development purposes only, for all as-yet unlicensed viral infection treatment indications. The MOU also clarified the roles and responsibilities of the parties and essentially codified the process that the parties have adopted since inception. The MOU further codified the treatment of all future milestone payments arising from any current or future license agreements to TheraCour to be consistent with the principles adopted in the February 12, 2024 Amendment to the COVID License Agreement.

COVID-19 Related Drugs: Patent Coverage and Lifetime

Two 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 transferred property and equipment, to the Company, at cost, in the approximate amounts of $47,000 and $115,000 for the fiscal years ended June 30, 2025 and 2024, respectively.

Accounts payable to TheraCour were approximately $584,000 and $720,000 at June 30, 2025 and 2024, respectively.

Development fees and other costs charged by TheraCour were approximately $2,490,000 and $2,550,000 for the years ended June 30, 2025 and 2024, respectively. No royalties are due or have been paid from inception through June 30, 2025.

As of June 30, 2025 TheraCour owned 470,961 shares of the Company's outstanding common stock and 681,859 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.

Line of Credit - Related Party – Anil Diwan

On November 13, 2023, the Company's President and Executive Chairman, Dr. Anil Diwan, entered into a Line of Credit Agreement whereby Dr. Diwan agreed to provide a standby Line of Credit to the Company in the maximum amount of $2,000,000. All amounts outstanding under the Line of Credit, including principal, accrued interest and other fees and charges, will be due and payable on December 31, 2024. Amounts drawn down under the Line of Credit shall bear interest at a fixed rate of 12%. Advancements under the Line of Credit will be collateralized by an Open End Mortgage Deed on the Company's real property at 1 Controls Drive, Shelton, Connecticut and a Chattel Mortgage (U.C.C - 1 filing) against the Company's equipment and fixtures. Any draw down under the Line of Credit requires the approval of the Company's Board of Directors. On February 12, 2024 the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Extension Agreement which extended the maturity of the Company's Line of Credit from December 31, 2024 to December 31, 2025. On September 23, 2024, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil R. Diwan, signed an Amendment Agreement which increased the available line of credit from $2,000,000 to $3,000,000, and extended the maturity of the Company's Line of Credit from December 31, 2025 to March 31, 2026.

On July 1, 2025, subsequent to the reporting period, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Amendment Agreement which extended the maturity of the Company's Line of Credit from March 31, 2026 to March 31, 2027. There were no other amendments to the original Line of Credit. The Company has not drawn against the Line of Credit facility as of June 30, 2025.

Karveer Meditech, Private Limited (KMPL)

On March 27, 2023 the Company entered into a License Agreement with KMPL, wherein the Company granted to KMPL 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. KMPL 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. KMPL 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, KMPL 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, KMPL will pay the Company a royalty of seventy (70%) percent of the final invoiced sales net of costs to unaffiliated third parties.

On April 20, 2023, the Company was notified that the Company's licensee, KMPL, was authorized to enter into Phase Ia/Ib 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 19, 2023 KMPL commenced the equivalent of Phase I clinical trials in India. The Company has incurred clinical trial costs payable to KMPL of $9,932 and $442,845 for the years ended June 30, 2025 and 2024 respectively, As of June 30, 2025 and 2024, respectively, $0 and $227,435 of such costs were accrued by the Company pursuant to the license agreement between the Company and KMPL. The aforesaid clinical trial related costs, at actual amounts, of $237,367 have since been invoiced and recorded in accounts payable-related parties. Accounts payable to KMPL at June 30, 2025 is $237,367.

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, 2025	$ 207,900
June 30, 2024	$ 251,370

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.

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
3.2	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	Director Retainer Agreement between NanoViricides, Inc. and Makarand Jawadekar	Form 8-K	10.1	February 11, 2020
10.9	Director Retainer Agreement, dated as of May 15, 2020, between NanoViricides, Inc. and Todd Rokita	Form 8-K	10.1	May 19, 2020
10.10	Director Retainer Agreement dated November 13, 2020 between NanoViricides, Inc. and Brian Zucker	Form 8-K	10.1	November 13, 2020
10.11	License Agreement dated September 7, 2021 between NanoViricides, Inc. and TheraCour Pharma, Inc.	Form 8-K	10.1	September 9, 2021
10.12	Extension to Employment Agreement with A. Diwan	Form 8-K	10.2	September 9, 2021
10.13	Extension to Employment Agreement with A. Diwan	Form 8-K	10.2	October 11, 2022
10.14	License Agreement with Karveer Meditech Private Limited	Form 8-K	10.1	March 27, 2023
10.15	Deferred Expense Exchange Agreement between NanoViricides, Inc. and TheraCour Pharma, Inc.	Form 8-K	10.2	August 29, 2023
10.16	Convertible Promissory Note between NanoViricides, Inc and TheraCour Pharma, Inc., effective July 19, 2023	Form 8-K	10.3	August 29, 2023
10.17	Extension to Employment Agreement with A. Diwan effective July 1, 2023	Form 10-K	10.25	October 13, 2023
10.18	Extension to CFO Agreement with Meeta Vyas effective July 1, 2023	Form 10-K	10.26	October 13, 2023

10.19	Amendment to License Agreement between NanoViricides, Inc. and TheraCour, dated February 13, 2024	Form 8-K	10.2	February 16, 2024
10.20	Line of Credit Agreement between NanoViricides, Inc. and Dr. Anil R. Diwan, dated November 13, 2023	Form 8-K	10.3	February 16, 2024
10.21	Extension Agreement between the Company and Dr. Anil R. Diwan, dated February 12, 2024	Form 8-K	10.4	February 16, 2024
10.22	Letter from TheraCour Pharma, Inc.	Form 8-K	10.5	February 16, 2024
10.23	At Market Issuance Sales Agreement by and between NanoViricides, Inc. and EF Hutton LLC	Form 8-K	1.1	April 5, 2024
10.24	Extension of Employment Agreement with Anil Diwan effective July 1, 2024	Form 8-K	10.1	August 9, 2024
10.25	Extension of Employment Agreement with Meeta Vyas effective July 1, 2024	Form 8-K	10.2	August 9, 2024
10.26	Amendment to Line of Credit Agreement dated September 22, 2024			
14.1	Code of Ethics	Form 10-SB	10.10	November 14, 2006
19.1	NanoViricides, Inc. Insider Trading Policy effective September 20, 2024	Form 10.K	19.1	September 27, 2024
23	Consent of EisnerAmper LLP			
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)			

ITEM 16. FORM 10-K SUMMARY

None.

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: September 29, 2025

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:

September 29, 2025

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

September 29, 2025

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

September 29, 2025

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

September 29, 2025

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

September 29, 2025

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

NanoViricides, Inc.
Index to the Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NanoViricides, Inc. (the "Company") as of June 30, 2025 and 2024, 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, 2025 and 2024, 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.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring net losses and net cash flow used in operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

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.

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 for research and development activities of approximately $820,000 as of June 30, 2025 and research and development costs incurred with related parties of approximately $2,500,000 included in research and development expenses for the year ended June 30, 2025.

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; and (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 party. 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
September 29, 2025

NanoViricides, Inc.
Balance Sheet

	June 30, 2025	June 30, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,558,564	$ 4,797,778
Prepaid expenses	112,146	172,742
Total current assets	1,670,710	4,970,520
Property and equipment, net	6,833,891	7,512,463
Intangible assets, net	317,039	325,308
OTHER ASSETS		
Service agreements	2,445	14,562
Total assets	$ 8,824,085	$ 12,822,853
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 459,094	$ 376,270
Accounts payable – related party	821,456	720,039
Accrued expenses	25,969	262,467
Total current liabilities	1,306,519	1,358,776
COMMITMENTS AND CONTINGENCIES (NOTE 11)		
STOCKHOLDERS' EQUITY:		
Series A convertible preferred stock, $0.00001 par value, 10,000,000 shares designated, 905,717 and 892,625 shares issued and outstanding, at June 30, 2025 and 2024, respectively. (Note 9)	9	9
Common stock, $0.00001 par value; 150,000,000 shares authorized, 16,606,832 and 13,144,055 shares issued and outstanding at June 30, 2025 and 2024, respectively. (Note 8)	166	131
Additional paid-in capital	156,359,252	150,838,832
Accumulated deficit	(148,841,861)	(139,374,895)
Total stockholders' equity	7,517,566	11,464,077
Total liabilities and stockholders' equity	$ 8,824,085	$ 12,822,853

See accompanying notes to the financial statements

NanoViricides, Inc.
Statements of Operations

	Year Ended June 30,	
	2025	2024
OPERATING EXPENSES		
Research and development	$ 5,549,101	$ 5,437,297
General and administrative	4,042,544	3,078,814
Total operating expenses	9,591,645	8,516,111
LOSS FROM OPERATIONS	(9,591,645)	(8,516,111)
OTHER INCOME (EXPENSE):		
Interest income	124,828	271,773
Interest expense	(149)	(49,808)
Other income (expense), net	124,679	221,965
NET LOSS	$ (9,466,966)	$ (8,294,146)
Net loss per common share- basic and diluted	$ (0.63)	$ (0.70)
Weighted average common shares – basic and diluted	15,116,548	11,871,054

See accompanying notes to the financial statements.

NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the period from July 1, 2023 through June 30, 2025

	Series A Preferred Stock: Par $0.00001		Common Stock: Par $0.00001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholder Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, July 1, 2023	547,674	$ 5	11,698,497	$ 117	$145,946,257	$(131,080,749)	$ 14,865,63
Proceeds from sale of common stock in connection with equity financings net of issuance costs of $117,314	—	—	1,308,651	13	3,120,024	—	3,120,03
Series A preferred stock issued for employee stock compensation	13,092	—	—	—	43,245	—	43,24
Series A preferred stock issued upon conversion of related party promissory note	331,859	4	—	—	1,499,996	—	1,500,00
Common stock issued for consulting and legal services rendered	—	—	101,542	1	131,599	—	131,60
Warrants issued to Scientific Advisory Board	—	—	—	—	563	—	56
Common stock issued for employee compensation	—	—	1,786	—	2,340	—	2,34
Forgiveness of interest on related party debt	—	—	—	—	49,808	—	49,80
Common stock issued for Directors fees	—	—	33,579	—	45,000	—	45,00
Net loss	—	—	—	—	—	(8,294,146)	(8,294,14
Balance, June 30, 2024	892,625	9	13,144,055	131	150,838,832	(139,374,895)	11,464,07
Proceeds from sale of common stock in connection with equity financings net of issuance costs of $202,746	—	—	3,351,096	34	5,296,395	—	5,296,42
Series A preferred stock issued for employee stock compensation	13,092	—	—	—	60,722	—	60,72
Common stock issued for consulting and legal services rendered	—	—	79,149	1	115,499	—	115,50
Warrants issued to Scientific Advisory Board	—	—	—	—	679	—	67
Common stock issued for employee compensation	—	—	1,786	—	2,125	—	2,12
Common stock issued for Directors fees	—	—	30,746	—	45,000	—	45,00
Net loss	—	—	—	—	—	(9,466,966)	(9,466,96
Balance, June 30, 2025	905,717	$ 9	16,606,832	$ 166	$156,359,252	$(148,841,861)	$ 7,517,56

See accompanying notes to the financial statements

NanoViricides, Inc.
Statements of Cash Flows

	Year Ended June 30, 2025	Year Ended June 30, 2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,466,966)	$ (8,294,146)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	60,722	43,245
Common shares issued as compensation and for services	162,625	178,940
Warrants granted to Scientific Advisory Board	679	563
Depreciation	735,536	750,744
Amortization	8,269	8,270
Changes in operating assets and liabilities:		
Prepaid expenses	60,596	122,744
Other assets	12,117	(201)
Accounts payable	82,824	219,213
Accounts payable - related parties	101,417	486,605
Accrued expenses	(236,498)	168,516
NET CASH USED IN OPERATING ACTIVITIES	(8,478,679)	(6,315,507)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(56,964)	(156,560)
NET CASH USED IN INVESTING ACTIVITIES	(56,964)	(156,560)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	5,296,429	3,120,037
NET CASH PROVIDED BY FINANCING ACTIVITIES	5,296,429	3,120,037
NET CHANGE IN CASH AND CASH EQUIVALENTS	(3,239,214)	(3,352,030)
Cash and cash equivalents at beginning of period	4,797,778	8,149,808
Cash and cash equivalents at end of period	$ 1,558,564	$ 4,797,778
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	$ 149	$ —
NON CASH FINANCING AND INVESTING ACTIVITIES:		
Fair value od Series A Preferred shares issued upon conversion of related party convertible promissory note	$ —	$ 1,500,000
Forgiveness of interest onrealted party debt	$ —	$ 49,808

See accompanying notes to the financial statements

NanoViricides, Inc.
June 30, 2025, and 2024
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 platform. The Company's platform is based on host-mimicry, and thereby has uniquely enabled development of broad-spectrum antiviral drugs that the viruses would be unable to escape, a critical unmet need in antiviral therapeutics. NanoViricides possesses its own 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.

NanoViricides, Inc. is domiciled under the laws of the State of Delaware, with its principal operations located in the State of Connecticut. The Company's fiscal year begins on July 1st and ends on the next June 30th of the calendar year. The Company operates in one reportable business segment.

Note 2 – Liquidity and Going Concern

The Company's financial statements have been prepared assuming that it will continue as a going concern, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the normal course of business. As reflected in the financial statements, the Company has an accumulated deficit at June 30, 2025 of approximately $148.8 million and a net loss of approximately $9.5 million and net cash used in operating activities of approximately $8.5 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, 2025, the end of the reporting period, the Company had approximately $1.6 million in cash and cash equivalents. The Company's liabilities at June 30, 2025 were approximately $1.3 million, including accounts payable of approximately $459 thousand payable to third parties, accounts payable to related parties of approximately $821 thousand, and accrued expenses of approximately $26 thousand. Management believes that the Company's cash and cash equivalents balance of approximately $1.6 million at June 30, 2025, additional capital raised of approximately $1.25 million by At the Market ("ATM") sales of our common stock from July 1, 2025 through September 24, 2025, and the Company's existing resources, including availability under its $3 million line of credit will not 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. As a result substantial doubt exists about the Company's ability to continue as a going concern.

The ability of the Company to continue as a going concern is dependent upon controlling its overall expenses and identifying and securing additional financing.

The Company believes that it has several important milestones, building on the successful Phase Ia/Ib human clinical trial for the Company's broad-spectrum, antiviral drug NV-387 as described elsewhere, with further progress of NV-387 into Phase II clinical trials. The Company has received a draft of the Phase Ia/Ib clinical study report ("CSR"). We believe the report should be finalized soon. The Company plans on submitting the final CSR to the regulatory authorities in India, which would be a significant milestone in the regulatory progress of NV-387.

Additional milestones include filing of a Clinical Trial Application (CTA) for a Phase II clinical trial of NV-387 as treatment for MPox, execution of the Phase II clinical trial and attendant top-line readout, and the anticipated successful completion of the clinical trial. The Company anticipates that its Phase II clinical trial will be successful in demonstrating that NV-387 is effective and safe in the treatment of MPox infection, based on the known safety of NV-387 in both animal studies and the observations in Phase I human clinical trial, and the activity of NV-387 against lethal orthopoxvirus infection in animal models that simulate the dermal transfer of infection as well as direct lung infection. Further, the Company continues toward developing the Pre-IND and IND applications for a Phase IIa clinical trial of NV-387 for the treatment of RSV infection in adults, to be followed by a Phase IIb/III clinical trial of NV-387 for the treatment of RSV infection in hospitalized pediatric patients. To this end, the Company is also evaluating the possibility of a Phase IIa clinical

trial of a RSV Infection Challenge in Humans. The Company executes its plans in a manner consistent with available resources, which can lead to reshuffling of priorities in its programs. Nevertheless, the Company has in the past and will continue to progress towards its goal of revolutionizing antiviral therapeutics.

Management believes that as these various milestones are achieved, the Company would likely experience improvement in the liquidity of the Company's stock, and such improvement, if any, would enhance the Company's ability to raise funds on the public markets at terms that may be favorable to the terms offered at present.

Management is actively exploring additional required funding through non-dilutive grants and contracts, partnering, as well as 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 it has on-going access to the capital markets including the "At-The-Market" (ATM) agreement with D. Boral Capital (Formerly EF Hutton LLC), the Sales Agent.

There can be no assurance that the Company's 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 Company 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.

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, 2025	June 30, 2024
Warrants	5,720	6,862

The Company has 905,717 and 892,625 shares of Series A preferred stock outstanding as of June 30, 2025 and 2024, 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, 2025 and 2024 the number of potentially dilutive shares of the Company's common stock into which these Series A preferred shares can be converted into is 3,170,010 and 3,124,188, 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. 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 did not identify any indicators or impairment and has not recorded an impairment charge for the years ended June 30, 2025 and 2024.

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 patent is less than its carrying amount as a basis for determining whether it is necessary to complete quantitative impairment assessments.

Research and Development

All costs of research and development are expensed as incurred.

When preparing our financial statements, we are required to estimate our accrued clinical expenses. This process involves reviewing contracts and communicating with the personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with third parties depend on factors, such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones, which is usually the case with clinical services contracts.

When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense 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 8 to the financial statements.

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 Taxes

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, 2025 and 2024. 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.

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, 2025 and 2024.

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.

ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires public business entities (PBEs) to disclose, in interim and annual reporting periods, additional information about certain expenses in the notes to financial statements. The requirements of ASU 2024-03 apply to all public business entities. The ASU requires disaggregated disclosure of income statement expenses for public business entities (PBEs). The ASU does not change the expense captions an entity presents on the face of the income statement; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the footnotes to the financial statements. ASU 2024-03 is effective for all PBEs for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. 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 and the Company's disclosures.

ASU 2023-09 Income Taxes (Topic 740) Improvements to Income Tax Disclosures. The amendments in this Update require that public business entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income [or loss] by the applicable statutory income tax rate). Additionally, the ASU requires all entities to disclose the amount of income taxes paid disaggregated by federal, state, and foreign taxes, as well as individual jurisdictions where income taxes paid are equal to or greater than 5 percent of total income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 31, 2024. Early adoption is permitted and this ASU should be applied on a prospective basis. 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 and the Company's disclosures.

Recently Adopted Accounting Standards

Segment and geographic information

The Company adopted ASU 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, as of January 1, 2024. This ASU requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"), an amount for other segment items by reportable segment with a description of its composition, and disclosure of the title and position of the CODM.

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the CODM, or decision making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment: life science. The life science segment consists of the development of clinical and preclinical product candidates for the development of the Company's proprietary anti-viral therapies. The Company's CODM is the President and Executive Chairman of the Board of Directors.

Segment revenue, profit or loss, significant segment expenses and other segment items - The accounting policies of the Company's single operating and reportable segment are the same as those described in this Summary of Significant Accounting Policies. The Company's method for measuring segment profitability includes net income (loss), which the CODM uses to assess performance and make decisions for resource allocation, consistent with the measurement principals for net income (loss) as reported on the Company's statement of operations. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company's statement of operations, and expenses are not regularly reviewed on a more disaggregated basis for purposes of assessing segment performance and deciding how to allocate resources.

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 ("KMPL")	An entity where Dr. Anil Diwan is a passive investor and advisor without operating control

Property and Equipment

	For the Year Ended	
	June 30, 2025	June 30, 2024
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.	$ 46,764	$ 114,651

Accounts Payable- Related Party- Theracour

	As of June 30, 2025	As of June 30, 2024
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. On February 12, 2024, TheraCour and the Company agreed to suspend the license requirement for a two month advance until the Company raises sufficient capital, therefore no advance offset of the accounts payable due TheraCour at June 30, 2025 and at June 30, 2024.	$ 584,089	$ 720,039

Accounts Payable- Related Party-KMPL

	As of June 30, 2025	As of June 30, 2024
KMPL has retained a local clinical research organization (CRO) to conduct the clinical trials. The Phase1 human clinical trial of NV-CoV-2 began in India on June 17, 2023. Under the agreement with KMPL, the Company agreed to 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. In prior periods the amount due KMPL had been accrued and recorded in accrued expenses. At June 30, 2024, the aforesaid clinical trial related costs, as budgeted, of $227,434 were recorded as accrued expense in the accompanying June 30, 2024 balance sheet. The aforesaid clinical trial related costs, at actual amounts, of $237,367 have since been invoiced and recorded in accounts payable-related parties. Accounts payable to KMPL at June 30, 2025 and June 30, 2024 were:	$ 237,367	$ —

Research and Development Costs - Related Party

	For the Year Ended June 30, 2025	For the Year Ended June 30, 2024
Development fees and other costs charged by TheraCour pursuant to the Exclusive License Agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at June 30, 2025 and 2024.	$ 2,490,274	$ 2,550,466

Clinical Trial Costs - Related Party

	For the Year Ended June 30, 2025	For the Year Ended June 30, 2024
Clinical trial related and other costs were accrued by Company pursuant to the license agreement between the Company and KMPL 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 as of June 30, 2024. The amount has been recorded within accrued expenses in the accompanying balance sheet as of June 30, 2024. The aforesaid clinical trial related costs of $237,367 have since been invoiced and recorded in accounts payable-related party at June 30, 2025. See Accounts Payable- Related Party-KMPL above.	$ 9,932	$ 442,845

License Milestone Fee – Related Party

On September 7, 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, KMPL was authorized to enter into Phase Ia/Ib 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, KMPL had commenced volunteer recruitments for Phase Ia/Ib 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.

On 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 accrues simple interest at the rate of 12% per annum and is due and payable on January 19, 2025, the maturity date. The principal of the Note is convertible, at TheraCour's option, into 331,859 shares of the Company's Series A preferred stock, par value $0.00001 at the conversion price, specified as the fair value of the Series A shares on July 19, 2023 in the terms and conditions contained within the Note. On October 27, 2023 TheraCour exercised its right to convert the principal of the July 19, 2023 Note into 331,859 shares of the Company's Series A preferred stock. Furthermore, TheraCour cancelled all of the accrued interest on the Note totaling $49,808 which has been reported as a capital transaction credit to additional paid in capital on the accompanying statements of changes in stockholders' equity. Total interest incurred under the Note for the year ended June 30, 2024 was $49,808.

On February 12, 2024, the Company entered into an Amendment to the COVID License Agreement with TheraCour dated September 7, 2021, whereby any further cash milestone payments that would be earned upon milestone event would only become payable upon the Company having sufficient revenues, with only a portion of revenues to be used for satisfying such milestone payments.

Line of Credit - Related Party

On November 13, 2023, the Company's President and CEO, Dr. Anil Diwan, entered into a Line of Credit Agreement whereby Dr. Diwan agreed to provide a standby Line of Credit to the Company in the maximum amount of $2,000,000. All amounts outstanding under the Line of Credit, including principal, accrued interest and other fees and charges, will be due and payable on December 31, 2024. Amounts drawn down under the Line of Credit shall bear interest at a fixed rate of 12%. Advancements under the Line of Credit will be collateralized by an Open End Mortgage Deed on the Company's real property at 1 Controls Drive, Shelton, Connecticut and a Chattel Mortgage (U.C.C - 1 filing) against the Company's equipment and fixtures. Any draw down under the Line of Credit requires the approval of the Company's Board of Directors. On February 12, 2024 the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Extension Agreement which extended the maturity of the Company's Line of Credit from December 31, 2024 to December 31, 2025.

On September 23, 2024 the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Amendment Agreement which increased the available line of credit from $2,000,000 to $3,000,000, and extended the maturity of the Company's Line of Credit from December 31, 2025 to March 31, 2026.

On July 1, 2025, subsequent to the reporting period, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Amendment Agreement which extended the maturity of the Company's Line of Credit from March 31, 2026 to March 31, 2027. There were no other amendments to the original Line of Credit. The Company has not drawn against the Line of Credit facility as of June 30, 2025.

Note 5 – Property and Equipment

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

	June 30, 2025	June 30, 2024
GMP Facility	$ 8,168,045	$ 8,168,045
Land	260,000	260,000
Office Equipment	77,425	63,056
Furniture and Fixtures	5,607	5,607
Lab Equipment	6,512,173	6,469,578
Total Property and Equipment	15,023,250	14,966,286
Less Accumulated Depreciation	(8,189,359)	(7,453,823)
Property and Equipment, Net	$ 6,833,891	$ 7,512,463

Depreciation expense for the years ended June 30, 2025 and 2024 was $735,536 and $750,744 respectively.

Note 6 – Intangible Assets

Intangible assets, net consists of the following:

	June 30, 2025			June 30, 2024		
	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	(141,915)	—	(141,915)	(133,646)	—	(133,646)
Intangible Assets, Net	$ 11,478	$ 305,561	$ 317,039	$ 19,747	$ 305,561	$ 325,308

Amortization expense amounted to $8,269 and $8,270 for the years ended June 30, 2025 and 2024, 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, 2025	June 30, 2024
Personnel and compensation costs	$ 25,969	$ 23,532
Consultant	—	11,500
Clinical trial costs due to KPML	—	227,435
	$ 25,969	$ 262,467

Note 8 – Equity Transactions

Fiscal Year Ended June 30, 2025 Transactions

On July 1, 2024, 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, 2024 through June 30, 2025 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, 2024, December 31, 2024, March 31, 2025 and June 30, 2025. The Company recognized

non-cash compensation expense related to the issuance of the Series A preferred stock of $49,834 during the year ended June 30, 2025, which was the fair value on the date of issuance.

On April 15, 2024, the Company entered into a new ATM sales agreement with. E.F. Hutton (now D.Boral Capital), the Sales Agent, pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agent, shares of common stock having an aggregate offering price of up to $50 million. From July 1, 2024 through June 30, 2025 the Company sold 3,351,096 shares of common stock at an average price of approximately $1.64 per share. The shares were issued pursuant to a prospectus supplement dated May 5, 2023 and filed with the Securities and Exchange Commission on May 5, 2023 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-271706, which became effective on May 22, 2023). The net proceeds to the Company from July 1, 2024 through June 30, 2025 was approximately $5,296,000 after placement agent fees and other estimated offering expenses.

The Company accounted for the proceeds of the ATM Offering, approximately, as follows:

Gross proceeds	$	5,499,000
Less: offering costs and expenses		203,000
Net proceeds from issuance of common stock	$	5,296,000

For the year ended June 30, 2025, the Scientific Advisory Board was granted fully vested warrants to purchase 1,144 shares of common stock at exercise prices between $1.55 - $2.35 per share expiring in the fiscal year ending June 30, 2029. The fair value of the warrants was $679 for the year ended June 30, 2025 and recorded as consulting expense.

For the year ended June 30, 2025, 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	48.43-54.18 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.85-4.29 %

For the year ended June 30, 2025, 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 $10,809 during the year ended June 30, 2025, which is the fair value on the date of issuance.

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 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, 2025, the Company's Board of Directors authorized the issuance of 1,786 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $2,125 which was the fair value on the date of issuance.

For the year ended June 30, 2025, the Company's Board of Directors authorized the issuance of 79,149 fully vested shares of its common stock with a restrictive legend for consulting and legal services. The Company recorded an expense of $115,500, which was the fair value on the dates of issuance.

For the year ended June 30, 2025, the Company's Board of Directors authorized the issuance of 30,746 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 on the dates of issuance.

Fiscal Year Ended June 30, 2024 Transactions

On 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 earned under the COVID License Agreement. The Note accrued simple interest at

the rate of 12% per annum and was due and payable on January 19, 2025, the maturity date. The principal of the Note was convertible, at TheraCour's option, into 331,859 shares of the Company's Series A preferred stock, par value $0.00001 at the conversion price, specified as the fair value of the Series A shares on July 19, 2023 in the terms and conditions contained within the Note. On October 27, 2023 TheraCour exercised its right to convert the principal of the July 19, 2023 Note into 331,859 shares of the Company's Series A preferred stock. Furthermore, TheraCour cancelled all of the accrued interest on the Note totaling $49,808 which has been reported as a capital transaction credit to additional paid in capital on the accompanying statements of changes in stockholders' equity. Total interest incurred under the Note for the year ended June 30, 2024 was $49,808.

On October 6, 2023, 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, 2023 through June 30, 2024 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, 2023, December 31, 2023, March 31, 2024 and June 30, 2024. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $32,498 during the year ended June 30, 2024, which was the fair value on the date of issuance.

On April 15, 2024, the Company entered into a new ATM sales agreement with. E.F. Hutton Securities, the Sales Agent, pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agent, shares of common stock having an aggregate offering price of up to $50 million. From May 8, 2024 through June 30, 2024 the Company sold 1,308,651 shares of common stock at an average price of approximately $2.47 per share. The shares were issued pursuant to a prospectus supplement dated May 5, 2023 and filed with the Securities and Exchange Commission on May 5, 2023 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-271706, which became effective on May 22, 2023). The net proceeds to the Company from the offering was approximately $3,120,000 after placement agent fees and other estimated offering expenses.

The Company accounted for the proceeds of the ATM Offering, approximately, as follows:

Gross proceeds	$	3,237,000
Less: offering costs and expenses		117,000
Net proceeds from issuance of common stock	$	3,120,000

For the year ended June 30, 2024, the Scientific Advisory Board was granted fully vested warrants to purchase 1,144 shares of common stock at exercise prices between $1.43- $2.43 per share expiring in the fiscal year ending June 30, 2028. The fair value of the warrants was $563 for the year ended June 30, 2024 and recorded as consulting expense.

For the year ended June 30, 2024, 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	50.13-55.28 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	4.29-4.60 %

For the year ended June 30, 2024, 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 $10,747 during the year ended June 30, 2024, which is the fair value on the date of issuance.

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 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, 2024, the Company's Board of Directors authorized the issuance of 1,786 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $2,340 which was the fair value on the date of issuance.

For the year ended June 30, 2024, the Company's Board of Directors authorized the issuance of 101,542 fully vested shares of its common stock with a restrictive legend for consulting and legal services. The Company recorded an expense of $131,600, which was the fair value on the dates of issuance.

For the year ended June 30, 2024, the Company's Board of Directors authorized the issuance of 33,579 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 on the dates of issuance.

Note 9 – Common Stock Warrants

Stock Warrants

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual life	Aggregate Intrinsic
Outstanding and exercisable at July 1, 2023	8,004	$ 4.96	—	$ 238
Granted	1,144	1.76	3.50	—
Exercised	—	—	—	—
Expired	2,286	5.26	—	—
Canceled	—	—	—	—
Outstanding and exercisable at June 30, 2024	6,862	$ 3.64	1.67	$ 399
Granted	1,144	1.79	3.50	—
Exercised	—	—	—	—
Expired	2,286	5.26	—	—
Canceled	—	—	—	—
Outstanding and exercisable at June 30, 2025	5,720	$ 2.62	1.70	$ 4

Of the above warrants; 2,288 expire in fiscal year ending June 30, 2026; 1,144 expire in fiscal year ending June 30, 2027; 1,144 expire in fiscal year ending June 30, 2028 and 1,144 expire in fiscal year ending June 30, 2029.

Note 10 – Income Tax Provision

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

The income tax expense for the years ended June 30, 2025 and 2024 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, 2025	June 30, 2024
Federal statutory rate	(21.00)%	(21.00)%
Research and development credit	4.71 %	3.45 %
State tax rate	(5.93)%	(5.93)%
Nondeductible tax rate	(0.01)%	—
Other	(0.75)%	(0.86)%
Valuation allowance	22.98 %	24.43 %
Effective tax rate	—	—

The significant components of the Company's deferred tax assets at June 30, 2025 and 2024 are as follows:

	June 30, 2025	June 30, 2024
Net operating loss	$ 31,115,532	$ 29,351,534
Research and development credit	8,600,732	8,154,686
IRC Sec.174 R&E capitalization	2,748,509	2,243,662
Other	27,271	22,087
Total gross deferred tax assets	42,492,044	39,771,969
Less: valuation allowance	(42,492,044)	(39,771,969)
Net deferred tax asset	$ —	$ —

At June 30, 2025 and 2024, the Company has recorded a full valuation allowance against its net deferred tax assets of $42,492,044 and $39,771,969, respectively, since in the judgment of management, these assets are not more than likely than not to be realized. The Total gross deferred assets increased $2,720,075 from $39,771,969 at June 30, 2024 to $42,492,044 at June 30, 2025.

As of June 30, 2025, the Company has approximately $116 million of gross net operating loss carryforwards available to reduce future taxable income, if any for federal and state tax purposes. The aggregate federal net operating losses generated for the years ended June 30, 2025 and 2024 of approximately $11 million can be carried forward indefinitely. However, the deduction for net operating losses incurred in tax years beginning after January 1, 2018 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, 2025 and 2024, research and development credit carryforwards for federal and state purposes are $8,600,732, and $8,154,686, 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 June 30, 2025 and June 30, 2024 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 US 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.

Note 11 – 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, 2025, NanoViricides, Inc. entered into an Extension Agreement (the "Extension") of the 2024 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, 2025 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, 2026 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, 2025 and fully vest on June 30, 2026. The Company will recognize non-cash compensation expense related to the issuance of the Series A preferred stock during the year ended June 30, 2026. 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.

As of July 1, 2025, NanoViricides, Inc. consummated an Extension to the CFO Agreement with its Chief Financial Officer Meeta Vyas effective July 1, 2025 (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, 2025 through June 30, 2026 under the same general terms as the prior CFO Agreement.

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 7, 2021, the Company entered into a world-wide, exclusive, sub-licensable, license ("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. 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 I 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 III 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 KMPL wherein the Company granted to KMPL 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. KMPL 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. KMPL 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, KMPL will receive a customary clinical trials manager fee of thirty percent (30%) of such costs and applicable taxes. Upon commercial sales of any resulting approved drugs, KMPL will pay the Company a royalty of seventy (70%) percent of the final invoiced sales to unaffiliated third parties.

On February 12, 2024, the Company entered into an Amendment to the COVID License Agreement with TheraCour dated September 7, 2021, whereby any further cash milestone payments that would be earned upon milestone event would only become payable upon the Company having sufficient revenues, with only a portion of revenues to be used for satisfying such milestone payments.

On September 23, 2024, the Company entered into a "Memorandum of Understanding for All Antivirals Drug Development" (the MoU) with TheraCour that granted to the Company, a limited, non-assignable, non-sublicensable, exclusive Right of First Refusal to License to any antiviral drugs in development or to be developed by TheraCour for research and development purposes only, for all as-yet unlicensed viral infection treatment indications. The MoU also clarified the roles and responsibilities of the Parties and essentially codified the process that the parties have adopted since inception. The MoU further codified the treatment of all future milestone payments arising from any current or future license agreements to TheraCour to be consistent with the principles adopted in the February 12, 2024 Amendment to the COVID-19 License Agreement.

Note 12 - Subsequent Events

As discussed at Note 8 to the financial statements, on April 15, 2024, the Company entered into a sales agreement with. D. Boral Securities (formerly EF Hutton, LLC), the Sales Agent, pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agents, shares of common stock At-the-Market or ATM Offering. From July 1, 2025 through September 24, 2025, the Company sold 824,535 shares of common stock at an average price of approximately $1.57 per share. The shares were issued pursuant to a prospectus supplement dated May 5, 2023 and filed with the Securities and Exchange Commission on May 5, 2023 in connection with the Company's shelf registration statement on Form S-3, as amended File No. 333-271706, which became effective on May 22, 2023. The net proceeds to the Company from the offering from July 1, 2025 through September 24, 2025 was approximately $1.25 million after placement agent fees and other estimated offering expenses.

As of July 1, 2025, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Amendment Agreement which extended the maturity of the Company's Line of Credit from March 31, 2026 to March 31, 2027. There were no other amendments to the original Line of Credit. The Company has not drawn against the Line of Credit facility as of June 30, 2025.