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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, 2022

Commission File Number 001-36081

NANOVIRICIDES, INC.

(Name of Business Issuer in Its Charter)

NEVADA	76-0674577
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

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

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

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

Yes ☐ No ☒

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

Yes ☐ No ☒

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

Yes ☒ No ☐

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

Yes ☒ No ☐

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

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

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

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

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

Yes ☐ No ☒

On October 13, 2022, there were approximately 11,592,000 shares of common stock of the registrant issued and outstanding.

The aggregate market value of the voting stock held on December 31, 2021, by non-affiliates of the registrant was approximately $40,756,000 based on the closing price of $3.72 per share, as reported on the NYSE American on December 31, 2021, the last business day of the registrant's most recently completed fiscal second quarter (calculated by excluding all shares held by executive officers, directors and holders known to the registrant of five percent or more of the voting power of the registrant's common stock, without conceding that such persons are "affiliates" of the registrant for purposes of the federal securities laws).

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PART I

SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

The information in this report contains forward-looking statements. All statements other than statements of historical fact made in this report are forward looking. In particular, the statements herein regarding industry prospects and future results of operations or financial position are forward-looking statements. These forward-looking statements can be identified by the use of words such as “believes,” “estimates,” “could,” “possibly,” “probably,” anticipates,” “projects,” “expects,” “may,” “will,” or “should,” “designed to,” “designed for,” or other variations or similar words. No assurances can be given that the future results anticipated by the forward-looking statements will be achieved. Forward-looking statements reflect management’s current expectations and are inherently uncertain. Our actual results may differ significantly from management’s expectations.

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

ITEM 1: BUSINESS

Organization and Nature of Business

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

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

We are a development stage company with several drugs 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 have several drugs in our pipeline. Of these, two drugs developed to combat the COVID-19 pandemics, namely NV-CoV-2 and NV-CoV-2-R, are our most advanced drug candidates. We believe that the essential preclinical work including GLP Safety/Toxicology studies has been completed for taking NV-CoV-2 into human clinical trials evaluation. We are working diligently towards the goal of filing an Investigational New Drug Application (IND) for NV-CoV-2 as soon as possible. We are also working towards the goal of starting clinical trials outside of the USA for NV-CoV-2. We believe that once Phase I clinical trials of NV-CoV-2 are successful, both NV-CoV-2 and NV-CoV-2-R can enter Phase II and further clinical studies. We have successfully made oral formulations of NV-CoV-2 as both (i) NV-CoV-2 Oral “Gummies” and (ii) NV-CoV-2 Oral Syrup. In addition, we have developed the injectable form, (iii) NV-CoV-2 for Injection, Infusion or Inhalation. The other drug, NV-CoV-2-R comprises NV-CoV-2 with remdesivir encapsulated in the belly of the polymeric micelles. The clinical program is expected to start with evaluation of the NV-CoV-2 Oral Syrup and NV-CoV-2 Gummies in adults, with extension to pediatric populations upon success. Clinical Trials of the Injectable NV-CoV-2 are expected to follow thereafter. We will report on these objectives via press releases as meaningful advancements take place.

In response to the recent Monkeypox virus (MPXV) epidemic, we have begun a limited drug development program to treat MPXV patients. At present, while it appears that this epidemic is quieting down, experts expect that this virus will become endemic in the Western world, as it is in the African subcontinent (https://www.cdc.gov/poxvirus/monkeypox/cases-data/technical-report/report-3.html#dynamics). A vaccine against smallpox appears to have substantial effectiveness in protecting vaccinated persons from MPXV infection. The only currently available drug, tecovirimat (TPOXX®, SIGA), approved for smallpox, has a low resistance

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barrier for virus mutations, i.e., the virus can readily escape it by simple mutations, and has other limitations on its use. Thus there remains an urgent need for broad-spectrum drugs that can treat MPXV, smallpox, and other poxviruses.

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

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

We plan on undertaking further clinical advancement of our other lead drug candidate, NV-HHV-1 skin cream for the treatment of shingles (previously referred to as NV-HHV-101), after the COVID-19 program completes initial human clinical studies. The essential preclinical work including GLP Safety/Toxicology studies of NV-HHV-1 were completed and we began to assemble a draft IND application just when the global COVID-19 pandemic struck. We continued to work on NV-HHV-1 until we had developed viable drug candidates against COVID-19, circa May/June 2020, and thereafter focused completely on the COVID-19 drug development, putting the NV-HHV-1 program on hold.

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, which 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.

NanoViricides is one of a few biopharma companies that has its own cGMP-compliant manufacturing facility. The Company intends to produce its drugs for clinical trials in this facility. The Company has 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 first-in-human use in the current SARS-CoV-2 pandemic for our anti-coronavirus drug in development, as well as for the anticipated clinical trials of NV-HHV-1 skin cream for the treatment of shingles.

We would like to note that in response to the current global COVID pandemic, the scientific community at large and regulatory efforts to date have remained focused on (a) vaccines, (b) antibodies, and (c) re-development of pre-existing drugs. Even as alarm bells were raised by renowned scientists regarding the likelihood of escape mutations and the limitations of any vaccines and antibody therapies in combating a rapidly evolving global viral pandemic, there has been an effort to downplay these risks at all levels. This has left the world now grappling with a situation where vaccines are being rolled out even as virus variants that are highly likely to be resistant or are already resistant to current vaccines and antibody drugs have already been found to be spreading rapidly. Current vaccines are now assumed to require constant updates, as in the recent bi-valent vaccines that incorporate the original antigen and a new one from the Omicron family of variants, and re-inoculation campaigns (aka "booster shots") to keep up with ongoing changes in the virus. Attention needs to be focused instead on broad-spectrum antiviral therapeutics that minimize the possibility of virus variants escaping the drug, thereby making the costly ongoing development of vaccine updates, their deployment and re-inoculation campaigns, practically unnecessary.

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

Additionally, to the best of our knowledge, we are the only Company that is developing antiviral treatments that are designed to (a) directly attack the virus and disable it from infecting human cells, and (b) simultaneously block the reproduction of the virus that has already gone inside a cell. Together, we expect this strategy of a two-pronged attack against the virus, both inside the cell and outside the cell, can to result in a cure for coronaviruses and other viruses that do not become latent.

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The Company's nanoviricides® platform technology is based on biomimetic engineering that copies the features of the human cellular receptor of the virus. No matter how much the virus mutates, all virus variants bind to the same receptor in the same fashion. It appears that the later variants of SARS-CoV-2 may have evolved to bind to the human cellular receptor ACE2 more strongly, in general, based on published datasets. Thus, if these features of the cellular receptor are appropriately copied, the resulting nanoviricide drug would remain effective against current and future variants of the virus.

Our current drug candidates to combat the COVID-19 pandemic are designed to attack not only SARS-CoV-2 and its current and future variants, but also many other coronaviruses, and therefore are expected to be valuable even after the pandemic is over, since several coronaviruses are endemic in human populations. SARS-CoV-2 with its variants and substantial penetration into human populations worldwide is on course to become an endemic virus, or may have already become endemic by now.

Our COVID-19 drug candidates successfully entered core safety pharmacology studies required prior to commissioning human clinical trials around October/November, 2020. These studies have now been completed and we have received the GLP Safety/Toxicology reports from the external CRO in August 2021. We are now engaged in the preparation of clinical trial protocols and other activities that would be necessary for filing of an IND with the US FDA or equivalent regulatory filings for entering into human clinical trials in other countries.

The need for the broad-spectrum nanoviricide SARS-CoV-2 drug cannot be overstated in the current circumstances and the present status of the pandemic. To understand this, we are providing a short review of the current state of the pandemic below:

Strong government support led to rapid emergency use approval, and later full approval, of an already known antiviral drug now called Veklury (Remdesivir, Gilead) early on. Strong fiscal support and regulatory enablements from the government also led to the emergency use approval of two different antibody drugs, one from Regeneron (REGN-CoV-2, a monoclonal antibody cocktail containing two different antibodies) and one from Eli Lilly (bamlanivimab, a single antibody for restricted use) in the fastest ever drug development timeframe. All of these antibody drugs target the viral Spike protein that binds to the human cellular receptor, ACE2.

Even stronger commitments and strong government support led to the fastest ever emergency use approval of two vaccines, both employing nanotechnology: one by Pfizer-BioNTech, and one by Moderna. Subsequently, additional vaccines have been approved in various countries and several are in development. Almost all of these vaccines target the original 2019-nCoV-Wuhan variant, and all but a few target primarily its Spike protein. Pfizer and Moderna have introduced bivalent vaccines with Wuhan antigen and an early Omicron antigen in the same vaccine as of this writing.

Yet, as the vaccines and boosters have been deployed, several new virus variants of tremendous concern have already emerged. Additional virus variants will continue to emerge at an even faster rate because of the widespread dissemination of the virus with many patient bodies serving as virus factories providing historically the greatest ever opportunities for the virus to escape existing vaccines and antibody drugs. It has already been found that as new variants emerge, the effectiveness of the antibody drugs against the new variants is diminishing rapidly. Failure of vaccines and antibody drugs is therefore certain; the only question is how long will it be before the vaccines become substantially ineffective.

Replacing current vaccines with a new vaccine, as has been suggested, would be an endless game of chasing a rapidly changing epidemic that would be costly and also would remain substantially non-responsive to the threat, since the virus will continue to remain many steps ahead of the vaccine. Giving booster doses of existing vaccines repeatedly is scientifically epidemiologically or ethically unsupportable except for specific subsets of populations that do not respond to the vaccine without multiple boosters. An additional complicating factor is that it is now generally believed that immunity from these vaccines is not enduring; in fact the protective effect of vaccines has been estimated to be as short as 3 to 6 months only, although weak protection may remain for a longer period. Since introduction of the first vaccines circa January/February 2021, there are already a total of 4 shots of vaccines given by May/June 2022, and new bi-valent vaccines (2 shots) beginning in September/October 2022, a cycle of potentially six shots in less than 2 years!

It is well known that viruses, particularly RNA viruses, mutate rapidly, and that such changes produce "variants" that can escape from vaccines as well as from antibody drugs. SARS-CoV-2 has a repair mechanism that retains some fidelity during reproduction, and therefore it changes less rapidly than Influenza A viruses or HIV. Nevertheless, given the significant penetration of the virus into human population, and the very high viral loads achieved in severe cases of the infection, the virus has a huge opportunity to change. Additional virus variants will undoubtedly continue to emerge

at an even faster rate because of the widespread dissemination of the virus through many patients, their bodies effectively serving as “factories”. This important concern, voiced by several eminent scientists, has not been

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regarded with the seriousness it deserves by supporting and enabling rapid regulatory development of broad-spectrum drugs targeted at the coronaviruses.

The world has already witnessed at least five important SARS-CoV-2 variants with significant impact, as a result of the large number of persons becoming infected. The very first important variant, namely D614G, replaced the original Wuhan strain completely and rapidly during the first wave of the pandemic itself. In the second wave, we have seen emergence of the lineage B.1.1.7 variant from United Kingdom (Kent and London; now called alpha variant), the N501Y-V.2 (also called lineage B.1.351) from South Africa, and the P.1 variant (also called lineage B.1.1.248) from Brazil. California has seen lineage B.1.429 /(CAL.20C) variant become dominant in Los Angeles county recently, with over 50% of the infections. It appeared to be replacing the earlier dominant CAL.20G variant.

The delta variant from India replaced the alpha variant almost globally and caused a widely spread and severe wave of infections. It was subsequently replaced by the Omicron variant that was far more infectious and transmissible, but thankfully less pathogenic compared to delta, possibly because of residual immunity from earlier variants and vaccinations. Nevertheless, the sheer large number of infections resulting from Omicron led to higher fatalities than caused by the delta variant. The original Omicron variant was soon replaced by additional variants in the same family of mutations. At present, there are several variants that all have substantially escaped existing antibody drugs as well as existing vaccines. These include BA.4, BA.5, BA.2.75, and more recently BA2.75.2 and BQ.1. With each successive variant, the transmissibility appears to be greater than the previous one, but rates of hospitalization and fatality appear to remain the same, indicating some possible reduction in pathogenicity. However, it is quite possible that a variant can emerge that combines the near complete immune escape of these newer variants and the high pathogenicity of the delta variant. Such a possibility cannot be ignored as long as the coronavirus cases go down to negligible levels. Besides, SARS-CoV-2 can and does infect animals. This implies that it would not be possible to completely eliminate this coronavirus. It is on its path to become an endemic, as we had anticipated when we undertook our coronavirus drug development program.

At the low or lull-level of the pandemic, the current projected US fatality rates in excess of 150,000-200,000 annually directly ascribable to SARS-CoV-2 is still over five times more than the typical seasonal influenza fatalities, approximately 35,000 in a non-pandemic year.

It is generally believed that existing vaccines have provided significant reduction in hospitalizations and fatalities, while they worked. As the newer Omicron variants have almost completely escaped the original vaccines, new bi-valent vaccines have been developed. Clearly, it can be reasonably expected that these new bi-valent vaccines would lose effectiveness in face of new variants that would certainly arise within a matter of months.

Most of the previously available antibodies under EUA have had their EUA's revoked because of loss of effectiveness as resistant variants have emerged. The new variants have exhibited significant resistance to even the Evusheld cocktail that was expected to be broadly neutralizing. It is only a matter of time that any remaining available antibodies lose utility as new escape variants emerge.

Remdesivir is the only approved drug at present and requires long infusions. It is approved for use in hospitalized patients or patients with high risk of hospitalization. Its human clinical effectiveness has not matched its strong effectiveness in cell cultures. Molnupiravir (Merck/Ridgeback), an oral nucleoside analog, was a known mutagen and its EUA was based on very limited protection. Paxlovid® (Pfizer), another oral drug, was found to be superior to molnupiravir. However, recent clinical study reports have indicated that its effectiveness is limited to patients over 65 years of age with co-morbidities. In the general patient population not matching these criteria, the effect of Paxlovid was not distinguishable from placebo. (Arbel et al., Nirmatrelvir Use and Severe Covid-19 Outcomes during the Omicron Surge. N Engl J Med 2022; 387:790-798 DOI: 10.1056/NEJMoa2204919).

Thus, the current set of tools available for combating the COVID-19 pandemic is not robust enough to allow a "Living with COVID" attitude.

Clearly, "Living with SARS-CoV-2" is not a viable option unless a strong, broad-spectrum antiviral is developed, which we believe is the promise of NV-CoV-2. We have seen extremely strong effectiveness of NV-CoV-2 in preclinical studies in comparison to the known most effective drug, remdesivir. This gives us the belief that NV-CoV-2 is likely to be one of the best oral and injectable drugs available, if not the best. The strong preclinical safety we have found for NV-CoV-2 is expected to enable increased dosages if necessary to control the infection.

A major concern is the fact that the variants that are now becoming dominant have an accumulation of multiple mutations. This is predictive of such variants being more resistant to drugs and vaccines in use. These variants are likely to have been selected against drug

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pressure or immune system pressure, and thus would likely have resistance to vaccines, antibody drugs, as well as other commonly used drugs, as suggested by eminent scientists. Further, it is now well known that some of the new variants can cause infection of a previously recovered coronavirus patient, as well as previously vaccinated persons, and sometimes may lead to more severe disease than the earlier infection. Such new variants can be logically expected to be resistant to antibodies as well as vaccines. Additionally, it has already been found or suspected that many of the new variants are or are expected to be increasingly resistant to existing antibody drugs. Given the known weak effectiveness of available antibody drugs, even a small resistance would likely allow a variant to escape the current antibody drugs.

Of note, the currently approved drugs, namely remdesivir, the Regeneron antibody cocktail, or the Eli Lilly single antibody drug, had demonstrated only moderate effectiveness in clinical trials. Remdesivir reduced the length to recovery in severe disease cases in hospitalized patients by approximately six days, from 18 days to 12 days in a clinical trial, NIAID ACIT-1, as reported in its European (CHMP) Product Information. The Regeneron drug dosing in a clinical trial was at 2.4g or 8g of total antibody, while the Eli Lilly antibody drug dose in the combination therapy clinical trial was at 5.6g, although single antibody therapy dosages from 700mg upwards are also being evaluated. These high dosage levels are indicative of relatively weak effectiveness. The U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for the Regeneron REGEN-COV cocktail, and also to an Eli Lilly single antibody bamlanivimab (LY-CoV555) with both authorizations restricted to the treatment of mild to moderate COVID-19 only. The effectiveness of oral Paxlovid was similarly limited but it led to a significant statistical reduction in hospitalization rate. Thus, further loss of effectiveness of the existing drugs as new variants emerge would have devastating consequences.

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The SARS-CoV-2 virus, despite its current and future variants, is extremely unlikely to escape a broad-spectrum anti-coronavirus drug like the drugs NV-CoV-2 and NV-CoV-2-R that we are developing. This is in complete contrast with drugs based on antibodies, antibody cocktails, small chemicals such as paxlovid or remdesivir, as well as with preventative vaccines.

In the reported year and subsequently to date, we are working diligently towards the goal of filing an Investigational New Drug Application (IND) for NV-CoV-2 as soon as possible. We have almost completed medical writing of the IND-enabling studies including Chemistry, Manufacture and Controls (CMC) and Pre-clinical Safety/Toxicology, Pharmacology, and Animal and Cell Culture Effectiveness Studies. We will be able to complete the process of developing the Clinical Protocols and complete the IND for the US FDA after engaging a Clinical Research Organization to define and execute the clinical trials. We are also working towards the goal of initiating clinical trials outside of the USA for NV-CoV-2. We will report on these as meaningful advancements take place in our objectives.

We have been developing broad-spectrum anti-coronavirus drug candidates since the early reports of the new virus from China, then known as 2019-nCoV. We were able to bootstrap this development using our knowledge gained in the earlier endeavors working on SARS-CoV-1 and MERS coronaviruses.

We have been able to conduct this novel drug development at an accelerated pace because of the benefits of our platform technology. We were able to bootstrap our SARS-CoV-2 drug development efforts using the c-GMP-compatible manufacturing processes developed for our then flagship NV-HHV-1 drug candidate for shingles dermal treatment. Further, we have a tremendous advantage in that the Company has its own cGMP-capable manufacturing facility in Shelton, CT. This facility is capable of producing approximately 4kg of the COVID-19 drug (API, or active pharmaceutical ingredient) per batch. We anticipate that this scale would be sufficient for human clinical trials, and possibly for initial introduction under Compassionate Use, EUA or similar regulatory approval.

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

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We intend to develop NV-CoV-2 through Phase1/2a clinical trials first. Most other drugs for COVID-19 have received EUA only. Dexamethasone, a well-known anti-inflammatory drug, has been found to be very useful in the treatment of severe COVID-19 and is thought to act by suppressing the body's own immune reaction that is responsible for substantial portion of the lung damage seen in COVID-19, but has severe side effects at the dosages employed. It is not expected to be reducing the viral load itself.

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

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

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

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

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

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

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

The strong effectiveness of NV-CoV-2 and NV-CoV-2-R drug candidates in this animal model is consistent with their previously reported effectiveness in cell culture studies against infection of two human coronaviruses, hCoV-NL63, which was used in this animal efficacy study, and hCoV-229E, another circulating coronavirus that uses a distinctly different receptor, namely APN. In contrast, while remdesivir was highly effective in the cell culture studies, it was not very effective in this animal efficacy study, a result that is consistent with human clinical studies of remdesivir.

The effectiveness of NV-CoV-2-R observed in this study can be understood as a combination of (a) the improvement in the effectiveness of remdesivir due to encapsulation, and (b) the effectiveness of NV-CoV-2 by itself.

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

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

We have developed NV-CoV-2 and NV-CoV-2-R based on the Company's platform nanoviricides® technology. This approach enables rapid development of new drugs against a number of different viruses. A nanoviricide is a "biomimetic" - it is designed to "look like" the cell surface to the virus. The nanoviricide technology enables direct attacks at multiple points on a virus particle. It is believed that such attacks would lead to the virus particle becoming ineffective at infecting cells. Antibodies in contrast attack a virus particle at only two attachment points per antibody.

It is anticipated that when a virus comes in contact with the nanoviricide, not only would it land on the nanoviricide surface, binding to the copious number of ligands presented there, but it would also get entrapped because the nanomicelle polymer would fuse with the virus lipid envelope, 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 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.

In addition, the nanoviricide technology also simultaneously enables attacking the rapid intracellular reproduction of the virus by incorporating one or more active pharmaceutical ingredients (APIs) within the core of the nanoviricide. The nanoviricide® technology is the only technology in the world, to the best of our knowledge, that is capable of both (a) attacking extracellular virus, thereby breaking the reinfection cycle, and simultaneously (b) disrupting intracellular production of the virus, thus blocking the complete lifecycle of the virus, enabling complete control of a virus infection.

We have developed NV-CoV-2-R based on this encapsulation capability that is built into its nanoviricide NV-CoV-2. The Company has chosen to encapsulate remdesivir as the participating drug for blocking the viral replication cycle. Remdesivir is approved by the US FDA for the treatment of patients hospitalized with COVID-19. Encapsulation of remdesivir in the nanoviricide envelope is believed to protect it from metabolism in the body. This protection can be expected to lead to significant enhancement in the effectiveness of remdesivir itself (in the encapsulated form), by potentially increasing both the effective remdesivir concentration and its duration of action. This could be an additional favorable effect for the Company's anti-coronavirus drug candidate NV-CoV-2-R. Remdesivir is sponsored by Gilead. The Company is developing its drug candidates independently at present.

It should be noted that animals metabolize remdesivir relatively rapidly, and this has been cited as a reason for poor efficacy of remdesivir in animal models. We further note that the human clinical evidence of remdesivir efficacy against SARS-CoV-2 appears to reflect substantial metabolism in humans as well, albeit perhaps not as strong as in rats, because the human clinical data to date did not reflect as strong an effectiveness of remdesivir in blocking the viral infection as would be expected based on its cell culture studies. Thus, treatment with NV-CoV-2 and with NV-CoV-2-R, at both dose levels employed, markedly extended survival of rats infected intra-tracheally (directly into the lungs) with a lethal dose of human Cov-NL63 virus emulating the SARS-CoV-2 lung disease. Importantly, both treatments were also markedly superior to Remdesivir treatment alone.

Therefore, we believe that both NV-CoV-2 and NV-CoV-2-R have shown strikingly superior effectiveness in animal models of the lung disease caused by the surrogate coronavirus, as compared to the standard of care, remdesivir. The strong safety of NV-CoV-2 is expected to allow its use in circumstances where remdesivir may not be recommended or may be contra-indicates, such as pregnancy or pediatric situations.

The non-GLP safety/toxicology studies in rats have been completed for both NV-CoV-2 and NV-CoV-2-R. Rats dosed at up to 562 mg/kg body weight by tail vein intravenous injection on Days 0,1,3,5,7,and 9 for a total of 3,375mg/kg dose of NV-CoV-2 showed no side effects. No evidence of any severe adverse reactions was observed during the administration of the NV-CoV-2 or Vehicle during the study period and at postmortem examination in all dose groups of animals. All groups including the NV-CoV-2 and Vehicle groups tolerated the compounds similarly. The body fluids and fecal analysis showed no significant difference between the groups. Histopathological examination showed no changes either in the areas of small intestine or large intestine. No changes in organ weight or histology were observed in all dose groups.

The GLP Safety/toxicology studies for NV-CoV-2 have been completed with no evidence of adverse effects. In a GLP neuro-pulmonary safety pharmacology study in rats, the following conclusion was drawn: The intravenous administration of NV-CoV-2 at doses of 25, 50 and 100 mg/kg did not affect respiratory function in rats.

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In a GLP cardiovascular function study in the NHP cynomolgus monkeys, the following conclusion was drawn: Intravenous infusion of NV-CoV-2 at 25, 37.5, and 50 mg/kg did not have any toxicologic effects on cardiac rhythm or ECG morphology in cynomolgus monkeys in this study. No significant effects on blood pressure and heart rate were observed after the intravenous infusion of NV-CoV-2.

The broad-spectrum anti-coronavirus effectiveness of NV-CoV-2 and NV-CoV-2-R was established in cell culture studies. Both NV-CoV-2 and NV-CoV-2-R were found to be highly effective in comparison to remdesivir against two distinctly different coronaviruses in our new cell culture studies. Remdesivir is one of the most effective anti-coronavirus drugs in cell culture studies. Therefore our finding that NV-CoV-2 was highly effective and comparable to remdesivir in activity in these cell culture studies was pleasantly surprising. Even more striking was the finding that NV-CoV-2-R exceeded the effectiveness of remdesivir itself in these cell culture studies. These results indicate that NV-CoV-2 and NV-CoV-2-R could be some of the strongest weapons in the fight against coronaviruses and the current COVID-19 global pandemic. These results are consistent with the effectiveness of NV-CoV-2 and NV-CoV-2-R in animal studies against a coronavirus with lung pathology similar to the COVID-19 pathology.

Additionally, strong SARS-CoV-2 infection inhibition activity of NV-CoV-2 was observed in a standard pseudovirion study. Pseudovirion assay is a standard method for evaluating virus entry-inhibitors in BSL2 laboratories and is primarily used for viruses that require high security BSL3 or BSL4 laboratories otherwise. In this study, SARS-CoV-2-pseudovirions virus particles that carry a green fluorescent protein (GFP) producer mRNA inside, and use the SARS-CoV-2 S1 protein on their surface to bind to ACE2 receptor protein on cells were made. They were incubated with NV-CoV-2, or a known neutralizing antibody (positive control), or just the vehicle buffer (negative control). Then these solutions were separately used to infect ACE2 positive cells and the virus allowed to grow. The virus infectivity was determined by measuring the number of GFP positive cells (i.e. infected cells) versus the uninfected cells. In this well-known assay, NV-CoV-2 was as effective as the neutralizing antibody in reducing the virus infection. This study demonstrates that NV-CoV-2 attacks the SARS-CoV-2 virus particle and renders it incapable of binding to the ACE2 positive cells.

NV-CoV-2-R

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

Pharmacokinetics of Encapsulated Remdesivir Compared to Standard Formulation

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

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

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

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

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

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

NV-CoV-2-R combines two different mechanisms of attack against the virus and therefore is expected to be substantially more difficult for the virus to evade than either NV-CoV-2 or remdesivir alone. This is important because scientists believe it is only a matter of time before variants of SARS-CoV-2 that evade current vaccines and antibody drugs become commonplace.

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

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

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

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

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

Thus we believe that we will be able to develop oral formulations suitable for use in pediatric patients, and we plan to include pediatric cohorts into clinical trials at the appropriate stages. As the variants evolve, pediatric infections and their severity have begun to rise, causing major worldwide concerns even as the world is trying to move towards normalcy in education and child social interactions.

Corporate Events - Intellectual Property

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

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for several drugs with specific targeting mechanisms for the treatment of a number of human viral diseases including coronaviruses, herpesviruses, VZV, HIV, Influenza, and others.

On June 9, 2020, we reported in a press release that the Company signed a Memorandum of Understanding ("CovMoU") with respect to anti-viral treatments for coronavirus derived human infections (the "Field") with TheraCour. The MoU specifically provides a limited, exclusive license to all research and development in the Field for further research and development purposes towards human clinical trials. Dr. Diwan recused himself in the Board's discussions on the MoU, and recuses himself from the Company's discussions regarding the license agreements as well. Our Board of Directors retained an independent consultant for the evaluation of the assets in order to develop the full license agreement. 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.

On September 14, 2021, we announced execution of a license agreement for the field comprising anti-viral treatments for coronavirus derived human infections with TheraCour on September 9, 2021 (the "CoV Agreement"). The licensed field includes antiviral drugs to treat SARS-CoV-2 and its variants that cause the COVID-19 disease resulting in a global pandemic that continues to rage through the world, wave after wave, as new variants develop and take hold. There was no upfront cash payment for the license and the compensation terms were generally consistent with prior licenses, and are summarized below.

Under the CoV Agreement, we have obtained a world-wide, exclusive, sub-licensable, license to use, promote, offer for sale, import, export, sell and distribute antiviral drugs that treat human Coronavirus infections using TheraCour's proprietary as well as patented technology and intellectual property, including the new patent application cited above. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. We will not make any upfront cash payments to TheraCour and we have agreed to the following milestone payments to TheraCour: 100,000 shares of the Company's Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock") upon the execution of the Agreement; 50,000 shares of Series A Preferred Stock after the grant of the approval of Licensee's Investigational New Drug (IND) Application, or its equivalent; cash payments of $1,500,000 after the initiation of Phase I clinical trials or its equivalent; $2,000,000 after the completion of Phase 1 Clinical Trials or its equivalent for at least one product within twelve (12) months from the date of the acceptance of the IND; $2,500,000 no later than six (6) months after the completion of Phase 2A Clinical Trials or its equivalent for at least one product within twenty (24) months from the date of the completion of Phase 1 or its equivalent; 100,000 shares of Series A Preferred Stock after the initiation of Phase 3 clinical trials or its equivalent; and, at TheraCour's option, $5,000,000 in cash or 500,000 shares of Series A Preferred Stock, no later than six (6) months after the completion of Phase 3 Clinical Trials or its equivalent for at least one product within thirty-six (36) months from the completion of Phase 2 Clinical Trials or its equivalent. In addition, we agreed to pay to TheraCour fifteen percent (15%) of net sales of licensed products and any income from sublicensed products, consistent with previous agreements. Under the CoV Agreement, TheraCour retains the exclusive right to develop and manufacture the Licensed Products. The Agreement contemplates that the parties will enter into a separate Manufacturing and Supply Agreement for the commercial manufacture and supply of the drug products if and when we intend to engage into commercialization of the drugs. The CoV Agreement provides that the Manufacturing and Supply agreement would be on customary and reasonable terms, on a cost-plus basis, using a market rate based on then-current industry standards, and include customary backup manufacturing rights, as with prior agreements. The Series A Convertible Preferred Shares are only convertible upon a "change of control" of the Company as defined in its full specification, are non-transferrable and have no trading market. Each Series A share carries 9 votes, and is convertible only upon a change of control into 3.5 shares of the Company's common stock.

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

A new international PCT patent application regarding coronavirus drug candidates has been 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 was filed on June, 28, 2022, with a requested priority date of the 2021 application. The intellectual property covered by both of these patent applications is automatically licensed by us under the CoV Agreement for the licensed field. 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,

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manufactured products, and methods of use, among other specifics. The first of these patent application was filed on June 25, 2021, application number PCT/US21/39050, entitled "Self-Assembling Amphiphilic Polymers As Anti-Covid-19 Agents", and the second one was filed on June 28, 2022, application number PCT/US22/35210, entitled "Self-Assembling Amphiphilic Polymers As Anti-Covid-19 Agents". The nominal expiry date 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 we currently do not need a license for the use of remdesivir in developing the novel nanoviricide drug candidates that encapsulate remdesivir. We have undertaken encapsulation of remdesivir into the drug candidate NV-CoV-2-R for the treatment of coronavirus because we believe that this encapsulation would result in substantial patient benefits. However, we believe that our anti-coronavirus drug candidate NV-CoV-2 by itself has shown significant anti-coronavirus activity in cell culture and animal studies, and therefore is expected to be highly effective drug against human coronavirus infection, without encapsulating remdesivir.

We believe that encapsulation of remdesivir inside the polymeric micelles of NV-CoV-2, thereby resulting in the drug NV-CoV-2-R, would improve the pharmacokinetics of remdesivir and thereby improve its effectiveness when in encapsulated form in human clinical trials, in close correspondence with what was seen in animal studies. These possibilities can only be evaluated in a human clinical trial. We believe that any license for the use of remdesivir encapsulation in our novel drugs, if necessary, will be feasible in the interests of resolving the pandemic. We would also be willing to collaborate with Gilead Sciences, Inc., the developer of remdesivir, for developing the encapsulated drug. There is currently no collaboration agreement with Gilead Sciences, Inc., nor any assurance that such an agreement can be reached. The Company is currently developing its anti-coronavirus clinical drug candidates NV-CoV-2 and NV-CoV-2-R independently.

Corporate Events - Financing

We had approximately $14.1 million cash in hand as of June 30, 2022, the end of the reporting period. We spent approximately $5.9 million in cash on operating activities in the reported year, although our expenditures are expected to increase upon commissioning of human clinical trials. We believe we have sufficient financing to complete at least the initial set of human clinical trials for our most advanced drug candidate, namely, NV-CoV-2, which is anticipated to occur during fiscal 2023.

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

On July 31, 2020, we entered into an At Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc. and Kingswood Capital Markets, a division of Benchmark Investments, Inc. (each a "Sales Agent" and collectively, the "Sales Agents"), pursuant to which we may offer and sell, from time to time, through or to the Sales Agents, shares of common stock (the "Placement Shares"), having an aggregate offering price of up to $50 million (the "ATM Offering"). Sales pursuant to the Sales Agreement will be made only upon instructions by us to the Sales Agents, and we cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. Actual sales will depend on a variety of factors to be determined by us from time to time, including (among others) market conditions, the trading price of our common stock, capital needs and determinations by us of the appropriate sources of funding. We are not obligated to make any sales of common stock under the Sales Agreement and we cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. We will pay a commission rate of up to 3.5% of the gross sales price per share sold and agreed to reimburse the Sales Agents for certain specified expenses, including the fees and disbursements of its legal counsel in an amount not to exceed $50,000 and have agreed to reimburse the Sales Agents an amount not to exceed $2,500 per quarter during the term of the Sales Agreement for legal fees to be incurred by the Sales Agents. We have also agreed pursuant to the Sales Agreement to provide each Sales Agent with customary indemnification and contribution rights.

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

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

Corporate Events - Board

On November 19, 2020, we announced that Mr. Brian Zucker, CPA, has joined the Company's Board of Directors, effective November 13, 2020, as an independent director. He was also appointed as a member of the Board's Audit Committee, Nomination Committee and Compensation Committee. Mr. Zucker is a Partner at CFO Financial Partners, LLC (https://www.cfopartners.com/), 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. He 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). Since May 2018, he has been serving as the CFO of EIG Energy Partners Capital Markets, LLC. Brian holds a CPA in States of New Jersey and New York, and holds several FINRA licenses. 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. We believe we have thus strengthened our Audit Committee and our Board of Directors with the addition of Mr. Brian Zucker who brings valuable multi-faceted experience with public companies, as well as financings and banking institutions to our Board.

On January 15, 2022 Mr. Stan Glick, CPA, Chair of the Audit Committee and Director of NanoViricides, passed away. Stan joined the Board as the first Independent Director circa June, 2012 and guided us in uplisting NanoViricides from the OTC Bulletin Board to NYSE American exchange, in the project of building the new world-class nanomedicines R&D and Manufacturing campus facility at 1 Controls Drive, Shelton. His hallmark traits were competence, calmness, integrity, clarity, strength, and support. We will miss him. Mr. Brian Zucker, CPA, a member of the Audit Committee has been named as Interim Chair of the Audit committee.

The Nanoviricide Platform Technology in Brief

The Company develops its class of drugs, that we call nanoviricides®, using a platform technology. This approach enables rapid development of new drugs against a number of different viruses. A nanoviricide is a "biomimetic" - it is designed to "look like" the cell surface to the virus. The nanoviricide® technology enables direct attacks at multiple points on a virus particle. It is believed that such attacks would lead to the virus particle becoming ineffective at infecting cells. Antibodies in contrast attack a virus particle at only a maximum of two attachment points per antibody. In addition, the nanoviricide technology also simultaneously enables attacking the rapid intracellular reproduction of the virus by incorporating one or more active pharmaceutical ingredients (APIs) within the core of the nanoviricide. The nanoviricide® technology is the only technology in the world, to the best of our knowledge, that is capable of both (a) attacking extracellular virus, thereby breaking the reinfection cycle, and simultaneously (b) disrupting intracellular production of the virus, thereby enabling complete control of a virus infection.

The Company's 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 cognate receptor. These ligands are chemically attached to a nanomicelle, to create a nanoviricide®.

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

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Our Drug Programs for COVID-19 (Table 2.A):

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

(i) NV-CoV-2 Oral Syrup,

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

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

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

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

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

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

The safety and effectiveness of NVN-CoV-2 was discussed already.

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

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

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

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

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

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

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.

On August 5, 2019 we reported that NV-HHV-1 has been found to be safe and well tolerated at all dosage levels in the clinical observation portion of the GLP Safety/Toxicology study of NV- HHV-101 as a dermal treatment. The in-life stage of the first part of the GLP Safety/Toxicology studies was completed. Both the non-GLP and GLP Safety/Toxicology studies were conducted by Bioanalytical Systems ("BASi"), Evansville, IN, a Contract Research Organization that is specialized in IND-enabling safety/toxicology studies.

On December 9, 2019, we further reported the current status of NV-HHV-1 in a press release, as discussed at the Annual Shareholders' Meeting held on December 7, 2019. The in-life animal studies portions of the required GLP safety/toxicology studies were already completed then and resulting blood samples were sent by the contract research organization, BASi, to other laboratories for different analyses. We had also sent the NV-HHV-1 drug product for other required testing to different laboratories. Most of the studies were already completed by the external collaborators and we were then awaiting draft reports from the completed studies to guide the IND application drafting.

However, the COVID-19 epidemic expanded across the US, and also globally, since March 2020, and did not show signs of abating rapidly. It became apparent that this epidemic would have a significant impact on any new clinical trials for other viruses such as for our shingles treatment development. The impact would be in terms of the ability to recruit and retain patients, as well as in the design of the clinical trial in presence of COVID-19 related contingencies, and most importantly, in the interpretation of the resulting datasets. We therefore determined that it was better to wait for resolution of the COVID-19 epidemic prior to entering into NV-HHV-1 clinical trials.

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.

Our NV-HHV-1 drug is thus in the IND-enabling stage and we intend to file the IND soon after the COVID-19 epidemic situation resolves. Assuming an IND application is approved by the US FDA, we will then be able to commence clinical trials in this program.

In addition to these highest priority and most advanced drug programs, we have several additional drug programs at various stages and different levels of priorities that are discussed further below under "**The Company's Drug Pipeline**".

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

Market Size, Shingles, Herpes HSV-1 and HSV-2:

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

The market size for our immediate target drugs in the HerpeCide™ program is variously estimated at billions to tens of billions of dollars. The Company believes that its dermal topical cream for the treatment of shingles rash will be its first drug heading into clinical

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trials in the HerpeCide program. The Company believes that additional topical treatment candidates in the HerpeCide™ program, namely, HSV-1 "cold sores" treatment, and HSV-2 "genital ulcers" treatment are expected to follow the shingles candidate into IND-enabling development and then into human clinical trials.

Our Coronavirus Drug Development Program Prior to Clinical Candidate Declaration – Rapid Development of Novel drug Candidates Against a Novel Disease-Causing Virus was Enabled by Our Platform Technology:

Since January 2020, the Company began working on developing a treatment for the SARS-CoV-2 virus (then known as 2019-nCoV virus) infection that causes COVID-19 spectrum of diseases. Our efforts were at that time boot-strapped upon existing work being performed for our Shingles treatment drug candidate and earlier work that we had performed on developing drug candidates for MERS-Coronavirus in 2014, and for SARS-Coronavirus in 2012. Although we had designed and made drug candidates for MERS-CoV, these candidates were not tested as the global efforts quickly shifted to the Ebola epidemic in the 2014-2015 timeframe. For the SARS-CoV-2 drug development program, we had a good head start because the structure of the first SARS-CoV and its interaction with the human receptor ACE2 had been solved. SARS-CoV-2 uses the same receptor, ACE2, as does SARS-CoV, and another coronavirus, namely h-CoV-NL63. Also it was found that SARS-CoV antibodies were cross-reacting with SARS-CoV-2.

The Company achieved several milestones in the newly instituted drug development program against SARS-CoV-2 since beginning these efforts.

Very quickly, in January 2020, we developed anti-viral ligands capable of binding to the SARS-CoV SPIKE protein (i.e. S1 antigen) at the same site where this viral spike protein binds to the human ACE2 cellular receptor protein as a doorway to enter and infect the cell. We perform design of such anti-viral ligands using molecular modeling tools. We continued to evolve these developments further as the program progressed. We already had some of the lead chemicals or their fragments for these newly designed ligands in our existing chemicals and ligands library. We used the same polymer backbone as used for NV-HHV-1 to speed up the development, and attached the different test anti-coronavirus ligands to the polymer backbone using covalent chemical linkages, resulting in new anti-coronavirus nanoviricides test compounds.

Viral mutations lead to viruses escaping drugs such as antibodies and small chemicals in the field. In spite of mutations, the virus binds to the same site on the same cellular receptor in the same fashion. We develop small chemical ligands that are designed to bind to the virus protein at the same binding area, mimicking the cellular receptor. Thus, even if the virus mutates, the nanoviricide drugs so designed would continue to work, provided they mimic the cellular receptor adequately and successfully.

We also developed anti-coronavirus assays for testing these compounds in our own BSL2 certified Virology laboratory very quickly. These cell culture assays employ known less hazardous, circulating human coronaviruses. Of these, coronavirus hCoV-NL63 uses the same ACE2 receptor, but causes a milder disease with similar pathological manifestations, as do SARS-CoV-1 and -2. HCoV-NL63 is known to cause severe lower respiratory tract infections in young children leading to hospitalization. The symptoms are generally less severe than SARS-CoV-2 but are similar. In most cases, hCoV-NL63 causes relatively mild disease, often associated with croup, bronchiolitis, and lower respiratory tract disease in children, and is considered to cause some of the common colds in adults. Thus, the clinical manifestation of hCoV-NL63 infection in pediatric patients is similar to that of SARS-CoV-2, although much less severe. SARS-CoV-2 causes clinically similar milder forms of disease in most patients, but moderate to severe disease requiring hospitalizations in about 15-20% of infected persons. These similarities imply that hCoV-NL63 should be a reasonable model virus for antiviral cell culture and animal studies in BSL2 environment in the course of antiviral drug development for SARS-CoV-2. Thus NL63 serves as a good surrogate for SARS-CoV-2 drug development. Another coronavirus we are testing against, namely hCoV-229E, uses a different but somewhat related receptor (in terms of biophysics). Investigating against both of these strains would allow us to examine which of the test candidates have more broad-spectrum effectiveness against coronaviruses. However, there can be no assurance that successful results against these forms of coronaviruses will lead to similar results against SARS-CoV-2. There can be no assurance that even successful results against SARS-CoV-2 itself will lead to successful clinical trials or a successful pharmaceutical product. This is true of every drug development effort against SARS-CoV-2. The effectiveness of a drug against SARS-CoV-2 will need to be evaluated in human clinical trials.

We confirmed in a press release on January 30, 2020, that we had begun working on developing a broad-spectrum anti-coronavirus drug for the treatment of SARS-CoV-2 and other coronaviruses.

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On March 16, 2020, we reported in a press release that we had completed synthesis of certain test candidates that we had designed, and that we had completed development of anti-Coronavirus assays for testing such novel candidates, in our own laboratories.

On May 12, 2020, in a press release, we reported that we had successfully developed drug candidates that demonstrated very high anti-viral effectiveness in cell culture studies against multiple human coronaviruses. Two of the tested nanoviricides drug candidates were highly effective in cell culture assays against multiple coronaviruses that infect humans. In particular, they were several-fold more effective than favipiravir (aka T-705), against the tested viruses. favipiravir is a broad-spectrum nucleoside-like analog drug that is in clinical testing against SARS-CoV-2, originally developed by Fujifilm. We tested these drug candidates for anti-viral effectiveness against two distinctly different, unrelated coronaviruses that cause human disease, namely hCoV-NL63, and hCoV-229E. The assays evaluated the reduction caused by the drug candidate in cell death upon viral infection, formally known as cytopathic effects (CPE) assays.

We found that the same two nanoviricides drug candidates were highly effective against hCoV-NL63, the coronavirus that uses the same cellular receptor as SARS-CoV-2, as well as another coronavirus, namely hCoV-229E, that causes seasonal common colds in humans. HCoV-229E uses the APN (Aminopeptidase-N) membrane protein on human cells as its receptor to enter cells, different from the ACE2 receptor used by hCoV-NL63 and SARS-CoV-2. ACE2 and APN may be considered to belong to a common super family of enzyme membrane proteins in terms of biophysics. The various receptors used by different coronaviruses all appear to fall in the broad family of membrane-associated serine proteases. As a family, they share several structural features. Their substrate specificities are dictated by specific amino acid residues and their positions.

We believe the fact that these nanoviricides anti-coronavirus drug candidates are highly effective against two distinctly different coronaviruses that use different cellular receptors is very significant. Specifically, we believe this provides substantial confidence and scientific rationale that even as the SARS-CoV-2 coronavirus mutates resulting in variants, these nanoviricides can be expected to continue to remain effective. In contrast, it is now well known that SARS-CoV-2 escapes antibodies as drugs as well as immune protection from vaccines as new variants are generated. Antibodies are known to become ineffective upon viral mutations.

We believe that broad-spectrum anti-coronavirus drugs such as our nanoviricides drug candidates would be expected to provide the ideal solution for combating COVID-19, provided that the candidates show effectiveness in human clinical trials.

On May 20, 2020, we reported in a press release that strong effectiveness against infection by an ACE2-utilizing coronavirus in an animal model was observed for our test drug candidates in development against SARS-CoV-2 to treat COVID-19 spectrum of diseases. In this lethal, direct-lung-infection model, animals in all groups infected with hCoV-NL63 developed lung disease which later led to multi-organ failures, a clinical pathology resembling that of the SARS-CoV-2. Reduction in loss of body weight at day 7 was used as the primary indicator of drug effectiveness. Rats were infected directly into lungs with lethal amounts of hCoV-NL63 virus particles and then different groups were treated separately with five different nanoviricides test drug candidates, remdesivir as a positive control, and the vehicle as a negative control. The treatment was intravenous by tail-vein injection.

Animals treated with the five different nanoviricides showed significantly reduced body weight loss. The body weight loss was only 3.9% for the best nanoviricide candidate, ranging to 11.2% for the potentially least effective one, as compared to 20% in the vehicle-treated control group, in female animals (n=5 in each group). Male animals treated with the same nanoviricides also showed significantly reduced body weight loss. The body weight loss in male animals was 8.0% for the best nanoviricide candidate and ranged up to 10.9% for the potentially least effective one, as compared to 25% in the vehicle-treated control group (n=5 in each group). In comparison, remdesivir treatment led to a body weight loss of 15.2% in females and 18.6% in males in this study. Remdesivir is known to be rapidly metabolized in native animal models, and its effectiveness was evaluated in specially constructed serum esterase negative mice in published literature. Importantly, this study demonstrated that our drug candidates were highly effective in a native animal model of lethal coronavirus lung infection, which may be considered more stringent than the clinical condition in human patients. Smaller numbers mean less loss in body weight compared to starting body weight in the group, and indicate greater drug effectiveness.

The striking difference in weight loss between the two sexes in this animal model was remarkable. It has been widely reported that men are more likely to suffer severe infection and fatalities from SARS-CoV-2 than women in the current

pandemic. This feature was replicated in our animal model study indicating that biological sex differences are the driver of the differences in the severity of infection by the coronaviruses that utilize the ACE2 receptor.

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The strong effectiveness of nanoviricide test drug candidates in this model is consistent with the effectiveness observed in cell culture studies against infection of both hCoV-NL63, which was used in this study, and hCoV-229E, another circulating coronavirus that uses a distinctly different receptor, namely APN.

Thus this study corroborated the cell-culture effectiveness and provided confidence that these nanoviricides drug candidates may be expected to result in a clinical candidate to be pursued in human clinical trials.

On July 8, 2020, we reported in a press release that excellent safety and tolerability of the drug candidates in development against SARS-CoV-2 to treat COVID-19 spectrum of diseases was observed in an animal model. Three different drug candidates at three different dosage levels (low, medium, and high) and vehicle control were administered to separate groups of mice intravenously in this non-GLP Safety-Tolerability study. Sixteen mice in each group (8 males, 8 females), were administered one of the three drug candidates at one of the three dose levels, and additionally, one group was administered vehicle control, for seven days by daily tail-vein intravenous infusion in this blinded study with additional evaluations on 8th day. This non-GLP safety/tolerability study was conducted under GLP-like conditions by AR BioSystems, Inc., Tampa, FL.

There were no clinical signs of immune or allergic reactions such as itching, biting, twitching, rough coat, etc. Further, there were no observable changes in any organs including large intestine or colon on post mortem in gross histology. The only reportable changes observed were, in the high dosage groups of two of the three drug candidates tested, associated with the non-absorption of water, in the colon. This is consistent with the clinical observation of loosened stools in the same groups. In clinical usage, the drug candidates are not anticipated to be administered in such high levels. The objective of this study was to discover the dosage level at which such an effect may occur. Loose or very loose stools at very high dosages in such a study is an expected and acceptable side effect of the polyethylene glycol (PEG) moiety, which we believe forms the backbone of the nanoviricides drug candidates. PEG is used prior to colonoscopy in humans to promote loose stools and internal cleaning of the intestines, by causing non-absorption of water.

Clinical observations and gross post-mortem studies showed that the tested drug candidates were safe and well tolerated, thereby clearing the path for further development towards a treatment for SARS-CoV-2 infection that has caused the current COVID-19 pandemic.

On the basis of these studies, we have developed a strategy for drug development with the goal of creating the most effective medicine to obtain regulatory approval for emergency use in the COVID-19 pandemic in the shortest timeline feasible, after having achieved proof of concept of broad-spectrum anti-coronavirus effectiveness of test candidates. To this end, we have worked to harness the full power of the nanoviricide platform, which (1) enables attacking the virus particle blocking infection by itself as described above, as well as (2) enables protection and delivery of other payload drug(s) that can interfere with the replication of the virus inside cells.

A curative treatment for a virus such as SARS-CoV-2 coronavirus would require a multi-faceted attack that shuts down (i) the ability of the virus to infect host cells, and simultaneously, (ii) the ability of the virus to multiply inside the host cells. The nanoviricide® platform enables direct multi-point attack on the virus that is designed to disable the virus and its ability to infect new cells. At the same time, a nanoviricide is also capable of carrying payload in its “belly” (inside the micelle) that can be chosen to affect the ability of the virus to replicate. The nanoviricide is designed to protect the payload from metabolism in circulation. Thus, the nanoviricide platform provides an important opportunity to develop a curative treatment against SARS-CoV-2, the cause of COVID-19 spectrum of pathologies.

We accelerated the development of a second generation nanoviricide against COVID-19 given that a well known drug that affects the replication cycle is already, namely Remdeservir, available and is the only direct-acting antiviral currently authorized in the U.S.A. While highly effective in cell cultures, the human clinical effectiveness of remdesivir is known to be limited by the rapid metabolism it undergoes in the bloodstream upon infusion. We had hypothesized that by encapsulating remdesivir into our nanoviricide, it may undergo limited metabolism thereby improving its effectiveness. This hypothesis has borne true as discussed above under the heading “Pharmacokinetics of NV-CoV-2-R”.

On September 16, 2020, we announced that we had nominated a clinical drug candidate, identified as NV-CoV-1-R for further development. We also continued to work on additional variants of various potential anti-coronavirus drug candidates. We thus guard against the risk of unknown effects in the drug development process.

One of these newer drug candidates, namely, NV-CoV-2 was found to have several advantages over NV-CoV-1 in terms of manufacturability and dose formulation. Therefore we determined that it was best to advance NV-CoV-2 and NV-

CoV-2-R as the top-level clinical drug candidates against COVID-19.

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Remdesivir is a well-known antiviral drug (developed by Gilead) that has been approved for emergency use treatment of SARS-CoV-2 infection or COVID-19 in several countries. NV-CoV-2 is a novel agent that is being used as an adjuvant to remdesivir in creating NV-CoV-2-R, to improve the overall effectiveness. It is well known that remdesivir suffers from rapid metabolism in circulation that breaks down the pro-drug to its nucleoside form which is not readily phosphorylated and therefore has poor effectiveness. We anticipate that encapsulation in NV-CoV-2 may protect remdesivir from this rapid metabolism. If this happens, the effective level and stability of remdesivir in the body would increase. This increase may lead to increased effectiveness if there are no adverse effects. Such increased effectiveness, if found, may also allow reduction in the required dosage of remdesivir in the encapsulated form, i.e. as NV-CoV-2-R. In this sense, NV-CoV-2 can be viewed to act as an adjuvant that enhances the effect of remdesivir, a known antiviral against SARS-CoV-2. We have already found that in animal studies indeed the remdesivir effective levels are increased in the encapsulated form of NV-CoV-2-R, and the effectiveness is also increased as an anti-coronavirus agent, as compared to the standard remdesivir/SBECD formulation Veklury (Gilead).

Investor Outreach

During the reporting period and thereafter, we continue to make significant efforts in our investor outreach programs. We have retained Tradigital, Inc. as its investor relations firm. In addition, we have presented at various investor conferences. We have also been interviewed on national and investor-oriented channels, unsolicited, due to our engagement in COVID-19 drug development efforts.

On February 4, 2020, the Company reported in a press release that Dr. Diwan was interviewed on the Kennedy show on Fox Business News (FBN), on January 23, 2020. The Company has licensed a copy of the video excerpt from FBN and it is available on the Company's website (www.nanoviricides.com) under the heading "NanoViricides In the News", by clicking on "Dr. Anil Diwan on Fox Business - 01/23/2020 - By - Kennedy".

On February 10, 2020, the Company reported in a press release that Dr. Diwan was interviewed on the Stuart Varney show on Fox Business News (FBN), on January 28, 2020. The Company has licensed a copy of the video excerpt from FBN and it is available on the Company's website (www.nanoviricides.com), home page, under the heading "Dr. Anil Diwan on Fox Business - 01/28/2020".

Dr. Diwan participated as a panelist on a virtual panel discussion entitled, "COVID-19: Current Pipeline and Innovations for Therapeutics and Vaccine", organized by BioCT, an association of biotechnology and pharmaceutical businesses in Connecticut, on April 8, 2020. The panel was moderated by Dr. Mostafa Analoui, Executive Director, Venture Development & Technology Incubation Program (TIP), Office of the Vice President for Research, University of Connecticut, Storrs, CT. A transcript of the panel discussion is available at https://www.youtube.com/watch?v=WpTP_wnEZKw&feature=youtu.be.

On April 13, 2020, the Company reported that Dr. Diwan and key staff members at the Company's Shelton, CT headquarters were interviewed by broadcast journalist Christine Corrado of Proactive Investors on March 27, 2020, remotely, from their New York office.

On April 22, 2020, Dr. Diwan presented a corporate update focused on the COVID-19 and shingles programs at the Planet Microcap Virtual Showcase 2020.

On June 30, 2020, we reported in a press release that Nanoviricides, Inc. had been added to the Russell Microcap® Index effective after the U.S. markets opened on Monday, June 29, 2020. Membership in the Russell Microcap® Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. Approximately $9 trillion in assets are benchmarked against Russell's US indexes. Russell indexes are part of FTSE Russell, a leading global index provider. Inclusion of NanoViricides in the Russell Microcap Index may be expected to increased participation in the NNVC stock positions of investment managers and institutional investors that purchase, follow or employ this index.

On July 21, 2020, Dr. Diwan, was invited to participate in the "B. Riley FBR Virtual Infectious Disease Summit – Therapeutics Day". The Conference was organized by B. Riley FBR, Inc. (https://brileyfbr.com/). Dr. Diwan participated in Panel #3 at 2020 at 2:10 p.m. ET, entitled "Taming the Severe Disease Presentations".

On September 3, 2020, Dr. Diwan provided a further update on our programs at the LD500 Virtual Conference, as reported by the Company in a press release issued on September 4, 2020.

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On September 30, 2021, Dr. Diwan presented an update at the Benzinga Healthcare Small Cap Conference-2021 on our programs entitled "Pan-coronavirus Broad-spectrum Nanomedicines NV-CoV-2 and NV-CoV-2-R to Attack the SARS-CoV-2 Virus and its Variants in the Global Pandemic".

We have provided updates on our progress via press releases.

Thus we have made strong progress in drug development, despite engaging into a novel drug program against coronaviruses in response to the current pandemic, as well as financing and leadership building in the reported year.

The Company's primary focus is on bringing its broad-spectrum anti-coronavirus drug into human clinical trials as soon as possible, in response to the current pandemic, as detailed above.

Our other lead program, namely NV-HHV-1 skin cream for treatment of shingles rash, is now in IND-ready stage, with clinical trial design and clinical trial selection as the remaining steps prior to filing an IND. 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. In addition, we have drug candidates in development against severe influenzas (including bird flu), HIV, Dengue, Ebola/Marburg and other viruses at different preclinical stages. According to a 2014 market report prepared by Jain PharmaBiotech ("Jain"), entitled "Antiviral Therapeutics, Technologies, Markets & Companies," the overall market size for our potential drugs is estimated to be between $40~65 Billion by 2023. This broad pipeline is enabled by our unique post-immunotherapeutic "bind-encapsulate-destroy" technology platform.

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

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 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. The Company has exclusive licenses from TheraCour for drug candidates derived from and based on TheraCour's technologies for several viruses. In 2005, the Company 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, 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 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, the Company completed the process of licensing the VZV (shingles, chicken pox virus) field from TheraCour in November 2019.

The Company further completed the process of licensing antivirals for the field of human coronavirus indications in September 2021. 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.

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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.

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

The Nanoviricide® Platform Technology

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

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

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

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

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

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

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

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

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

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

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

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

Broad-Spectrum Nanoviricide Drug Candidates

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

Formulation is Inherent in the Design Aspect of a Nanoviricide

Since declaring our clinical candidate, namely NV-HHV-1formulated as a skin cream for topical treatment of shingles rash, further development of this drug towards scale-up, formulation, and cGMP-like manufacture has already been accomplished in a relatively rapid manner. Formulation development for novel drugs in normal pharmaceutical paradigm often takes years. However, in the nanoviricide approach, the nanomicelle polymeric backbone itself takes care of the formulation aspects. The nanomicelle is designed to optimize the drug for its intended route of administration, be it injectable, skin cream, eye drops, or even oral. Thus, no specific or extensive formulation development is expected to be required after clinical candidate declaration.

We were able to rapidly develop the injectable/infusion formulation, an inhalable formulation for delivery directly into lungs, as well as an oral formulation of NV-CoV-2 and NV-CoV-2-R in a very short time because of the features of our nanomedicines technology.

We have previously manufactured multi-kilogram quantities of the final drug product for shingles cGLP Safety/Toxicology studies that are required for filing an IND.

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Uniform Polymer Nature Enables Nanomedicine Manufacturing Quality Assurance

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

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

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

Our BSL-2 Certified Virology Lab

We have a BSL-2 (Biological Safety Level 2) certification from the State of Connecticut for our Virology suite at the Shelton campus. This suite comprises three individual virology workrooms, enabling us to work on several different viruses and strains at the same time. This facility is designed only for cell culture studies on viruses, and no animal studies can be conducted at any of our own facilities.

We 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 have developed in-house cell culture screening capability for developing drug candidates against human Coronaviruses(h-CoV), VZV, HSV-1 and HSV-2, as well as influenzas and HIV, among others. This capability has substantially strengthened our drug development programs. We believe that this internal screening enables speedy evaluation of a much larger number of candidates than external collaborations allow. 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.

cGMP Manufacturing Facility

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 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 believe we are in a position to advance our drug candidates into clinical trials, produce the pre-clinical “tox package” batches, and the clinical drug substance batches.

We believe that this facility will be capable of scaling to the quantity of product needed for initial market introduction and revenue generation from our first drug when approved. We have already performed production of kilogram-scale batches of drug substance and multi-kg scale batches of drug product at this facility successfully. We believe this scale is sufficient for clinical trials, and, depending upon final dosage level, this scale may be sufficient for initial market entry.

Our Herpicide™ Drug Development Programs

In addition to the rapid advancement in drug development against human coronaviruses in response to the current pandemic undertaken since January 2020, as described earlier, in previous years, we had focused our efforts primarily on the HerpeCide program. We are developing drugs against three indications in this program in parallel at present, namely, HSV-1 “cold sores” (orolabial herpes and recurrent herpes labialis or RHL), HSV-2 “genital ulcers”, and VZV

shingles. We are developing topical treatments (skin creams or lotions) for these three indications. All of the drug candidates in these three leading indications comprise common chemistry features

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and are based on the same family of ligands and polymers, enabling efficient parallel development. Our parallel development of these indications maximizes return on investment and shareholder value. Of these, the shingles indication program is in the process of clinical trial design and clinical site selection, which will be a part of the IND application. The IND filing has been delayed due to the potential impact of COVID-19 on upcoming human clinical trials, and we will complete this task to engage into clinical trials as soon as the pandemic wears down to the point that these clinical trials can be conducted without excessive impact on design, execution, and cost of the trials. We believe that the other two indications will advance to an IND stage in the very near future.

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

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

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

Including the HerpeCide program explained above, we currently have nine different drug development programs, attesting to the strength of our platform technology. We have chosen to focus strategically on the anti-coronavirus program at present, and we believe that we have candidates that are worthy of human clinical trials. We are in the process of moving them into IND-enabling safety/toxicology studies at this time. We believe that these IND-enabling studies should be conducted rapidly due to the expedited nature of the anti-coronavirus programs at both the CROs and at the US FDA. After this, we plan on taking the NV-HHV-1 skin cream clinical drug candidate for treatment of shingles rash into human clinical trials, and further develop additional HerpeCide™ program indications and drug candidates that are expected to result in a robust franchise with drug approvals against a number of different herpes virus indications.

Our drug development strategies may be influenced by considerations regarding the ability to engage into licensing or co-development relationships with other pharmaceutical companies. Pharmaceutical drug development is an expensive and long duration proposition. Management's plan is to develop each of our nanoviricides to the necessary stage(s) for potential collaborations. Our drug development strategies may be influenced by considerations regarding the ability to engage into collaborations with other pharmaceutical companies. 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 the Company. The Company intends to develop its drugs on its 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 the Company will be successful in obtaining sufficient financing on terms acceptable to the Company.

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

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

We have continued to make significant progress in advancing our newly engaged anti-coronavirus drug program, and our HerpeCide program drug pipeline. Our drug development capabilities are substantially enhanced by the recent financings discussed earlier.

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 the Company's control.

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The Human Coronavirus Treatment Drug Program

In a very short time, we have been able to develop drug candidates worthy of human clinical trials to treat SARS-CoV-2 infection that causes COVID-19 spectrum of diseases. We are currently advancing NV-CoV-2 and NV-CoV-2-R as the clinical drug candidates towards human clinical studies.

Our coronavirus drug treatment candidates were shown to be highly active against multiple coronaviruses in cell culture studies, and also highly active against a coronavirus that uses the same ACE2 cellular receptor as the SARS-CoV-2 (and SARS-CoV-1), namely, h-CoV-NL63, in animal studies. We are therefore confident that these candidates may result in a drug that can be used not only during the pandemic but also normally for the various circulating human coronavirus diseases.

Due to the severe nature of the pandemic, several companies are developing treatments and vaccines for COVID-19. Of these, only two at present are directly acting on the virus itself, namely remdesivir (Gilead), and paxlovid (Pfizer). Remdesivir is currently fully approved for use in hospitalized patients in the USA and other countries, and oral Paxlovid is approved for emergency use in USA and other countries, for COVID-19. Both of these have limited effects. They both act inside the cell by blocking the replication cycle of the virus. Several known antivirals (developed against other viruses) have been tested clinically both alone and in combinations, with limited effect if any. Several of such clinical trials are on-going.

Our nanoviricide that is designed to destroy the external virus so it does not go inside cells should be complimentary to the approach of blocking viral replication inside cells. Blocking both the external virus and the internal replication cycle at the same time could potentially result in a cure, if effective agents to do so can be developed.

Additionally, several antibodies are in development to neutralize the external virus. Antibodies are generally highly specific and the viruses are known to escape antibody treatments readily. Convalescent plasma (plasma from recovered patients that contains neutralizing antibodies) is being attempted as a treatment. The new Omicron lineage variants of SARS-CoV-2 are resistant to almost all available antibodies, and the corresponding EUA's have been revoked. Further, several repurposed drugs that do not attack the virus but effect the host have entered clinical trials, and many of them have shown limited or little benefit. Dexamethasone, a corticosteroid, has been shown to help hospitalized patients with severe disease and reduce lethality, due to its effect on calming the human immune system attacking the lungs.

Several companies are advancing drug candidates for the management of COVID-19, and many have received EUA. Most of the drug candidates are designed to provide benefits that are not directly associated with attacking and controlling the virus. Merck and Ridgeback are developing an antiviral called molnupiravir, which may have oral use applicable to infected persons in very early stages of disease. Pfizer is developing several antivirals against coronaviruses. None of these drugs attack the external circulating virus particles or block the re-infection cycle as NV-CoV-2 is designed to do. Thus, their mode is complementary to NV- CoV-2 and combination therapy with one of these drugs and NV-CoV-2 may yield substantial benefits. We also note that none of these drugs in development attack the complete lifecycle of the virus as NV-CoV-2-R is designed to do, to the best of our knowledge.

There continues to remain a need for an effective, broad-spectrum anti-coronavirus drug, in spite of all of these efforts. We believe the Company is uniquely positioned to respond to this need with its novel technology.

The Shingles Topical Treatment Drug Program

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

Broad-Spectrum HerpeCide™ Drug Candidates Enable Additional Indications

The potential broad-spectrum nature of our anti-HSV drug candidates is expected to enable several anti-herpesviral indications. Thus, HSV-1 primarily affects skin and mucous membranes causing "cold sores". HSV-2 primarily affects skin and mucous membranes

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leading to genital herpes. HSV-1 infection of the eye causes herpes keratitis that can lead to blindness in some cases. In addition, human herpesvirus-3 (HHV-3), aka varicella-zoster virus (VZV) causes chickenpox in children and, when reactivated in adults, causes shingles. Shingles breakouts are amenable to topical treatment, as are the HSV cold sores, genital lesions, and herpes keratitis of the eye.

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

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

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

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

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

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

These results have enabled the identification and declaration of a clinical drug candidate in the HerpeCide program. We have taken this candidate, namely NV-HHV-101, into IND-enabling studies, towards human clinical trials. The first indication we intend for treatment with this drug is the topical treatment of shingles rash.

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

This dermal drug development workload is expected to be significantly shorter than the studies for ocular, injectable, or oral drugs. We anticipate filing an IND once the report of these IND-enabling studies is available.

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

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

HerpeCide Program Collaborations and Program Update

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

In addition, we have a continuing relationship with BASi, a CRO for GLP and non-GLP safety/toxicology ("Tox Package") studies. We have also engaged regulatory affairs consultants from time to time.

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

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

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

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

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

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

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

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

Shingles and Associated Pain, Postherpetic Neuralgia (PHN)

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

Acyclovir-based oral drugs, such as valacyclovir (Valtrex®), are available as systemic therapy for shingles. Intravenous acyclovir is also employed for treatment of various VZV indications. However, VZV is substantially less sensitive to

(val)acyclovir than is HSV-1.

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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.

HSV-1, HSV-2, Ocular Herpes Keratitis

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

We believe that we will be able to successfully develop a drug candidate for Ocular Herpes Keratitis (HK) as well. It is caused by HSV-1 or HSV-2 infection of the external eye. We are developing this drug as topical eye drops or eye lotion, in order to achieve maximum local drug effect while minimizing systemic exposure. We plan on testing these drug candidates against adenoviruses as well, to determine if the same drug would also be effective against epidemic keratoconjunctivitis (EKC, the severe "pink eye" disease). If the same drug works against herpes virus and adenovirus infections of the eye, 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)

The Company is 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 followed by oral acyclovir derivatives

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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.

cGMP Manufacture

We have already manufactured our drug candidate, NV-HHV-101, in a cGMP-compliant manner at this facility for the 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 also manufactured our developmental drug candidates for the treatment of human coronaviruses at approximately 0.5kg scale already in our scale-up manufacturing facility and in our cGMP-compliant manufacturing facility.

The FluCide™ Program

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

DengueCide™

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.

HIVCide™

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. The Company believes that this strong effect and sustained effect together indicate that HIVCide can be developed as a single agent that would provide “Functional Cure” from HIV/AIDS. The Company believes that substantially all HIV 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, the Company believes that this therapy would also minimize the chances of HIV transmission. The Company is currently optimizing the anti-HIV drug candidates. These drug candidates are effective against both the R5 and X4 subtypes of HIV-1 in cell cultures. The Company believes that these drug candidates are “broad-spectrum”, i.e. they are expected to be effective against most strains and mutants of HIV, and therefore escape of mutants from our drugs is expected to be minimal. Certain anti-HIV nanoviricides have already been demonstrated that appear to provide extended viral load suppression for as long as 30 days or more even after stopping the drug, in animal studies. Given the chronic nature of HIV/AIDS, such a drug that has long sustained effect is expected to provide significant benefits to the patient. We believe once a week dosing is possible. Anti-HIV drug development is both expensive and slow because of the nature of the animal studies that require SCID mice whose immune system is destroyed and then replaced by surgically implanting and growing human immune system tissues in the mouse body. Due to our limited resources, HIVCide development is further hampered.

EKC

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

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the anti-EKC drug development program and the ocular Herpes Keratitis drug development program, to develop a single drug that is effective against both diseases, i.e. effective against both adenoviruses and herpes viruses. This work is in research stage.

Other Drug Programs: Ebola, Rabies and others

In addition, 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.

To date, the Company does not have any commercialized products. The Company continues to add to our existing portfolio of products through our internal discovery and clinical development programs and also seeks to do so through an in-licensing strategy.

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

Safety and Toxicology Studies

Our novel drug candidate for COVID-19 treatment, NV-CoV-2 has successfully completed GLP safety/toxicology studies required for filing an IND application in the near future. Both NV-CoV-2 and NV-CoV-2-R have successfully completed pre-clinical safety/toxicology studies.

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. This, 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. Based upon these results, a GLP Safety/Toxicology study of dermal treatment in mini-pigs has been commissioned. These safety results are in agreement with histopathological observations in the human skin organ culture model studies.

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

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

Clinical and Regulatory Strategy

From time to time we have engaged a number of regulatory consultants with US FDA experience, to advise us on the regulatory pathways, and the studies required for the IND applications for the various disease indications.

We are expeditiously working on taking one of our anti-coronavirus developmental candidates into human clinical trials for the treatment of the SARS-CoV-2 infection that causes COVID-19 spectrum of diseases.

After the COVID-19 clinical program advances, we plan on taking our anti-VZV drug candidate NV_HHV-101 into human clinical studies.

The other HerpeCide™ program drug candidates are expected to follow into clinical development, as the necessary additional safety and efficacy studies in cell culture and animal models are performed. We depend upon external collaborators for animal safety and efficacy studies, limiting the speed of our drug development work. While we seek collaborators and providers that have animal models

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that may be predictive of efficacy in human clinical trials, pharmaceutical drug development relies on what is available and what is doable rather than this gold standard. Newly implemented animal models require validation studies to establish how reproducibly they can discriminate between placebo and drugs that are known to work in the clinic, when such drugs are available. In many cases, we have to rely upon research level animal models that have not yet established such robustness. Nevertheless, we can continue to use such models to obtain preliminary indications for drug candidate refinements.

We believe that the efficacy we have observed of our anti-VZV drug candidates in the *ex vivo* Human Skin patch Organ Culture "SOC" model in the Moffat Lab is a strong indicator that these drug candidates are worthy of clinical development. There is no well-established animal model for shingles at present. As such we assume that these datasets will be sufficient for filing an IND.

With the non-GLP Safety/Toxicology data, and our Chemistry, Manufacture and Controls (CMC) manufacturing dataset, we filed a pre-IND application with the US FDA for NV-HHV-1 as a topical treatment for shingles rash.

On June 3, 2019, the Company reported that the US FDA (the Agency) has generally agreed in its pre-IND response that the plan of drug development presented by the Company to the FDA is generally adequate at this time. The Company received the response on May 23, 2019.

In particular, the Agency agreed that the Company's strategy for drug substance and drug product acceptance criteria is adequate. The Agency further agreed that the IND-enabling non-clinical studies proposed by the Company are generally adequate. The US FDA also said 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 are generally consistent with the Company's planned IND-enabling non-clinical studies. The Company has discussed the Agency's comments and suggestions in detail with its regulatory consultants from Biologics Consulting Group, VA, and has continued the pre-clinical development program accordingly.

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

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

We have not attempted to evaluate the market size of coronavirus drug candidates. During the pandemic, it is clear that hundreds of billions of dollars are being spent on vaccines and therapeutics for COVID-19 treatment worldwide. However, it is expected that overall number of cases and their severity would go down as time progresses assuming that the available vaccines remain effective. Novel SARS-CoV-2 variants however continue to evolve and continue to improve in their transmissibility, infectiousness, as well as vaccine and antibody avoidance. Further, given the penetration of this virus, it is generally believed that it will become endemic. Based on these considerations, it can be expected that the market size for anti-coronavirus drugs will continue to be in several billions of dollars annually even after the pandemic abates.

The current market size for drugs for the treatment of different herpes simplex infections is estimated to be approximately $2-4 billion. The current market size for the treatment of shingles is estimated to be approximately $500 million to $1 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.

The approximate market size for severe cases of shingles may be approximately one billion dollars. Severe cases of shingles may lead to hospitalization in several thousand cases in the USA every year. In addition, shingles appearing on the face may reach the eye and may cause significant vision issues. 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. A new two-dose shingles vaccine called Shingrix® 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 supplies of this vaccine are limited at present. Shingles is not seen as a life-threatening or life-modifying disease, the use of vaccines is limited, and may continue to be limited, especially if an effective drug is developed.

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In addition, the estimated market size for an effective anti-Influenza drug is expected to be in tens of billions of dollars. The current estimate of anti-influenza drug market size is approximately $4 billion. The current market size for anti-HIV treatments is in excess of $20 billion. Other drugs in our pipeline, taken together, are estimated to be several billion dollars in market sizes.

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

Our Campus in Shelton, CT

The multi-kilogram production scale of our cGMP-capable manufacturing facility would enable the potential for NanoViricides to become a fully integrated pharmaceutical company (“FIPCO"), organically growing by generating revenues from initial market entry, if our first drug is approved for marketing by appropriate regulatory authorities. As an example, a similar transition from R&D to FIPCO at Alexion (stock symbol: ALXN) led to a significant upswing in the market value of that company.

With the large R&D labs, Analytical labs, the Bio labs, the Process Scale-Up production facility, and the cGMP-capable manufacturing facility established at our Shelton campus, we are in a much stronger position than ever to move our drug development programs into the clinic rapidly. These capabilities have enabled the rapid progress of our first drug candidate from development cycles through clinical drug candidate declaration to IND-enabling non-GLP and GLP Safety/Toxicology studies over the past two years.

Process Scale-Up Production Capability

The Process Scale-up area is available and operational at scales of 200g to 2kg per step for different chemical synthesis and processing steps as required. It comprises reactors and process vessels on chassis or skids, ranging from 1L to 30L capacities, as needed. Many of the reactors or vessels have been designed by us for specific tasks.

cGMP Production Capability

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

We believe that the production scale is sufficient for initial market entry of the current drugs in the HerpeCide program.

This cGMP-capable facility can handle multiple reactors on chassis of up to 75L capacities.

At present, we move operations to our cGMP-capable manufacturing facility from the Process Scale-up facility as the operational steps are developed to the level needed for moving them into the cGMP facility. This requires the development of draft-level Standard Operating Procedures, training, and drill-through of operations. We now have a functional Quality Assurance and Quality Control Department.

Our BSL-2 Certified Virology Lab

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

We have the ability to work on multiple types of viruses or multiple virus strains at the same time, as this facility comprises three independent virological rooms. We also have the capability for performing HIV screening assays based on cell culture in house now,

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once we re-engage that program. We also have the ability to perform limited anti-influenza drug screening assays in cell culture in house.

It is now possible for us to implement several other cell culture-based assays for many different viruses. These capabilities are expected to enable rapid drug development once we re-engage the drug development efforts in areas beyond the HerpeCide program again.

We do not have the facilities for performing animal model studies for any of our programs. We depend upon external collaborators for such studies.

Manufacturing Requirements of Some of Our Drug Candidates

The anti-coronavirus batch drug candidate manufacturing requirements are expected to be modest. We have sufficient capacity to support potential clinical trials from possibly a single batch of production, depending upon dosage requirements. We may have the ability to produce sufficient drug to produce tens of thousands of patients, depending upon dosage requirements, at our current facility itself.

The HerpeCide program drug product batch requirements are estimated to be fairly modest because of the topical nature of treatment. In consultation with BASi and BCG, we had estimated a batch size of approximately 1kg drug substance to be sufficient for the "Tox Package" (i.e. safety and toxicology) studies of our dermal topical shingles drug candidate. NV-HHV-101 drug substance manufactured at approximately 1kg scale in a cGMP-compliant manner and formulated into drug products at different concentrations at scales of up to 5kg was manufactured for the GLP Safety/Toxicology studies in our facility. Performing the manufacture in house has saved us a significant amount of money, possibly in tens of millions of dollars, as well as in time, possibly at least one year.

We are estimating that a ~500g batch will be more than sufficient for initial Phase-I human clinical studies as well. Our current estimate for a Phase 2a human clinical efficacy study is also in the range of a ~500g batch requirement. We already have the facilities for producing up to 1kg per batch or more.

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

Patents, Trademarks, Proprietary Rights: Intellectual Property

The nanomedicine technologies licensed from TheraCour serve as the foundation for our intellectual property. NanoViricides holds a worldwide exclusive license to certain 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 has entered into an Additional License Agreement with TheraCour granting NanoViricides 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.

On September 1, 2005, the Company entered into a Material License Agreement, (the "License Agreement") with TheraCour. Initially, TheraCour granted the Company an exclusive license for technologies developed by TheraCour for six virus types: HIV, HCV, Herpes Simplex Virus (HSV-1 and HSV-2), Rabies, Asian (bird) flu and Influenza. In consideration for obtaining this exclusive license, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of certain costs as a development fee and such development fees shall be due and payable in periodic installments as billed; (2) to pay $25,000 per month for usage of lab supplies and chemicals from existing stock held by TheraCour; (3) to pay the greater of $2,000 or actual costs, for other general and administrative expenses incurred by TheraCour on our behalf; (4) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour; (5) that TheraCour shall retain the exclusive right to develop and manufacture the Licensed Products, exclusively for NanoViricides, and unless such license is terminated, will not develop or synthesize the Licensed Products for its own sake or for others; and (6) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. TheraCour may terminate the

License upon a material breach by us as specified in the agreement. However, the Company has the opportunity to cure the breach within 90 days of receipt of notice to terminate the License. On

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February 15, 2010, the Company approved an Additional License Agreement with TheraCour. Pursuant to the exclusive Additional License Agreement, in consideration for the issuance of 2,000,000 shares of the Company's Series A Preferred Stock, (the "Series A Preferred"), the Company was granted exclusive license, under the same terms as the original License Agreement, 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 2015 TheraCour stopped billing the Company and the Company stopped paying for the $25,000 per month usage fee for prior existing materials, by mutual agreement. There was no amendment to the license contract effected for this purpose.

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. 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.

In September 2021, we entered into a Licensing Agreement (the "CoV Agreement") with TheraCour for an exclusive license for us to use, promote, offer for sale, import, export, sell and distribute products for the treatment of human coronavirus derived indications, described in detail earlier. These licenses are not limited to underlying patents, but also include the know-how, trade secrets, and other important knowledge base that is utilized for developing the drugs and making them successful.

In addition, these extremely broad licenses are not limited to some specific chemical structures but comprise all possible structures that we could deploy against the particular virus, based on the licensed technologies. Further, the licenses are held by NanoViricides for worldwide use. 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 files bankruptcy or otherwise declares insolvency and the inability to conduct its business.

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, a company controlled by our founder and the holder of the patents underlying our licensed technology, we actively seek patent protection both in the United States and internationally and intend to file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

The Company believes that our drugs by themselves may be eligible for patent protection. The Company, in conjunction with TheraCour, plans on filing patent applications for protecting these drugs when we have definitive results from in vitro or in vivo studies that enable further drug development and IND application filing.

COVID-19 Related Drugs: Patent Coverage and Lifetime

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

The 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.

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Table 1: Intellectual Property, Patents, and Pending Patents Licensed by the Company				
Patent or Application	**Date of Issue/ Application**	**US Expiry Date**	**International**	**Owners**
US6,521,736 (Certain specific amphiphilic polymers). (*)	Issued: Feb 18, 2003	Feb. 18, 2020	N/A	TheraCour Pharma and Univ. of Massachusetts, Lowell.
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].
*:Nonexclusive license to UMasss Lowell from TheraCour Pharma due to collaboration. Nonexclusive license to NanoViricides from TheraCour Pharma. This Patent IP is not in use for NanoViricides' current drug developments.				
**: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 fundamental patent on the polymeric micelles composition, structure and uses was issued in the USA with substantially broad claims. This validates the novelty of our approach as well as our leadership position in the nanomedicines based on polymeric micelle technologies. This patent application has so far been issued, granted, and/or validated, with substantially similar broad claims as 52 different patents in different countries and multi-country intellectual property organizations. A fundamental patent on which the nanoviricides® technology is based (US Patent No. 8,173,764) for "Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers" was issued on May 8, 2012. The patent term is expected to last through October 1, 2028, including anticipated extensions in compensation for time spent in clinical trials. This US Patent has been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The disclosed structures enable self-assembling, biomimetic nanomedicines. NanoViricides, Inc. holds exclusive, perpetual, worldwide licenses to these technologies for a broad range of antiviral applications and diseases. The other national and

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regional counterparts of the international Patent Cooperation Treaty ("PCT") application number PCT/US06/01820, which was filed in 2006, have issued as a Singapore National Patent Publication, a South African patent, and also as an ARIPO regional patent, an OAPI regional patent (covering Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, and Togo). It has also issued as a granted patent in New Zealand, China, Mexico, Japan, Australia, Canada, several countries in Europe, Hong Kong, Indonesia, Israel, Korea, Malaysia, Philippines, Pakistan, and Vietnam among others. Estimated expiry dates range nominally from 2026 to 2027, prior to accounting for various extensions available in different regions and countries. Additional issuances are continuing in Europe, and in several other countries around the world.

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

A total of at least, 61 patents have been issued globally, on the basis of the two international PCT patent families that cover the fundamental aspects of 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 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.

As with COVID patents (see above), we plan on filing additional specific patents to cover our other fields of use for specific classes of drugs as the drugs mature towards clinical trials. 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 2042-2047.

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

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. The Company controls the research and work TheraCour performs on its behalf and no costs may be incurred without the prior authorization or approval of the Company.

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or reexamination proceedings regarding the enforcement or validity of our licensor, TheraCour's

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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.

Trademarks

The Company currently has no registered trademarks.

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.

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

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

The Company's Drug Pipeline

Over the first several years of our operations, we continued to work on different viruses every year, creating a broad pipeline of drug candidates. This provided a validation for our novel technologies. In addition, we were pursuing non-dilutive drug development and partnering opportunities such as government grants and contracts as well as partnering with other non-governmental agencies, or medium and large pharmaceutical companies.

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

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

The Company currently is focused on the coronavirus drug program, and has multiple development candidates, with at least one of them moving towards human clinical studies. In addition, the Company is developing drug candidates for several indications in various stages of development in the HerpeCide program alone, described further below. Of these, the drug candidate NV-HHV-1 Skin Cream for the topical dermal treatment of shingles rash (VZV) has substantially completed IND-enabling GLP Safety/Toxicology studies, having completed candidate optimization through rapidly performed human skin organ culture assays in Professor Jennifer Moffat's lab at the SUNY Syracuse Upstate Medical Center. We believe that the Skin Cream for the dermal topical treatment of HSV-1 cold sores and the skin cream for the dermal topical treatment of HSV-2 genital ulcers are expected to rapidly mature towards human clinical trials in short succession after the clinical VZV drug candidate, namely NV-HHV-1. We have expanded the HerpeCide program to include additional indications for which we are developing drugs that are the same as or simple modifications of the existing drug candidates in the HerpeCide program, generally with a different formulation due to a different delivery pathway. This enables us to maximally leverage current R&D while expanding our drug pipeline and potential market and making a greater impact on patient lives.

Given the large development costs associated with FluCide, HIVCide and other drug programs, we believe that these drug candidates will follow later because of the significant development work that needs to be performed in pre-clinical studies against a number of different influenza virus strains and subtypes.

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

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

Oral Drug Development Programs

We have made tremendous progress in developing pan-coronavirus drug candidates, since the pandemic broke out. These are now ready to go into human clinical trials. Of note, in addition to injectable formulation, we were able to develop orally active nanomedicines in this program. Based on the success of this oral drug development, we have now added oral drug development programs across all of our drug development programs.

About the Priority Levels for Our Drug Development Programs:

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

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

Our drug pipeline against SARS-CoV-2 variants for the treatment of COVID-19 disease is described earlier. We are working on getting ready to commence human clinical trials for the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies Drug Products initially. We are planning a Phase I/II clinical trial that should give us an indication of human safety as well as effectiveness in mild to moderate COVID-19 disease in a small pool of patients.

Table 2. A. Coronavirus Program; NanoViricides Drug Products in Development Broad-Spectrum Antiviral to Treat Coronavirus Infections SARS-CoV-2 and Seasonal Coronaviruses

No.	Drug	Indications	Development Stage	Priority
1	NV-CoV-2 Oral Gummies	● Mild to Moderate COVID-19 ● Non-hospitalized ● Patients of all ages, pediatric to over 65; with or without co-morbidities ● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test) ● Seasonal coronavirus afflictions	IND-filing (Phase I/II)	A
2	NV-CoV-2 Oral Syrup	● Mild to Moderate COVID-19 ● Non-hospitalized ● Patients that require drug titration (i.e. specified mg/Kg dosing, as with younger pediatric populations); with or without co-morbidities ● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test) ● Seasonal coronavirus afflictions	IND-filing (Phase I/II)	A
3	NV-CoV-2 Injectable Solution for Injection, Infusion or Inhalation: Use for Injection or for Infusion	● Moderate to Severe COVID-19 ● Hospitalized or with Urgent Risk of Hospitalization ● Patients of all ages, pediatric to over 65; with or without co-morbidities ● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test) ● Seasonal coronavirus afflictions	IND-Extension (Phase I/II) (Clinical Trial after Phase I studies of Oral Syrup and Oral Gummies)	B
4	NV-CoV-2 Injectable Solution for Injection, Infusion or Inhalation: Use for Inhalation and for Infusion	● Moderate to Severe COVID-19, requiring Oxygen Support ● Hospitalized or with Urgent Risk of Hospitalization ● Patients of all ages, pediatric to over 65; with or without co-morbidities ● Long COVID (patient positive for SARS-CoV-2 in ultra-sensitive test) ● Seasonal coronavirus afflictions	IND-Extension (Phase II/III) (Clinical Trial after Phase II studies of NV-CoV-2 Injectable Infusion above)	B

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We plan on adding PhaseI/II clinical trials of the NV-CoV-2 Injectable Solution for moderate to severe COVID-19 disease indication as the clinical trials of the oral forms provide safety data. We then aim to follow with Phase II/III human clinical trials for severe hospitalized cases possibly for both Inhalation and Infusion of NV-CoV-2; the details of clinical trial design can only be worked out after initial data from Phase I/II clinical trial of the Injectable solution becomes available. With the fortunate decrease in hospitalizations for COVID-19, the clinical trials for hospitalized COVID-19 patients are expected to become more complex and difficult to run, primarily due to the difficulty of recruiting patients.

NanoViricides Drug Pipeline in the HerpeCide™ Program:

We currently have performed substantial preclinical work against several viruses in the Herpesviridae family of DNA viruses. These include VZV (Varicella-Zoster Virus), the cause of shingles and chickenpox; HSV-1 (Herpes Simplex Virus-1), that primarily causes “cold sores”, recurrent herpes labialis (RHL), and Herpes Keratitis (HK), a disease of the external eye; HSV-2 (Herpes Simplex Virus-2), that primarily causes genital ulcers. We have also performed some preliminary work in viral Acute Retinal Necrosis (vARN), a disease of the eye retina that can be caused by any of these three viruses. The drugs that we are working on developing in this program are shown in the Tables 2.B through 2.F below.

Potential Drug Pipeline Against VZV (Shingles, Chickenpox, PHN) (Table 2.B)

The drug products that we plan on developing to treat shingles, chickenpox, and PHN are summarized in Table 2.B.

NV-HHV-1 Oral Gummies for the Treatment of Shingles and Chickenpox

NV-HHV-1 Skin Cream against Shingles is our most advanced drug candidate that has substantially completed IND-enabling studies in the HerpeCide program drug development efforts.

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In most cases shingles is a annoying but relatively mild disease with limited spread of the lesions on the body. We have developed NV-HHV-1 Skin Cream as a dermal topical for most immediate relief and for drug delivery at highest possible levels at the site of viral presence.

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

NV-HHV-1 Oral Gummies for the Treatment of Shingles and Chickenpox

In some patients, shingles outbreak covers relatively large portions of the body. Chickenpox also usually covers relatively large portions of the body. For mild to moderate cases of shingles with large body coverage, or for mild to moderate cases of chickenpox, or when topical application is not recommended (e.g. rash in or around the eye), a systemic drug is desirable, and may be used in conjunction with the skin cream. Acyclovir is currently in use but has limited effect and significant toxicities including “zombiness”.

We plan on developing Oral Gummies formulation of the same API that is in the NV-HHV-1 Skin Cream for these indications for systemic treatment. This will require additional safety studies and there may be a risk of adverse events even though the skin cream has

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been found to be safe for dermal topical application. If so, we may have to modify the API or develop another API from our backup drug candidates for Shingles.

Oral Syrup for the Treatment of Shingles and Chickenpox

We also plan on developing Oral Syrup for the systemic treatment of Shingles and Chickenpox. This will require modifications to the API for improving solubility and additional safety/toxicology studies. The resulting drug may need to go through additional battery of tests. Oral syrup has the advantage of being able to titrate the amount of dosing based on body weight of the patient, which is desirable for pediatric use against chickenpox.

Solution for Injection for the Treatment of Moderate to Severe Shingles and Chickenpox

The same API that goes into the Oral Syrup formulation would be made available in a form that can be used for infusion or injection in moderate to severe cases of shingles or chickenpox, including hospitalized cases or patients with high risk of hospitalization. The resulting drug may need to go through additional battery of tests for use as an injectable. Injectables have the advantage of 100% bio-availability and therefore highest effectiveness level, as well as rapid effect which is desirable for hospitalized cases.

Post-Herpetic Neuralgia (PHN): NV-HHV-1 Oral Gummies

In some persons, even after the obvious shingles rash is gone, the pain and tingling sensation may persist for several months. This is called post-herpetic neuralgia. We plan to evaluate whether an extended course of the NV-HHV-1 oral gummies continued even after the obvious rash is gone reduces the occurrence of PHN, or whether it reduces the symptoms of PHN, after the shingles drug has gone into Phase II clinical trials.

After the clinical trials for treatment of the acute episodes of Shingles and Chickenpox, we plan on engaging clinical studies for the treatment of Post-Herpetic Neuralgia (PHN), a disease that involves persistent pain and suffering generally at the sites of injury from the initial acute episode that lasts anywhere from an additional three to nine months or longer beyond the acute episode. PHN is a multi-factorial disease, with components of uncured persistent virus infection, immune response, as well as nerve damage that occurred in the acute episode. We plan on focusing the subset of cases with persistent viral infection. Such studies have not been undertaken previously and may be challenging.

PHN: Oral Syrup; Solution for Injection

When we engage in the PHN clinical trials, we plan on including Oral Syrup treatment arm as well as Injectable treatment arm, in addition to the NV-HHV-1 Oral Gummies treatment arm and appropriate negative and positive controls.

Potential Drug Pipeline Against HSV-1 ("Cold Sores", RHL) (Table 2.C)

We have performed significant pre-clinical work in the drug development for the treatment of HSV-1 infection. The same API that we have used for NV-HHV-1 was originally developed for HSV-1 and was successfully tested in cell culture models. We therefore feel confident that we can rapidly develop an effective dermal topical skin cream for the topical treatment of acute episodes of HSV-1 cold sores or herpes labialis.

HSV-1 becomes dormant in nerve cells. Therefore it is important to develop a systemic drug for its treatment in addition to a topical drug. Similar to the systemic drug development for VZV infection, we plan on developing systemic treatments for HSV-1 for moderate to severe acute episodes of herpes labialis. If and when successful, we plan on developing drug candidates for treatment of Recurrent Herpes Labialis with the goal of reducing the frequency of recurrence.

We believe that we are close to identifying a drug candidate for further development towards human clinical trials for the Dermal Topical Skin Cream and Oral Gummies for the treatment of acute episodes of herpes labialis.

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These drug programs are listed in Table 2.C. The ultimate goal of elimination of HSV-1 virus from the body is part of our on-going long-term technology development (Table 2.F).

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

Potential Drug Pipeline Against HSV-2 ("Genital Ulcers") (Table 2.D)

We have performed initial pre-clinical work in the drug development for the treatment of HSV-2 infection. The same API that we have used for NV-HHV-1 was originally developed for HSV-1 and is expected to be successful against HSV-2 as well. We therefore feel confident that we can rapidly develop an effective dermal topical skin cream for the topical treatment of acute episodes of HSV-2 genital sores or genital herpes.

HSV-2 becomes dormant in nerve cells. Therefore it is important to develop a systemic drug for its treatment in addition to a topical drug. Similar to the systemic drug development for VZV infection, we plan on developing systemic treatments for HSV-2 for moderate to severe acute episodes of herpes genitalis. If and when successful, we plan on developing drug candidates for treatment of Recurrent Herpes Genitalis with the goal of reducing the frequency of recurrence.

We plan on developing drug candidates for Dermal Topical Skin Cream and Oral Gummies for the treatment of acute episodes of herpes genitalis, once we have identified a candidate for these purposes against HSV-1. We believe that the same drugs can be expected to work against both HSV-1 and HSV-2, given the broad-spectrum nature of our chosen drug candidates.

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These drug programs are listed in Table 2.D. The ultimate goal of elimination of HSV-2 virus from the body is part of our on-going long-term technology development (Table 2.F).

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

Potential Drug Pipeline Against Eye Diseases Caused by Viruses in the Herpesviridae family (HK, vARN) (Table 2.E)

We have performed initial pre-clinical work in the drug development for the treatment of HSV-1 infection causing Herpes Keratitis in a rabbit eye whole animal model with successful results.

We have also performed initial pre-clinical work in the drug development for the treatment of internal eye HSV-2 infection causing Viral Acute Retinal Necrosis (vARN) in a mouse eye whole animal model with successful results.

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We plan on building on these successes to develop drugs for the treatment of HK and drugs for the treatment of vARN after the drugs for the treatment of acute episodes of HSV-1 Cold Sores and HSV-2 Genital Ulcers progress into clinical trials (Table 2.E).

Table 2.E. Eye Diseases Caused by Herpesviruses (HSV-1, HSV-2, VZV); NanoViricides Drug Products in Development

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

Potential Drug Pipeline Against Many Other Viruses (Table 2.F)

In addition, since NanoViricides was formed, we have performed preclinical developments against many other viruses. Some of these have advanced to the level of selection of drug candidate(s) for further development towards an IND. In particular, we have a drug against HIV that had shown strong effectiveness in cell culture models using orthogonal HIV strains (one that uses CCR5 as co-receptor, and one that uses CXCR4 as co-receptor), as well as in the standard SCID-hu Mouse model of HIV infection.

We have held a pre-IND meeting with the US FDA for a potential drug in the FluCide™ pipeline. This pre-IND resulted in a substantial work burden that is required for an Influenza drug to progress into clinical studies in the USA, and we had to de-prioritize this program due to resource constraints. We have since held a pre-IND meeting for our Shingles Skin Cream drug candidate with the US FDA. These two pre-IND meetings have helped significantly expand our understanding of the development requirements for antiviral drugs.

These drug programs in Table 2.F have been relegated to lower priorities (E, F) primarily because of resource constraints and changes in priorities resulting from the strategy of focusing on taking a drug into clinical trials in the

fastest possible timeline. We plan on

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restarting these programs as resources become available, potentially from non-dilutive funding, or from funding through partnerships or internal revenues.

Table 2. F. All Other Programs; NanoViricides Drug Products in Development					
	Program	**Virus**	**Indications**	**Development Stage**	**Priority**
1	Monkeypox Treatment	Monkeypox Virus and Related Poxviruses	Monkeypox Virus	Screening Existing Drugs in Our Pipeline	TBD
2	Adenovirus 71 Treatment	Adenovirus 71 or Related Viruses	Severe Pediatric Hepatitis Caused by Adenovirus 71 or Related Viruses	Screening Existing Drugs in Our Pipeline	TBD
3	HerpeCide™ Program Expansion Drug Projects	Possible EBV, HCMV, HHV-6A, HHV-6B, HHV7, KSHV	Broad-Spectrum nanoviricide drugs against different herpes viruses for different indications	R&D	E
4	HIVCide ™	HIV/AIDS	Escape-resistant Anti-HIV nanoviricide	Preclinical	E
5	FluCide™ Broad-Spectrum Anti-Influenza nanoviricide	All Influenza A	Injectable FluCide™ for hospitalized patients	Advanced Preclinical Pre-IND Meeting held with US FDA	F
		All Influenza A	Oral Flucide™ for outpatients	Preclinical. Pre-IND Meeting held with US FDA	F
6	Nanoviricide Eye Drops	Adenoviruses, HSV-1	Eye Drops for Viral Diseases of the External Eye	Preclinical	F
7	DengueCide™	Dengue viruses, all types	Broad-Spectrum nanoviricide against all types of Dengue viruses	Preclinical	F
8	HIVCide ™	HIV/AIDS	Escape-resistant Anti-HIV nanoviricide	Preclinical	E
9	Other Nanoviricides Drug Projects	Ebola/Marburg, Rabies, MERS, Others	Broad-Spectrum nanoviricide drugs against different viruses and indications	R&D	G
10	Long Term Projects	Various Persistent Viruses	Technologies for Cures for Persistent Viral Diseases	R&D	G

We have included our recent Monkeypox Virus (MPXV) project as well as our Enterovirus project in the Table 2.F with no assigned priority, because these are at an early stage of screening our existing library of compounds against these viruses. If we are successful in identifying viable drug candidates, then we will include these drug developments in further planning based on the then-existing societal urgency and potential for non-dilutive funding.

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Finally, we have been developing technologies under "Long Term Projects" that may result in complete elimination of a persistent or latent virus from the body, for complete cure of incurable viruses such as HIV, HSV-1, HSV-2, EBV, etc. Some of these technologies involve excision of the integrated viral genome, similar to the recent CRISPR/Cas9 based technologies. The advantage we have over the current CRISPR/Cas9 technologies is that whereas the CRISPR/Cas9 system is packaged in a viral vector for delivery and transformation in the target cell, we do not require a viral vector for introduction of our excision system because we are delivering using non-viral delivery vectors based on our nanoviricides® platform technology for this purpose. We do not have sufficient resources to focus on these developments at present. However, as and when time becomes available, we spend some time on developing these technologies.

Broad and Expanding Drug Pipeline Enabled by the NanoViricides Platform Technology

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

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

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

The overall market size addressed by our programs can be estimated at $20 billion to $40 billion, according to research reports prepared by Jain PharmaBiotech and Nanotech Plus, LLC. Of this, the market size for a highly effective shingles treatment has been estimated by Nanotech Plus in excess of one billion dollars, after taking into account the recent introduction of the new Shingrix® vaccine (GSK). The overall market size for the HerpeCide program is estimated at over $5 billion based on published market reports from Jain PharmaBiotech in 2014.

Drug Development Plan

We intend to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour, the exclusive source for these nanomaterials. With sourcing of materials from TheraCour, the Company prefers to manufacture these drugs in our own facility. However, the Company may manufacture these drugs under subcontract arrangements with external manufacturers that carry the appropriate regulatory licenses and have appropriate capabilities. The Company intends to distribute these drugs via subcontracts with distributor companies or in partnership arrangements. The Company plans to market these drugs either on its own or in conjunction with marketing partners. The Company also plans to actively pursue co-development, as well as other licensing agreements with other pharmaceutical companies. Such agreements may entail up-front payments, milestone payments, royalties, and/or cost sharing, profit sharing and many other instruments that may bring early revenues to the Company. Such licensing and/or co-development agreements may shape the manufacturing and development options that we may pursue.

Manufacturing

Manufacturing of Research Materials

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

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Manufacturing of Drugs

All of the manufacture for pre-clinical cell culture and animal studies as needed is performed by TheraCour under subcontract from NanoViricides. We perform some of the cell culture testing in or own bSL2 Virology lab in Shelton, Connecticut. We send the materials for all other testing including additional cell culture studies, non-GLP safety and efficacy studies, GLP safety and efficacy studies, and other IND-enabling studies to external contract research organizations.

We intend to manufacture the cGMP-compliant human Clinical Trial Supply of the drugs such as the Coronavirus drug candidates NV-CoV-2 Oral Syrup, Oral Gummies, the Dermal Topical anti-VZV, anti-HSV-1, anti-HSV-2 candidates and drugs, as well as anti-HSV Eye Drops/Gels, Injectable and Oral FluCide, HIVCide, DengueCide, RabiCide and other drugs, in facilities owned by us, through human clinical trials of each of the clinical drug candidates. Our cGMP-capable manufacturing facility in Shelton, CT has sufficient capacity for supply of the pre-clinical and clinical batches needed for all of our drug candidates as and when they are anticipated to be needed. We may go to a cGMP third party provider for the final fill-and-finish of the clinical drug products if necessary. We believe we now have sufficient cGMP manufacturing capacity for human clinical trials of most if not all of our intended drug candidates.

With recent successes in production scale-up, we believe that we now have sufficient capacity at the Shelton cGMP-capable manufacturing facility to enable market-entry of our first drugs upon approval, potentially enabling us to build the Company into a fully integrated pharmaceutical company ("FIPCO"), which could provide substantial shareholder value. We note as a risk factor that there is no guarantee that we can take its drug candidates successfully through clinical trials, and if we do, that we can obtain marketing approval, and if we do, that we can market the drugs successfully. For our future commercial products, we will need to develop additional commercial scale manufacturing capabilities and establish additional third-party suppliers to manufacture sufficient quantities of our product candidates to manufacture sufficient quantities of any products that are approved for commercial sale. If we are unable to develop manufacturing capabilities internally or contract for large scale manufacturing with third parties on acceptable terms for our future antiviral products, our ability to meet customer demand for commercial products would be adversely affected.

We believe that the technology we use to manufacture our products and compounds is proprietary, 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 believe that we are in compliance with all material environmental regulations related to the manufacture of our products.

Competition

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

- efficacy;
- safety;
- tolerability;
- acceptance by doctors;

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- patient compliance;
- patent protection;
- ease of use;
- price;
- insurance and other reimbursement coverage;
- distribution;
- marketing; and
- adaptability to various modes of dosing.

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

Several EUAs have been issued for antibodies and antibody cocktails for the treatment of COVID-19. Many of these have been revoked as SARS-CoV-2 variants that were resistant to these drugs became widespread. The newest variants of Omicron have recently been found to be resistant to the last of the remaining antibody treatments under EUA.

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

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

There are currently no approved drugs for the treatment of diseases caused by VZV, namely, Shingles, PHN, and Chickenpox. Valcyclovir or other acyclovir-class drugs are often prescribed orally but have little effect on shingles. 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.

The Company is aware of no approved drugs for the treatment of viral diseases of the external eye.

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

There are a growing number of anti-HIV drugs being sold or in advanced stages of clinical development. Companies with HCV and HIV products include Gilead, Bristol-Myers Squibb Company (BMS), Roche, Boehringer Ingelheim, Merck & Co., Inc. (Merck), in addition to several other pharmaceutical and biotechnology firms.

Currently there are two accepted methods of rabies prophylaxis: rabies vaccines and rabies immune globulin, manufactured by many foreign and multinational manufacturers including Aventis Pasteur and Chiron (acquired by Novartis). These accepted methods would be the standard against which our new anti-rabies drug in development will be judged.

In order to compete successfully, we must develop proprietary positions in patented drugs for therapeutic markets. Our products, even if successfully tested and developed, may not be adopted by physicians over other products and may not offer economically feasible alternatives to other therapies.

Government Regulation

Our operations and activities are subject to extensive regulation by numerous government authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation by the United States Food and Drug Administration (“FDA”). The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and the product approval process is very expensive and time consuming.

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

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FDA Approval Process

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

Preclinical Testing

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

- Completion of preclinical testing of new pharmaceutical or biological products, generally conducted in the laboratory and in animal studies in accordance with GLP standard, and applicable requirements for the humane use of laboratory animals or other applicable regulations to evaluate the potential efficacy and safety of the product candidate;

- Submission of the results of these studies to the FDA as part of an Investigational New Drug application, which must become effective before clinical testing in humans can begin;

- Manufacturing of investigational medicine under cGMP standard;

- Performance of adequate and well-controlled human clinical trials according to GCPs and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the product candidate for its intended use;

- Submission to the FDA of a new drug application, or NDA, for any new chemical entity drug we seek to market that includes substantive evidence of safety, purity, and potency, or safety and effectiveness from results of nonclinical testing and clinical trials;

- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced, packaged and distributed, to assess compliance with cGMPs, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- Potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the NDA; and

- FDA review and approval of the NDA.

Clinical Trials

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

- Phase 1. The drug is given to a small number of healthy human subjects or patients to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.

- Phase 2. The drug is given to a limited patient population to determine the effect of the drug in treating the disease, the best dose of the drug, and the possible side effects and safety risks of the drug.

- Phase 3. If a compound appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 clinical trials are long-term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug. It is not uncommon for a drug that appears promising in Phase 2 clinical trials to fail in the more rigorous and reliable Phase 3 clinical trials.

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

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

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

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.

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

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

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

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

Orphan Drug Designation

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

United States Post-Approval Requirements

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

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

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.

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

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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.

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.

A Note on US FDA Priority Review Vouchers

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

Economists at Duke University, who proposed the voucher concept in 2006, have calculated that reduction of the FDA approval time from 18 to six months could be worth more than $300 million to a company with a top-selling drug with a net present value close to $3 billion. At this level, the voucher would be expected to offset the substantial investment and risk required for discovery and development of a new treatment for a neglected tropical disease. (David B. Ridley, Henry G. Grabowski and Jeffrey L. Moe, “Developing Drugs For Developing Countries”, Health Affairs, 25, no. 2 (2006): 313-324; doi: 10.1377/hlthaff.25.2.313; © 2006 by Project Hope. and (http://blogs.cgdev.org/globalhealth/2007/10/fda_priority_review.php). Some of the PRVs have been “sold” for as much as $250M or so recently.

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

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Time Schedules, Milestones and Development Costs

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

- Complete IND-enabling studies for a coronavirus clinical drug candidate.
- File an IND for coronavirus SARS-CoV-2 treatment for Phase I and Phase II human clinical trials.
- Potentially achieve an emergency use authorization for our SARS-CoV-2 clinical drug candidate.

After the COVID-19 drug candidate has entered human clinical trials, and when an effective clinical trial plan for our Shingles drug candidate can be developed, knowing that SARS-CoV-2 will still be around, we would be able to reengage human clinical trials for the shingles treatment program. We then intend to:

- Finalize human clinical trials designs for Phase I and Phase II trials for NV-HHV-1 for topical treatment of shingles rash, with clinical trial patient intake criteria and results evaluation criteria that appropriately account for COVID-19.
- Engage a contract Clinical Research Organization for conducting the human clinical trials for shingles.
- Submit an IND-application to the US FDA, or an appropriate international regulatory agency for Shingles.
- Initiate and conduct Phase I human clinical trials, to determine safety and tolerability of NV-HHV-1 in human subjects.
- If possible, initiate Phase II human clinical trials to determine effectiveness of NV-HHV-1 in controlling shingles rash and to study the effectiveness of NV-HHV-1 regarding shingles pain.

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 the Company's control.

Management believes it has sufficient financing to pursue its COVID-19 drug candidate NV-COV-2 into initial human clinical trials (Phase I and Phase IIa) in fiscal 2023 based on currently available finances. There is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company to fund complete drug development through approval. The Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. We have estimated approximately $500,000 to $1,500,000 for initiation of Phase I and Phase IIa clinical trials. The total cost of Phase I and Phase IIa trials could be significantly more. If so, we may need to raise additional funds to support continued program development through Phase II and Phase III studies at least and revenue realization.

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

Drug Development Status

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

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The work-plan we have developed for the next twelve months is expected to enable us to file an investigational new drug application (IND) for the coronavirus drug program and, provided that our clinical plan is approved by the regulatory agency, to begin Phase1/2a human clinical trials. Given our dependence on external collaborators for the studies and study reports, we cannot provide time estimates. Our work-plan is extremely dependent on external factors, collaborations, and unanticipated delays can occur. We are experiencing extreme staffing constraints as well as facility and resources constraints. We note as a risk factor that these resource constraints may cause further delays in our estimated timelines.

We have taken on the most important risk in nanomedicines, that of enabling cGMP manufacture, with consistent product from batch to batch, "head on" so to speak. Having established critical quality parameters in our manufacturing processes ahead of cGMP scale-up, we believe that we have minimized the risk related to manufacturing capabilities.

During the scale up and optimization of our production level operations, we continue to work on a number of different polymer backbones (“nanomicelles”) and several antiviral ligands in order to make sure that different formulation and pharmacokinetic-pharmacodynamic (PK-PD) needs can be met during the PK-PD programs for our various drug candidates. While this loads up our initial activities, it is expected to minimize the risk for further drug development towards IND or regulatory filings by making available backup drug candidates with different PK-PD profiles.

This work-plan is expected to reduce certain risks of drug development. We have completed the work plan in the last year leading us to successfully completing IND-enabling Non-GLP and GLP Safety/Toxicology and Pharmacology studies that have established excellent safety and efficacy of our anti-coronavirus drug candidates in animal models. We believe these data will enable us to file an IND application under the expedited FDA COVID-19 regulatory processes. We believe that in the ensuing fiscal year we will be able to perform Phase I/IIa human clinical trials and obtain valuable information on the safety and tolerability of our anti-coronavirus clinical drug candidate in humans, towards the goal of obtaining Emergency Use Approval. If NV-CoV-2 is found to be not sufficiently effective in human clinical studies, we plan on filing an IND for and initiating Phase 2 human clinical trials for the
NV-CoV-2-R drug candidate, which promises to be a potential cure for coronaviruses as it packs a double attack against the virus, blocking both replication and reinfection. If our human clinical studies in COVID-19 program are not successful, we will have to develop additional drug candidates and perform further studies, or further advance our other programs, for example VZV, HSV-1 or HSV-2 drug candidates, into human clinical trials. If our studies are successful, we would be more confident in further developing our Coronavirus, HerpeCide as well as other program drug candidates and may be in a position to re-engage our highly valuable drug programs including HIVCide and FluCide.

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

Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies for further development of NV-CoV-2. Management intends to use equity-based and debt financing, as required, to fund the Company’s operations and to raise additional capital for conducting human clinical trials as we advance our pipeline towards IND stage. There can be no assurance that we will be able to obtain the additional financial resources necessary to fund our anticipated obligations over the next year.

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

Our Collaborations and Service Contract Agreements

Our development model is to employ collaborations and service contract relationships with renowned academic labs, government labs, as well as service contracts with external service providers in order to minimize our capital requirements.

All of our agreements provide for the evaluation of Nanoviricides® substances created and provided by the Company to the Laboratory (or Collaborator). In general, the Laboratory is compensated for certain material and personnel costs for these evaluations. The evaluations involve in vitro and in vivo scientific studies at the Laboratory using their established protocols. In some cases, the Company provides scientific input regarding certain modifications to their protocols as may be needed. The Laboratory returns the results and data

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to the Company. The Laboratory is allowed to publish the results after allowing time for the Company to protect intellectual property (IP) as needed. The Company sends nanoviricides as well as positive control (i.e. known therapeutics) and negative control (i.e. known not to work) compounds as needed in a fully formulated, ready to use form, to the Laboratory. All IP related to the nanoviricide materials, their formulations and reformulations, and their usage, rests with the Company. Any IP developed by the Laboratory regarding their own know-how, such as laboratory tests and protocols, their modifications, etc. rests with the Laboratory. Joint inventions are treated as per applicable US Laws.

The Company tries to choose the scientific laboratories with the most appropriate facilities and know-how relating to a particular field for the evaluation of an antiviral agent developed by the Company. In addition, the Company tries to work with more than one laboratory for the evaluation of an antiviral agent developed by the Company. The Company also tries to work with more than one laboratory for a given group of viruses whenever possible. We seek to improve confidence by obtaining independent datasets for corroboration of the efficacy and safety of the nanoviricides we develop. Further, the Company tries to minimize dependence on a particular Laboratory for the development of any specific drug candidate in our product pipeline.

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

Our current relationships are summarized below:

For Coronavirus Infections:

1. AR Biosystems, Odessa, FL. (for Non-GLP Safety and Animal Efficacy Studies).

2. Calvert Labs, Scott Township, PA. (for GLP Safety Toxicology Studies).

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

1. The Moffat Lab at SUNY Upstate Medical Center, Syracuse, NY.

2. The CORL at the University of Wisconsin, Madison, WI

3. The Romanowski Lab at the University of Pittsburg

For Influenza Viruses:

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

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

1. AR Biosystems, Inc., Odessa, FL (non-GLP studies)

2. Bio-Analytical Services, Inc., MI, (“BASi”) – IND-Enabling non-GLP and GLP “Tox Package” studies

For Regulatory Pathway and Business Development:

From time to time, we have retained independent consultants with extensive knowledge of FDA requirements and FDA processes, to help us with the Chemistry, Manufacture and Controls, Non-clinical Studies, Human Clinical Studies Design, as well as eCTD submission of an IND.

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

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

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

In September 2014, we signed an agreement with BASi. BASi has performed our IND-enabling Safety/Toxicology studies for NV-HHV-1, our skin cream for shingles rash treatment. BASi will also perform the safety toxicology studies for the anti-herpes nanoviricide drug candidates in our HerpeCide program. We have signed a Master Services Agreement with Bio-Analytical Services, Inc., MI, ("BASi") to perform cGLP and GLP-like safety and toxicological studies that are necessary for filing an IND for each of our drugs.

AR Biosystems, Inc., Odessa, FL

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

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

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

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

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

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

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

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

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

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severe cases of shingles. However, the cytotoxicity of cidofovir is known to cause ulceration of the skin to which it is applied, followed by natural wound healing.

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

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

We believe that the VZV drug candidate program is now our most advanced program to advance into Safety/Toxicology studies that are needed for an IND filing and human clinical trials.

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

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

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

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

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

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

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

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

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

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

The term of this agreement was three years from its execution. The Company agrees to supply necessary quantities of its products in order for Southern to complete specific studies as to the efficacy and safety of the Company's compounds. The Company shall pay

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charges associated with each task order and provide payment in the amount and as indicated therein. Under this agreement, Southern will estimate the work load and invoices for additional task orders, subject to the Company's agreement on costs.

The Company's anti-HIV drug testing in cell cultures was performed at the Southern Research Institute in Frederick, MD. Southern has closed the Frederick site and the new work is now expected to be performed at their Alabama facilities.

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.

On September 9, 2021 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 human Coronavirus derived indications. In consideration for the agreement the Company issued 100,000 shares of the Company's Series A preferred shares upon execution of the agreement and agreed to further milestone payments to TheraCour as the milestones are achieved.

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

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) the greater of $2,000 or actual costs monthly, whichever is higher, for other general and administrative expenses incurred by TheraCour on our behalf; (3) make royalty payments (calculated as a percentage of net sales of the licensed drugs) of 15% to TheraCour; (4) TheraCour retains the exclusive right to develop and manufacture the licensed drugs. TheraCour will manufacture the licensed drugs exclusively for NanoViricides, and unless such license is terminated, will not manufacture such product for its own sake or for others; and (5) TheraCour may request and NanoViricides, Inc. will pay an advance payment (refundable) equal to twice the amount of the previous month's invoice to be applied as a prepayment towards expenses. TheraCour may terminate the license upon a material breach by us as specified in the agreement. However, we may avoid such termination if within 90 days of receipt of such termination notice we cure the breach.

Development costs and other costs charged by TheraCour for the years ended June 30, 2022 and 2021 were $2,369,022 and $2,803,827, respectively. At June 30, 2022, $214,397 was due to TheraCour.

No royalties are due TheraCour from the Company's inception through June 30, 2022.

TheraCour is affiliated with the Company through Dr. Anil Diwan, President, who is a director of the corporation, and owns approximately 90% of the capital stock of TheraCour, which itself owns approximately 4.1% of the common stock of the Company at June 30, 2022.

TheraCour owns 470,959 shares of the Company's outstanding common stock and 300,000 shares of the Company's Series A preferred stock at June 30, 2022.

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Employees

As of June 30, 2022 the Company had approximately seventeen employees, including those at TheraCour. In addition, most of the business activities of the Company including accounting and legal work and business development are provided by subcontractors and consultants. Further, the Company has subcontracted nanomaterials research and development ("R&D") to TheraCour under the license agreement with TheraCour. TheraCour currently has a staff of approximately ten, most of who are scientists with PhD or advanced degrees and experience. The Company has subcontracted its animal studies to various contract research organizations, government institutes, academic labs, and private institutions. In the future, the Company anticipates having additional service providers. We believe that we have good relations with our employees and subcontractors.

Reports to Security Holders

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

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

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.

We intend to make available through our website, all of our filings with the Commission and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink to the EDGAR website containing our reports.

Our Contact Information

Our principal executive offices are currently located at 1 Controls Drive, Shelton, Connecticut 06484 and our telephone number is (203) 937-6137 (voice mail). We can be contacted by email at info@nanoviricides.com.

Description of Property

The Company's principal executive offices are located at 1 Controls Drive, Shelton, CT, and include approximately 18,000 square feet of office, laboratory, and cGMP-capable drug manufacturing space. These facilities are fully owned by the Company.

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

Legal Proceedings

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

condition or results of operations.

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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:

- The COVID-19 pandemic has adversely affected our business and its continued impact is unknown and difficult to predict.
- 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.

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- The Company's collaborative relationships with third parties could cause the Company to expend significant resources and incur substantial business risk with no assurance of financial return.
- The Company may be liable for damages caused by biological and hazardous material.
- The Company depends on senior management and their loss or unavailability could put the Company at a competitive disadvantage.
- There exist conflicts of interest among officers, directors and stockholders.
- Risks relating to dependence on U.S. government contracts.
- Company common stock may be considered "penny stock".
- Management of the Company has identified a material weakness in internal controls that if not remediated could result in material misstatements in our financial statements.

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

Risk Related to the COVID-19 Pandemic

The recent COVID-19 pandemic may adversely affect our business, and ability to file timely and accurate financial information.

While the complete impact on our business from the recent outbreak of the COVID-19 coronavirus is unknown at this time and difficult to predict, various aspects of our business are being adversely affected by it and may continue to be adversely affected.

COVID-19 has been declared a pandemic by the World Health Organization, has been declared a National Emergency by the United States Government and has resulted in several states being designated disaster zones. COVID-19 coronavirus caused significant volatility in global markets, including the market price of our securities. The spread of COVID-19 coronavirus has caused public health officials to recommend precautions to mitigate the spread of the virus, especially as to travel and congregating in large numbers.

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. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenues. Our ability to generate revenue depends heavily on:

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

All of our existing product candidates are in early stages of development. It will be several years, if ever, until we have a commercial drug product available for resale. If we do not successfully develop and commercialize these products, we will not achieve

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revenues or profitability in the foreseeable future, if at all. If we are unable to generate revenues or achieve profitability, we may be unable to continue our operations.

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

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

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

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

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

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

We have incurred significant operating losses and may not ever be profitable. As of June 30 2022, we had a cash and cash equivalent balance of $14,066,359. Also, we have incurred significant operating losses since its inception, resulting in an accumulated deficit of $122,492,176 at June 30, 2022. Such losses are expected to continue for the foreseeable future.

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

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

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However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates.

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, have not yet conducted any clinical trials and may not be able to successfully develop any drugs.

Until the formation of NanoViricide, Inc. (the Company's predecessor prior to the reverse merger in 2005) our management and key personnel had no experience in pharmaceutical drug development and, consequently, may not be able to successfully develop any drugs. To date, we have engaged only in pre-clinical activities and have not yet conducted any clinical trials. 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;

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- enter into arrangements with third parties to manufacture our products on our behalf; and
- enter into arrangements with third parties to provide sales and marketing functions.

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

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

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

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

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

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

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

The process of obtaining FDA approval has historically been costly and time consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include: (1) the successful conclusion of pre-clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND application to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a New Drug Application, or NDA, for a drug product or a biological license application, or BLA, for a

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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.

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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 all of our product candidates are in preclinical development. In particular, none of our product candidates 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.

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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. For example, U.S. FDA is now requiring that IND applications be submitted in eCTD format.

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 its budgeted Research and Development and other costs.

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

We have estimated a total cash expenditure budget of approximately $10 million for the period of July 2022 through October 2023 which approximately $7 million is expected to be spent on research and development for our drug candidates, including the IND filing, human clinical trials of one of our lead drug candidates NV-CoV-2 and possibly NV-CoV-2-R for treatment of coronavirus diseases, and approximately $3 million is budgeted for general and administrative expenses.

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

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

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

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

- pre-clinical study results that may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or 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 Food and Drug Administration ("FDA"). The regulatory process to obtain approval for drugs for commercial sale involves numerous steps. Drugs are subjected to clinical trials that allow development of case studies to examine safety, efficacy, and other issues to ensure that sale of drugs meets the requirements set forth by various governmental agencies, including the FDA. In the event that our protocols do not meet standards set forth by the FDA, or that our data is not sufficient to allow such trials to validate our drugs in the face of such examination, we might not be able to meet the requirements that allow our drugs to be approved for sale.

Because we have limited experience in conducting or supervising clinical trials, we plan 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

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clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

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

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

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

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

As of the date of this filing, we have approximately seventeen employees including the employees at TheraCour, and several consultants and independent contractors. The only consultant/contractor that we consider critical to the Company is TheraCour. Our relationship with TheraCour is discussed below. All other consultant/contractors would be more readily replaceable. The anticipated expansion of our business, provided we are successful in our clinical trials, will continue to place a significant strain on our limited managerial, operational and financial resources. We may need to hire additional personnel, in key managerial, technical, financial, R&D and operations areas. We have no experience in integrating multiple employees when hired. Therefore, there is a substantial risk that we will not be able to integrate new employees into our operations which would have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

Our ability to develop, manufacture and sell the products the Company plans to develop is derived from our Licensing Agreements with TheraCour. The Agreements may be terminated by TheraCour as a result of: the insolvency or bankruptcy proceedings by or against the Company, a general assignment by the Company to its creditors, the dissolution of the Company, cessation by the Company of business operations for ninety (90) days or more or the commencement by the Company or an affiliate to challenge or invalidate the issued patents.

The Company does not hold the rights to any other patents nor does the Company conduct its own research and development to develop other products to manufacture and sell. In addition, TheraCour is the sole developer of our licensed products and we are required to pay TheraCour fess 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, that comprise the intellectual property that we license, expire between 2022 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; reliance on third parties.

The Company does not have facilities that could be used to conduct clinical testing. We expect to contract with third parties to conduct all clinical testing required to obtain approvals for any drugs that we might develop. We currently outsource all 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.

The Company has never manufactured products in the highly regulated environment of pharmaceutical manufacturing. There are numerous regulations and requirements that must be maintained to obtain licensure and the permits required to commence manufacturing, as well as additional requirements to continue manufacturing pharmaceutical products. We now own facilities that could be used to manufacture clinical quantities of any products that might be developed by the Company. We believe that this cGMP-capable facility may allow us to produce limited quantities of a drug after approval for initial market entry, and that such an effort may make commercial sense if the treatment course requirements and afflicted patient populations are limited, and if the remuneration for the treatment course is appropriate. However, we do not own, nor lease facilities suitable for cGMP manufacture of any of our drug candidates in large commercial quantities, nor do we have the resources at this time to acquire or lease suitable facilities. At present, we have not retained any contract manufacturing organizations (CMO) for commercial manufacture or for clinical product manufacture.

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

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

We have no sales and marketing personnel.

We are an early stage development company with limited resources. We do not currently have any products available for sale, so have not secured sales and marketing staff at this early stage of operations. We cannot generate sales without a sales or marketing staff and 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

The Company has 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. The Company controls the research and work TheraCour performs on its behalf and no costs may be incurred without the prior authorization or approval of the Company.

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

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

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

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

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

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

Management of our relationships with our collaborators will require:

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

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

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

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

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

Our R&D and manufacturing activities will involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We carry $7,000,000 casualty and general liability insurance policies. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources and insurance coverage, and our clinical trials or regulatory approvals could be suspended.

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

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

The Company believes that Dr. Anil Diwan, 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, 2022, owned 4.1% of our common stock, and 300,000 shares of the Company's Series A preferred stock, and provides the nanomaterials to the Company with which it intends to develop its products and is the holder of the intellectual property rights the Company uses to conduct its operations. While the Company is not aware of any conflict that has arisen or any transaction that has not been conducted on an arm's length basis to date, Dr. Diwan may have conflicting fiduciary duties between the Company and TheraCour, for which he must recuse himself from certain decision-making processes of the Company.

The Company does not allow a conflicted shareholder, director, or executive officer to vote on matters wherein a conflict may be perceived. The conflicted person or entity is not allowed to nominate an alternate person to vote for them either. Other than this safeguard, the Company currently does not have any policy in place, should such a conflict arise.

In particular:

- Our executive officers or directors or their affiliates may have an economic interest in, or other business relationship with, partner companies that invest in us.

- Our executive officers or directors or their affiliates have interests in entities that provide products or services to us.

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In any of these cases:

- Our executive officers or directors may have a conflict between our current interests and their personal financial and other interests in another business venture.
- Our executive officers or directors may have conflicting fiduciary duties to us and the other entity.
- The terms of transactions with the other entity may not be subject to arm's length negotiations and therefore may be on terms less favorable to us than those that could be procured through arm's length negotiations.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our management has identified a material weakness in our internal control over financial reporting and has concluded that, due to such material weakness, our disclosure controls and procedures were not effective as of June 30, 2022. The material weakness in internal control over financial reporting resulted from the lack of timely and effective review of the Company's period-end closing process and adequate personnel and resources. The material weakness has not been remediated as of June 30, 2022. If not remediated, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our financial statements and a failure to meet our reporting and financial obligations, each of which could have a material adverse effect on our financial condition and the trading price of our common stock.

Risks Related to the Biotechnology/Biopharmaceutical Industry

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

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

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

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Our shingles drug candidate would compete with Valtrex®, an approved drug (valacyclovir), and other acyclovir-related nucleoside analogs, and new drugs in the pipeline. FV-100, a VZV-specific nucleoside analog was in Phase III clinical trials that were terminated. Development of ASP2151, a helicase/primase inhibitor, was terminated due to adverse events in healthy persons in clinical trials. We are not aware of any further drugs in clinical trials for the treatment of shingles. Painkillers such as lidocaine formulations and oxycodone formulations were in clinical trials for symptomatic relief of PHN.

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

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

We 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;

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- 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 the international situation.

The international securities markets situation has become highly unstable in the aftermath of extensive spending by the governments to combat COVID-19, new supply chain limitations resulting from COVID-19 disruptions that continue throughout the world but particularly in China with its zero-COVID policy, 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, and other external factors. These uncertainties have resulted in declines in all market sectors, increases in volumes due to flight to safety and governmental actions to support the markets. 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 necessary capital to pursue our strategic plan and may have to reduce the planned future growth and scope of our operations.

General securities market uncertainties resulting from the COVID-19 pandemic.

Since the outset of the pandemic the US and worldwide national securities markets have undergone unprecedented stress due to the uncertainties of the pandemic and the resulting reactions and outcomes of government, business and the general population. These uncertainties have resulted in declines in all market sectors, increases in volumes due to flight to safety and governmental actions to support the markets. As a result, until the pandemic has stabilized, the markets may not be available to us for purposes of raising required capital. 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 necessary capital 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.

As of September 25, 2013, our common stock became listed on the NYSE MKT (now known as "NYSE American"), a national securities exchange, which imposes continued listing requirements with respect to listed shares. If, however, we fail to satisfy the continued listing standards, such as, for example, the requirement that our shares not trade "for a substantial period of time at a low price per share," 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 anon-compliance letter or initiate delisting proceedings. If our securities are delisted from trading on the NYSE American and we are not able to list our securities on another exchange or to have them quoted on NASDAQ, our securities could be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;

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- 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 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;

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- government regulatory action affecting our products or our competitors' products in both the United States and foreign countries;
- developments or disputes concerning patent or proprietary rights;
- general market conditions for emerging growth and pharmaceutical companies;
- economic conditions in the United States or abroad;
- actual or anticipated fluctuations in our operating results;
- broad market fluctuations; and
- changes in financial estimates by securities analysts.

There is a risk of market fraud.

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

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

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

At June 30, 2022, shareholders of the Company held 1,379,637 shares of restricted stock, or approximately 11.9% 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.

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

The Company's continued viability depends on its ability to raise capital. Changes in economic, regulatory or competitive conditions may lead to cost increases. Management may also determine that it is in the best interest of the Company to develop new services or products. In any such case additional financing is required for the Company to meet its operational requirements. There can be no assurances that the Company will be able to obtain such financing on terms acceptable to the Company and at times required by the Company, if at all. In such event, the Company may be required to materially alter its business plan or curtail all or a part of its operational plans as detailed further in Management's Discussion and Analysis in this prospectus. 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. In the event that the Company is unable to raise or borrow additional funds, the Company may be required to curtail significantly its operational plans as further detailed in Requirements for Additional Capital in the Management's Discussion and Analysis of this prospectus.

The Company is authorized to issue up to 150,000,000 shares of common stock without additional approval by shareholders. As of June 30, 2022, we had 11,592,173 shares of common stock outstanding, 9,146 warrants convertible to 9,146 shares of common stock, and 484,582 shares of Series A preferred stock convertible into 1,696,037 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, 2022, 1,379,637, of 11,592,173 issued and outstanding shares of the Company's common stock were restricted securities as defined under Rule 144 of the Securities Act of 1933, as amended (the "Act") and under certain circumstances may be resold without registration pursuant to Rule 144. In addition the 484,582 shares of Series A Preferred Stock are restricted and convertible into 1,696,037 shares of common stock only in the event of a Change of Control of the Company.

Approximately 779,755 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 includes, among other things, activities necessary for supporting our independent public auditors. This effort may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we may need to hire additional accounting and financial persons with appropriate public company experience and technical accounting knowledge, and we cannot assure you that we will be able to do so in a timely fashion.

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

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

ITEM 1B: UNRESOLVED STAFF COMMENTS.

None.

ITEM 2: PROPERTIES

Description of Property

The Company's principal executive offices are located at 1 Controls Drive, Shelton, CT, and include approximately 18,000 square feet of office, laboratory, and cGMP-capable drug manufacturing space. These facilities are fully owned by the Company.

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

ITEM 3: LEGAL PROCEEDINGS.

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

ITEM 4: MINE SAFETY DISCLOSURES.

Not applicable.

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PART II

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

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

Quarter ended	Low price	High price
June 30, 2022	$ 1.30	$ 2.21
March 31, 2022	$ 1.70	$ 3.92
December 31, 2021	$ 3.62	$ 5.47
September 30, 2021	$ 3.55	$ 6.19
June 30, 2021	$ 3.65	$ 4.76
March 31, 2021	$ 3.15	$ 5.65
December 31, 2020	$ 3.08	$ 4.08
September 30, 2020	$ 3.82	$ 8.71

Number of Shareholders.

As of June 30, 2022, a total of 11,592,173 shares of the Company's common stock are outstanding and held by 150 shareholders of record. This number of shareholders does not reflect the persons or entities that hold their stock in nominee or street name through various brokerage firms. Of this amount, 10,212,536 shares are unrestricted, of which, 0 shares are held by affiliates, 779,755 shares are restricted securities held by non-affiliates, and the remaining 599,882, shares are restricted securities held by affiliates. These shares may only be sold in accordance with Rule 144. As of June 30, 2022 there were 9,146 warrants to purchase the Company's common stock outstanding.

Dividends.

The Company has not paid any cash dividends since its inception. The Company currently intends to retain any earnings for use in its business, and therefore does not anticipate paying dividends in the foreseeable future.

Long-Term Incentive Plans Awards in Last Fiscal Year

The NanoViricides, Inc. Executive Equity Incentive Plan (the "2018 Plan") was adopted to assist the Company in attracting, motivating, retaining and rewarding high-quality executives and other employees, officers, directors, consultants and other persons who provide services to us, by enabling such persons to acquire or increase a proprietary interest in the Company. The 2018 Plan provides for the issuance of stock options, stock appreciation rights, or SARs, restricted stock, restricted stock units, reload options, and other stock-based awards. Performance awards may be based on the achievement of certain business or personal criteria or goals, as determined by the Committee. The total number of shares of our common stock that may be subject to the granting of awards under our 2018 Plan is equal to 250,000 shares and 100,000 shares of our Series A preferred stock. To date, no shares of common stock or Series A preferred stock have been issued under the 2018 Plan.

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Fiscal Year Ended June 30, 2021 Transactions

On July 11, 2018 the Board of Directors approved an extension of the employment agreement with Dr. Anil Diwan, the Company's President. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 26,250 of the Company's Series A preferred stock to Dr. Anil Diwan. The shares shall be vested in one-third increments on June 30, 2019, June 30, 2020 and June 30, 2021 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $182,610 for the year ended June 30, 2021.

For the year ended June 31, 2021, the Scientific Advisory Board was granted fully vested warrants to purchase 2,288 shares of common stock at exercise prices between $3.94- $6.86 per share expiring in the fiscal year ending June 30, 2025. The fair value of the warrants was $6,103 for the year ended June 30, 2101 and was recorded as consulting expense.

On July 8, 2020 the Company entered into an Underwriting Agreement with Kingswood. Pursuant to the terms and conditions of the Underwriting Agreement, the Company agreed to issue and sell 1,369,863 shares of our common stock, par value $0.001 per share (the "Underwritten Shares"), at a price to the public of $7.30 per share. Pursuant to the Underwriting Agreement, the Company also granted the underwriter an option to purchase up to an additional 205,479 shares of common stock (together with the Underwritten Shares, the "Shares") within 45 days after the date of the Underwriting Agreement to cover over-allotments, if any. The shares were issued pursuant to a prospectus supplement dated July 8, 2020 which was filed with the Securities and Exchange Commission on July 9, 2020 in connection with a takedown from the Company's shelf registration statement on Form S-3, as amended (File No. 333-237370), which became effective on April 2, 2020 and the base prospectus dated April 2, 2020 contained in that registration statement. The offering was consummated on July 10, 2020, whereby the Company sold 1,369,863 shares of common stock and a fully exercised Underwriters' overallotment of 205,479 additional shares at the public offering price of $7.30 per share. The net proceeds to the Company from the offering was approximately $10.4 million after placement agent fees and other estimated offering expenses.

On July 31, 2020, the Company entered into a Sales Agreement with the Sales Agents, 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. On March 2, 2021, the Company sold 814,242 shares of common stock at an average price of approximately $7.83 per share. The shares were issued pursuant to a prospectus supplement dated December 3, 2020 filed with the Securities and Exchange Commission on December 10, 2020 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-237370), which became effective on April 2, 2020. The net proceeds to the Company from the offering was approximately $6.1 million after placement agent fees and other estimated offering expenses.

For the year ended June 30, 2021, 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 $43,693, which is the fair value at 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 Series A preferred stock fair value is based on the greater of i) the converted value to common stock at a ratio of 1:3.5; or ii) the value of the voting rights since the holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a change of control.

The Series A preferred stock fair value is based on the converted value to common stock at a ratio of 1:3.5 multiplied by the monthly average of the daily open and close price of the common stock.

For the year ended June 30, 2021, the Company's Board of Directors authorized the issuance of 3,572 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $15,038, which was the fair value on the date of issuance.

For the year ended June 30, 2021, the Company's Board of Directors authorized the issuance of 25,434 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $108,000, which was the fair value at the dates of issuance.

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For the year ended June 30, 2021, the Company's Board of Directors authorized the issuance of 13,166 fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of $56,250, which was the fair value at date of issuance.

Fiscal Year Ended June 30, 2022 Transactions

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

For the year ended June 30, 2022, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

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

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

On September 14, 2021, the Board of Directors and Dr. Anil Diwan, President and Chairman of the Board agreed to the extension of Dr. Diwan's employment agreement for a period of one year from July 1, 2021 through June 30, 2022 under the same general terms and conditions. The Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares vested in quarterly installments of 2,551 shares on September 30, 2021, December 31, 2021, March 31, 2022 and June 30, 2022. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $108,982.

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

There is currently no market for the shares of Series A preferred stock and they can only be converted into shares of common stock upon a change of control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Series A preferred stock granted to various employees and others on the date of grant. The Series A preferred stock fair value is based on the converted value to common stock at a ratio of 1:3.5 multiplied by the monthly average of the daily open and close price of the common stock. The conversion of the shares is triggered by a change of control.

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

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

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

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For the year ended June 30, 2022, the Company's Board of Directors authorized the issuance of 16,863 fully vested shares of its common stock with a restrictive legend to satisfy open accounts payable of $37,500 for consulting services. The number of shares issued to settle the accounts payable was calculated using the market price of the common stock on the settlement date.

The securities described above (the "Securities") were offered and sold without registration under the Securities Act of 1933, as amended (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. The Securities have not been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

ITEM 6: SELECTED FINANCIAL DATA

The selected financial data presented below are for each fiscal year in the five-year period ended June 30, 2022. This data is derived from, and qualified by reference to, our audited financial statements and notes thereto appearing elsewhere in this Form 10-K.

Statements of Operations Data:

	Year Ended June 30,				
	2022	2021	2020	2019	2018
Operating expenses:					
Research and development	$ 5,784,862	$ 6,114,541	$ 4,695,524	$ 5,921,720	$ 5,913,720
General and administrative	2,328,737	2,629,565	3,300,935	2,737,962	3,411,449
Total operating expenses	8,113.599	8,744,106	7,996,459	8,659,682	9,325,169
Loss from operations	(8,113,599)	(8,744,106)	(7,996,459)	(8,659,682)	(9,325,169)
Other income (expense):					
Interest income	11,859	9,348	17,079	55,497	100,429
Interest expense	(5,123)	(85,405)	(93,670)	—	—
Gain on warrant settlement	—	—	614,494	—	—
Loss on issuance of Series A Preferred stock for accounts payable-related party	—	—	(142,669)	—	—
Interest expense on convertible debentures	—	—	—	(185,274)	
Loss on extinguishment of debt	—	—	—	(1,348,747)	
Discount on convertible debentures	—	—	—	(359,214)	
Loss on disposal of property and equipment	—	(2,026)			
Change in fair value of derivatives	—	—	(5,845,313)	179,745	2,554,020
Other (expense)income, net	(6,736)	(78,083)	(5,450,079)	235,242	761,714
Loss before income tax provision	(8,106,863)	(8,822,189)	(5,450,079)	(8,424,440)	(8,563,455)
Income tax provision	—	—	—	—	—
Net loss	$ (8,106,863)	$ (8,822,189)	$ (13,446,538)	$ (8,424,440)	$ (8,563,455)
NET LOSS PER COMMON SHARE - Basic & diluted	$ (0.70)	$ (0.81)	$ (2.39)	$ (2.35)	$ (2.64)
Weighted average common shares outstanding - Basic & diluted	11,534,698	10,900,955	5,616,728	3,590,070	3,246,043

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Balance Sheets Data:

	As of June 30,				
	2022	2021	2020	2019	2018
Cash and cash equivalents	$ 14,066,359	$ 20,516,677	$ 13,708,594	$ 2,555,207	$ 7,081,771
Working capital	14,003,543	20,472,633	11,829,280	(22,732)	6,440,080
Total assets	23,494,862	30,262,313	23,914,339	13,448,513	18,546,212
Long-term liabilities	—	—	—	—	—
Accumulated deficit	(122,492,176)	(114,385,313)	(105,563,124)	(92,116,586)	(83,692,146)
Stockholders' equity	23,082,025	29,911,167	21,757,962	10,600,360	17,664,264

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, 2022. Readers should carefully review the risk factors disclosed in this Form 10-K and other documents filed by the Company with the SEC.

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

PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Management's Plan of Operation

The Company's drug development business model was formed in May 2005 with a license to the patents and intellectual property held by TheraCour 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 discloses the risk that the Company may want to add further virus types to its drug pipeline as the Company progresses further. The Company would then need to negotiate with TheraCour appropriate license

agreements to include those of such additional viruses that the Company determines it wants to follow for further development. Historically, the Company initiates negotiations for

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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") and International regulatory agencies for these drugs. The Company plans, when appropriate, to seek regulatory approvals in several international markets, including developed markets such as Europe, Japan, Canada, Australia, and Emerging Regions such as Southeast Asia, India, China, Central and South America, as well as the African subcontinent. The seeking of these regulatory approvals would only come when and if one or more of our drugs have significantly advanced through the US FDA and international regulatory process. If and as these advances occur, the Company may attempt to partner with more established pharmaceutical companies to advance the various drugs through the approval process.

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

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

There can be no assurance that other developments in the field would not impact our business plan adversely. For example, successful creation and availability of an effective vaccine may reduce the potential market size for a particular viral disease, or an effective drug may be developed by competitors that becomes difficult to compete against with our limited resources. Our goal, which we can give no assurance that we will achieve, is for NanoViricides, Inc. to become the premier company developing highly safe and effective drugs that employ an integrated multiplicity of actions as enabled by our nanomedicine approach for anti-viral therapy.

To date, we have engaged in organizational activities; developing and sourcing compounds and preparing nano-materials; and experimentation involving preclinical studies using cell cultures and animal models of efficacy and safety. We have generated funding through the issuances of debt and the sales of securities under our shelf registration and the private placement of common stock (*See,* Item 5). The Company does not currently have any long-term debt. We have not generated any revenues and we do not expect to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or we may not become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations.

Current Financial Status

NanoViricides technology is now maturing rapidly toward clinical drug trials, with the new facility, expanded staff, and the financial strength that we have attained since uplisting to NYSE American in September 2013. We are working diligently towards entering our first broad-spectrum anti-coronavirus drug, NV-CoV-2 for the treatment of SARS-CoV-2 infection that causes COVID-19, into human clinical trials.

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As of June 30, 2022, the end of the reporting period, we had $14,066,359 in cash and cash equivalents, prepaid expenses of $350,021 and $8,694,194 of property and equipment, net of accumulated depreciation. Our liabilities at June 30, 2022 are $412,837 including a short term loan payable of $94,788 payable to BankDirect, accounts payable of $57,960 payable to third parties and accounts payable to TheraCour of $214.397. Stockholders' equity was $23,082,025 at June 30, 2022. In comparison, as of June 30, 2021, we had $20,516,677 in cash and cash equivalents, prepaid expenses of $307,102 and property and equipment was $9,084,901, net of accumulated depreciation. Our liabilities at June 30, 2021 were $351,146, including accounts payable of $200,016 payable to third parties, and accounts payable to TheraCour of $31,539. Stockholders' equity was $29,911,167 at June 30, 2021.

During the year ended June 30, 2022, we spent approximately $5.9 million in cash toward operating activities and approximately $324,000 in capital investment. In contrast, we spent approximately $8.2 million in cash toward operating activities and approximately $239,000 in capital investment in the year ended June 30, 2021. We anticipate capital expenditures of approximately $200,000 in the next twelve months.

As of June 30, 2022, we have a cash and cash equivalent balance of $14,066,359 that is expected to be sufficient to fund our currently budgeted operations for more than one year from the filing of the Company's Form 10K.

The Company has an accumulated deficit at June 30, 2022 of approximately $122.5 million and a net loss of approximately $8.1 million and net cash used in operating activities of approximately $5.9 million for the fiscal year then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. The Company believes that it has several important milestones that it will be achieving in the ensuing year. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced.

Management believes that the Company's existing resources will be sufficient to fund the Company's planned operations and expenditures through October 2023. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The accompanying audited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

Results of Operations

The Company is a biopharmaceutical company and does not have any revenue for the years ended June 30, 2022 and June 30, 2021.

Comparison of the Year End June 30, 2022 to the Year Ended June 30, 2021

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

Operating Expenses - Research and development expenses for the year ended June 30, 2022 decreased $329,679 to $5,784,862 from $6,114,541 for the year ended June 30, 2021. This year-to-year decrease is generally attributable to decreases in lab supplies and chemicals, employee compensation expenses and lab fees for pre IND studies offset by a payment of a license fee. General and administrative expenses decreased $300,828 to $2,328,737 for the year ended June 30, 2022 from $2,629,565 for the year ended June 30, 2021. The decrease in general and administrative expenses is generally attributable to decreases in legal and professional expenses.

Interest Income - Interest income was $11,859 and $9,348 for the years ended June 30, 2022 and 2021, respectively. Interest income increased due to higher interest rates for the majority of the year ended June 30, 2022 offset by lower cash balances.

Interest Expense- The Company has incurred interest expense of $5,123 and $85,405 for the years ended June 30, 2022 and June 30, 2021 respectively. The decrease results from the payoff of a mortgage loan in December, 2020.

Income Taxes **-** There is no provision for income taxes due to ongoing operating losses. As of June 30, 2022, we had estimated cumulative tax benefits and development tax credits and other deferred tax credits resulting in a deferred tax asset of $36,506,779. This amount has been offset by a full valuation allowance.

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Net Loss - For the year ended June 30, 2022, the Company had a net loss of $8,106,863, or a basic and fully diluted loss per share of $0.70 compared to a net loss of $8,822,189, or a basic and fully diluted loss per share of $0.81 for the year ended June 30, 2021. The decrease in the Company's net loss for the year ended June 30, 2022 from the year ended June 30, 2021 of $715,326 is generally attributable to an decrease in operating expenses and interest expense in the year ended June 30, 2022.

Liquidity and Capital Reserves

The Company had cash and cash equivalents of $14,066,359 and $20,516,677 as of June 30, 2022 and 2021, respectively. On the same dates, current liabilities outstanding totaled $412,837 and $351,146, respectively. As of June 30, 2022 and June 30, 2021, total current liabilities included short term loan payable of $94,788 and $95,306, respectively

Since inception, the Company has expended substantial resources on research and development. Consequently, we have sustained substantial losses. The Company has an accumulated deficit of $122,492,176 and $114,385,313 at June 30, 2022 and 2021, respectively.

The Company anticipates several important milestones that it will be achieving in the ensuing year. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced.

Management believes that the Company's existing resources will be sufficient to fund the Company's planned operations and expenditures through October 2023. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The accompanying audited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

Research and Development Costs

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

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

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

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

Table 4: R&D Cost Allocations

	Year Ended June 30, 2022	Year Ended June 30, 2021
HerpeCide™ Program. Herpes Simplex virus infections (HSV-1, HSV-2) and VZV Indications: Cold Sores, Genital Ulcers, Shingles and ARN	$ 100,000	$ 550,000
Covid -19	5,684,862	5,564,541
Total	$ 5,784,862	$ 6,114,541

Anticipated Budgets and Expenditures in the Near Future

The Company has ended the year on a reasonable financial footing by controlling costs and expenditures. We project that our current available financing is sufficient for accomplishing the goal of filing one IND or equivalent regulatory applications and executing initial

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human trials of our lead drug candidate, NV-CoV-2. We will need additional financing to execute on our business plan and to complete human clinical trials of our drug candidates into drug approval. Our Coronavirus drug candidate NV-CoV-2 has completed IND-enabling studies, we are currently working on compiling the IND application and finding and engaging an appropriate Clinical Research Organization for planning and executing the clinical studies. NV-CoV-2 is expected to rapidly move into human clinical studies in response to the COVID-19 pandemic. Our Shingles Skin Cream, has completed IND-enabling studies, and we intend to file an IND for this drug once the COVID-19 situation abates. We have completed scale-up and manufacture of NV-387, the drug substance (API) in NV-CoV-2, and the drug products NV-CoV-2 Orals Syrup and NV-CoV-2 Oral Gummies. We have scheduled cGMP-compliant clinical batch production of the same. After NV-CoV-2 drug candidate enters clinical trials, we plan on undertaking further development of the NV-HHV-1 Skin Cream for the treatment of Shingles, including scale-up of manufacture, cGMP compliant batches, and additional studies that may be required. We anticipate that these drug candidates will move forward into IND or equivalent regulatory filings, and ensuing human clinical trials. As these drug candidates are advancing into the clinic, we believe that our additional drug candidates, including two or more drug candidates in the HerpeCide program will also move forward into IND-enabling studies. We intend to further re-engage our FluCide and HIVCide drug development programs once we have established our platform technology with the Coronavirus and HerpeCide program drug candidates. We are thus poised for strong growth with a number of drug candidates in a number of disease indications.

Financings

On July 31, 2020, the Company entered into an At Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc. and Kingswood Capital Markets, a division of Benchmark Investments, Inc. (each a "Sales Agent" and collectively, the "Sales Agents"), pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agents, shares of Common Stock (the "Placement Shares"), having an aggregate offering price of up to $50 million (the "ATM Offering"). Sales pursuant to the Sales Agreement will be made only upon instructions by the Company to the Sales Agents, and the Company cannot provide any assurances that it will issue any Shares pursuant to the Sales Agreement. Actual sales will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Company's common stock, capital needs and determinations by the Company of the appropriate sources of funding for the Company. The Company is not obligated to make any sales of common stock under the Sales Agreement and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. On March 2, 2021 the Company sold 814,242 shares of common stock at an average price of $7.83 under the Sales Agreement with B. Riley Securities, Inc. The net proceeds to the Company from the offering was approximately $6.1 million after deducting underwriting discounts and commissions and other offering expenses.

As of June 30, 2022, we had a cash and cash equivalent balance of $14,066,359 that is expected to be sufficient to fund the Company's planned operations and expenditures through October 2023. The Company also believes that additional non-dilutive financing will be available under the COVID-19 program upon advancing it further toward or into human clinical trials. The Company also believes that due to the pandemic, it will be possible to rapidly take our anti-coronavirus drug into human clinical trials under the COVID-19 regulatory pathways of the US FDA or other regulatory authorities.

Requirement for Additional Capital

The Company believes that our cash and cash equivalent balance will provide sufficient funds for us to be able to advance at least one of its drug candidates into human clinical trial stage, and to continue our operations through October, 2023 with the available cash. The Company estimates that it will need additional funding to continue further development of its drug candidates through later stages of human clinical trials if it does not form a collaborative licensing or partnership agreement with a party that would provide such funding such as Big Pharma.

Based on our current rate of expenditures and anticipated changes, we have estimated a total cash expenditure budget of approximately $10 million from July 1, 2022 through October 2023, of which approximately $7 million is expected to go towards IND filing and initial human clinical trials of NV-CoV-2, our antiviral treatment for COVID, and approximately $3 million is budgeted for general and administrative expenses.

These anticipated expenses for the subsequent period commencing on July 1, 2022 can be summarized as follows:

1. Planned costs of $4,500,000: Planned costs for further prepatory research and development work for Phase II/III clinical trials for NV-CoV-2 and NV-CoV-2-R. These include GLP and non-GLP in vivo and in vitro

studies required as per

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regulatory guidance, the VZV (Shingles) drug development program, and other indications in HerpeCide program.This includes staffing costs of approximately $2,500,000, for the scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to FDA compliance, as required for development of necessary data for filing an Investigational New Drug with the United States Food and Drug Administration.

2. Clinical trial manufactured batch of drug product approximately $1,000,000 for Phase 1 and 2a for the first Coronavirus (COVID-19) program drug candidate NV-CoV-2.

3. Anticipated clinical trial costs for the COVID-19 drug candidate of approximately $1,500,000 for Phase 1 and 2a. We anticipate that these clinical trials will be designed with the goal of an emergency use approval during the current pandemic provided it continues to persist. We may need to modify the program to seek full-fledged approval for our broad-spectrum coronavirus drug candidate if the pandemic is resolved by the time we are completing Phase 2a human clinical trials of this drug candidate.

4. Corporate overhead of $2,800,000: This amount includes budgeted office salaries, legal, accounting, investor relations, public relations, business development, and other costs expected to be incurred by being a public reporting company.

5. Capital costs of $200,000: This is the estimated cost for additional equipment and laboratory improvements.

We estimate that beyond the current budgetary one-year period ending October 15, 2023, to the period ending October 15, 2024, further human clinical development of NV-CoV-2 towards Emergency Use Authorization, followed by expansion of studies towards full approval, for further clinical studies towards full-fledged approval of our Coronavirus drug candidate as may be necessary, development for IND and initial human clinical studies of the NV-HHV-1 Skin Cream for Topical Treatment of Shingles, and for developing additional drug indications based on the Shingles skin cream candidate, NV-HHV-1, in the HerpeCide program, we may need approximately an additional $14 million, or approximately $10 million more than our anticipated remaining cash as of October 2023. The additional funds will be needed to pay additional, subcontract costs related to the expansion and further development of our drug pipeline, for human clinical trials, and for additional capital and operational expenditures

These anticipated additional expenses for the two-year period commencing October 16, 2022 can be summarized as follows:

1. Planned research and development costs of $8,000,000: Planned costs for additional indications in HerpeCide program, This includes staffing costs of approximately $5,000,000, for the scientific staff and consulting firms to assist with FDA compliance, material characterization, pharmaco-kinetic, pharmaco-dynamic and toxicology studies, and other items related to FDA compliance, as required for development of necessary data for filing an Investigational New Drug with the United States Food and Drug Administration.

2. Clinical trial manufactured batch of drug product approximately $2,000,000 for Phase 2b and 3 for the NV-CoV-2 Coronavirus program candidate, and $1,000,000 for Phase 1 and 2a for the NV-HHV-1 VZV Shingles program drug candidate.

3. Clinical Trials Costs budgeted as follows: anticipated Phase 2b and 3 Clinical Trial Costs for the COVID-19 of approximately $5,000,000, and $1,000,000 for the Phase 1 and 2a clinical trials for the skin cream for Shingles for the Skin Cream for Shingles.

4. Corporate overhead of $6,000,000.

5. Capital costs for laboratory and pilot manufacturing equipment of $1,000,000.

6. As our programs mature and as we are able to move additional drug candidates into human clinical trials we will continue to require additional funding for such activities. As a rule of thumb, we estimate that, for each drug candidate that goes into clinical trials, if Phase I and Phase II are successful, we anticipate approximately $10 million for Phase III human clinical trials for that drug candidate to enable us to file a New Drug Application (NDA) with the US FDA for obtaining marketing approval. These estimates are based on rough quotes from potential investigators, and assumptions relative to additional

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costs. These estimates assume that our drug candidates are highly effective and therefore would require relatively few patients in each arm of the each trial in order to establish statistically significant results.

We believe that as we become a clinical stage company, and 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. If so, we believe that we will be able to raise the additional necessary funds through public financings as needed. We believe that our coronavirus program is maturing rapidly towards human clinical trials, and if we are successful in achieving an emergency use approval for a coronavirus drug candidate, we may be able to generate substantial revenues during the current pandemic using our existing cGMP-capable manufacturing capacity itself.

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

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

We believe that the coming year's work plan will lead us to obtain certain information about the safety and efficacy of our coronavirus drug candidate NV-CoV-2 in human clinical trials. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further studies in animal models to obtain necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles and further human clinical studies, expanding into Phase 2b, and Phase 3 human clinical trials of our drug candidates.

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

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

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

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

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

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

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

Off Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements during the year ended June 30, 2022.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

RECENT ACCOUNTING PRONOUNCEMENTS

Recently Issued Accounting Pronouncements

The Company considers the applicability and Impact of all Accounting Standard Updates ("ASU's"). There were no recent ASU's that are expected to have a material impact on the Company's balance sheets or statements of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is not exposed to market risk related to interest rates on foreign currencies.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by Item 8 appears after the signature page to this report.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

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

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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, 2022, an evaluation was carried out under the supervision and with the participation of our management, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are not effective as of June 30, 2022 due to a material weakness in our internal control over financial reporting described below.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness, as of June 30, 2022, of our internal control over financial reporting based on the framework in 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was not effective as of June 30, 2022 due to the material weakness described below:

Management did not maintain effective procedures pertaining to the review of the 10-K. The material weakness resulted from the lack of timely and effective review of the Company's period-end closing process and adequate personnel and resources. Specifically, the Company has not established procedures for thorough review by management, on a timely basis, of Form 10-K and other filings. Management's responsibility is to oversee that the Company is capable of developing accurate and timely financial information. The Company must continue to reinforce additional procedures ensuring that Form 10-K as well as other required filings are done on a timely and accurate basis.

Changes in Internal Control over Financial Reporting

Other than what was described below, there were no material changes in our system of internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the year ended June 30, 2022 that has materially affected, or is likely to materially affect, our internal control over financial reporting. However, as noted below, we have begun to implement changes in our internal control over financial reporting to address the material weakness described above.

Remediation Plan

The Company has established a financial reporting controls committee comprised of members of senior management and a member of the Audit Committee of the Board of Directors. The committee will provide oversight to the Company's efforts for ensuring appropriate internal control over financial reporting including, but not limited to, remediation of the aforesaid material weakness and identifying and testing for potential internal control weakness in the financial reporting process to assure reliability and accuracy. Management believes the foregoing efforts will effectively remediate the material weakness identified above. As we continue to evaluate and work to improve our internal control over financial reporting, management may execute additional measures to address potential control deficiencies or modify the remediation plan described above and will continue to review and make necessary changes to the overall design of our internal controls.

ITEM 9B. OTHER INFORMATION

None.

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

Not applicable

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

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

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

Name	Age	Title
Anil Diwan, PhD.	64	President; Chairman of the Board and CEO
Makarand “Mak” Jawadekar	71	Director, Independent
Theodore Edward (“Todd”) Rokita	52	Director, Independent
Brian Zucker	60	Director, Independent
Meeta Vyas	64	Chief Financial Officer

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

Anil Diwan, PhD, age 64, has been President and the Chairman of the Board of Directors of the Company since consummation of the merger on June 1, 2005. Dr. Diwan simultaneously therewith and since its formation, has also served as the Chief Executive Officer and Director of AllExcel, Inc. (from 1995 to the present) and TheraCour Pharma, Inc. (from 2004 to the present) and is the original inventor of the technologies licensed to NanoViricides Inc., as well as the TheraCour polymeric micelle technologies and products based on them. Since 1992, he has researched and developed TheraCour nanomaterials. Dr. Diwan was the first to propose the development of novel pendant polymers for drug delivery that led to an explosion of research in pharmacological applications of polymeric micelles. Dr. Diwan has won over 12 NIH SBIR grants. Dr. Diwan holds several issued patents, and three PCT international patent applications in various stages of prosecution in a number of countries, and also has several additional patentable discoveries. Dr. Diwan has held several scholastic distinctions, including an All-India 9th rank on the Joint Entrance Examination of all IIT’s. He holds a Ph.D. in Biochemical Engineering from Rice University (1986) and B.S. in Chemical Engineering from Indian Institute of Technology (IIT) Bombay (1980). We concluded Dr. Diwan’s experience plus his status as creator of the Company’s technologies render him uniquely qualified to serve in these capacities.

Makarand “Mak” Jawadekar, 71, was appointed as an Independent Member of the Board of Directors, and will serve 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,

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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, 52, Director. Mr. Rokita was appointed as an Independent Member of the Board of Directors, and will serve as a member of the Company's Audit, Compensation and Nominating Committees. Mr. Rokita currently serves as co-owner and General Counsel and Vice President of External Affairs, Apex Benefits Group, Inc. where he serves as a member of the executive team and the corporate board. He is 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 serves as the public face of the company and is 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 Advisory Board member (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, 60, 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.

Meeta Vyas, SB, MBA, age 64, is known as a strong leader with board level experience and successful achievements as a Senior Executive in a broad range of entities including publicly listed corporations, non-revenue generating entities, and medium to large size companies. Ms. Vyas has over twenty-five years of experience in performance and process improvement of both publicly listed companies and non-revenue producing entities, in areas ranging from Finance and Operations to Strategy and Management. Meeta holds the distinction of being the first Indian woman to be named CEO of a publicly listed U.S. corporation, Signature Brands, Inc., best known for "Mr. Coffee" and "Health-O-Meter" brand products. As CEO, acting COO and Vice Chairman of the Board of Signature Brands, Inc., she was responsible for the development and implementation of a turnaround plan, resulting in Signature's return to profitability and growth. Later, as the CEO of the World-Wide Fund for Nature - India (WWF-India) and then as a Vice President of the

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National Audubon Society (USA), both non-revenue generating entities, Meeta successfully raised unrestricted funding that significantly exceeded annual requirements and also instituted financial processes to measure a variety of performance metrics. Earlier in her career, she was responsible for designing the strategy and initiating the implementation plan for the highly successful information technology outsourcing program at General Electric ("GE"). Also at GE, Ms. Vyas ran GE Appliances' Range Products business unit having revenues exceeding $1 billion where her team doubled operating income in less than two years. Prior to that, as a management consultant with McKinsey and Company, she served publicly listed companies in chemicals, industrial, and technology markets, primarily focusing on growth strategies, valuations, post-merger integrations, and logistics operations. Ms. Vyas is married to Anil Diwan, the Company's President and Chairman and principal shareholder of TheraCour Pharma, Inc. Ms. Vyas holds a MBA in Finance from Columbia University's Graduate School of Business, and a SB in Chemical Engineering from the Massachusetts Institute of Technology. We concluded that Ms. Vyas' experience and training render her qualified to serve as the Company's Chief Financial Officer.

AUDIT COMMITTEE

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. Since the Death of Stanley Glick, in January 2022 Brian Zucker has been acting Chair of the Audit Committee. On May 15, 2020 Theodore Edward ("Todd") Rokita was appointed as an independent directors and member of the Audit Committee. The Company has appointed a Search Committee to identify and select candidates for the position of independent director and member of the Audit Committee. The Search Committee will update the Board as appropriate on the progress of the search process.

CODE OF ETHICS

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

ITEM 11. EXECUTIVE COMPENSATION

The following table reflects all forms of compensation for the years ended June 30, 2022, 2021 and 2020.

Name and Principal Position	Year	Salary	Bonus ($)	Stock Award(s) ($)	Option Awards(#)	All Other Compensation ($)	Total ($)
Anil Diwan	2022	$ 400,000	$ —	$ 108,982		$ —	$ 508,982
CEO, President, Director	2021	$ 400,000	$ —	$ 182,610		$ —	$ 582,610
	2020	$ 400,000	$ —	$ 189,038		$ —	$ 589,038
Meeta Vyas	2022	$ 129,600	$ —	$ 18,129	—	$ —	$ 147,729
CFO	2021	$ 129,600	$ —	$ 24,548	—	$ —	$ 154,548
	2020	$ 129,600	$ —	$ 20,869	—	$ —	$ 150,469

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

Name and Principal Position	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested	Market Value of Shares or Units of Stock that Have Not Vested	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested
Anil Diwan, President and Director	—	—	$ —	—	—	—	—	—
Irach Taraporewala	—	—	$ —	—	—	—	—	—
Mukund Kulkarni	—	—	$ —	—	—	—	—	—
Stanley Glick	—	—	$ —	—	—	—	—	—
Meeta Vyas	—	—	$ —	—	—	—	—	—

COMPENSATION OBJECTIVES

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

ELEMENTS OF COMPENSATION

BASE SALARY. All full time executives are paid a base salary. Base salaries for our executives are established based on the scope of their responsibilities, professional qualifications, academic background, and the other elements of the executive's compensation, including stock-based compensation. However, at this time current total annual compensation is not in line with comparable companies, because our philosophy was to pay modest salaries with minimum bonuses to conserve capital resources for future company growth. Our intent is to set executives' base salaries near the median of the range of salaries for executives in similar positions with similar responsibilities at comparable companies, in line with our compensation philosophy. Base salaries are reviewed annually, and may be increased to align salaries with market levels after taking into account the subjective evaluation described previously.

EQUITY INCENTIVE COMPENSATION. We believe that long-term performance is achieved through an ownership culture participated in by our executive officers through the use of stock-based awards. Currently, we do not maintain any incentive compensation plans based on pre-defined performance criteria. The Board of Directors has the general authority, however, to award equity incentive compensation, i.e. stock options, to our executive officers in such amounts and on such terms as the committee determines in its sole discretion. The Board of Directors does not have a determined formula for determining the number of options available to be granted. The Board of Directors will review each executive's individual performance and his or her contribution to our strategic goals periodically. With the exception of stock options automatically granted in accordance with the terms of the employment

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agreement with our executive officers, our Board of Directors grants equity incentive compensation at times when we do not have material non-public information to avoid timing issues and the appearance that such awards are made based on any such information.

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.

BENEFICIAL OWNERSHIP OF COMPANY COMMON STOCK BY DIRECTORS, OFFICERS AND PRINCIPAL STOCKHOLDERS

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

The following table sets forth, as of June 30, 2022, certain information regarding the beneficial ownership of the Company's Common Stock and Series A Convertible Preferred Stock outstanding by (i) each person known to us to own or control 5% or more of our Common Stock, (ii) each of our directors, (iii) each of our "Named Executive Officers" (as defined in Item 402(a)(3) of Regulation S-K) and (iv) our current Named Executive Officers and directors as a group. Unless otherwise indicated, each person named in the table below has sole voting and investment power with respect to the shares beneficially owned.

	Common Stock		Series A Convertible Preferred Stock[1]		
Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner[2]	Percent of Class[2]	Amount and Nature of Beneficial Owner[2]	Percent of Class[2]	Percent of Voting Power[3]
TheraCour Pharma, Inc.[4]	470,959	4.1 %	300,000	61.9 %	19.9 %
Anil Diwan[4][5]	—	—	96,275	19.9 %	5.0 %
Meeta Vyas[6]	7,129	0.1 %	14,044	2.9 %	0.1 %
Makarand Jawadekar	9,866	0.1 %	—	—	* %
Theodore Rokita	9,339	0.1 %	—	—	* %
Brian Zucker	8,116	0.1 %	—	—	* %
All Directors and Executive Officers as a Group (6 persons)	505,409	4.5 %	410,319	84.7 %	25.9 %

(1) The Series A Convertible Preferred Shares (the "Series A") vote at the rate of nine shares of Common Stock per each share of Series A and is convertible into three and one half shares of Common Stock upon a change in control of the Company.

(2) For each shareholder, the calculation of percentage of beneficial ownership is based upon 11,592,173 shares of Common Stock and 484,582shares 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.

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(5) Does not include 470,959 shares of common stock nor the 300,000 shares of Series A preferred stock owned by TheraCour Pharma, Inc. which votes at the rate of 3 and one-half shares of common stock for each Share of Series A preferred stock (the "Series A preferred stock"), over which Anil Diwan holds voting and dispositive power. Does not include the beneficial ownership of the securities held by Meeta Vyas, the wife of Anil Diwan, and Armstoo Irrecvocable 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, President and Chairman of the Board of Directors, entered into an employment agreement effective July 1, 2015 for a term of three years. Dr. Diwan's compensation is $350,000 for the first year of employment, $375,000 for the second year and $400,000 for the final year. Additionally, Dr. Diwan was awarded a grant of 225,000 shares of the Company's Series A Preferred Stock. 75,000 shares vested on June 30, 2016, 2017 and 2018. The employment agreement also provided incentive bonuses of $75,000 per year payable on or before July 31, 2016, 2017 and 2018. Incentive bonuses for 2016 and 2017 have been paid according to the terms of the contract. The Company and Dr. Diwan agreed that the 2018 bonus would be earned and paid upon a filing of an IND. The Company and Dr. Diwan entered into an extension of employment agreement effective July 1, 2018 for a term of three years. Dr. Diwan's will be paid an annual base salary of $400,000. Additionally, Dr. Diwan was awarded a grant of 26,250 shares of the Company's Series A preferred stock. 8,750 shares vest equally on June 30, 2019, 2020 and 2021. Any unvested shares are subject to forfeiture. On September 24, 2021, the Company and Dr. Diwan entered into extension of the employment agreement for a period of one year from July 1, 2021 through June 30, 2022 under the same general terms and conditions. The Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A Preferred Stock. The shares will be deemed partially vested in quarterly installments following the grant date and fully vested on June 30, 2022. The employment agreement is renewable annually with approval by the Board of Directors. On October 6, 2022, the Company agreed to the extension of the employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares will be deemed partially vested in quarterly installments following the grant date and fully vested on June 30, 2023.

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 March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provided for a term of four years with a base salary of $150,000. In addition, the Company issued 1,786 shares of common stock upon entering into the agreement, and will issue an additional 1,786 shares of common stock on each anniversary date of the agreement. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

On May 30, 2013, the Company entered into an employment agreement with Meeta Vyas, wife of our President and Chairman of the Board, to serve as its Chief Financial Officer. The employment agreement provided for a term of three years with a base salary of $9,000 per month and 129 shares of Series A preferred stock, also on a monthly basis. On January 1, 2015, her cash compensation was increased to $10,800 per month. The agreement is renewable on an annual basis. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

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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 $36,250 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 meetings per annum. As compensation, each member of the Scientific Advisory Board (SAB) will be granted 572 warrants each quarter to purchase the Company's common stock at 120% of the Company's closing stock quote on the day following the meeting. Should the Company not call a quarterly meeting, quarterly warrants will be granted on May 15, August 15, November 15, and February 15. The warrants have a four-year expiration date. In addition the Company will reimburse each SAB member for travel and other out-of-pocket expenses incurred in the course of performing their services. For the year ended June 30, 2022, and 2021, the SAB was granted a total of 2,288 and 2,288 of stock warrants, respectively. The warrants are exercisable into common shares at prices from $1.46 to $5.92, and $3.94 to $6.86 per share, respectively.

EMPLOYEES AND SERVICE PROVIDERS

The Company, including TheraCour, has seventeen 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. Some of the Company's R&D work was performed by agencies in Vietnam. In the future, the Company anticipates having additional service providers. We believe that we have good relations with our employees and subcontractors.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

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

On December 16, 2019, the Company entered into an Open End Mortgage Note (the "Note") with Dr. Anil Diwan, the Company's founder, Chairman, President and CEO, to loan the Company up to $2,000,000 in two tranches of $1,000,000 (the "Loan"). The Note was paid off on December 31, 2020. The Note bore interest at the rate of 12% per annum and was secured by a mortgage granted against the Company's headquarters. Dr. Anil Diwan received 10,000 shares of the Company's Series A preferred stock as a loan origination fee which was amortized over the one year term of the loan using the effective interest method. The fair value of the 10,000 shares of the Company's Series A preferred stock when issued on December 16, 2019 was $39,301. The Series A preferred stock fair value is based on the greater of the i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the Holder would lose the voting rights upon conversion. For the assumptions used in calculating the fair value of the preferred shares, the conversion of the shares is triggered by a change of control. Amortization expense on the loan origination fee for the years ended June 30, 2022 and 2021 was $0 and $18,013 respectively, The Company had drawn down $1.1 million of this loan. Interest was payable only on the amount drawn down. The lender had escrowed $132,000 of interest payable pursuant to the Loan. For the years ended June 30, 2022 and 2021, the Company incurred interest expense of $0 and $62,773, respectively, which reduced the interest escrow balance included in prepaid expenses to zero.

TheraCour Pharma, Inc.

On May 12, 2005, we entered into a Material License Agreement, amended as of January 8, 2007 (the "License") with TheraCour Pharma, Inc. ("TheraCour"), an approximately 5.3% common shareholder. 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

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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 October 2, 2018, we entered into an agreement with TheraCour to defer the $25,000 payment until the earlier of April 2, 2019 or the date that we file an IND with the FDA. On May 9, 2019, we entered into an agreement with TheraCour that extended the April 2, 2019 date to June 30, 2019 and on September 24, 2019 we entered into an agreement with TheraCour that extended such date to the later of December 31, 2019 or the filing on an IND with the FDA. Deferred development fees as of June 30, 2021 was $200,000.

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

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

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

Under the CoV Agreement, the Company obtained a world-wide, exclusive, sub-licensable, license to use, promote, offer for sale, import, export, sell and distribute antiviral drugs that treat human Coronavirus infections using TheraCour's proprietary as well as patented technology and intellectual property, including the new patent application cited above. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be

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performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. We will not make any upfront cash payments to TheraCour and we have agreed to the following milestone payments to TheraCour: 100,000 shares of the Company's Series A Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock") upon the execution of the Agreement; 50,000 shares of Series A Preferred Stock after the grant of the approval of Licensee's Investigational New Drug (IND) Application, or its equivalent; cash payments of $1,500,000 after the initiation of Phase I clinical trials or its equivalent; $2,000,000 after the completion of Phase 1 Clinical Trials or its equivalent for at least one product within twelve (12) months from the date of the acceptance of the IND; $2,500,000 no later than six (6) months after the completion of Phase 2A Clinical Trials or its equivalent for at least one product within twenty (24) months from the date of the completion of Phase 1 or its equivalent; 100,000 shares of Series A Preferred Stock after the initiation of Phase 3 clinical trials or its equivalent; and, at TheraCour's option, $5,000,000 in cash or 500,000 shares of Series A Preferred Stock, no later than six (6) months after the completion of Phase 3 Clinical Trials or its equivalent for at least one product within thirty-six (36) months from the completion of Phase 2 Clinical Trials or its equivalent. In addition, we agreed to pay to TheraCour fifteen percent (15%) of net sales of licensed products and any income from sublicensed products, consistent with previous agreements. Under the CoV Agreement, TheraCour retains the exclusive right to develop and manufacture the Licensed Products. The Agreement contemplates that the parties will enter into a separate Manufacturing and Supply Agreement for the commercial manufacture and supply of the drug products if and when we intend to engage into commercialization of the drugs. The CoV Agreement provides that the Manufacturing and Supply agreement would be on customary and reasonable terms, on a cost-plus basis, using a market rate based on then-current industry standards, and include customary backup manufacturing rights, as with prior agreements. The Series A Convertible Preferred Shares are only convertible upon a "change of control" of the Company as defined in its full specification, are non-transferrable and have no trading market. Each Series A share carries 9 votes, and is convertible only upon a change of control into 3.5 shares of the Company's common stock.

To assist in the analysis of the terms of the CoV Agreement, we commissioned research reports on Coronavirus drug market sizes for the Coronavirus antivirals 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.

COVID-19 Related Drugs: Patent Coverage and Lifetime

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

TheraCour acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, to the Company, at cost, in the amounts of $183,428 and $171,668 for the fiscal years ended June 30, 2022 and 2021 respectively.

Accounts payable to TheraCour were $214,397 and $31,539 at June 30, 2022and June 30, 2021, respectively.

Development costs charged by and paid to TheraCour were $2,369,022 and $2,803,827for the years ended June 30, 2022 and 2021, respectively. No royalties are due or have been paid from inception through June 30, 2022.

As of June 30, 2022 TheraCour owned 470,959 shares of the Company's outstanding common stock and 300,000 shares of series A preferred stock, which votes at the rate of nine shares of common stock per each share of series A preferred stock and is convertible into three and one half shares of common stock upon a change in control of the Company. Dr. Diwan, also serves as the CEO and Director of TheraCour and owns approximately 90% of the outstanding capital stock of TheraCour.

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ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees for each of the last two years for professional services rendered by the independent registered public accounting firm for our audits of our annual financial statements and interim reviews of our financial statements included in our fillings with Securities and Exchange Commission on Form 10-K and 10-Qs or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for those years were approximately:

June 30, 2022	$	218,700	EisnerAmper LLP
June 30, 2021	$	206,960	EisnerAmper LLP.

Pre-Approval Policies

The Board of Directors, and the Audit Committee appointed by the Board, currently does not have any pre-approval policies or procedures concerning services performed by EisnerAmper LLP. All the services performed by EisnerAmper LLP as described above were pre-approved by the Audit Committee.

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ITEM 15. EXHIBITS

Exhibits	Description	Filed / furnished / incorporated by reference from	Incorporated by reference from exhibit	Date filed
1.1**	Form of Underwriting Agreement			
3.1	Amended and Restated Articles of Incorporation	Schedule 14C	A	April 23, 2009
3.2	Certificate of Change	Form 8-K	3.1	September 9, 2013
3.3	Certificate of Change	Form 8-K	3.1	September 26, 2019
3.4	Certificate of Amendment	Form 8-K	3.1	March 20, 2020
3.4	Amended and Restated Bylaws	Form 10-Q	3.1	February 22, 2010
4.1	Specimen Common Stock Certificate of the Registrant	Form 10-SB	4.1	November 14, 2006
4.2	Certificate of Designation of Series A Convertible Preferred Stock	Form 10-Q	4.1	February 22, 2010
4.3*	Certificate of Amendment to Certificate of Designation of Series A Convertible Preferred Stock			
4.4*	Certificate of Amendment to Certificate of Designation of Series A Convertible Preferred Stock			
4.5	Form of Warrant	Form 8-K	10.2	March 1, 2019
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	Form of First Subscription Agreement	Form 10-SB	10.8	November 14, 2006
10.4	Form of Second Subscription Agreement	Form 10-SB	10.9	November 14, 2006
10.5	Amendment to License Agreement with TheraCour Pharma, Inc.	Form 10-SB	10.11	January 17, 2007
10.6	Memorandum of Understanding with Vietnam's National Institute of Hygiene and Epidemiology (NIHE) dated December 23, 2005	Form 10-SB	10.12	January 17, 2007
10.7*	Employment Agreement with M Vyas			
10.8	Agreement of Purchase and Sale between the Registrant and Inno-Haven, LLC	Form 8-K	10.1	January 7, 2015
10.9	Conversion and Settlement Agreement	Form 8-K	10.1	February 13, 2017
10.10	Confidential Separation Agreement and General Release of Eugene Seymour	Form 8-K	10.1	May 4, 2018
10.11	Employment Agreement with Anil Diwan	Form 8-K	10.1	July 23, 2018
10.12	Employment Agreement with Irach Taraporewala	Form 8-K	10.2	July 23, 2018
10.13	Securities Purchase Agreement, dated February 27, 2019, between the Registrant and certain purchasers	Form 8-K	10.1	March 1, 2019
10.14	Letter Agreement with Chardan Capital Markets, LLC	Form 8-K	10.3	March 1, 2019
10.15	Director Retainer Agreement, dated as of June 6, 2019, between the Registrant and Mark Day	Form 8-K	10.1	June 10, 2019
10.16*	Form of Series A Conversion Waiver			
10.17	Underwriting with Aegis Capital Corp. dated January 21, 2020	Form 8-K	10.1	January 27, 2020
10.18	Form of Settlement Agreement and Mutual Release	Form 8-K	10.1	January 28, 2020

10.19	Form of Exchange Agreement	Form 8-K	10.2	January 28, 2020
10.20	Form of Common Stock Purchase Warrant	Form 8-K	10.3	January 28, 2020
10.21	Director Retainer Agreement between NanoViricides, Inc. and Makarand Jawadekar	Form 8-K	10.1	February 11, 2020
10.22	Director Retainer Agreement, dated as of May 15, 2020, between NanoViricides, Inc. and Todd Rokita	Form 8-K	10.1	May 19, 2020

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10.23	Form of Securities Purchase Agreement dated May 21, 2020 by and between NanoViricides, Inc. and certain purchasers	Form 8-K	10.1	May 22, 2020
10.24	Placement Agent Agreement, dated May 21, 2020 by and between among NanoViricides, Inc. Maxim Group LLC and Kingswood Capital Markets, a division of Benchmark Investments, Inc.	Form 8-K	10.2	May 22, 2020
10.25	Underwriting Agreement with Kingswood Capital Markets, a Division of Benchmark Investments, Inc. dated July 8, 2020.	Form 8-K	10.1	July 13, 2020
10.26	At Market Issuance Sales Agreement by and between NanoViricides, Inc., B. Riley Securities, Inc. and Kingswood Capital Markets, a division of Benchmark Investments, Inc., dated July 31, 2020	Form 8-K	1.1	August 3, 2020
10.27	Director Retainer Agreement dated November 13, 2020 between NanoViricides, Inc. and Brian Zuckar	Form 8-K	10.1	November 13, 2020
10.28	License Agreement dated September 7, 2021 between NanoViricides, Inc. and TheraCour Pharma, Inc.	Form 8-K	10.1	September 9, 2021
10.29	Extension to Employment Agreement with A. Diwan	Form 8-K	10.2	September 9, 2021
10.30	Extension to Employment Agreement with A. Diwan	Form 8-K	10.2	October 11, 2022
14.1	Code of Ethics	Form 10-SB	10.10	November 14, 2006
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended			
31.2	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended			
32.1	Certification of Chief Executive Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2	Certification of Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101.INS	Inline XBRL Instance Document.			
101.SCH	Inline XBRL Schema Document.			
101.CAL	Inline XBRL Calculation Linkbase Document.			
101.DEF	Inline XBRL Definition Linkbase Document.			
101.LAB	Inline XBRL Label Linkbase Document.			
101.PRE	Inline XBRL Presentation Linkbase Document.			
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)			

ITEM 16. FORM 10-K SUMMARY

None.

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SIGNATURES

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

Dated: October 13, 2022

NANOVIRICIDES, INC.

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

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

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

October 13, 2022

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

October 13, 2022

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

October 13, 2022

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

October 13, 2022

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

October 13, 2022

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

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NanoViricides, Inc.

Index to the Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NanoViricides, Inc. (the "Company") as of June 30, 2022. and 2021, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Related Party Transactions

As discussed in Note 4 to the financial statements, the Company enters into certain agreements which grant exclusive licenses for technologies developed by a related party for various virus types. As part of these agreements, the Company is required to pay certain costs charged by the related party. These costs include research and development costs resulting from their research and development activities which include the performance of preclinical studies and/or clinical trials, 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 $214,397 as of June 30, 2022 and research and development costs paid to related party of $2,369,022, included in research and development expenses for the year ended June 30, 2022.

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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 judgment, 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 sufficiency of related party assets and 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 and expenses are properly recorded in accordance with the agreements and that appropriate approval from management and 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 and that related party transactions were accounted for and disclosed properly.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
October 13, 2022

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NanoViricides, Inc.
Balance Sheets

	June 30, 2022	June 30, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,066,359	$ 20,516,677
Prepaid expenses	350,021	307,102
Total current assets	14,416,380	20,823,779
PROPERTY AND EQUIPMENT		
Property and equipment	14,658,014	14,333,666
Accumulated depreciation	(5,963,820)	(5,248,765)
Property and equipment, net	8,694,194	9,084,901
TRADEMARK AND PATENTS		
Trademark and patents	458,954	458,954
Accumulated amortization	(117,106)	(108,836)
Trademark and patents, net	341,848	350,118
OTHER ASSETS		
Security deposits	3,515	3,515
Service agreements	38,925	—
Other assets	42,440	3,515
Total assets	$ 23,494,862	$ 30,262,313
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 57,960	$ 200,016
Accounts payable – related party	214,397	31,539
Loan payable	94,788	95,306
Accrued expenses	45,692	24,285
Total current liabilities	412,837	351,146
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A convertible preferred stock, $0.001 par value, 10,000,000 shares designated, 484,582 and 371,490 shares issued and outstanding, at June 30, 2022 and 2021, respectively	485	372
Common stock, $0.001 par value; 150,000,000 shares authorized, 11,592,173 and 11,515,170 shares issued and outstanding at June 30, 2022 and 2021, respectively	11,592	11,515
Additional paid-in capital	145,562,124	144,284,593
Accumulated deficit	(122,492,176)	(114,385,313)
Total stockholders' equity	23,082,025	29,911,167
Total liabilities and stockholders' equity	$ 23,494,862	$ 30,262,313

See accompanying notes to the financial statements

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NanoViricides, Inc.
Statements of Operations

	Year Ended June 30,	
	2022	2021
OPERATING EXPENSES		
Research and development	$ 5,784,862	$ 6,114,541
General and administrative	2,328,737	2,629,565
Total operating expenses	8,113,599	8,744,106
LOSS FROM OPERATIONS	(8,113,599)	(8,744,106)
OTHER INCOME (EXPENSE):		
Interest income	11,859	9,348
Interest expense	(5,123)	(85,405)
Loss on disposal of property and equipment	—	(2,026)
Other (expense) income, net	6,736	(78,083)
LOSS BEFORE INCOME TAX PROVISION	(8,106,863)	(8,822,189)
INCOME TAX PROVISION	—	—
NET LOSS	$ (8,106,863)	$ (8,822,189)
Net loss per common share- basic and diluted	$ (0.70)	$ (0.81)
Weighted average common shares – basic and diluted	11,534,698	10,900,955

See accompanying notes to the financial statements.

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NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the period from July 1, 2020 through June 30, 2022

	Series A Preferred Stock: Par $0.001		Common Stock: Par $0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, July 1, 2020	368,602	$ 369	9,083,414	$ 9,083	$127,311,634	$(105,563,124)	$ 21,757,962
Series A preferred stock issued for employee stock compensation	2,888	3	—	—	226,303	—	226,306
Net proceeds from issuance of common stock in connection with equity financings	—	—	2,389,584	2,390	16,561,307	—	16,563,697
Common stock issued for consulting and legal services rendered	—	—	25,434	25	107,975	—	108,000
Warrants issued to Scientific Advisory Board	—	—	—	—	6,103	—	6,103
Common stock issued for employee compensation	—	—	3,572	4	15,034	—	15,038
Common stock issued for Directors fees	—	—	13,166	13	56,237	—	56,250
Net loss	—	—	—	—	—	(8,822,189)	(8,822,189)
Balance, June 30, 2021	371,490	$ 372	11,515,170	$11,515	$144,284,593	$(114,385,313)	$ 29,911,167
Series A preferred stock issued for employee stock compensation	13,092	13	—	—	135,387	—	135,400
Series A preferred stock issued for license agreement	100,000	100	—	—	934,988	—	935,088
Common stock issued for consulting and legal services rendered	—	—	38,863	39	107,961	—	108,000
Warrants issued to Scientific Advisory Board	—	—	—	—	4,215	—	4,215
Common stock issued for employee compensation	—	—	3,572	3	6,765	—	6,768
Common stock issued for Directors fees	—	—	17,705	18	52,482	—	52,500
Common stock issued for professional services	—	—	16,863	17	35,733	—	35,750
Net loss	—	—	—	—	—	(8,106,863)	(8,106,863)
Balance, June 30, 2022	484,582	$ 485	11,592,173	$11,592	$145,562,124	$(122,492,176)	$ 23,082,025

See accompanying notes to the financial statements

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NanoViricides, Inc.
Statements of Cash Flows

	Year Ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,106,863)	$ (8,822,189)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	135,400	226,306
Preferred shares issued pursuant to license agreement	935,088	—
Common shares issued as compensation and for services	203,018	179,288
Warrants granted to Scientific Advisory Board	4,215	6,103
Depreciation	715,055	696,268
Amortization of loan origination fees	—	18,013
Amortization	8,270	8,270
Loss on disposal of property and equipment	—	2,026
Write-off of deferred financing costs	—	12,190
Changes in operating assets and liabilities:		
Prepaid expenses	191,279	205,436
Other long term assets	(38,925)	10,158
Accounts payable	(142,056)	(180,711)
Accounts payable - related parties	182,858	(530,041)
Accrued expenses	21,407	(44,953)
NET CASH USED IN OPERATING ACTIVITIES	(5,891,254)	(8,213,836)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(324,348)	(238,765)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants	—	16,563,697
Payment of note payable- related party	—	(1,100,000)
Payment of loan payable	(234,716)	(203,013)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(234,716)	15,260,684
NET CHANGE IN CASH AND CASH EQUIVALENTS	(6,450,318)	6,808,083
Cash and cash equivalents at beginning of period	20,516,677	13,708,594
Cash and cash equivalents at end of period	$ 14,066,359	$ 20,516,677
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	$ 5,123	$ 4,858
Income tax paid	$ —	$ —
NON CASH FINANCING AND INVESTING ACTIVITIES:		
Directors and Officers Insurance financed through loan	$ 234,198	$ 235,476

See accompanying notes to the financial statements

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NanoViricides, Inc.
June 30, 2022, and 2021
Notes to the Financial Statements

Note 1 – Organization and Nature of Business

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

The Company has several drugs in various stages of early development. COVID-19 has become our lead drug program due to the necessity of responding to the pandemic. The Company has a clinical lead candidate NV-CoV-2 for the treatment of SARS-CoV-2 infection (COVID-19 disease) that has shown excellent effectiveness and safety in pre-clinical studies. IND-enabling studies of NV-CoV-2 have been completed. The Company is working on IND writing and engaging a Clinical Trials Clinical Research Organization in pursuit of Phase I/II human clinical trials of this drug. The Company is also working on performing clinical trials of this drug outside the USA. The Company began development of a drug to treat COVID-19 patients just as the cases of the novel disease were being reported from China. The Company cannot provide a timeline at this point because of external dependencies in the filing of regulatory applications, their approval(s) and beginning of clinical trials. As of June 30, 2022, there is only one antiviral drug (remdesivir) approved, and two non-antibody antiviral drugs (Paxlovid, Pfizer and Molnupiravir, Merck) given Emergency Use Authorization (EUA) by the FDA. Several of previously approved antibody therapies have lost efficacy and their EUAs have been revoked, as the virus mutated and new variants came in the field, as previously predicted by the Company. The antibodies that remain under EUA are expected to lose effectiveness as the virus continues to mutate and new escape variants take over. All of these drug approvals are restricted to specific population subsets, and there is no drug that is generally approved for treatment of COVID-19, particularly for patients with no co-morbidities and not at risk of hospitalization (https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs). In addition, there are at least three vaccines licensed in the USA and several more are in use internationally. Internationally, virus variants have continued to emerge with resistance to drugs and vaccines. Scientists believe it is only a matter of time before escape variants against existing antibodies and vaccines, including the newly introduced Omicron/Original Strain bi-valent vaccines, and therapeutics become commonplace. Thus there is an unmet need that the Company's broad-spectrum, pan-coronavirus drug NV-CoV-2 is expected to fulfill for therapeutics that the virus would not escape by mutations. Additionally, specific populations such as immune-compromised persons, HIV-positive persons, and others would require therapeutics even if they are fully vaccinated, as the weak immune system in these populations limits the ability of vaccines to protect from COVID-19 infection and disease.

In response to the recent Monkeypox virus (MPXV) epidemic, the Company has begun a limited drug development program to treat MPXV patients. At present, while it appears that this epidemic is quieting down, experts expect that this virus will become endemic in the Western world, as it is in the African subcontinent (https://www.cdc.gov/poxvirus/monkeypox/cases-data/technical-report/report-3.html#dynamics). A vaccine against smallpox appears to have substantial effectiveness in protecting vaccinated persons from MPXV infection. The only currently available drug, tecovirimat, approved for smallpox, has a low escape barrier for virus mutations, and has other limitations on its use. Thus there remains an urgent need for broad-spectrum drugs that can treat MPXV, smallpox, and other poxviruses.

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

The Company intends to run both MPXV and EVD68 programs by initially evaluating the Company's existing drug candidate library for effectiveness. If effective existing drug candidates are found, the Company intends to undertake additional work as well as seek additional financing, preferably via non-dilutive funding sources.

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The Company plans on re-engaging our other lead antiviral program against herpes viruses, i.e. the HerpeCide™ program, as soon as it becomes feasible to conduct the corresponding antiviral human clinical studies. In the HerpeCide program alone, the Company has drug candidates against at least five indications at different stages of development. Of these, the Company is advancing the shingles drug candidate towards human clinical trials. The IND-enabling Safety/Toxicology studies required for doing so have been completed and the Company was in the process of preparing an IND application for this drug candidate when the SRAS-CoV-2 virus struck, whereupon we pivoted our efforts to respond to the threat of what has now become the COVID-19 pandemic. In addition, the Company's drug candidates against HSV-1 "cold sores" and HSV-2 "genital herpes" are in advanced studies and are expected to follow the shingles drug candidate into human clinical trials. Shingles in adults and chicken pox in children is caused by the same virus, namely VZV (Varicella-zoster virus, aka HHV-3 or human herpesvirus-3). There are estimated to be approximately 120,000-150,000 annual chickenpox cases in the USA in the post-vaccination-era, i.e. since childhood vaccination with the live attenuated varicella virus Oka strain has become standard. In addition, the Company has drugs in development against all influenzas in our FluCide™ program, as well as drug candidates against HIV/AIDS, Dengue, Ebola/Marburg, and other viruses.

The Company's drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. ("TheraCour"), to which the Company has broad, exclusive licenses. The first license agreement the Company executed with TheraCour on September 1, 2005 ("Exclusive License Agreement"), gave the Company an exclusive, worldwide license for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV), Influenza and Asian Bird Flu Virus. On February 15, 2010, the Company executed an Additional Agreement ("Additional License Agreement") with TheraCour. Pursuant to the Additional License Agreement, the Company was granted exclusive licenses for technologies, developed by TheraCour, for the development of drug candidates for the treatment of Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes. In addition, on November 1, 2019, the Company entered into a world-wide, exclusive, sub-licensable, license ("VZV License Agreement") to use, promote, offer for sale, import, export, sell and distribute drugs that treat VZV 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. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement. The Company was not required to make any upfront payments to TheraCour and agreed to the following milestone payments to TheraCour; the issuance of 75,000 shares of the Company's Series A preferred stock upon the grant of an IND Application; $1,500,000 in cash upon completion of Phase I Clinical Trials; $2,500,000 in cash upon completion of Phase II clinical trials; and $5,000,000 in cash upon completion of Phase III clinical trials.

On September 9, 2021, the Company entered into a world-wide, exclusive, sub-licensable, license ("Covid-19 License Agreement") to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. 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 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 IND Application or its equivalent by a competent regulatory authority; (iii) $1,500,000 upon initiation of Phase I clinical trials, or its equivalent, for at least one licensed product within-the field on, or before, three (3) months from the date of the authority's acceptance of the IND, or its equivalent; (iv) $2,000,000 in cash upon completion of Phase 1 clinical trials; (v) $2,500,000 in cash upon completion of Phase IIA clinical trials, or, its equivalent; (vi) the issuance of 100,000 shares of the Company's Series A preferred stock upon the initiation of Phase 3 clinical trials, or, its equivalent, for at least one licensed product within the field; and (vii) $5,000,000 in cash, or 500,000 shares of the Company's Series A preferred stock upon completion of Phase III clinical trials, or its equivalent. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement.

At present the Company does not hold a license for monkeypox therapeutics. As with the Company's standard policy, if the exploratory work commissioned by the Company leads to potentially effective candidates, and if the Company chooses to further engage in commercial development of the same, then the Company will perform the activities required to obtain such a license. TheraCour has not denied any licenses to NanoViricides to date.

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Note 2 – Liquidity

The Company's financial statements have been prepared assuming that it will continue as a going concern, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the normal course of business. As reflected in the financial statements, the Company has an accumulated deficit at June 30, 2022 of approximately $122.5 million and a net loss of approximately $8.1 million and net cash used in operating activities of approximately $5.9 million for the fiscal year then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of June 30, 2022, the Company had available cash and cash equivalents of approximately $14.1 million.

Since the onset of the COVID-19 pandemic, the Company has focused its efforts primarily on a single lead program to minimize cost outlays, namely, taking the COVID-19 drug candidate against SARS-CoV-2 into human clinical trials. The prior lead program for a shingles drug will follow the COVID-19 drug program.

On July 31, 2020, the Company entered into an At The Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc. and Kingswood Capital Markets, a division of Benchmark Investments, Inc. (each a "Sales Agent" and collectively, the "Sales Agents"), pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agents, shares of common stock (the "Placement Shares"), having an aggregate offering price of up to $50 million (the "ATM Offering"). Sales pursuant to the Sales Agreement will be made only upon instructions by the Company to the Sales Agents, and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. Actual sales will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Company's common stock, capital needs and determinations by the Company of the appropriate sources of funding for the Company. The Company is not obligated to make any sales of common stock under the Sales Agreement and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. The Company will pay a commission rate of up to 3.5% of the gross sales price per share sold and agreed to reimburse the Sales Agents for certain specified expenses, including the fees and disbursements of its legal counsel in an amount not to exceed $50,000 and have agreed to reimburse the Sales Agents an amount not to exceed $2,500 per quarter during the term of the Sales Agreement for legal fees to be incurred by the Sales Agents. The Company has also agreed pursuant to the Sales Agreement to provide each Sales Agent with customary indemnification and contribution rights.

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

The Company believes that it has several important milestones that it will be achieving in the ensuing year. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced.

The Company has not experienced a direct financial adverse impact of the effects of the Coronavirus (COVID-19) pandemic. However, the pandemic required the Company to reorganize its priorities, because of the impact on the ability to conduct antiviral drug trials for the Company's then lead program for Shingles drug treatment. While clinical trials were in general adversely affected, the ability to enroll patients into the shingles antiviral drug clinical trial with the desired inclusion criteria became limited due to the widespread coronavirus infection. The shingles clinical trial design and conduct would also become more complex The Company pivoted successfully into rapidly developing a drug to treat SARS-CoV-2 infections, since early days of the pandemic. Two of the Company's novel drug candidates, NV-CoV-2 and NV-CoV-2-R have reached human clinical readiness status. Of these, the IND-enabling GLP and non-GLP safety/toxicology studies in animal models as well as pre-clinical efficacy studies have been completed for the novel drug candidate NV-CoV-2. The Company is working on IND writing and engaging a Clinical Trials Clinical Research Organization in pursuit of Phase I/II human clinical trials of this drug. The Company is also working on performing clinical trials of this drug outside the USA.

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Management believes that the Company's existing resources will be sufficient to fund the Company's planned operations and expenditures through October 13, 2023. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company will need to raise additional capital to fund its long-term operations and research and development plans including human clinical trials for its various drug candidates until it generates revenue which reaches a level sufficient to provide self-sustaining cash flows. 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 stock options, 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 effect were anti-dilutive:

	Potentially Outstanding Dilutive Common Shares	
	For the Years Ended	
	June 30, 2022	June 30, 2021
Warrants	9,146	9,146
Options	—	5,000
Total	9,146	14,416

The Company has 484,582 and 371,490 shares of Series A preferred stock outstanding as of June 30, 2022 and 2021, 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, 2022 and 2021 the number of potentially dilutive shares of the Company's common stock into which these Series A preferred shares can be converted into is 1,696,037 and 1,300,215, respectively, and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

Use of Estimates

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

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Fair Value of Financial Instruments

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

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

Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets and would be charged to earnings. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. The Company has not recorded an impairment charge for the years ended June 30, 2022 and 2021.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents.

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, using the straight-line method. The Company generally assigns useful lives of thirty years for assets classified as GMP facility, fifteen years for assets classified as furniture and fixtures, ten years for assets classified as lab equipment, and five years for assets classified as office equipment. Expenditures for major additions and betterments are capitalized. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of property and equipment, the related cost and accumulated depreciation are removed from the accounts and any gain or loss is reflected in the statements of operations.

Trademarks and Patents

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

Research and Development

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

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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. 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 10 to the financial statements.

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

- Expected term of share options and similar instruments: The expected term of share options and similar instruments represents the period of time the options and similar instruments are expected to be outstanding taking into consideration the contractual term of the instruments and employees' expected exercise and post-vesting employment termination behavior into the fair value of the instruments. The Company uses the simplified method to calculate expected term of share options and similar instruments, as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

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

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

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

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

Income Tax Provision

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

The Company recognizes uncertainty in income taxes in the financial statements using a recognition threshold and measurement attribute of a tax position taken or expected to be taken in a tax return. The Company applies the "more-likely-than-not" recognition threshold to all tax positions, which resulted in no unrecognized tax benefits as of June 30, 2022 and 2021. The Company has opted to classify interest and penalties that would accrue, if any, according to the provisions of relevant tax law as general and administrative expenses, in the statements of operations. For the years ended June 30, 2022 and 2021 the Company paid interest to the state of Connecticut of $1,258 and $0, respectively.

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Concentrations of Risk

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

Recently Issued Accounting Pronouncements

The Company considers the applicability and impact of all Accounting Standard Updates ("ASU's"). There were no recent ASU's that are expected to have a material impact on the Company's balance sheets or statements of operations.

Note 4 – Related Party Transactions

Related Parties

Related parties with whom the Company had transactions are:

Related Parties	Relationship
Dr. Anil R. Diwan	Chairman, President, CEO, significant stockholder and Director
TheraCour Pharma, Inc. ("TheraCour")	An entity owned and controlled by Dr. Anil R. Diwan

Property and Equipment

	For the Year Ended	
	June 30, 2022	June 30, 2021
During the reporting period, TheraCour acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment at cost, to the Company	$ 183,428	$ 171,668

Accounts Payable- Related Party

	As of	
	June 30, 2022	June 30, 2021
Pursuant to an Exclusive License Agreement entered into with TheraCour, the Company was granted exclusive licenses for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. On November 1, 2019, the Company entered into the VZV Licensing Agreement with TheraCour. In consideration for obtaining these exclusive licenses it was agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of certain direct costs as a development fee and such development fees shall be due and payable in periodic installments as billed, (2) the Company will pay $2,000 or actual costs each month, whichever is higher for other general and administrative expenses incurred by TheraCour on the Company's behalf, (3) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour and; (4) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. Accounts payable due TheraCour at June 30, 2022 was $679,397 which was offset by a two month advance (see above) of $465,000. Accounts payable due TheraCour at June 30, 2021 was $522,539 which was offset by a two month advance (see above) of $491,000.	$ 214,397	$ 31,539

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Research and Development Costs Paid to Related Party

	For the Year Ended	
	June 30, 2022	June 30, 2021
Development fees and other costs charged by TheraCour pursuant to the License Agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at June 30, 2022 and 2021.	$ 2,369,022	$ 2,803,827

License Milestone Fee – Related Party

On September 9, 2021, the Company entered into a Covid-19 License Agreement to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. Pursuant to such license agreement, the Board of Directors authorized the issuance of 100,000 fully vested shares of the Company's Series A preferred stock as a license milestone payment and recorded an expense to Research and Development of $935,088 for the year ended June 30, 2022.

Mortgage Note Payable - Related Party

On December 16, 2019, the Company entered into an Open End Mortgage Note (the "Note") with Dr. Anil Diwan, the Company's founder, Chairman, President and CEO, to loan the Company up to $2,000,000 in two tranches of $1,000,000 (the "Loan"). The Note was paid off on December 31, 2020. The Note bore interest at the rate of 12% per annum and was secured by a mortgage granted against the Company's headquarters. Dr. Anil Diwan received 10,000 shares of the Company's Series A preferred stock as a loan origination fee which was amortized over the one year term of the loan using the effective interest method. The fair value of the 10,000 shares of the Company's Series A preferred stock when issued on December 16, 2019 was $39,301. The Series A preferred stock fair value is based on the greater of the i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the Holder would lose the voting rights upon conversion. For the assumptions used in calculating the fair value of the preferred shares, the conversion of the shares is triggered by a change of control. Amortization expense on the loan origination fee for the years ended June 30, 2022 and 2021 was $0 and $18,013 respectively. The Company had drawn down $1.1 million of this loan. Interest was payable only on the amount drawn down. The lender had escrowed $132,000 of interest payable pursuant to the Loan. For the years ended June 30, 2022 and 2021, the Company incurred interest expense of $0 and $62,773, respectively, which reduced the interest escrow balance included in prepaid expenses to zero.

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Note 5 – Property and Equipment

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

	June 30, 2022	June 30, 2021
GMP Facility	$ 8,149,416	$ 8,020,471
Land	260,000	260,000
Office Equipment	57,781	57,781
Furniture and Fixtures	5,607	5,607
Lab Equipment	6,185,210	5,989,807
Total Property and Equipment	14,658,014	14,333,666
Less Accumulated Depreciation	(5,963,820)	(5,248,765)
Property and Equipment, Net	$ 8,694,194	$ 9,084,901

Depreciation expense for the years ended June 30, 2022 and 2021 was $715,055 and $696,268 respectively.

Note 6 – Trademark and Patents

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

	June 30, 2022	June 30, 2021
Trademarks and Patents	$ 458,954	$ 458,954
Less Accumulated Amortization	(117,106)	(108,836)
Trademarks and Patents, Net	$ 341,848	$ 350,118

Amortization expense amounted to $8,270, and $8,270 for the years ended June 30, 2022 and 2021, respectively.

The Company amortizes its trademarks and patents over their expected original useful lives and,

Amortization expense in future years is as follows:

Years ended June 30,	
2023	$ 8,271
2024	8,271
2025	8,271
2026	8,271
2027	8,271
Thereafter	300,493
Total amortization	$ 341,848

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Note 7 – Accrued expenses

Accrued expenses consisted of the following:

	June 30, 2022	June 30, 2021
Personnel and compensation costs	$ 38,676	$ 24,285
Consultant	7,016	—
	$ 45,692	$ 24,285

Note 8 – Loan Payable

The Company financed its Directors and Officers liability insurance policies through BankDirect for the periods January 1, 2022 to December 31, 2022 and January 1, 2021 to December 31, 2021. The original loan balances as of January 1, 2022 and January 1, 2021 was $234,198 and $235,476, respectively, payable at the rate of $23,932 and $24,062 monthly including interest at an annual rate of 4.74% and 4.74%, respectively, through October of each year. At June 30, 2022 and June 30, 2021, the loan balance was $94,788 and $95,306, respectively. For the years ended June 30, 2022 and June 30, 2021 the Company incurred interest expense of $5,123 and $4,858, respectively.

Note 9 – Equity Transactions

Fiscal Year Ended June 30, 2022 Transactions

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

For the year ended June 30, 2022, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

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

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

On September 14, 2021, the Board of Directors and Dr. Anil Diwan, President and Chairman of the Board agreed to the extension of Dr. Diwan's employment agreement for a period of one year from July 1, 2021 through June 30, 2022 under the same general terms and conditions. The Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares vested in quarterly installments of 2,551 shares on September 30, 2021, December 31, 2021, March 31, 2022 and June 30, 2022. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $108,982 during the year ended June 30, 2022, which is the fair value on the date of issuance.

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

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There is currently no market for the shares of Series A preferred stock and they can only be converted into shares of common stock upon a change of control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Series A preferred stock granted to various employees and others on the date of grant. The Series A preferred stock fair value is based on the converted value to common stock at a ratio of 1:3.5 multiplied by the monthly average of the daily open and close price of the common stock. The conversion of the shares is triggered by a change of control.

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

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

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

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

Fiscal Year Ended June 30, 2021 Transactions

On July 11, 2018 the Board of Directors approved an extension of the employment agreement with Dr. Anil Diwan, the Company's President. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 26,250 of the Company's Series A preferred stock to Dr. Anil Diwan. The shares vested in one-third increments on June 30, 2019, June 30, 2020 and June 30, 2021 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $182,610 for the year ended June 30, 2021.

For the year ended June 30, 2021, the Scientific Advisory Board was granted fully vested warrants to purchase 2,288 shares of common stock at exercise prices between $3.94- $6.86 per share expiring in the fiscal year ending June 30, 2025. The fair value of the warrants was $6,103 for the year ended June 30, 2021 and recorded as consulting expense.

For the year ended June 30, 2021, the Company estimated the fair value of the warrants granted quarterly to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following weighted-average assumptions:

Expected life (year)	4
Expected volatility	91.14-91.92 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	0.24-.58 %

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On July 8, 2020 the Company entered into an Underwriting Agreement with Kingswood. Pursuant to the terms and conditions of the Underwriting Agreement, the Company agreed to issue and sell 1,369,863 shares of our common stock, par value $0.001 per share (the "Underwritten Shares"), at a price to the public of $7.30 per share. Pursuant to the Underwriting Agreement, the Company also granted the underwriter an option to purchase up to an additional 205,479 shares of common stock (together with the Underwritten Shares, the "Shares") within 45 days after the date of the Underwriting Agreement to cover over-allotments, if any. The shares were issued pursuant to a prospectus supplement dated July 8, 2020 which was filed with the Securities and Exchange Commission on July 9, 2020 in connection with a takedown from the Company's shelf registration statement on Form S-3, as amended (File No. 333-237370), which became effective on April 2, 2020 and the base prospectus dated April 2, 2020 contained in that registration statement. The offering was consummated on July 10, 2020, whereby the Company sold 1,369,863 shares of common stock and a fully exercised Underwriters' overallotment of 205,479 additional shares at the public offering price of $7.30 per share. The net proceeds to the Company from the offering was approximately $10.4 million after placement agent fees and other estimated offering expenses.

The Company accounted for the proceeds of the offering at July 10, 2020 as follows:

Gross proceeds	$ 11,499,997
Less: offering costs and expenses	(1,057,781)
Net proceeds from issuance of common stock	$ 10,442,216

On July 31, 2020, the Company entered into a Sales Agreement with the Sales Agents, 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. On March 2, 2021 the Company sold 814,242 shares of common stock at an average price of approximately $7.83 per share. The shares were issued pursuant to a prospectus supplement dated December 3, 2020 filed with the Securities and Exchange Commission on December 10, 2020 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-237370), which became effective on April 2, 2020. The net proceeds to the Company from the offering was approximately $6.1 million after placement agent fees and other estimated offering expenses.

The Company accounted for the proceeds of the ATM Offering at March 2, 2021 as follows:

Gross proceeds	$ 6,374,211
Less: offering costs and expenses	(252,730)
Net proceeds from issuance of common stock	$ 6,121,481

For the year ended June 30, 2021, 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 $43,696, which is the fair value at 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 Series A preferred stock fair value is based on the converted value to common stock at a ratio of 1:3.5 multiplied by the monthly average of the daily open and close price of the common stock. The conversion of the shares is triggered by a change of control.

For the year ended June 30, 2021, the Company's Board of Directors authorized the issuance of 3,572 fully vested shares of its common stock for employee compensation. The Company recognized a noncash compensation expense of $15,038, which was the fair value on the date of issuance.

For the year ended June 30, 2021, the Company's Board of Directors authorized the issuance of 25,434 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $108,000, which was the fair value at the dates of issuance.

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For the year ended June 30, 2021, the Company's Board of Directors authorized the issuance of 13,166 fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of $56,250, which was the fair value at date of issuance.

Note 10 – Stock Options and Warrants

Stock Options

The following table presents the activity of stock options for the years ended June 30, 2022 and 2021:

Stock Options	Number of Shares	Weighted Average Exercise Price per share ($)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($)
Outstanding and exercisable at June 30, 2020	5,000	$ 10.00	1.16	—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Canceled	—	—	—	—
Outstanding and exercisable at June 30, 2021	5,000	$ 10.00	0.16	—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Expired	5,000	—	—	—
Outstanding and exercisable at June 30, 2022	—	$ —	—	—

On September 1, 2018, Dr. Taraporewala was appointed as Chief Operating Officer and was granted options to purchase 15,000 shares of Nanoviricides common stock of which 5,000 options were vested and exercisable on September 1, 2018. On January 24, 2019, Dr. Taraporewala resigned as the Chief Operating Officer of the Company and all remaining unvested options were forfeited. The vested options expired on August 31, 2021. See Note 14.

For the years ended June 30, 2022 and 2021, the Company did not recognize compensation expense related to vested options granted to Dr. Taraporewala. As of June 30, 2022, there was no unrecognized compensation cost.

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Stock Warrants

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual	Aggregate Intrinsic
Outstanding and exercisable at June 30, 2020	22,218	$ 30.82	2.28	$ 4,533
Granted	2,288	5.26	—	—
Exercised	—	—	—	—
Expired	2,860	34.26	—	—
Canceled	12,500	40.00	—	—
Outstanding and exercisable at June 30, 2021	9,146	$ 10.80	2.00	$ 1,943
Granted	2,288	3.68	3.50	—
Exercised	—	—	—	—
Expired	2,288	22.63	—	—
Canceled	—	—	—	—
Outstanding and exercisable at June 30, 2022	9,146	$ 6.06	2.00	$ 238

Of the above warrants; 2,287 expire in fiscal year ending June 30, 2023; 2,287 expire in fiscal year ending June 30, 2024; 2,286 expire in fiscal year ending June 30, 2025 and 2,288 expire in fiscal year ending June 30, 2026

Note 11 – Income Tax Provision

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

The income tax expense for the years ended June 30, 2022 and 2021 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, 2022	June 30, 2021
Federal Statutory Rate	(21.00)%	(21.00)%
Research and Development Credit	8.90 %	0.62 %
State Tax Rate	(5.93)%	(5.93)%
Stock Based Compensation	— %	— %
Other	2.73 %	— %
Valuation Allowance	15.30 %	26.31 %
Effective Tax Rate	—	—

The significant components of the Company's deferred tax assets and liabilities at June 30, 2022 and 2021 are as follows:

	June 30, 2022	June 30, 2021
Net operating loss	$ 27,127,620	$ 26,676,579
Research and development credit	7,774,567	7,053,228
Other	1,604,592	1,536,892
Total gross deferred tax assets	36,506,779	35,266,699
Less: valuation allowance	(36,506,779)	(35,266,699)
Net deferred tax asset	$ —	$ —

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At June 30, 2022 and 2021, the Company has recorded a full valuation allowance against its net deferred tax assets of $36,506,779 and $35,266,699, respectively, since in the judgment of management, these assets are not more than likely than not to be realized. The increase in the valuation allowance during the year ended June 30, 2022 was $1,240,080.

As of June 30, 2022, the Company has approximately $100.9 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, 2022 and 2021 of approximately $16.1 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, 2022 and 2021, research and development credit carryforwards for federal and state purposes are $7,774,567, and $7,053,228, respectively. The state net operating loss and credit carryforwards begin to expire in 2025. Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's net operating loss carry-forwards could be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carryforwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carryforward is subject to any Internal Revenue Code Section 382 limitation. To the extent there is a limitation, there could be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

The Company does not have any uncertain tax positions at December 31, 2021 and December 31, 2020 that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of unrecognized tax benefits over the next twelve months. Because the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available. If and when applicable, the Company will recognize interest and penalties as part of income tax expense.

Note 12 – Commitments and Contingencies

Legal Proceedings

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

Employment Agreements

The Company and Dr. Anil Diwan, President and Chairman of the Board of Directors, entered into an extension of employment agreement effective July 1, 2018 for a term of three years. Dr. Anil Diwan's will be paid an annual base salary of $400,000. Additionally, Dr. Anil 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. The extension agreement is renewable annually with consent of the Board of Directors. On September 14, 2021, the Board of Directors agreed to the 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. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares were 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.

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The Company and Dr. Irach Taraporewala, the Company's Chief Executive Officer, entered into an employment agreement effective September 1, 2018, for a term of three years. Dr. Taraporewala would be paid an annual base salary of $360,000. Additionally, Dr. Taraporewala was awarded a grant of 15,000 options to purchase shares of the Company's common stock. 5,000 options vested on September 1, 2018 and the remainder of the options would vest over the two-year vesting period and are subject to forfeiture. On January 24, 2019, Dr. Taraporewala resigned as the Chief Executive Officer of the Company for personal reasons. Also on that date, the Company and Dr. Taraporewala agreed that Dr. Taraporewala would become a consultant for the Company for a period of two years. In connection with his resignation and new consulting services, the Company and Dr. Taraporewala entered into a Confidential Separation and Consulting Agreement and General Release (the "Agreement") pursuant to which the Company will pay Dr. Taraporewala monthly consulting payments of $3,000 from February 1, 2019, the effective date of the Agreement, through January 31, 2021. The Agreement includes a general release of claims against the Company, obligations of confidentiality, non-disclosure, non-disparagement and other customary provisions found in similar agreements. The remaining 10,000 options not vested upon resignation have been forfeited.

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 March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provided for a term of four years with a base salary of $150,000. In addition, the Company issued 1,786 shares of common stock upon entering into the agreement, and will issue an additional 1,786 shares of common stock on each anniversary date of the agreement. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

On May 30, 2013, the Company entered into an employment agreement with Meeta Vyas, wife of our President and Chairman of the Board, to serve as its Chief Financial Officer. The employment agreement provided for a term of three years with a base salary of $9,000 per month and 129 shares of Series A preferred stock, also on a monthly basis. On January 1, 2015, her cash compensation was increased to $10,800 per month. The agreement is renewable on an annual basis. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

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.

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On September 9, 2021, the Company entered into a world-wide, exclusive, sub-licensable, license ("Covid-19 License Agreement") to use, promote, offer for sale, import, export, sell and distribute drugs that treat Covid-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. 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 cash payments to TheraCour and agreed to the following milestone payments to TheraCour: (i) the issuance of 100,000 shares of the Company's Series A preferred stock within 30 days upon execution of this agreement; (ii) the issuance of 50,000 shares of the Company's Series A preferred stock upon the approval of the Company's Investigational New Drug (IND) Application or its equivalent by a competent regulatory authority; (iii) $1,500,000 upon initiation of Phase I clinical trials, or its equivalent, for at least one Licensed Product within the field on, or before, three (3) months from the date of the Authority's acceptance of the IND, or its equivalent; (iv) $2,000,000 in cash upon completion of Phase 1 clinical trials; (v) $2,500,000 in cash upon completion of Phase IIA clinical trials, or, its equivalent; (vi) the issuance of 100,000 shares of the Company's Series A preferred stock upon the initiation of Phase 3 clinical trials, or, its equivalent, for at least one Licensed Product within the field; and (vii) $5,000,000 in cash, or 500,000 shares of the Company's Series A preferred stock upon completion of Phase III clinical trials, or its equivalent. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement.

Note 13 - Subsequent Events

On October 6, 2022, NanoViricides, Inc. entered into an Extension Agreement (the "Extension") of the Employment Agreement with Dr. Anil R. Diwan entered into on July 1, 2018 (the "Employment Agreement") to continue to serve as the President of the Company, effective July 1, 2022.The Extension and the Agreement provide Dr. Diwan will continue to serve as the Company's President until June 30, 2023 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 t 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 Convertible Preferred Stock, par value $0.001 per share (the "Series A Preferred Stock") to Dr. Diwan. Dr. Diwan's rights in the shares shall vest in equal, quarterly installment commencing on September 30, 2022 and fully vest on June 30, 2023. Dr. Diwan will be eligible to receive severance if he is terminated by the Registrant other than for cause in which event the Registrant 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 Registrant may elect to pay such severance compensation in a lump sum or in equal payments over a period of not more than six (6) months.