Summary

NanoViricides, Inc. is a global leader in the development of nanomedicine drugs against viruses. Our unique nanoviricide® platform technology defines a novel mechanism enabling first-in-class drugs against viruses.

A nanoviricide is designed to specifically attack enveloped virus particles, on the same sites that they use to bind to cells, and dismantle them, blocking reinfection cycle, going beyond what antibodies and immunotherapeutics do. A nanoviricide can also be designed to deliver anti-viral payload into infected cells sparing uninfected cells to block replication cycle without toxicity. Our unique biomimetic approach enables creation of drugs that a virus would be highly unlikely to escape due to mutations.

NanoViricides is one of the few biopharma companies with its own multi-kilogram-scale c-GMP capable manufacturing facility for the drug substance as well as drug product, in Shelton, CT. This facility is fully owned by the Company with no mortgage and is a major asset. This flexible, multi-product pilot plant can supply drug product for all of our programs through human clinical trials. Our cGMP manufacturing ability enables substantial time and cost savings in our drug development programs. Further, it is capable of production for initial marketing, enabling early revenues upon drug approval, of about $100MM−$500MM per year.

The Company is focused on bringing its first drug candidate in the HerpeCide™ program into human clinical trials soon. This drug candidate, NV-HHV-101, was found to be well tolerated in both on-going GLP Safety/Toxicology studies as well as the completed non-GLP portion of the studies. We are awaiting reports from IND-enabling studies in progress for the preparation of an IND application. We have received a favorable response from the US FDA to our pre-IND application for NV-HHV-101.

This first drug candidate is a topical treatment for shingles rash. Topical treatment has the advantage of delivering very high concentrations of the active ingredient (API) at the site of infection to eradicate the virus. We are already working on expansion to several additional indications in the HerpeCide™ program with variations of the same broad-spectrum drug, maximizing return on investments. These indications in the pipeline include: (ii) HSV-1 “cold sores”, (iii) HSV-2 “genital ulcers”, (iv) eye drops for the treatment of herpes keratitis (HK), (v) intravitreal injection to treat intra-ocular herpes and viral acute retinal necrosis (v-ARN; a cause of corneal transplants & blindness), among others. The market size for our HerpeCide program is in excess of $10Bn, with the market size for NV-HHV-101 estimated at between $0.5Bn−$2Bn by independent market studies.

In addition, the Company has drug candidates in development against influenzas (including bird flu), HIV, Dengue, Ebola/Marburg and other viruses at different preclinical stages. We have already proven animal model effectiveness and preliminary safety in many of these programs which are ready for candidate optimization and clinical candidate selection studies. These programs comprise a market size of $40−70 Billion.

This broad pipeline is enabled by our unique post-immunotherapeutic “bind-encapsulate-destroy” technology platform.

IND-ready Lead Candidate - Addresses Unmet Medical Need - Shingles Rash Treatment - Dermal Topical

Our most advanced drug candidate is a nanoviricide against VZV (varicella-zoster virus), the virus that causes debilitating shingles in adults and chickenpox in children. Its first indication will 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 is estimated to be in billions of dollars. There is no approved drug against shingles, PHN (“post-herpetic neuralgia”), or chickenpox. In addition, once this candidate goes into Phase I clinical trials, we anticipate advancing two additional drug candidates into IND-enabling development, for the treatment of HSV-1 “cold sores” and of HSV-2 “genital ulcers”.

Our drug candidate designated “NV-VZV-101” was found to be highly effective against VZV in ex vivo human skin organ culture model studies as well as in cell culture studies. VZV only infects humans and there is no appropriate animal model for evaluating dermal treatment. These ex vivo human studies are expected to be strongly predictive of effectiveness in human clinical trials.

This drug candidate has been found to be safe and well tolerated in on-going IND-enabling GLP Safety/Toxicology studies and was found to be extremely safe in the preceding non-GLP portion of the Safety/Toxicology studies even at Maximum Feasible Dose (MFD) levels. The in-life portion of the GLP study was recently completed in July, 2019, conducted by BASi, IN, a well known contract research organization specializing in such studies. We anticipate preparing & filing an IND once the GLP “Tox Package” studies report is available.
We have completed production of the drug in multi-Kg quantities for the GLP portion of the IND enabling Safety/Toxicology studies. This production was performed under cGMP-compliant conditions in our State of the Art cGMP-capable Manufacturing Facility for Clinical Drug Production in Shelton, CT. We have engaged in the production of the cGMP manufactured drug product for the upcoming human clinical trials at this plant. cGMP Manufacturing capability is a major risk for new pharma companies, especially in nanomedicines. We are happy to report that we are tackling this risk head on, by building our own capability. We believe we have thus minimized the manufacturing risk for our entire platform technology.

The NanoViricides facility in Shelton, CT, contains customizable multi-product cGMP manufacturing capability, as well as advanced nanomedicines characterization and R&D laboratory, to support clinical drug manufacture of any of our drug candidates, enabling cost-effective, speedy entry to clinic. Moreover, its Manufacturing Scale is more than sufficient to support initial marketing needs, enabling early revenues upon drug approval.

**Clinical Success is Anticipated to Mirror Pre-Clinical Studies Success: Strong Efficacy, Safety, Risk Reduction**

**Leveraging Breakthrough Biomimetic Nanotechnology to Create Powerful Novel Treatments Against Viruses Results in Strong In-Vivo Effectiveness in Animal and ex-vivo Human Skin Studies**

The shingles drug candidate was tested in ex-vivo human skin organ culture model, and has shown extremely high effectiveness. HSV-1 candidates have shown remarkable total survival of lethally infected animals in repeated studies in a skin infection model using an aggressive neurotropic HSV-1 H129 strain. HSV-2 candidates are in candidate optimization animal studies. Previously, our anti-influenza drug candidates had shown 3 logs (i.e. 1,000X) viral load reduction, superior to known work at that time and to date. Our anti-HIV drug candidate had shown complete suppression of the virus in the human immune system bearing SCID-hu Thy/Liv mouse model with persistent effect, potentially enabling a “functional cure”.

**Strong Safety Established in Multiple Animal Studies and Multiple Animal Species**

The shingles drug candidate has shown excellent safety in on-going GLP and preceding non-GLP portion of IND-enabling safety/toxicology studies at very high dosages, and is moving towards IND filing. Injectable FluCide was found to be well tolerated in mice even at maximum feasible dosage levels in a non-GLP safety-toxicology study. Thereafter, a non-GLP tox study in rats found that a related drug candidate was also safe at as much as a total of 4,200mg/kg given in 14 days. These non-GLP and GLP Safety/Toxicology studies were performed by BASI, Indiana, a CRO specializing in such studies. In all animal studies and in all of our programs conducted to date, no evidence of toxicity has been found for our drug candidates even at very high dosage levels.

**Safety is built into the nanoviricide's structure**

The polymer is based on PEG in the backbone and fatty chains forming the “belly” of the nanoviricide. PEG is well known and is used in virtually all antibody drugs (“PEGylation”) as well as many nanomedicines to protect the drug from attack by the body’s reticuloendothelial system (RES). We design the ligands to avoid potential toxicity issues.

**Complex Nanomachine R&D to attack virus only everywhere sparing host**

Our current nanoviricides work primarily on the virus in circulation. Additionally, the targeting nanoviricide technology can be harnessed to attack only virus-infected cells, sparing normal cells, as the infected cells present viral antigens which nanoviricides recognize. The nanoviricide technology has the ability to encapsulate (hold) active ingredients that could kill or disrupt virus production inside infected cells only. Our leading R&D in this field should lead to the best ever antiviral medicines in the future.

**Effectiveness in Human Clinical Trials is Anticipated, based on Effectiveness in Animal Studies** because a nanoviricide is designed to work directly against the virus particle, and not on host targets. A nanoviricide works independently of the host’s physiology. A stronger argument presents for the shingles drug candidate because it was tested in human skin model.

**Large Markets Could Explode with Transformative, First Indication Treatments**

Our Programs Address Large Markets, $40-70 Billion estimated.

**HerpesVirus Multiple Drugs Franchise as well as FluCide Multiple Drugs Franchise Could Result in Treatment-Transformations and Market Size Explosions**

Using the nanoviricides® platform technology, the Company has developed drug candidates targeting some of the world’s most pervasive viruses (see the table at right and our product pipeline).

Whenever an effective drug is developed addressing an unmet need, large new markets appear (ex.: Lipitor, Sovaldi). We anticipate such market explosion due to transformative treatment could happen for some drugs in our anti-Herpes drugs franchise, in our FluCide franchise, and possibly other drugs in our pipeline.

<table>
<thead>
<tr>
<th>Disease/Virus</th>
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<td>HIV/AIDS</td>
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<td>Influenzas</td>
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<tr>
<td>Eye Drops Antiviral</td>
<td>$1–5 B</td>
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<td>Hepatitis C</td>
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<td>Dengue, Rabies, other NTD’s</td>
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Global, Strong, Pioneering, Intellectual Property with Runway Beyond 2039

Strong Global Intellectual Property Position with First Drug Patents to Expire Beyond 2039

All of our drug candidates are based on broad & exclusive world-wide licenses in perpetuity from TheraCour Pharma, Inc. A license for VZV will be completed soon. HSV-1 and HSV-2 are already licensed, as are several other viruses including Influenzas, HIV, Dengue, Ebola, Marburg, Rabies, etc. These licenses are extremely broad and cover development of drugs attacking the stated virus in pathological indication benefitting from viral load reduction. NanoViricides intends to own the regulatory drug licensure (use of entity for indication), and may commercialize the same on its own or further sublicense to other Pharma companies.

NanoViricides has exclusive worldwide licenses from TheraCour Pharma, Inc., to field-defining, pioneering, proprietary intellectual property and global patent applications, that have already issued into 61 patents in countries including the U.S., Australia, Japan, China, Canada, and all of Africa. Issued patents are “first-in-class” with no prior art, showcasing the Company’s leadership position in this field. The patents cover broad compositions of matter, methods of making, and uses. The first of the fundamental patents has expiration date in 2026. We also intend to patent each of our drug candidates separately. The first of our individual drug patents would not expire before 2039. This provides substantial runway for commercial realization.

Unique, Novel, Post-ImmuTherapeutic “Bind-Encapsulate-Destroy” Mechanism Enables First-In-Class Products

Beyond Antibodies and Vaccines: Antibodies have been developed as drugs against viruses. However, each antibody only binds by two points to the virus, and destruction of the complex requires effective immune function, which is not the case in sickness. Vaccines only train the body into producing antibodies against the virus in the vaccine. Antibodies and vaccines are easily overcome by viruses by mutating in the field, hence the need for annual influenza vaccine updates.

A Nanoviricide is A Nanomachine that Completes the Task of Destroying Virus without Help from the Patient’s Immune System

Key Issue of Drug Resistance from Viral Mutations is Unlikely with Nanoviricides Drugs due to Unique Biomimetic Technology

In contrast, a nanoviricide should work against all strains of the virus because they still bind the same way to the same host cell receptor. The nanoviricide® technology platform mimics the host cell. We design and develop a virus-binding ligand that mimics the site on the host cell receptor to which the virus binds. This ligand is then chemically attached to a special polymer to make a nanoviricide®. The virus is expected to be fooled into binding to the nanoviricide, like a venus-fly-trap. The nanoviricide is then expected to engulf the virus and possibly destroy it. A nanoviricide attacks the virus with hundreds of virus-binding sites on its surface. The nanoviricide is capable of dismantling the virus, and the resulting complexes are fully biodegradable in the body.

Financial Position - Low Burn Rate, Strong Long Term Assets

As of June 30, 2019, the Company had approximately $2.8 million in cash & cash-equivalents, which is expected to be sufficient to fund “Tox Package” study of our first drug candidate. The Company currently spends only about $1.6 million per quarter. In addition, the Company has approximately $10.2 million in fixed assets net of depreciation. The Company has no debt. We anticipate raising additional funds as our drug pipeline progresses further towards and into clinical trials.

Bright Future with Broad and Deep Pipeline Enabled by Nanoviricides® Platform Technology

Variants of NV-HHV-101 are expected to become clinical drug candidates for topical treatment of HSV-2 "genital ulcers", and HSV-1 “cold sores” soon after NV-HHV-101 goes into clinical studies. NV-HHV-101 is anticipated to further expand into additional indications against chickenpox - a possibly orphan drug in the USA - and PHN (a morbidity of shingles persistent pain that may last for six months or longer, after the rash resolves).

In addition to the five different indications in the HerpeCide program, we continue to develop (vi) our broad-spectrum anti-influenza drug, injectable FluCide™, for hospitalized patients, and (vii) our oral FluCide™ for out-patients, in parallel. NanoViricides, Inc. is possibly the first in the world to have developed an orally effective nanomedicine. We are also developing drugs against (viii) HIV/AIDS. We are working towards the objective that such nanomedicine would work against only the virus particles outside the cell and inside only the infected cells, sparing un-infected cells to minimize toxicity.

Thus, our drug development opportunities are only limited by available resources.
Actual costs may be substantially greater than our projections. Thereby, note: achievements described have a strong dependence on factors outside Company's control. Actual costs may be substantially greater than our projections. Therefore, the Company may adjust its priorities resulting in delays in accomplishments.

Near Future Goals Anticipated

We are close to completing IND-enabling Tox Package studies for the first HerpeCide program drug candidate. We believe we will be able to file an IND and begin Phase I clinical trials soon. Thereafter, we plan on completing the optimization and advancing the HSV-1 “cold sores” and HSV-2 “genital ulcers” drug candidates towards human clinical trials. In parallel, we intend to advance the FluCide™ and HIVCide™ programs. We will continue to optimize our business plan based on available resources. Note: Activities described have a strong dependence on factors outside Company’s control. Actual costs may be substantially greater than our projections. Therefore, the Company may adjust its priorities resulting in delays in accomplishments.

Disclosure Statement
NanoViricides, Inc. (“the Company”) is a publicly traded company (stock symbol: NNVC, NYSE-Amer.). This is not an offering memorandum and should not be construed as such. It is provided as a non-confidential document for informational purposes only. NanoViricides, Inc.(www.nanoviricides.com) is a development stage company that is creating special purpose nanomaterials for anti-viral therapeutics. The Company’s novel nanoviricide® class of drug candidates are designed to specifically attack enveloped virus particles and to dismantle them. This document contains forward-looking statements that reflect the current expectation of the Company regarding future events. Actual events could differ materially and substantially from those projected herein and depend on a number of factors. Certain statements are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond the Company’s control and that would materially affect actual performance or achievements. The Company assumes no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated, even if new information becomes available in the future. Important factors that could cause actual results to differ materially from the Company’s expectations include, but are not limited to, factors that are disclosed under the heading “Risk Factors” and elsewhere in documents filed by the Company from time to time with the U.S. Securities and Exchange Commission and other regulatory authorities. Although it is not possible to predict or identify all such factors, they may include the following: demonstration and proof-of-principle in preclinical trials that a nanoviricide is safe and effective; successful development of our product candidates; our ability to raise additional financing when needed; our ability to seek & obtain regulatory approvals, including with respect to the indications we are seeking; the successful commercialization and market acceptance of our products.