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

**FORM 10-Q**

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934.**

**For the quarterly period ended September 30, 2022**

*Commission File Number: 001-36081*

**NANOVIRICIDES, INC.**

*(Exact name of Company as specified in its charter)*

NEVADA

76-0674577

(State or other jurisdiction)  
of incorporation or organization)

(IRS Employer Identification No.)

**1 Controls Drive**

**Shelton, Connecticut 06484**

(Address of principal executive offices and zip code)

(203) 937-6137

*(Company's telephone number, including area code)*

Indicate by check mark whether the Company (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the Company 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 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 Company is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	NNVC	NYSE-American

As of November 14, 2022, there were approximately 11,610,000 shares of common stock of the registrant issued and outstanding.

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Balance Sheets**

	<u>September 30, 2022</u>	<u>June 30, 2022</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 12,918,044	\$ 14,066,359
Prepaid expenses	231,557	350,021
Total current assets	<u>13,149,601</u>	<u>14,416,380</u>
PROPERTY AND EQUIPMENT		
Property and equipment	14,702,520	14,658,014
Accumulated depreciation	<u>(6,145,155)</u>	<u>(5,963,820)</u>
Property and equipment, net	<u>8,557,365</u>	<u>8,694,194</u>
TRADEMARK AND PATENTS		
Trademark and patents	458,954	458,954
Accumulated amortization	<u>(119,173)</u>	<u>(117,106)</u>
Trademark and patents, net	<u>339,781</u>	<u>341,848</u>
OTHER ASSETS		
Security deposits	3,515	3,515
Service agreements	<u>32,073</u>	<u>38,925</u>
Other assets	<u>35,588</u>	<u>42,440</u>
Total assets	<u>\$ 22,082,335</u>	<u>\$ 23,494,862</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Loan payable	\$ 23,837	\$ 94,788
Accounts payable	37,690	57,960
Accounts payable – related party	433,119	214,397
Accrued expenses	<u>23,712</u>	<u>45,692</u>
Total current liabilities	<u>518,358</u>	<u>412,837</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A convertible preferred stock, \$0.001 par value, 10,000,000 shares designated, 495,173 and 484,582 shares issued and outstanding, at September 30, 2022 and June 30, 2022, respectively	495	485
Common stock, \$0.001 par value; 150,000,000 shares authorized, 11,610,037 and 11,592,173 shares issued and outstanding, at September 30, 2022 and June 30, 2022, respectively	11,610	11,592
Additional paid-in capital	145,614,690	145,562,124
Accumulated deficit	<u>(124,062,818)</u>	<u>(122,492,176)</u>
Total stockholders' equity	<u>21,563,977</u>	<u>23,082,025</u>
Total liabilities and stockholders' equity	<u>\$ 22,082,335</u>	<u>\$ 23,494,862</u>

*See accompanying notes to the financial statements*



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**Nanoviricides, Inc.**  
**Statements of Operations**  
**(Unaudited)**

	For the Three Months Ended September 30,	
	2022	2021
OPERATING EXPENSES		
Research and development	\$ 1,112,659	\$ 2,096,920
General and administrative	509,701	515,445
Total operating expenses	<u>1,622,360</u>	<u>2,612,365</u>
LOSS FROM OPERATIONS	<u>(1,622,360)</u>	<u>(2,612,365)</u>
OTHER INCOME (EXPENSE):		
Interest income	52,562	188
Interest expense	<u>(844)</u>	<u>(891)</u>
Other expense, net	<u>51,718</u>	<u>(703)</u>
LOSS BEFORE INCOME TAX PROVISION	(1,570,642)	(2,613,068)
INCOME TAX PROVISION	<u>—</u>	<u>—</u>
NET LOSS	<u>\$ (1,570,642)</u>	<u>\$ (2,613,068)</u>
Net loss per common share- basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.23)</u>
Weighted average common shares outstanding- basic and diluted	<u>11,592,367</u>	<u>11,515,279</u>

*See accompanying notes to the financial statements*

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**NanoViricides, Inc.**  
**Statement of Changes in Stockholders' Equity**  
**For the three months ended September 30, 2022**  
**(Unaudited)**

	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, June 30, 2022	484,582	\$ 485	11,592,173	\$ 11,592	\$ 145,562,124	\$ (122,492,176)	\$ 23,082,025
Series A preferred stock issued for employee stock compensation	10,591	10	—	—	13,854	—	13,864
Common stock issued for consulting and legal services rendered	—	—	12,710	13	26,987	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	480	—	480
Common shares issued for Directors fees	—	—	5,154	5	11,245	—	11,250
Net loss	—	—	—	—	—	(1,570,642)	(1,570,642)
Balance, September 30, 2022	<u>495,173</u>	<u>\$ 495</u>	<u>11,610,037</u>	<u>\$ 11,610</u>	<u>\$ 145,614,690</u>	<u>\$ (124,062,818)</u>	<u>\$ 21,563,977</u>

*See accompanying notes to the financial statements*

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**NanoViricides, Inc.**  
**Statement of Changes in Stockholders' Equity**  
**For the three months ended September 30, 2021**  
**(Unaudited)**

	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, 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	10,591	10	—	—	32,880	—	32,890
Series A preferred stock issued for license agreement	100,000	100	—	—	934,988	—	935,088
Common stock issued for consulting and legal services rendered	—	—	6,509	6	26,994	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	1,352	—	1,352
Common shares issued for Directors fees	—	—	3,524	4	14,996	—	15,000
Net loss	—	—	—	—	—	(2,613,068)	(2,613,068)
Balance, September 30, 2021	<u>482,081</u>	<u>\$ 482</u>	<u>11,525,203</u>	<u>\$ 11,525</u>	<u>\$ 145,295,803</u>	<u>\$ (116,998,381)</u>	<u>\$ 28,309,429</u>

*See accompanying notes to the financial statements*

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**Nanoviricides, Inc.**  
**Statements of Cash Flows**  
**(Unaudited)**

	<u>For the Three Months Ended</u>	
	<u>September 30,</u> <u>2022</u>	<u>September 30,</u> <u>2021</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (1,570,642)	\$ (2,613,068)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	13,864	32,890
Preferred shares issued pursuant to license agreement	—	935,088
Common shares issued as compensation and for services	38,250	42,000
Warrants granted to Scientific Advisory Board	480	1,352
Depreciation	181,335	174,357
Amortization	2,067	2,067
Changes in operating assets and liabilities:		
Prepaid expenses	118,464	111,423
Other assets	6,852	—
Accounts payable	(20,270)	(83,768)
Accounts payable - related party	218,722	673,638
Accrued expenses	(21,980)	(210)
NET CASH USED IN OPERATING ACTIVITIES	<u>(1,032,858)</u>	<u>(724,231)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	<u>(44,506)</u>	<u>(24,313)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of loan payable	<u>(70,951)</u>	<u>(71,339)</u>
NET CASH (USED IN) FINANCING ACTIVITIES	<u>(70,951)</u>	<u>(71,339)</u>
NET CHANGE IN CASH AND CASH EQUIVALENTS	(1,148,315)	(819,883)
Cash and cash equivalents at beginning of period	14,066,359	20,516,677
Cash and cash equivalents at end of period	<u>\$ 12,918,044</u>	<u>\$ 19,696,794</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	\$ 844	\$ 892

*See accompanying notes to the financial statements*

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**NANOVIRICIDES, INC.**  
**September 30, 2022**  
**NOTES TO THE FINANCIAL STATEMENTS**  
**(Unaudited)**

**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 September 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 be a revertant of the attenuated strain of poliovirus that is used for vaccination in certain underdeveloped countries.



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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.

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.

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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 September 30, 2022 of approximately \$124 million and a net loss of approximately \$1.6 million and net cash used in operating activities of approximately \$1.0 million for the three months 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 September 30, 2022, the Company had available cash and cash equivalents of approximately \$12.9 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 for at least 12 months from the date of the filing of this Form 10-Q. 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 – Interim Financial Information*

The accompanying unaudited interim financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission for Interim Reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim financial statements furnished reflect all adjustments (consisting of normal recurring accruals) that are, in the opinion of management, considered necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. The accompanying financial statements and the information included under the heading "Management's Discussion and Analysis or Plan of Operation" should be read in conjunction with the Company's audited financial statements and related notes included in the Company's Form 10-K for the fiscal year ended June 30, 2022 filed with the SEC on October 13, 2022.

The June 30, 2022 year-end balance sheet data in the accompanying interim financial statements was derived from the audited financial statements.

For a summary of significant accounting policies, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2022 filed on October 13, 2022.

*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 they were anti-dilutive:

	<u>Potentially Outstanding Dilutive Common Shares</u>	
	<u>For the Three Months Ended September 30, 2022</u>	<u>For the Three Months Ended September 30, 2021</u>
<b>Warrants</b>	<u>8,860</u>	<u>9,146</u>

The Company has 495,173 shares of Series A preferred stock outstanding as of September 30, 2022. 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 September 30, 2022, the number of potentially dilutive shares of the Company's common stock into which these Series A preferred shares can

be converted into is 1,733,106, and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

[Table of Contents](#)**Note 4 - Related Party Transactions**Related Parties

Related parties with whom the Company had transactions are:

<u>Related Parties</u>	<u>Relationship</u>
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

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

<u>For the three months ended</u>	
<u>September 30,</u>	<u>September 30,</u>
<u>2022</u>	<u>2021</u>

\$ 25,876	\$ 19,154
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<u>As of</u>	
<u>September 30,</u>	<u>June 30,</u>
<u>2022</u>	<u>2022</u>

Account Payable – Related Party

Pursuant to an Exclusive License Agreement 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, the Company 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 September 30, 2022 and June 30, 2022 were \$898,119 and \$679,397, respectively, which were each offset by a two month advance of \$465,000.

\$ 433,119	\$ 214,397
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<u>For the three months ended</u>	
<u>September 30,</u>	<u>September 30,</u>
<u>2022</u>	<u>2021</u>

Research and Development Costs Related Party

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 September 30, 2022 and September 30, 2021.

\$ 612,711	\$ 550,034
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[Table of Contents](#)*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 upon execution of the agreement during the three months ended September 30, 2021.

**Note 5 - Property and Equipment**

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

	<u>September 30, 2022</u>	<u>June 30, 2022</u>
GMP Facility	\$ 8,168,045	\$ 8,149,416
Land	260,000	260,000
Office Equipment	57,781	57,781
Furniture and Fixtures	5,607	5,607
Lab Equipment	<u>6,211,087</u>	<u>6,185,210</u>
Total Property and Equipment	14,702,520	14,658,014
Less Accumulated Depreciation	<u>(6,145,155)</u>	<u>(5,963,820)</u>
Property and Equipment, Net	<u>\$ 8,557,365</u>	<u>\$ 8,694,194</u>

Depreciation expense for the three months ended September 30, 2022 and 2021 was \$181,335 and \$174,357, respectively.

**Note 6 - Trademark and Patents**

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

	<u>September 30, 2022</u>	<u>June 30, 2022</u>
Trademarks and Patents	\$ 458,954	\$ 458,954
Less Accumulated Amortization	<u>(119,173)</u>	<u>(117,106)</u>
Trademarks and Patents, Net	<u>\$ 339,781</u>	<u>\$ 341,848</u>

Amortization expense amounted to approximately \$2,067 and \$2,067 for the three months ended September 30, 2022 and 2021, respectively.

[Table of Contents](#)**Note 7 – 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 were \$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 September 30, 2022 and June 30, 2022, the loan balance was \$23,837 and \$94,788, respectively. For three months ended September 30, 2022 and September 30, 2021 the Company incurred interest expense of \$844 and \$848, respectively.

**Note 8 - Equity Transactions**

On September 14, 2022 the Company's Board of Directors approved the employment extension of Dr. Anil Diwan, President and Chairman of the Board. On October 6, 2022, the Company and Dr. Anil Diwan executed an extension of his 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 shall be vested in quarterly installments of 2,551 shares on September 30, 2022, December 31, 2022, March 31, 2023 and June 30, 2023 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$10,930 for the three months ended September 30, 2022. The balance of \$32,791 will be recognized as the remaining 7,653 shares vest and service is rendered for the year ended June 30, 2023.

For the three months ended September 30, 2022, the Company's Board of Directors authorized the issuance of 387 fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of \$2,934 for the three months ended September 30, 2022 related to these issuances.

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

<u>Date</u>	<u>Shares</u>	<u>Fair Value</u>
07/31/2022	10,333	\$ 44,623
08/31/2022	129	1,178
09/30/2022	129	854
	<u>10,591</u>	<u>\$ 46,655</u>

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 conversion of the shares is triggered by a change of control. The valuations of the Series A Convertible preferred stock at each issuance used the following inputs:

- The common stock price for the three months ended September 30, 2022 was in the range \$1.53 to \$3.65. Series A preferred stock issued to employees as compensation, were valued at the common stock price on the date of issuance multiplied by the conversion rate of 3.5.
- The conversion value is based on an assumption, for calculation purposes only, of a change in control in 3.5 years from the date of issuance.
- 28.4% discount for lack of marketability (based upon a call put analysis): 85.12%% historical volatility, 4.16% risk free rate applied to the converted common stock.

The Scientific Advisory Board was granted in August 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$3.40 per share expiring in August 2026. The fair value of the warrants was \$480 for the three months ended September 30, 2022 and was recorded as consulting expense.



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The Company estimated the fair value of the warrants granted 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	85.12 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.025 %

For the three months ended September 30, 2022, the Company's Board of Directors authorized the issuance of 12,710 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of \$27,000 for the three months ended September 30, 2022, which is the fair value on the date of issuance.

For the three months ended September 30, 2022, the Company's Board of Directors authorized the issuance of 5,154 fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of \$11,250 for the three months ended September 30, 2022, which is the fair value on the date of issuance.

### **Note 9 - Stock Warrants and Options**

#### Stock Warrants

<u>Stock Warrants</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per share (\$)</u>	<u>Weighted Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (\$)</u>
Outstanding and exercisable at June 30, 2022	9,146	\$ 6.06	2.00	\$ 238
Granted	286	3.40	3.88	—
Expired	(572)	8.16	—	—
Outstanding and exercisable at September 30, 2022	<u>8,860</u>	<u>\$ 5.84</u>	<u>1.94</u>	<u>\$ 152</u>

Of the above warrants 1,716 expire in fiscal year ending June 30, 2023, 2,286 expire in fiscal year ending June 30, 2024, 2,286 warrants expire in the fiscal year ending June 30, 2025, 2,286 warrants expire in the fiscal year ending June 30, 2026, and 286 warrants expire in the fiscal year ending June 30, 2027.

### **Note 10 - 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

On September 14, 2022 the Company's Board of Directors approved the extension of Dr. Diwan's employment agreement, and on October 6, 2022, the Company and Dr. Diwan executed an extension of his 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.



[Table of Contents](#)*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 VZV License 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.

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. 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.

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### **Item 2. 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 Management’s Discussion and Analysis of Financial Condition and Results of Operations set forth in 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-Q, 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 Report contains forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical fact made in this report are forward looking. In particular, the statements herein regarding industry prospects and future results of operations or financial position are forward-looking statements. These include statements about our expectations, beliefs, intentions or strategies for the future, which we indicate by words or phrases such as “anticipate,” “expect,” “intend,” “plan,” “will,” “we believe,” “Company believes,” “management believes” and similar language. These forward-looking statements can be identified by the use of words such as “believes,” “estimates,” “could,” “possibly,” “probably,” “anticipates,” “projects,” “expects,” “may,” “will,” or “should,” or other variations or similar words. No assurances can be given that the future results anticipated by the forward-looking statements will be achieved. Forward-looking statements reflect management’s current expectations and are inherently uncertain. The forward-looking statements are based on the current expectations of NanoViricides, Inc. and are inherently subject to certain risks, uncertainties and assumptions, including those set forth in the discussion under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this report. Actual results may differ materially from results anticipated in these forward-looking statements.

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

#### **Organization and Nature of Business**

NanoViricides, Inc. (the “Company,” “we,” or “us”) was incorporated in Nevada on April 1, 2005. Our corporate offices are located at 1 Controls Drive, Shelton, Connecticut 06484 and our telephone number is (203) 937-6137. Our Website is located at <http://www.Nanoviricides.com>.

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.

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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 this drug. 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, 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 (TPOXX®, SIGA), approved for smallpox, has a low resistance barrier for virus mutations, i.e., the virus can readily escape it by simple mutations, and has other limitations on its use. Thus there remains an urgent need for broad-spectrum drugs that can treat MPXV, smallpox, and other poxviruses.

Additionally, in response to the ongoing pediatric “acute flaccid myelitis” (AFM, a disease that can lead to paralysis) cases that appear to be on an uptick, 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 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.

After developing viable drug candidates against COVID-19 in 2020 in a matter of a few months, the Company focused substantially on the COVID-19 drug development, resulting in two drug candidates that are shown to be extremely effective in pre-clinical studies compared to the currently most effective drug, remdesivir, namely NV-CoV-2 and NV-CoV-2-R. Both these drug candidates have demonstrated pan-coronavirus, broad-spectrum effectiveness. This broad-spectrum effectiveness implies that SARS-CoV-2 variants that are continuously generated in the field are quite unlikely to escape either of these two drug candidates.

In contrast, we note that all of the existing antibodies and cocktails with emergency use approvals, including Evusheld, have lost effectiveness against the current SARS-CoV-2 Omicron variants, Paxlovid has been found to be effective only in adults over 65 years of age with co-morbidities, limiting its usefulness. Molnupiravir is a known mutagen and its use is not recommended or severely restricted by international health authorities. Remdesivir is the only FDA approved drug for treating COVID-19. It is only approved for hospitalized patients and requires long, daily infusions, and it has shown only marginal improvements, with reduction in hospital stay of a few days. Its effectiveness is limited by its metabolism. We developed NV-CoV-2-R to successfully improve the PK/PD (pharmacokinetics and pharmacodynamics) of remdesivir, thereby developing a highly active drug that is a potential cure, we believe. Additionally existing vaccines including the newest “bivalent” vaccines are now known to be only marginally effective, although they are still expected to reduce potential COVID-19 hospitalizations and deaths in the expected fall/winter wave that is expected to entail multiple Omicron variants that have already escaped existing antibodies and vaccines.



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Thus the world is woefully unprepared for a new SARS-CoV-2 wave, except for the fact that natural immunity and prior vaccine-boosted immunity may afford some protection. The therapeutics and preventatives tools available today are seemingly inadequate, as summarized above, leaving only masking, social distancing, and clean hygiene as the societal tools but no help for the patient who already has the disease. The extremely high infectiveness, of the current Omicron variants implies that even these societal tools would have limited effect unlike with the earlier alpha and delta waves of SARS-CoV-2 wherein lockdowns may have averted substantial spread and thus morbidity and mortality.

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. As new variants emerge, it is now well established that the efficacy of original vaccines continues to drop, and that the resistance to antibodies from these vaccines as well as antibody drugs continues to rise.

Thus there is an urgent need for rapid development of broad-spectrum, pan-coronavirus drugs such as NV-CoV-2 and NV-CoV-2-R, and the Company diligently continues to do the best it can with the limited resources at its disposal to meet this challenge in an expeditious manner.

Subsequent to entering NV-CoV-2 into human clinical trials and further advancements towards its commercialization, we plan on undertaking further clinical advancement of our other lead drug candidate, NV-HHV-1 skin cream for the treatment of shingles. The essential preclinical work including GLP Safety/Toxicology studies of NV-HHV-1 was substantially completed previously.

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, Adenoviral EKC, Dengue viruses, and Ebola/Marburg, which the Company plans to advance further towards clinical drug candidates as we progress further. Thus, the Company has 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. We are manufacturing the clinical supply of drug substances as well as the oral drug products for NV-CoV-2 at our own facility, simplifying and expediting the cGMP-compliant manufacturing operations. We have the capability to produce sufficient drugs for about 1,000 patients in a single batch of production, depending upon dosage. This production capacity is anticipated to be sufficient for Phase I, Phase II and Phase III human clinical trials in the on-going SARS-CoV-2 pandemic for our anti-coronavirus drugs in development, as well as for the anticipated clinical trials of NV-HHV-1 skin cream for the treatment of shingles.

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, pan-coronavirus drug development approach was adopted to ensure that our drug candidates should remain effective even as variants of SARS-CoV-2 continue to evolve in the field, just as we had already anticipated at the very beginning of the pandemic.

Additionally, we are the only company that, to the best of our knowledge, 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, this strategy of a two-pronged attack against the virus, both inside the cell and outside the cell, exemplified by NV-CoV-2-R, can be expected to result in a cure for coronaviruses and other viruses that do not become latent.

This total attack on the whole lifecycle of the virus is expected to result in the most effective drug candidates. It is now well accepted that multiple antivirals together produce better effectiveness than single ones individually. Our strategy goes beyond simply a mix of multiple antivirals. Our unique, shape-shifting nanomedicine technology leads to substantial improvement in the pharmacokinetic properties of the guest antiviral drug. We have shown that encapsulation of Remdesivir in NV-CoV-2 protects remdesivir from bodily metabolism in animal studies. This allows higher concentrations of remdesivir to be reached and simultaneously extends the effectiveness time period in comparison to the standard Veklury(R) (Gilead) formulation. The resulting drug, NV-CoV-2-R has not only significantly improved characteristics for its Remdesivir component, but additionally provides the novel re-infection blocking mechanism of NV-CoV-2.



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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 will be useful 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, if it is not endemic already.

Since completing the IND-enabling safety/toxicology studies, the Company has successfully developed orally active formulations of our drug candidates, in an oral syrup form, as well as an oral gummies ("Chewable Gel") form. We believe that for mild to moderate cases, for pediatric, and older patients, the oral syrup and gummies forms would be highly advantageous over tablets, capsules, injections, infusions, or lung inhalations. The Injectable form is expected to be valuable in the treatment of severe cases. The inhalation form is expected to provide greater benefits to more severe patients by providing high concentration of the drug locally in the lungs where the SARS-CoV-2 viruses cause the most damage. The inhalation form is designed to be delivered by a simple hand-held device as an aerosol.

We are working with advice from a clinical research organization and external consultants and collaborators on developing the initial human clinical studies plan and application documents. Simultaneously, we are working on putting the various agreements together as necessary. We are close to completing clinical trial application documents for evaluation of oral administration of NV-CoV-2, as well as most of the agreements. We expect to announce the resulting collaborations once the formal steps are completed.

We believe that the extremely strong effectiveness we have observed in cell culture studies and in lethal coronavirus lung infection animal studies, in comparison to Remdesivir, should translate into strong effectiveness of our drug candidates NV-CoV-2 and NV-CoV-2-R in human cases of COVID-19 SARS-CoV-2 infection.

We are developing a broad-spectrum antiviral drug candidate, NV-CoV-2, where the potential for escape of virus variants is minimized by the very design of the drug for the treatment of COVID-19 infected sick persons. In contrast, vaccines are not treatments for sick persons, and must be administered to healthy individuals, and further require several weeks for the recipient's immune system to become capable of protecting against the target virus strain. Variants have readily developed that are capable of infecting vaccinated persons although it is believed that vaccinated persons have a low risk of death from COVID-19 compared to unvaccinated persons.

An additional phenomenon called "ADE" poses a threat that should not be overlooked, SARS-CoV-1 was shown to have the potential for "Antibody-Dependent-Enhancement of Disease" ("ADE"). Dengue viruses are particularly known for ADE. When a virus variant or subtype infects persons that have antibodies to a previous virus of the same kind (but not the same) more severely and causing a greater risk of fatalities, it is called ADE. The newly infecting virus essentially uses the antibodies in the patient to hitch a ride to productively infect additional cells that bear receptors for antibodies, because the antibodies are not matched to, and therefore do not effectively block, the new virus. The antibodies in the patient may be because of a prior natural infection, vaccination, or therapeutic usage. Fortunately, as of now, there have been no reports of ADE-causing variants of SARS-CoV-2 to the best of our knowledge. However, such a potential for a next variant of SARS-CoV-2 cannot be ignored because (a) SARS-CoV-1 has already shown such potential, and (b) the Omicron variant and subvariant of SARS-CoV-2 have been productively infecting vaccinated persons, acquiring subsequent additional mutations.

Therefore, the development of highly active antivirals such as NV-CoV-2 and NV-CoV-2-R is of greater importance today than before vaccines were widely deployed.



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In addition to NV-CoV-2, the Company are also developing another anti-coronavirus drug candidate, NV-CoV-2-R. This drug candidate is comprised of holding Remdesivir inside our polymeric drug candidate NV-CoV-2 by a process known as encapsulation. Thus NV-CoV-2-R is potentially capable of (1) direct attack on extracellular virus, to break the “re-infection cycle” by virtue of NV-CoV-2, and (2) attack on intracellular reproduction of the virus to break the “replication cycle” as has been validated for remdesivir. If both of these cycles are broken, in theory, it is expected to result in a cure of the virus infection, or at least a substantially strong control of the virus infection. Remdesivir is a challenging drug, because it is rapidly converted by blood and cellular enzymes into a significantly less potent form. It is also almost insoluble in aqueous media. These issues have been cited as possible reasons for differing datasets from clinical trials and clinical usage conducted under different conditions. In randomized controlled clinical trials, Gilead reported that Remdesivir was effective in reducing the hospital stay of COVID-19 patients significantly. However, in analysis of field usage of remdesivir and other clinical trials, the World Health Organization (WHO) reported that Remdesivir was not as effective as was thought based on the clinical trials that led to first its emergency use approval (EUA) followed by full approval (Approval) by the FDA. Remdesivir continues to be the most active antiviral against COVID-19 to be used in hospitalized cases.

NV-CoV-2-R is expected to have significantly greater clinical activity than Remdesivir because it (a) significantly enhances the capabilities of Remdesivir due to encapsulation of Remdesivir and (b) further boosts the antiviral activity due to the “Re-Infection Blocking” mechanism of NV-CoV-2 itself, as explained earlier, by solving the challenges of existing Remdesivir formulations cited above. We have already shown that NV-CoV-2-R has significantly greater activity than Remdesivir in lethal coronavirus lung infection animal studies.

It is important to develop NV-CoV-2 by itself as a drug because the inherent toxicity of Remdesivir that can be inferred from its molecular structure may limit its usage in certain patient populations.

We were able to achieve the important milestone of completing the creation of NV-CoV-2-R from NV-CoV-2 and Remdesivir in a matter of just a few months. This rapid development was possible only because of the strong advantages of our nanoviricide platform technology.

We have been executing rapidly and efficiently, as well as in a cost-effective and productive manner, towards the goal of advancing the first drug candidate into human clinical trials as soon as possible. We believe that taking our first drug candidate into initial human clinical trials will be a very important milestone in that it would essentially validate our entire platform technology as being capable of producing drug candidates worthy of human clinical trials, and potentially of success in those clinical trials.

## **Recent Developments**

We began development of a nanoviricide drug to treat SARS-CoV-2, the virus that causes COVID-19 spectrum of diseases, and has become a historic worldwide pandemic, around January 2020, when the news of cases in China broke out. Since then, the Company has been working diligently on designing, testing, and advancing drug candidates against SARS-CoV-2.

During the three months ended September 30, 2022, we have been compiling and performing medical writings needed for developing an IND application to the US FDA for human clinical trials of NV-CoV-2 in COVID-19 patients. We have scaled up the processes cGMP-compliant for manufacture of the active ingredient (“drug substance”) NV-387 that goes into NV-CoV-2 drug product formulations to approximately 5 Kg final production scale. We have begun manufacture of clinical supply of the drug substance NV-387 at the 5 Kg production scale. It is expected that this amount would be sufficient to treat approximately 1,000 patients, although the actual required dose for efficacy will only be established in clinical trials.

After the active ingredient is made, it has to be formulated into actual drug products for use. We have developed three separate drug product formulations of NV-387: (i) NV-CoV-2 Oral Gummies, a fixed-dose form for use in mild to moderate out-patient treatment; (ii) NV-CoV-2 Oral Syrup, the dosing quantity of which can be adjusted, as is needed in the case pediatric patients (based on body weight); and (iii) NV-CoV-2 Solution (Sterile) for Injection, Infusion, and Inhalation. The injection of sterile solution is expected to be used in moderate to severe out-patient scenario, keeping the patient from hospitalization. The infusion of sterile solution is expected to be used in severe hospitalized cases permitting increased dosing. The inhalation directly into lungs of the same sterile solution using a simple nebulizer is

expected to be helpful for in severe cases with lung damage where the drug can be provided directly into the lungs at the site of viral attack for presumably enhanced effect.

We have begun the scale up of cGMP-compliant manufacture of these NV-CoV-2 drug products at our Shelton, CT facility.

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The formulated drug product must be suitably packaged for transport and distribution. We have developed the filling and packaging system for our NV-CoV-2 Oral Gummies, which is undergoing testing now. We have also established small-scale operation for filling and packaging of the NV-CoV-2 Oral Syrup into appropriate bottles. We plan on engaging a third party for the filling and packaging operation for the NV-CoV-2 Sterile Solution drug product. We are thus in the process of establishing drug product primary packaging operations at our cGMP-capable facility in Shelton, CT.

Thus NanoViricides is rapidly becoming one of very few small pharma companies that are fully “vertically integrated” (“vertically integrated” refers to having capabilities from R&D to manufacturing and packaging of drug products).

Additionally, we are in the process of preparing the dossiers for submission to regulatory agencies and related activities. We have substantially completed writing of the manufacturing and quality control section as well as the non-clinical IND-enabling studies section of a clinical trial application. We have substantially completed development of a clinical protocol for safety and preliminary efficacy evaluation of NV-CoV-2 in human clinical trials. It is expected that the clinical trial protocol we have developed may be modified by the Clinical Trial Provider contract research organization (CRO). We are in the process of engaging a CRO for US IND filing and clinical trials at present. The CRO will need to complete the writing of the clinical protocol section of the IND. Thereafter we can submit the IND to the US FDA. We also have efforts going on for conducting clinical trials of NV-CoV-2 in other regulatory jurisdictions.

We have previously established that NV-CoV-2 has broad-spectrum activity against many unrelated coronaviruses including SARS-CoV-2 in various assays. The broad-spectrum, pan-coronavirus activity of our drug candidates is important because it provides scientific rationale that as a virus mutates, it would not escape the drug. In addition, we anticipate the drugs the Company develops should work against seasonal or commonly circulating coronaviruses as well as potentially pandemic and pandemic coronaviruses. Antibodies, in contrast tend to be highly specific and are known to fail when the virus mutates. Vaccines are also known to fail when a virus mutates.

We have also previously observed that NV-CoV-2 has demonstrated extremely strong safety in animal studies. These studies were performed in a primate model (cyanomolgus monkeys) as well as murine models (mice and rats). We have performed GLP Safety/Pharmacology studies as well as non-GLP Safety/Toxicology studies to establish the safety of NV-CoV-2 (NV-387) in animal models. We have also found that NV-CoV-2 (NV-387) is non-immunogenic and non-allergenic. Further, it has not caused any hypersensitivity or adverse reactions at injection site or other adverse events in multiple animal studies. NV-CoV-2 (NV-387) was safe and well tolerated at very high dosages in single and multiple-dosing studies below the maximum tolerable dose (MTD) in animal models, based on available data. The maximum tolerable dosage in rats was determined to be 1,500 mg/Kg. Additionally NV-CoV-2 (NV-387) was found to be non-mutagenic and non-genotoxic.

We believe that the extremely strong safety we have observed in animal models should be indicative of a strong safety signal anticipated in Phase 1 human clinical trials. Thus we believe that the drug will be safe in human usage.

Remdesivir is known to be highly effective in cell culture studies against many coronaviruses as well as Ebola and other viruses. Thus NV-CoV-2-R can be expected to be at least as effective as remdesivir against all of these viruses in cell cultures. Moreover, NV-CoV-2-R would be expected to be significantly superior to Remdesivir in human clinical studies, if our encapsulation process effectively protects remdesivir from bodily metabolism as observed in animal model studies.

The strong effectiveness of the three drugs NV-CoV-2, NV-CoV-2-R, and Remdesivir against unrelated coronaviruses (namely hCoV-NL63, hCoV-229E, and SARS-CoV-2 pseudovirions) 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 third year.

The Company has developed NV-CoV-2 and NV-CoV-2-R based on its platform nanoviricides® technology (see further below). 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.

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The Company has 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 FDA for the treatment of patients hospitalized with COVID-19. Encapsulation of remdesivir in the Company's 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. Significant amounts of US government funding has been used in its development, from NIH as well as from BARDA. The Company is developing its drug candidates independently at present.

Based on (1) the safety of NV-CoV-2 in the different GLP and non-GLP studies employing different animal models, and (2) the anti-viral effectiveness in cell culture as well as in animal studies in comparison to remdesivir, we believe that our projected dosages would be safe and effective in human clinical trials. With these findings, the Company believes that it will be possible to administer repeated dosages of NV-CoV-2 in a human clinical trial, as needed, to achieve control over the coronavirus infection from SARS-CoV-2 or its variants.

Having our own cGMP-capable manufacturing facility has enabled rapid translation of our drug candidates to the IND application stage, saving years of manufacturing translation and set-up activities, as well as saving several millions of dollars of external costs, while ensuring requisite quality assurance, as compared to using a contract manufacturing organization ("CMO") for our complex nanomedicine drugs. We believe these benefits will continue to accrue as our first drug candidate goes through human clinical trials into commercialization, and will also accrue for the multitude of candidates in our broad drug pipeline.

We have upgraded our facilities to enable complete clinical drug product manufacture, which involves both formulation and packaging under cGMP-compliant processes. We are currently in the process of setting up the final drug product packaging at our facility.

Thus, we believe our anti-coronavirus drug program is now very close to entering the human clinical trials stage.

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 vaccines and therapeutics become commonplace. Thus the need for therapeutics that the virus would not escape by mutations, such as the broad-spectrum, pan-coronavirus nanoviricides drug candidates, remains unmet.

### ***The Nanoviricide Platform Technology in Brief***

NanoViricides is pioneering a unique platform for developing anti-viral drugs based on the "bind-encapsulate-destroy" principles. Viruses would not be able to escape a properly designed nanoviricide(R) drug by mutations because in doing so they would lose the ability to bind their cognate cellular receptor(s) and thus fail to infect productively, becoming incompetent.

The Company develops its class of drugs, that we call nanoviricides(R), 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(R) 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 Company believes that, to the best of our knowledge, only the nanoviricide<sup>(R)</sup> technology 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 further designing and making small chemicals that are called "ligands" that will bind to the virus in the same fashion as the

cognate receptor. We use molecular modeling techniques for these tasks. These ligands are then chemically attached to a nanomicelle, to create a nanoviricide.

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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 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.

### **Financial Status**

As of September 30, 2022 the Company had approximately \$12.9 million in cash and cash equivalents and \$8.6 million of property and equipment, net of accumulated depreciation. Our current liabilities are approximately \$0.52 million. Stockholder’s equity was approximately \$21.6 million at September 30, 2022.

During the three-month period ended September 30, 2022, the Company used approximately \$1.0 million in cash toward operating activities. The available cash is sufficient for more than twelve months of operations at the current rate of expenditures from the date of filing of this Quarterly Report on Form 10-Q. As our COVID-19 and shingles drug programs mature into human clinical trials, our expenditures are anticipated to increase due to the costs of the clinical trials. We estimate that the Company has sufficient funds in hand for initial human clinical trials of NV-CoV-2 at this time. 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.

We do not anticipate any major capital costs going forward in the near future. The Company believes that it has several important milestones that it will be achieving in the current year. Management believes that as it achieves these milestones, the Company’s ability to raise additional funds in the public markets would be enhanced.

### **NanoViricides’ Drug Programs in Brief**

We intend to take one of our broad-spectrum anti-coronavirus drug candidates into human clinical trials as soon as feasible. We intend to seek collaborations to develop the COVID-19 drug further towards emergency use approval and full approval by FDA as well as international regulatory authorities.

We have recently initiated two new programs in response to public health threats: (a) nanoviricides to treat Poxvirus infections (the Monkeypox epidemic); and (b) nanoviricides to treat enteroviral infections. Enterovirus EV-D68, causes a pediatric disease called acute flaccid myelitis (AFM) that can lead to paralysis (AFP) in a small number of children. The disease incidence appears to peak every two years and has been increasing in the USA. Poliovirus is also an enterovirus, and recently has been detected primarily in New York area. We are engaging these programs in a limited manner at present, and intend to evaluate effectiveness of our existing array of potential drug candidates against these viruses.

After NV-CoV-2 goes into clinical trials, we intend to focus on NV-HHV-1, and develop this drug through initial human clinical trials. We anticipate that, as the NV-HHV-1 drug (skin cream) for Shingles indication goes into human clinical testing, we would develop clinical candidates for topical as well as systemic treatment of HSV-1 “cold sores” and HSV-2 “genital ulcers”. Additional indications for these drug candidates or their derivatives as needed for different routes of administration and other considerations are expected to expand our drug pipeline in the near future. As these programs mature, the Company intends to re-engage its FluCide™ and HIVCide™ programs.

The market size for HerpeCide programs is in several tens of billions of dollars because neither cures nor very effective treatments are available. Approved treatments have limited effectiveness, demonstrating a significant unmet medical need. The market size for Influenza drugs is estimated to be in tens of billions of dollars.

Based on data in a Jain PharmaBiotech report prepared for the Company in March 2014, we believe the overall market size for the anti-viral market was \$40 billion in 2018 and may be \$65.5 billion in 2023, excluding the market size for COVID-19 pandemic responsive drugs and vaccines.



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Thus, the Company's technology has substantial capabilities and applications, and the potential to attack as-yet-unsolved problems caused by viral infection, and thus lead to a great health benefit to individuals and societies. We are seeking to add to our pipeline of drug candidates through our internal discovery pre-clinical development programs and through an in-licensing strategy. We believe the Company has a bright future with an expanding pipeline as it furthers the research programs driving towards cures beyond our current objectives of effective treatments.

NV-HHV-1 is the Company's lead candidate in the HerpeCide™ Program, with first indication as a Skin Cream for the treatment of Shingles Rash. NV-HHV-1 has consistently shown strong effectiveness as well as safety in human skin-based model of VZV infection. In cell culture studies, it was as much as five times more effective than acyclovir, the current standard of care. Our anti-VZV drug candidates have also shown strong effectiveness in studies involving VZV infection of human skin patches ex vivo. These studies were conducted by Professor Jennifer Moffat at the SUNY Upstate Medical Center in Syracuse, NY, an internationally recognized expert on varicella-zoster virus (VZV) infection, pathogenesis, and anti-viral agent discovery. Some of the earlier work was presented by the Moffat Lab at the 31st International Conference on Antiviral Research held June 11 - June 15, 2018 in Porto, Portugal.

There is a significant unmet medical need for the topical treatment of shingles rash. An effective therapy for shingles has been estimated to have a market size into several billions of dollars, if it reduces PHN incidence. An effective therapy against shingles rash reduction alone is estimated to have a market size of several hundred million dollars to low billion dollars. These market size estimates have taken into account the potential impact of the new Shingrix® GSK vaccine and the impact of the existing Zostavax® vaccine.

The Company is also developing drugs against HSV-1 "cold sores" and HSV-2 "genital ulcers", both based on the NV-HHV-1 drug candidate, although final clinical candidates are in pre-clinical optimization stage for both of these indications as of now.

Existing drugs given orally or systemically may not reach required concentrations at the site of shingles outbreak, limiting effectiveness. In addition, unlike HSV-1 and HSV-2, VZV does not have an effective TK enzyme that is required for producing active drug forms from the acyclovir class of drugs (such as Valtrex®), requiring frequent administration of very large doses to treat shingles. Additionally, a dermal topical cream formulation of Cidofovir is employed in very severe cases of shingles. Cidofovir is highly toxic, particularly towards kidneys. A safer, effective, drug is thus an unmet medical need for the treatment of VZV.

Zostavax and other attenuated VZV (Oka strain) vaccines for chickenpox are available, but not widely adopted. These vaccines may lead to a less severe form of shingles in adulthood or at a later age, compared to the "wild type" chickenpox virus ("rebound shingles"). A new vaccine, Shingrix® has been introduced by GSK recently, based on subunits or protein fragments of the virus, which cannot lead to rebound shingles, but suffers from a very severe side effects profile, and has limited availability at present.

While shingles presents with a debilitating "pins-and-needles" pain associated with the characteristic rash that is self-limiting within 2-3 weeks in most patients, in a substantial percentage of patients, it presents as a severe, debilitating disease that leads to complications including hospitalization(s) and in some cases may result in extended treatments including subsequent surgeries.

Limiting initial viral load is expected to minimize the occurrence of such complications, and is also expected to reduce the incidence of post-herpetic-neuralgia ("PHN"). PHN is defined as dermatomal nerve pain that persists for more than 90 days after an outbreak of herpes zoster affecting the same dermatome. Thus, we anticipate that NV-HHV-1 would have significant impact in reducing PHN incidence rates. We anticipate extending the NV-HHV-1 indication to include PHN after obtaining marketing approval for the first indication, namely effect on shingles rash.

Of note, the cGMP-like manufacture of both the active pharmaceutical ingredient (API, the nanoviricide against VZV), and the fully formulated skin cream (the drug product candidate), was accomplished at our own facilities at ~1kg scale (API), saving us millions of dollars and at least one year's worth of time, as opposed to going to an external contract manufacturer. Approximately 10kg of fully formulated drug product has already been manufactured. We believe this scale is sufficient for the requirements of Phase I human clinical trials.

The Company has now demonstrated that it has unique expertise in the industry of performing cGMP manufacture of complex nanomedicine drugs, including cGMP manufacture of (a) drug substance from simple chemical starting materials, (b) the formulated drug product, and (c) the final packaged drug.

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This establishment and execution of cGMP manufacturing is an extremely significant milestone for the Company. Our current multi-kg per batch scale of cGMP manufacturing capacity is expected to be more than sufficient for the anticipated Phase I and Phase II human clinical trials. In addition, we believe that our facility can supply required quantities of the drug for Phase III clinical trials as well. Thus, this in-house cGMP production capability is expected to result in significant cost savings across all our programs.

Manufacturing nanomedicines, especially under cGMP conditions, has been identified as a strong risk, and has led to failure of several nanomedicines programs. NanoViricides co-founder Dr. Anil Diwan and his team have employed considerations for cGMP manufacture of our nanomedicines right from the design, development and optimization of the drug candidates, the polymers and ligands that go into them, as well as the processes employed right from the small research scale to the initial process verification batches. The team has successfully and rapidly translated from the research scale production of several grams drug substance to kg-scale cGMP-compliant manufacture for two different drug candidates, namely NV-HHV-1 and NV-CoV-2 in a very short time span. This includes manufacture of the active ingredient (drug substance), the formulated drug products, and packaged drug products for clinical trials usage. External contract manufacturing organizations would likely have required at least three years to scale up each of these complex products, based on certain discussions we have had.

The Company has previously found that dermally applied nanoviricide drug candidates in the HerpeCide program led to full survival of lethally infected animals in a severe infection with the highly pathogenic, neurotropic strain of HSV-1, namely H129c. Thus the nanoviricide drug candidates applied topically appear to demonstrate strong efficacy. Topical application has the advantage of being able to deliver very high drug concentrations locally to completely eradicate the virus. In contrast, the local concentrations and therefore effectiveness of orally delivered medications is limited by the toxicity and bioavailability of the oral drug, as is known for the existing antiviral therapies for HSV-1, HSV-2, and VZV. Therefore, treating the HSV-1 cold sores, HSV-2 genital ulcers, or VZV chicken pox lesions or shingles rash using dermal topical creams is expected to be highly beneficial.

NV-HHV-1 is a broad-spectrum nanomedicine designed to attack herpesviruses that use the HVEM (“herpesvirus entry mediator”) receptor on human cells. This drug candidate is composed of a flexible polymeric micelle “backbone” to which a number of small chemical ligands are chemically attached. The ligands in this case are designed to mimic the binding site of the herpesviruses on HVEM, based on molecular modeling. NV-HHV-1 is expected to bind to VZV (or HSV-1 or HSV-2) virus particle via a number of binding sites (i.e. the ligands), thereby encapsulating the virus particle and destroying its ability to infect human cells. This “Bind, Encapsulate, Destroy” nanoviricide® strategy is distinctly different from the mechanism of action of existing antiviral drugs against VZV, HSV-1, and HSV-2.

### ***Our HerpeCide™ Product Pipeline***

We have focused our efforts exclusively on the anti-Coronavirus drug program at present. Until January 2020, we had focused our efforts almost exclusively on the HerpeCide™ program.

We currently have at least 10 different drug development programs, attesting to the strength of our platform technology. We are currently working on the Coronavirus program at the highest priority of an emergency program. In addition, we have been working on 3 of the HerpeCide program indications (namely VZV Shingles, HSV-1 Cold Sores, and HSV-2 genital Ulcers) in parallel, as explained below (priority level 1). The Herpes Keratitis program and v-ARN program (see below) are at a lower priority level. In addition, we continue to work on the FluCide™ program at the lower priority 3. HIVCide™ program is at priority level 4. We will continue to seek funding for further development in the remaining programs, namely Dengue and Ebola/Marburg antivirals.

The potential broad-spectrum nature of our anti-HSV drug candidates is enabling several anti-Herpes indications under our HerpeCide™ program. Of these, the (i) Topical Treatment for Shingles (VZV) is currently moving most rapidly towards clinical stage. We believe that the other anti-Herpes drug candidates, would follow this lead drug to the clinical stage, namely, (ii) skin cream for the treatment of orolabial herpes (“cold sores”) and recurrent herpes labialis (RHL) mostly caused by HSV-1, and (iii) skin cream for the treatment of genital herpes caused by HSV-2.

In addition, a fourth indication, (iv) ocular eye drops treatment for external eye herpes keratitis (HK), caused by HSV-1 or HSV-2, is expected to follow into further drug development. Further, we have announced that we have begun

preclinical drug development work on a fifth indication under the HerpeCide program, namely (v) viral Acute Retinal Necrosis (v-ARN), intravitreal injection.

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The market size for an effective anti-shingles drug is currently estimated to be in the range of several billions of dollars, even with the existence of the shingles vaccine, Shingrix® (GlaxoSmithKline) has been approved, based on a report performed for the Company by Dr. Myers of BioEnsemble, LLC, pharma industry consultants, commissioned by the Company. The current vaccine for prevention of chicken pox in children, i.e. the varicella vaccine, is based on the live attenuated virus derived from the Oka strain. Un-vaccinated children usually develop chicken pox at some point in their childhood, and the wild-type virus then remains latent in their bodies, in nerve ganglia. Similarly, Varicella vaccinated children may develop mild syndrome when vaccinated and the weakened Oka strain remains latent in their bodies. All of these children can develop shingles later in life. It is generally believed that the intensity of such disease would be much less severe with the weakened vaccine strain than with the natural or wild type strain. Nevertheless, the severity of the symptoms and overall effects depend upon the immune status of the individual. Pre-vaccination era, (i.e. before varicella vaccination was widely adopted in the USA), there were 3-4 million cases of chicken pox per year (matching the birth rate). Post-vaccination era, this rate has dropped to about 120,000-150,000 cases in the USA. However, in several developing and underdeveloped countries, the rates of chicken pox remain high due to limited access to the vaccine or limited adoption of the vaccine. As stated earlier, nearly every person may be expected to get shingles at some point in their lives, with varying severity. A preventive vaccine for adults, namely Zostavax® is available, based on the attenuated Oka strain. Its effectiveness is variously estimated at around 60-70%. Its coverage remains low, as most people do not get this vaccine. Shingrix is a subunit vaccine, that is, it does not contain intact living virus particles but only certain proteins derived from the virus. As such, it is expected to not have the issue of “breakthrough disease” which occurs when the live latent virus from the vaccine itself causes disease.

More specifically, the report estimated that the anti-shingles drug candidate could reach peak annual sales of as much as \$2 billion, depending upon the effectiveness determined in clinical trials, at an assumed 50% market penetration, if it is effective in reducing incidence of post-herpetic neuralgia (PHN). Based on current pre-clinical data, we believe that there is a very strong probability that the shingles treatment would significantly minimize the shingles pain, accelerate healing, and minimize nerve damage, thereby minimizing the occurrence and severity of post-herpetic neuralgia (PHN). Our pre-clinical drug design efforts have been aimed at developing a treatment for shingles that would have pain reduction effects as well as healing effects on skin.

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

The Company received an “Orphan Drug Designation” for our DengueCide™ drug from the FDA as well as the European Medicines Agency (EMA). This orphan drug designation carries significant economic benefits for the Company, upon approval of a drug.

We believe we have demonstrated that we can rapidly develop different types of formulations for different routes of administration, such as injectable, skin cream, lotion, gel, and even oral, because of the inherent strength of the nanoviricide platform tailorable technology. The technology also enables us to develop nasal sprays and bronchial aerosols. We plan to develop the appropriate formulations as necessary.

All of our drug programs are established to target what we believe are unmet medical needs.

Herpes simplex viral infections cause keratitis of the eye, and severe cases of infection may sometimes necessitate corneal transplants. Oral and genital herpes is also a well-known disease, with no cure and existing treatments that are not very effective. Shingles, caused by VZV, a herpesvirus, does not have an effective treatment at present, although some drugs are approved for use in shingles. Adenoviral Epidemic Kerato-Conjunctivitis (EKC) is a severe pink eye disease that may lead to blurry vision in certain patients after recovery. The epidemic and pandemic potential as well as the constantly changing nature of influenza viruses is well known. The HIV/AIDS worldwide epidemic and the “curse of slow death” nature of HIV viral infection are also well known. Dengue viral infection is also known as “breakbone fever”. What is worse, is that when a patient is infected with a dengue virus a second time, if the virus is a different serotype, then it can cause a severe dengue disease, or dengue hemorrhagic syndrome, with very high morbidity and a high rate of fatality. This is because, the patient’s immune system mounts an attack, but the antibodies that it generates, directed at the previous infecting virus, are not effective against the new infection, and instead the new infecting virus uses them to hitch a ride into host cells that it infects more severely. This phenomenon is called “Antibody-Dependent Enhancement” or “ADE” for short.

Our current development has focused on API suitable for formulating into a skin ointment for the treatment of VZV shingles, HSV-1 cold sores, or HSV-2 genital ulcers. As these drug candidates advance further, we plan on performing fully integrated drug development for developing eye drops for treatment of external eye infections such as herpes keratitis (a disease of the external eye).

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Thereafter we plan on undertaking the development of suitable materials for intravitreal or sub-retinal injections for the treatment of certain viral diseases involving the retina.

In the United States alone, approximately 1 million cases of shingles (i.e. zoster) occur annually. The risk of zoster increases with age, and with decreased immune system function, such as occurs in diabetics. Zoster is characterized by pain and rash. Discrete cutaneous lesions occur in groups on the skin. The Company believes that this presentation enables topical therapy for control of the viral outbreak.

One in four patients develop zoster-related pain that lasts more than 30 days. If it persists more than 3 months, it is called post-herpetic neuralgia (PHN), and may persist for years. It is thought that zoster-associated pain and PHN is a result of chronic ganglionitis, i.e. continued low-grade production of the virus in the infected ganglia and related immune response. The Company believes that effective control of the virus production would minimize or eliminate PHN, a debilitating morbidity of zoster.

Zoster occurs mostly in the abdominal region. However, in 20% of cases, it occurs in the head area, with reactivation involving trigeminal distribution. These cases of zoster can lead to serious complications including hemorrhagic stroke (VZV vasculopathy), VZV encephalitis, ophthalmic complications, and may result in fatalities.

Currently available anti-herpes drugs have had limited impact on zoster. Thus, an effective drug with a good safety profile could have a dramatic impact on zoster as well as possibly PHN.

External eye infections with HSV-1 have been reported to be the leading cause of infectious blindness in the developed world, with recurrent episodes of viral reactivation leading to progressive scarring and opacity of the cornea. HSV epithelial keratitis afflicts the epithelium of the cornea. In some cases, the disease progresses to HSV stromal keratitis, which is a serious condition. HSV stromal keratitis involves the stroma, the layer of tissue in the cornea, which is deeper in the eye than the epithelium. Its pathology disease involves the HSV infection of stromal cells, and also involves the inflammatory response to this infection. It can lead to permanent scarring of the cornea resulting in diminished vision. More serious cases require corneal replacement surgery. About 75% of corneal replacements are known to fail in a 20-year time frame, due to graft versus host disease (i.e. rejection of the foreign implant by the body), requiring a new procedure, or resulting in blindness.

Herpes keratitis incidence rates in the USA alone are reported to be in the range of 65,000 to 150,000 patients per year. Of these, approximately 10,000 per year may be estimated as requiring corneal transplants. The estimates of incidence rates vary widely based on source, and are also assumed to be underreported. A corneal transplant costs approximately \$15,000 to \$25,000 for the surgery, with additional costs for follow on drugs and treatments.

This scenario exists in spite of available drugs, namely the acyclovir class of drugs, trifluridine, and others, that are used for treatment of herpes keratitis. The failure of these drugs is primarily due to limited safety resulting in insufficient drug availability at the site of infection.

In addition, the Company is developing broad-spectrum eye drop formulations 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 herpesviruses. The Company has shown excellent efficacy of its drug candidates against EKC (adenoviral epidemic kerato-conjunctivitis) in an animal model. Further, our anti-HSV drug candidates have shown excellent efficacy in cell culture studies, as well as in a lethal skin infection animal model.

Thus, an effective drug with a good safety profile could have a dramatic impact on ocular viral infections. Merit-based compensation for the herpes keratitis treatment would enable strong financial incentive and could result in potential revenues in the several hundreds of millions range, depending upon the effectiveness of the drug. The Company believes that it has sufficient production capacity at its current site to supply the US requirement of the drug for treatment of (ocular) herpes keratitis upon drug licensure.



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Topical treatment of herpesvirus infections is important because of the disfiguring nature of herpesvirus breakouts, the associated local pain, and the fact that the virus grows in these breakouts to expand its domain within the human host further. Topical treatment can deliver much higher local levels of drugs than a systemic treatment can, and thus can be more effective and safer at the same time. 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 the side effects.

Herpesviruses 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 the side effects, leading to minimizing viral production at the site. Such effective local control of the virus titer is expected to lead to reduction in recurrence of herpesvirus “cold sores” or genital ulcers, and reduction in shingles related PHN.

The potential broad-spectrum nature of our anti-HSV drug candidates is expected to enable several antiviral indications. Thus, HSV-1 primarily affects skin and mucous membranes causing “cold sores”. HSV-2 primarily affects skin and mucous membranes leading to genital herpes. HSV-1 infection of the eye causes herpes keratitis that can lead to blindness in some cases. In addition, human herpesvirus-3 (HHV-3), a.k.a. 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. Most of these indications do not have satisfactory treatments at present, if any. Further, the treatment of herpesvirus infections caused by acyclovir- and famciclovir- resistant mutants is currently an unmet medical need. Drugs with mechanisms of action other than DNA-polymerase inhibitors (such as acyclovir) are needed for effective treatment.

The childhood chickenpox vaccine (varicella vaccine) has reduced the cases of chickenpox, but this is a live attenuated virus vaccine that persists in the body. All adults who have had chickenpox in childhood continue to harbor the chickenpox virus, and are expected to develop shingles at some time, with the risk of shingles increasing with age or weakening of the immune system surveillance. In addition to the shingles breakout itself, post-herpetic neuralgia (pain) (PHN) is a significant morbidity of shingles, and to a lesser extent, of oral and genital herpes. PHN is initially caused probably by the inflammation and immune response related to the local virus expansion, but persists well after the virus has subsided, the blisters have scabbed off, and the skin has recovered, due to the nerve damage that results from the local large viral load during infection. Current PHN treatments are symptomatic, affecting the pain signaling circuit (such as novocaine, pramoxine, capsaicin, etc.), and do not produce lasting control. An effective therapy that results in strong local control of the virus production during the breakout itself is expected to minimize the resulting immune responses and nerve damage, and thereby minimize or possibly eliminate PHN.

The Company thus believes that it can develop its broad-spectrum anti-herpes drug candidate towards at least five topical indications, namely, (a) shingles, (b) oral herpes (“cold sores”), (c) genital herpes, (d) herpes keratitis (external eye infection), and (e) ocular herpes including v-ARN (internal eye infection). As the HerpeCide™ program progresses, it is likely that additional herpesvirus related pathologies may become amenable to treatment with our herpesvirus drug candidates.

Currently, valacyclovir (Valtrex®) is approved as an oral drug for the treatment of severe shingles, but it has limited effectiveness. Another oral drug known as “FV-100” was studied in clinical trials for the treatment of shingles by Bristol-Myers Squibb, and later by Contravir. FV-100 works only against VZV and does not work against other herpesviruses. A Phase 3 study with PHN as end-point was completed in November 2017. Further development appears to have been stopped for FV-100.

There is also a new preventive vaccine for shingles, “Shingrix”. Given the number of cases of severe shingles, we believe that there is an unmet medical need for developing a topical skin cream for the treatment of shingles, even with a successful introduction of this vaccine. The Shingrix vaccine has been recently also been shown to produce adverse effects such as painful injection site reactions and pain in a significant number of patients. Local application of a nanoviricide drug should enable delivery of stronger, local doses of medicine, with a stronger patient benefit, than oral systemic dosing allows.



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Existing therapies against HSV include acyclovir and drugs chemically related to it. These drugs must be taken orally or by injection. Available topical treatments, including formulations containing acyclovir or chemically related anti-HSV drugs, are not very effective. Currently, there is no cure for herpes infection. Brincidofovir (CMX001) is being developed by Chimerix. It failed in a Phase 3 clinical trial for hCMV in organ transplants, and its Phase 1/2 clinical trial for HSV in neonates was withdrawn recently. Cidofovir is a known highly effective but also toxic, broad-spectrum nucleoside analog drug that was modified with a lipidic chain structure to create brincidofovir. Pritelivir, by AiCuris, is a DNA Helicase/Primase inhibitor (HSV-1 and HSV-2) that has successfully completed certain Phase 2 clinical trials, and its indication in immune-compromised patients has received a fast track status from the FDA. Letermovir (Merck/AiCuris), a terminase complex inhibitor, is effective only against hCMV and has entered a Phase 3 clinical study in kidney transplant patients.

Both the safety and effectiveness of any new drug has to be determined experimentally. The safety of a nanoviricide drug is expected to depend upon the safety of the nanomicelle portion as well as the safety of the antiviral ligand. We have observed excellent safety of our injectable anti-influenza drug candidates. This leads us to believe that the nanomicelle backbones of these drug candidates that were evaluated in preliminary safety studies should be safe in most if not all routes of administration.

We believe that when effective topical treatments against VZV shingles, HSV-1 cold sores and HSV-2 genital ulcers are introduced, their market sizes are likely to expand substantially, as has been demonstrated in the case of HIV as well as Hepatitis C.

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

We are currently focused on the development of an anti-coronavirus drug with urgency. We are also performing topical drug development against several indications related to infections by herpes family viruses.

### **Management Discussion - Current Drug Development Strategy**

During the reported quarter, we have focused on medical writing for an IND application for initiating human clinical trials of our COVID-19 drug candidate NV-CoV-2. We have prioritized our resources with the goal of filing our first IND or an equivalent regulatory submission for performing initial clinical trials of our COVID-19 drug candidates in the shortest possible timeframe.

We believe that our anti-coronavirus drug program could result in a cure for SARS-CoV-2, based on attacking both viral replication and the viral reinfection cycles. In addition to NV-CoV-2, we are developing a next generation nanoviricide in this program, NV-CoV-2-R, that is capable of attacking the virus particle and also is designed to encapsulate and deliver another drug (Remdesivir) to block the intracellular virus replication.

We believe that our anti-herpes drug candidates for the treatment of cold sores and for genital lesions should lead to effective control of the cold sores rapidly, and may also lead to a long lag time before a new recurrence episode occurs. This is because it is believed that recurrence rates increase by virtue of further infection of new nerve endings from the site of the herpesvirus outbreak, which result in additional nerve cells harboring the virus. If this in situ re-infection is limited, which we believe is the primary mechanism of nanoviricide drugs, then it is expected that the number of HSV harboring reservoir cells should decrease, and recurrence rate should go down.

We believe that it will be possible to expand our anti-herpes portfolio in the future to include many other herpes viruses such as cytomegalovirus (CMV), HHV-6A, HHV-6B, KSHV, and Epstein-Barr virus (EBV, cause of mononucleosis, and linked to Multiple Sclerosis and other auto-immune diseases). This would lead to a very large number of therapeutic indications beyond the four or five indications we are currently targeting.

We thus continue to expand our portfolio of opportunities, while also making progress towards the clinical trials stage.

Previously, in the FluCide™ program, we had demonstrated extremely high effectiveness in animal models against two unrelated influenza viruses, namely H1N1 and H3N2. In the HIVCide™ program, in the standard SCID-hy Thy/Liv mouse model of HIV infection, certain of our drug candidates were found to maintain viral load to the same level as an

approved triple combination drug therapy, beyond 40 days after the nanoviricide treatment was discontinued, even though the combo therapy was continued daily. We intend to reactivate these programs upon appropriate collaborations or funding. We have also demonstrated preliminary successes in developing drug candidates against Dengue viruses, and Ebola virus, among others.

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We believe we have demonstrated that we can rapidly develop different types of formulations for different routes of administration, such as injectable, skin cream, lotion, gel, and even oral, because of the inherent strength of the nanoviricide platform tailorable technology. The technology also enables us to develop nasal sprays and bronchial aerosols. We plan to develop the appropriate formulations as necessary.

### **Our Campus in Shelton, CT**

Our campus at Shelton, CT, is fully operative. With our R&D discovery labs, Analytical Labs, the Bio labs for virology R&D, the process scale-up production facility, and the cGMP-capable manufacturing facility established at our Shelton campus, we are in a strong position to move our drug development programs into the clinic rapidly. Staff is being trained to achieve full cGMP compliance to support clinical trial manufacture.

#### *Process Scale-Up Production Capability*

The Process Scale-up area is operational at kilogram to multi-kg scales for different chemical synthesis and processing steps now. It comprises reactors and process vessels on chassis or skids, ranging from 1L to 50L capacities, as needed. Many of the reactors and vessels have been designed by us for specific tasks related to our unique manufacturing processes.

#### *cGMP Production Capability*

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

We plan to produce multiple batches of a drug product. If we are satisfied with such strong reproducibility of our processes, we plan to register the facility as a cGMP manufacturing facility with the FDA.

We operate in a completely novel area of medicines, which is broadly described as polymeric-micelle based drug conjugates and complex nanomedicines. Our technologies are also completely novel, and unmatched in the industry. As such, we anticipate a longer training period for new employees than in normal small chemical or biological drugs. We continue to seek talented scientists and engineers with specialized training. However, it is difficult to attract such talent for a small, pre-revenue pharma company such as ours.

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

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### *Our BSL-2 Certified Virology Lab*

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

We have established several different types of assays for screening of candidates against Coronaviruses as well as VZV, HSV-1, HSV-2, and Enteroviruses in our lab. We have developed and implemented pseudovirion technology that enables us to develop drugs against BSL3 and BSL4 viruses by using model viruses that display only the glycoprotein of the target BSL3/4 virus on their surface. We have employed this well known methodology in our coronavirus drug development. Our BSL2 Virological capability has been instrumental in our rapid development of potential drug candidates for further investigation towards human clinical trials. 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 and accelerated 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.

### **NanoViricides Business Strategy in Brief**

NanoViricides, Inc. 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 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. There can be no assurance that the Company will be able to enter into co-development or other licensing agreements.

The Company has kept its capital expenditures to a minimum in the past, and we intend to continue to do the same, in order to conserve our cash for drug development purposes, and in order to minimize additional capital requirements.

### **Collaborations, Agreements and Contracts**

Our strategy is to minimize capital expenditures. We therefore rely on third party collaborations for the testing of our drug candidates. We continue to engage with our previous collaborators. We also seek to engage with additional collaborators, as necessitated for the progress of our programs.

We have engaged Calvert Labs (now part of Alta Sciences) for core safety/pharmacology studies of our anti-coronavirus drug candidates.

We have signed a collaboration agreement with the Professor Moffat Lab at SUNY Upstate Medical Center, Syracuse, NY, for evaluating safety and effectiveness studies of drug candidates in cell culture and in animal models for shingles VZV infections.

We have signed a collaboration agreement with the CORL at the University of Wisconsin, Madison, WI, for HSV-1 and HSV-2, with focus on small animal models for ocular disease.

We have contracted NorthEast BioLab, Hamden CT, to conduct the bio-analytical studies and facilitate the toxicokinetic analyses of NV-HHV-1. These studies and analyses are part of the required general safety and toxicology studies that will go into an IND Application to the FDA. NorthEast BioLab has already performed the bio-analytical assay development and validation and is in the process of determining the concentrations of NV-HHV-1 in blood samples from the general safety and toxicology studies that are required for IND.

We anticipate completing master services agreements, after performing our due diligence, with additional parties in furtherance of our anti-viral drug development programs.

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We have continued to achieve significant milestones in our drug development activities. Our lead program, NV-CoV-2 is in medical writing stage for preparing an IND submission to the US FDA to initiate human clinical trials. Our other lead clinical candidate program, NV-HHV-1 skin cream for the treatment of shingles rash, has substantially completed IND-enabling studies. All of our remaining drug development programs are presently at pre-clinical or advanced pre-clinical stage.

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

The nanomedicine technologies licensed from TheraCour, which licenses its intellectual property from AllExcel, serve as the foundation for our intellectual property. NanoViricides holds a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex Virus (HSV-1 and HSV-2), Influenza and Asian Bird Flu Virus. The Company has previously entered into an Additional License Agreement with TheraCour granting NanoViricides the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types: Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses.

In addition, on November 1, 2019, the Company entered into a world-wide, exclusive, sub-licensable, license 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. We were 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, 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 I clinical trials; (v) \$2,500,000 in cash upon completion of Phase IIA clinical trials, or its equivalent; (vi) the issuance of 100,000 shares of the Company's Series A preferred stock upon the initiation of Phase 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.

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 these 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.



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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 the Company creates. 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 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 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”.

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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.

<b>Table 1: Intellectual Property, Patents, and Pending Patents Licensed by the Company</b>				
<b>Patent or Application</b>	<b>Date of Issue/ Application</b>	<b>US Expiry Date</b>	<b>International</b>	<b>Owners</b>
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 UMass 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.				

The Company believes that the drugs by themselves, Coronavirus antiviral treatment, Shingles antiviral topical treatment, HerpeCide for Cold Sores, HerpeCide for genital ulcers, antiviral nanoviricide eye drops, Injectable FluCide, Oral FluCide, DengueCide, HIVCide, RabiCide, and others, would be eligible for patent protection. The Company plans on filing patent applications for protecting these drugs when we have definitive results from in-vitro or in-vivo studies that enable further drug development and IND application filing.

The previously issued 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 process, or other local considerations, such as licensing to a local majority held company. Many countries allow up to five years extension for regulatory delays.

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The estimated expiry date for HerpeCide patents, if and when issued, would be no earlier than 2040. No patent applications have been filed for the actual drug candidates that the Company intends to develop as drugs as of now. We intend to file the patent application for FluCide and HerpeCide compounds on or about when the drug candidates are entering human clinical trials, depending upon prevailing considerations regarding the confidentiality of the information.

We may obtain patents for our compounds many years before we obtains 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, the Company may be able to apply for patent term extensions, based on delays experienced in marketing products due to regulatory requirements. There is no assurance the Company 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 the Company will likely file in the future, do not always provide complete or adequate protection. Future litigation or reexamination proceedings regarding the enforcement or validity of our licensor, TheraCour's existing patents or any future patents, could invalidate TheraCour's patents or substantially reduce their protection. In addition, the pending patent applications and patent applications filed by TheraCour, may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing the same compounds and products that we have developed or are developing. In addition, certain countries do not permit enforcement of our patents, and manufacturers are able to sell generic versions of our products in those countries.

We also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. In particular, a great deal of our material manufacturing expertise, which is a key component of our core material technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by the individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors.

### **Trademarks**

The Company has no registered trademarks.

### **Analysis of Financial Condition, and Result of Operations**

As of September 30, 2022, we had cash and cash equivalents of \$12,918,044, prepaid expenses of \$231,557 and net property and equipment of \$8,557,365. Accounts payable and accrued expenses were \$494,521, inclusive of account payables to a related party of \$433,119. The accounts payable – related party is net of a two month advance of \$465,000. Our liabilities included a third party short term loan payable of \$23,837 at September 30, 2022. Stockholders' equity was \$21,563,977 at September 30, 2022.

In comparison, as of June 30, 2022, we had \$14,066,359 in cash and cash equivalents, prepaid expenses of \$350,021 and \$8,694,194 of net property and equipment. Our liabilities at June 30, 2022 were \$412,837 including a third party short term loan payable of \$94,788, accounts payable of \$57,960 payable to third parties and accounts payable to TheraCour of \$214,397, net of a two month advance of \$465,000.

During the three month period ended September 30, 2022, we used approximately \$1.0 million in cash toward operating activities. During the three month period ended September 30, 2021, we used approximately \$0.7 million in cash toward operating activities.



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The Company believes that its existing resources will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuance of these financial statements. However, the Company will need to raise additional capital to fund its long term operations and research and development plans until it generates revenue which reaches a level sufficient to provide self-sustaining cash flows. 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 the Company has sufficient funds in hand for initial human clinical trials of its first drug candidate for the treatment of SARS-CoV-2 infection. 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.

Management believes the Company will have to raise additional capital to fund and perform additional projected work and subsequent anticipated IND filings of human clinical trials of its HerpeCide program drug candidates.

The Company does not currently have any revenue. All of the Company's products are in the development stage and require successful development through regulatory processes before commercialization. We have historically generated funding through the issuances of debt and private placement of common stock and also the sale of our registered securities. The Company does not currently have any long-term debt. We have not generated any revenues and we may not be able 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.

## 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. Far fewer man-hours are spent on the projects at low priority than the projects at high priority. In this quarter, we have focused on our COVID-19 program drug candidates.

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 need to 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 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 we have developed sufficient data on our first drug candidate NV-CoV-2 for the treatment of SARS-CoV-2 infection (COVID-19), to support an IND or equivalent international regulatory application to enable Phase 1 human clinical trials for testing the drug in human patients. We believe we have developed sufficient pre-clinical data that will be needed prior to a Phase 2 human clinical trial as well. After completing the Phase 1 clinical trials for NV-CoV-2, we intend to extend the Phase 1 studies to pediatric populations, and also engage in Phase 2 studies towards an EUA for NV-CoV-2 in adult patients. We plan on undertaking the studies first in mild to moderate cases of COVID-19 and then extend the clinical trials to include separate cohorts of severe and hospitalized cases of COVID-19. We plan on studying our oral formulations in the Phase 1 and Phase 2 clinical trials first, followed by our injectable and inhalation formulations developed for the severely infected and hospitalized COVID-19 patients.

We have previously completed IND-enabling studies for a drug candidate for the treatment of shingles rash caused by reactivation of the chickenpox virus (aka varicella-zoster virus, VZV). We plan on taking the shingles drug candidate

into human clinical trials after clinical trials of our COVID-19 drug candidate.

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As a risk factor, we recognize that the FDA may require additional studies to be done before approving the IND. Assuming that the FDA allows us to conduct human clinical studies as we intend to propose, we believe that this coming year's work plan will lead us to obtain certain information about the safety and efficacy of one of the drugs under development in human clinical studies. 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 Phase II and Phase III human clinical studies, additional studies in animal models to obtain any necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles of our drug candidates towards drug approval or licensure from regulatory agencies.

As a strategy, we plan to develop the same drug, once initial clinical trials towards a first approval of the drug are completed, for commercial approval for additional indications, such as pediatric applications, special case applications for certain classes of immune-compromised patients, among others, provided that appropriate levels of funding become available. We believe that adding further indications would significantly expand market penetration and improve return on investment for our drugs.

### **Results of Operations**

The Company is a biopharmaceutical company and did not have any revenue for the three month period ended September 30, 2022.

**Research and Development Expenses** – Research and development expenses for the three months ended September 30, 2022 decreased \$984,261 to \$1,112,659 from \$2,096,920 for the three months ended September 30, 2021. The decrease in the cost of research and development expenses for the three months ended September 30, 2022 is primarily due to a milestone payment in the prior year of 100,000 shares of the Company's Series A preferred stock, with a fair value of approximately \$935,000 issued to TheraCour upon execution on September 9, 2021 of an exclusive license agreement for the sale of drugs to treat COVID-19 infections using TheraCour's technology, and a decrease in outside lab expenses and professional fees.

**General and Administration Expenses** – General and administrative expenses for the three months ended September 30, 2022 decreased \$5,744 to \$509,701 from \$515,445 for the three months ended September 30, 2021. The decrease in general and administrative expenses during the three months ended September 30, 2022 compared to the prior period resulted primarily from decreases in professional fees and in operating expenses in general.

**Interest Income** – Interest income for the three months ended September 30, 2022 increased \$52,374 to \$52,562 from \$188 for the three months ended September 30, 2021. The increase in interest income for the three months ended September 30, 2022 is due to an increase in interest rates.

**Interest Expense** – Interest expense decreased \$47 to \$844 for the three months ended September 30, 2022 from \$891 for the three months ended September 30, 2021. The decrease in interest expense for the three months ended September 30, 2022 is a result of a lower open balance of the Company's loan payable.

**Income Taxes** – There is no provision for income taxes due to ongoing operating losses.

**Net Loss** – For the three months ended September 30, 2022, the Company had a net loss of \$(1,570,642) or \$(0.14) per share compared to a net loss of \$(2,613,068) or \$(0.23) per share for the three months ended September 30, 2021. The decrease in the net loss for the three months ended September 30, 2022 is attributable to the factors discussed above.

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### ***Liquidity and Capital Reserves***

The Company had cash and cash equivalents of \$12,918,044, and prepaid expenses of \$231,557 as of September 30, 2022 and accounts payable, loan payable, and accrued expenses were \$518,358, inclusive of accounts payable of \$433,119 to a related party as of the same date. The accounts payable – related party is net of a two month advance of \$465,000. 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 \$124,062,818 at September 30, 2022. 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. On July 31, 2020, the Company entered into an At The Market (“ATM”) Sales Agreement with B. Riley Securities, Inc., pursuant to which the Company may offer and sell, from time to time, through or to B. Riley Securities, Inc., shares of common stock having an aggregate offering price of up to \$50 million. To date the Company has sold 814,242 shares for approximately \$6.4 million under the ATM Sales Agreement. Subject to the Company meeting certain requirements and market conditions, the Company could offer additional shares for sale under the ATM Sales Agreement. In addition, the Company believes that it has several important milestones that it anticipates achieving in the ensuing year. Management believes that assuming it achieves these milestones, the Company would likely experience improvement in the liquidity of the Company’s stock, and would eventually improve the Company’s ability to raise funds on the public markets at terms that may be more favorable to the terms we are offered at present.

The Company believes that its existing resources will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuance of these financial statements. However, 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. There is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company. The Company believes that the management plan, the Company’s existing resources and access to the capital markets will permit the Company to fund planned operations and expenditures. 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.

Our estimates for external costs are based on various preliminary discussions and “soft” quotes from contract research organizations that provide pre-clinical and clinical studies support. The estimates are also based on certain time estimates for achievement of various objectives. If we miss these time estimates or if the actual costs of the development are greater than the early estimates we have at present, our drug development cost estimates may be substantially greater than anticipated now. In that case, we may have to re-prioritize our programs and/or seek additional funding.

The Company does not have direct experience in taking a drug through human clinical trials. In addition, we depend upon external collaborators, service providers and consultants for much of our drug development work.

Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain such additional capital resources or that such financing will be on terms that are favorable to the Company.

### ***Off Balance Sheet Arrangements***

We have not entered into any off-balance sheet arrangements during the three months ended September 30, 2022.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Market risk is the risk of loss arising from adverse changes in market rates and prices, such as interest rates, foreign currency exchange rates and commodity prices. We currently have no foreign operations and are not exposed to foreign currency fluctuations. Our primary exposure to market risk is interest rate risk associated with our short-term cash equivalent investments, which the Company deems to be non-material. The Company does not have any financial instruments held for trading or other speculative purposes and does not invest in derivative financial instruments,

interest rate swaps or other investments that alter interest rate exposure. The Company does not have any credit facilities with variable interest rates.

[Table of Contents](#)**ITEM 4. CONTROLS AND PROCEDURES**

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-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 limitations of control 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 mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of September 30, 2022, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company’s disclosure controls and procedures were not effective as of September 30, 2022 due to a material weakness in internal control over financial reporting described in Item 9A of our Form 10-K for the fiscal year ended 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. This material weakness remains unremediated as of September 30, 2022.

*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 quarter ended September 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.

[Table of Contents](#)**PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

From time to time, we may be a party to legal proceedings in the ordinary course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

There are no 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.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

On September 14, 2022 the Company's Board of Directors approved the employment extension of Dr. Anil Diwan, President and Chairman of the Board. On October 6, 2022, the Company and Dr. Anil Diwan executed an extension of his 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.

For the three months ended September 30, 2022, the Company's Board of Directors authorized the issuance of 387 fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of \$2,934 for the three months ended September 30, 2022 related to these issuances.

During the three months ended September 30, 2022, the Scientific Advisory Board was granted in August 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$3.40 per share expiring in August 2026. The fair value of the warrants was \$480 for the three months ended September 30, 2022 and was recorded as consulting expense.

For the three months ended September 30, 2022, the Company's Board of Directors authorized the issuance of 12,710 fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of \$27,000 for the three months ended September 30, 2022.

For the three months ended September 30, 2022, the Company's Board of Directors authorized the issuance of 5,154 fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of \$11,250 for the three months ended September 30, 2022.

All of the securities referred to above were issued 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. All of the foregoing securities as well the Common Stock issuable upon conversion or exercise of such securities, have not been registered under the Securities Act or any other applicable securities laws and are deemed restricted securities, 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 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.



[Table of Contents](#)**ITEM 6. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
31.1	<a href="#">Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Executive Officer</a>
31.2	<a href="#">Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Financial Officer</a>
32.1	<a href="#">Section 1350 Certification of Chief Executive Officer</a>
32.2	<a href="#">Section 1350 Certification of Chief Financial Officer</a>
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

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## SIGNATURES

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

### NANOVIRICIDES, INC.

Dated: November 14, 2022

/s/ Anil R. Diwan

\_\_\_\_\_  
Name: Anil R. Diwan

Title: President, Chairman of the Board  
(Principal Executive Officer)

Dated: November 14, 2022

/s/ Meeta Vyas

\_\_\_\_\_  
Name: Meeta Vyas

Title: Chief Financial Officer  
(Principal Financial Officer)