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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 March 31, 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the 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 May 16, 2022, there were approximately 11,554,000 shares of common stock of the registrant issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NanoViricides, Inc.
Balance Sheets

	March 31, 2022 (Unaudited)	June 30, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 15,572,134	$ 20,516,677
Prepaid expenses	337,182	307,102
Deferred financing costs	37,408	—
Total current assets	15,946,724	20,823,779
PROPERTY AND EQUIPMENT		
Property and equipment	14,582,652	14,333,666
Accumulated depreciation	(5,777,932)	(5,248,765)
Property and equipment, net	8,804,720	9,084,901
TRADEMARK AND PATENTS		
Trademark and patents	458,954	458,954
Accumulated amortization	(115,038)	(108,836)
Trademark and patents, net	343,916	350,118
OTHER ASSETS		
Service agreements	45,702	—
Security deposits	3,515	3,515
Total other assets	49,217	3,515
Total assets	$ 25,144,577	$ 30,262,313
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 122,987	$ 200,016
Accounts payable – related party	73,587	31,539
Loan payable	164,905	95,306
Accrued expenses	25,252	24,285
Total current liabilities	386,731	351,146
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, $0.001 par value, 10,000,000 shares designated, 484,195 and 371,490 shares issued and outstanding, at March 31, 2022 and June 30, 2021, respectively	484	372
Common stock, $0.001 par value; 150,000,000 shares authorized, 11,554,476 and 11,515,170 shares issued and outstanding, at March 31, 2022 and June 30, 2021, respectively	11,554	11,515
Additional paid-in capital	145,457,987	144,284,593
Accumulated deficit	(120,712,179)	(114,385,313)
Total stockholders' equity	24,757,846	29,911,167
Total liabilities and stockholders' equity	$ 25,144,577	$ 30,262,313

See accompanying notes to the financial statements

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Nanoviricides, Inc.
Statements of Operations
(Unaudited)

	For the Three Months Ended March 31,		For the Nine Months Ended March 31,	
	2022	2021	2022	2021
OPERATING EXPENSES				
Research and development	$ 1,255,074	$ 1,464,177	$ 4,613,302	$ 4,530,448
General and administrative	532,801	643,358	1,707,514	2,139,392
Total operating expenses	1,787,875	2,107,535	6,320,816	6,669,840
LOSS FROM OPERATIONS	(1,787,875)	(2,107,535)	(6,320,816)	(6,669,840)
OTHER INCOME (EXPENSE)				
Interest expense	(4,789)	(495)	(6,050)	(77,471)
Loss on disposal of property and equipment	—	—	—	(2,026)
Other (expense) income, net	(4,789)	(495)	(6,050)	(79,477)
NET LOSS	$ (1,792,664)	$ (2,108,030)	$ (6,326,866)	$ (6,749,317)
Net loss per common share- basic and diluted	$ (0.16)	$ (0.19)	$ (0.55)	$ (0.63)
Weighted average common shares outstanding- basic and diluted	11,540,926	10,953,052	11,527,069	10,700,405

See accompanying notes to the financial statements

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NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the nine months ended March 31, 2022
(Unaudited)

	Series A Preferred Stock: Par $0.001		Common Stock: Par $0.001				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
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	482,081	$ 482	11,525,203	$ 11,525	$ 145,295,803	$ (116,998,381)	$ 28,309,429
Series A preferred stock issued for employee stock compensation	387	—	—	—	33,367	—	33,367
Common stock issued for consulting and legal services rendered	—	—	5,993	6	26,994	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	1,644	—	1,644
Common shares issued for Directors fees	—	—	3,288	3	14,997	—	15,000
Net loss	—	—	—	—	—	(1,921,134)	(1,921,134)
Balance, December 31, 2021	482,468	$ 482	11,534,484	$ 11,534	$ 145,372,805	$ (118,919,515)	$ 26,465,306
Series A preferred stock issued for employee stock compensation	1,727	2	—	—	39,399	—	39,401
Common stock issued for consulting and legal services rendered	—	—	11,632	12	26,988	—	27,000
Common stock issued for employee compensation	—	—	3,572	3	6,765	—	6,768
Warrants issued to Scientific Advisory Board	—	—	—	—	785	—	785
Common shares issued for Directors fees	—	—	4,788	5	11,245	—	11,250
Net loss	—	—	—	—	—	(1,792,664)	(1,792,664)
Balance, March 31, 2022	484,195	$ 484	11,554,476	$ 11,554	$ 145,457,987	$ (120,712,179)	$ 24,757,846

See accompanying notes to the financial statements

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NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the nine months ended March 31, 2021
(Unaudited)

	Series A Preferred Stock: Par $0.001		Common Stock: Par $0.001				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 2020	368,602	$ 369	9,083,414	$ 9,083	$127,311,634	$(105,563,124)	$ 21,757,962
Series A Preferred Stock issued for employee stock compensation	387	—	—	—	53,098	—	53,098
Common stock issued for consulting and legal services rendered	—	—	5,135	5	26,995	—	27,000
Net proceeds from issuance of common stock in connection with equity financing	—	—	1,575,342	1,576	10,440,640	—	10,442,216
Warrants issued to Scientific Advisory Board	—	—	—	—	1,986	—	1,986
Common shares issued for Directors fees	—	—	2,040	2	11,248	—	11,250
Net loss	—	—	—	—	—	(2,311,233)	(2,311,233)
Balance, September 30, 2020	368,989	$ 369	10,665,931	$10,666	$137,845,601	$(107,874,357)	$ 29,982,279
Series A Preferred Stock issued for employee stock compensation	387	—	—	—	50,602	—	50,602
Common stock issued for consulting and legal services rendered	—	—	7,411	7	26,993	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	1,215	—	1,215
Common shares issued for Directors fees	—	—	4,106	4	14,996	—	15,000
Net loss	—	—	—	—	—	(2,330,054)	(2,330,054)
Balance, December 31, 2020	369,376	$ 369	10,677,448	$10,677	$137,939,407	$(110,204,411)	$ 27,746,042
Net proceeds from issuance of common stock in connection with equity financing	—	—	814,242	815	6,120,666	—	6,121,481
Series A Preferred Stock issued for employee stock compensation	1,727	2	—	—	71,498	—	71,500
Common stock issued for consulting and legal services rendered	—	—	6,131	6	26,994	—	27,000
Common stock issued for employee compensation	—	—	3,572	4	15,034	—	15,038
Warrants issued to Scientific Advisory Board	—	—	—	—	1,750	—	1,750
Common shares issued for Directors fees	—	—	3,300	3	14,997	—	15,000
Net loss	—	—	—	—	—	(2,108,030)	(2,108,030)
Balance, March 31, 2021	371,103	$ 371	11,504,693	$11,505	$144,190,346	$(112,312,441)	$ 31,889,781

See accompanying notes to the financial statements

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Nanoviricides, Inc.
Statements of Cash Flows
(Unaudited)

	For the Nine Months ended	
	March 31, 2022	March 31, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,326,866)	$ (6,749,317)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	105,658	175,200
Preferred shares issued pursuant to license agreement	935,088	—
Common shares issued as compensation and for services	129,018	137,288
Warrants granted to Scientific Advisory Board	3,781	4,951
Depreciation	529,167	522,172
Amortization of loan origination fees	—	18,013
Amortization	6,202	6,202
Loss on disposal of property and equipment	—	2,026
Write-off of deferred financing costs	—	12,190
Changes in operating assets and liabilities:		
Prepaid expenses	204,118	180,988
Other assets	(45,702)	10,158
Accounts payable	(77,029)	(282,492)
Accounts payable - related party	42,048	21,495
Accrued expenses	967	(45,012)
NET CASH USED IN OPERATING ACTIVITIES	(4,493,550)	(5,986,138)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(248,986)	(154,122)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants	—	16,563,697
Payment of note payable - related party	—	(1,100,000)
Deferred financing costs	(37,408)	—
Payment of loan payable	(164,599)	(132,513)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(202,007)	15,331,184
NET CHANGE IN CASH AND CASH EQUIVALENTS	(4,944,543)	9,190,924
Cash and cash equivalents at beginning of period	20,516,677	13,708,594
Cash and cash equivalents at end of period	$15,572,134	$22,899,518
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	$ 3,488	$ 3,171
Non-Cash Financing and Investing Activities:		
Directors and Officers Insurance financed through loan	$ 234,198	$ 235,476

See accompanying notes to the financial statements

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NANOVIRICIDES, INC.
March 31, 2022 AND 2021
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 the Company develops, as well as for production scale-up, and c-GMP-like production in quantities needed for human clinical trials, where the Company's design, development, and production work is performed. The biological studies such as the effectiveness, safety, bio-distribution and Pharmacokinetics/Pharmacodynamics on the Company's 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 the Company's lead drug program due to the necessity of responding to the pandemic. 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's drug candidates for COVID-19 successfully entered core safety pharmacology studies required prior to any human clinical trials around October/November, 2020. The studies were completed in January and February 2021, and the Company had received, at that time, draft reports from the external Contract Research Organization (CRO). The final quality audited reports on these studies have been signed and released to the Company. These cGLP core safety pharmacology reports are required for an Investigational New Drug (IND) Application. The Company is currently working on a pre-IND application to the US Food and Drug Administration (FDA) to seek guidance for an IND. The Company is also involved with tasks needed for setting up and executing human clinical trials for the Company's COVID-19 drug candidates, including selection of a Clinical Trial Contract Research Organization. In addition to the FDA, the Company is also seeking to obtain regulatory approvals from other international bodies in order to perform the clinical trials in countries other than the USA. 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. There are 15 COVID-19 drugs that have received Emergency Use Authorization (EUA) and one drug that has received full approval (remdesivir) from the FDA (https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap#dashboard). In addition, there are at least three vaccines licensed in the USA and several more are in use internationally. Apart from remdesivir and antibodies, there are very few drugs with direct antiviral effect that have EUA or are in clinical trials. Internationally, virus variants have continued to emerge with resistance to drugs and vaccines. Scientists believe it is only a matter of time before resistant 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. 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.

The Company plans on re-engaging its 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 management pivoted its 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.

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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 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 March 31, 2022 of approximately $121 million and a net loss of approximately $6.3 million and net cash used in operating activities of approximately $4.5 million for the nine 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 March 31, 2022, the Company had available cash and cash equivalents of approximately $15.6 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 Market Issuance Sales Agreement (an "ATM") with B. Riley Securities, Inc. and Kingswood Capital Markets, pursuant to which the Company may offer and sell, from time to time, shares of common stock, having an aggregate offering price of up to $50 million. On March 2, 2021 the Company sold 814,242 shares of common stock at an average price of $7.83 under the Sales Agreement with B. Riley Securities, Inc. The net proceeds to the Company from the offering was approximately $6.1 million after deducting underwriting discounts and commissions and other offering expenses.

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 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 emergence of widespread health emergencies due to COVID-19 have led to regional quarantines, shutdowns, shortages, disruptions of supply chains, and economic instability. The impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted at this time. Though the Company has not experienced a direct financial impact, if the financial markets and/or the overall economy are impacted for an extended period, the Company's ability to raise funds, in the future, may be materially adversely affected.

Management believes that the Company's existing resources will be sufficient to fund the Company's planned operations and expenditures through May 15, 2023. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company will need to raise additional capital to fund its long-term operations and research and development plans including human clinical trials for its various drug candidates until it generates revenue which reaches a level sufficient to provide self-sustaining cash flows. The accompanying financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

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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, 2021 filed with the SEC on October 12, 2021.

For a summary of significant accounting policies, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2021 filed on October 12, 2021.

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:

	Potentially Outstanding Dilutive Common Shares	
	For the Nine Months Ended March 31, 2022	For the Nine Months Ended March 31, 2021
Options	—	5,000
Warrants	9,146	9,146
Total potentially outstanding dilutive common shares	9,146	14,146

The Company has 484,195 shares of Series A preferred stock outstanding as of March 31, 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 March 31, 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 1,694,683, and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

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Note 4 - Related Party Transactions

Related Parties

Related parties with whom the Company had transactions are:

Related Parties	Relationship
Dr. Anil R. Diwan	Chairman, President, CEO, significant stockholder and Director
TheraCour Pharma, Inc. ("TheraCour")	An entity owned and controlled by Dr. Anil R. Diwan

	For the three months ended		For the nine months ended	
	March 31, 2022	March 31, 2021	March 31, 2022	March 31, 2021
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	$ 39,324	$ 84,466	$ 120,041	$ 87,026

	As of	
	March 31, 2022	June 30, 2021
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 March 31, 2022 and June 30, 2021 was $564,587 and $522,539, respectively, which include $200,000 of deferred accounts payable due to TheraCour which is scheduled to be paid in May, 2022 and which was further offset by a two month advance (see above) of $491,000.	$ 73,587	$ 31,539

	For the three months ended		For the nine months ended	
	March 31, 2022	March 31, 2021	March 31, 2022	March 31, 2021
Research and Development Costs Paid to Related Party				
Development fees and other costs charged by and paid to TheraCour pursuant to the license agreements between TheraCour and the Company for the	$ 587,239	$ 706,537	$ 1,754,143	$ 1,961,603

development of the Company's drug pipeline. No royalties are due TheraCour from the Company at March 31, 2022 and June 30, 2021

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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 $0 and $935,088 for the three and nine months ended March 31, 2022, respectively.

Mortgage Note Payable - Related Party

On December 16, 2019, the Company entered into an Open End Mortgage Note (the "Note") with Dr. Anil Diwan, the Company's founder, Chairman, President and CEO, to loan the Company up to $2,000,000 in two tranches of $1,000,000 (the "Loan"). The Note was paid off on December 31, 2020. The Note bore interest at the rate of 12% per annum and was secured by a mortgage granted against the Company's headquarters. Dr. Anil Diwan received 10,000 shares of the Company's Series A preferred stock as a loan origination fee which was amortized over the one year term of the loan using the effective interest method. The fair value of the 10,000 shares of the Company's Series A preferred stock when issued on December 16, 2019 was $39,301. The Series A preferred stock fair value is based on the converted value of the Series A preferred stock to common at a ratio of 1:3.5. Amortization expense on the loan origination fee for the three and nine months ended March 31, 2021 was $0 and $18,013 respectively. The Company had drawn down $1.1 million of this loan. Interest was payable only on the amount drawn down. The lender had escrowed $132,000 of interest payable pursuant to the Loan. For the three and nine months ended March 31, 2021, the Company incurred interest expense of $0 and $62,773, respectively.

Note 5 - Property and Equipment

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

	March 31, 2022	June 30, 2021
GMP Facility	$ 8,149,416	$ 8,020,471
Land	260,000	260,000
Office Equipment	57,781	57,781
Furniture and Fixtures	5,607	5,607
Lab Equipment	6,109,848	5,989,807
Total Property and Equipment	14,582,652	14,333,666
Less Accumulated Depreciation	(5,777,932)	(5,248,765)
Property and Equipment, Net	$ 8,804,720	$ 9,084,901

Depreciation expense for the three months ended March 31, 2022 and 2021 was $179,492 and $174,076, respectively, and for the nine months ended March 31, 2022 and 2021 were $529,167 and $522,172, respectively.

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Note 6 - Trademark and Patents

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

	December 31, 2021	June 30, 2021
Trademarks and Patents	$ 458,954	$ 458,954
Less Accumulated Amortization	(115,038)	(108,836)
Trademarks and Patents, Net	$ 343,916	$ 350,118

Amortization expense amounted to approximately $2,067 and $2,067 for the three months ended March 31, 2022 and 2021, respectively, and for the nine months ended March 31, 2022 and 2021 were approximately $6,202 and $6,202, respectively.

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 was $234,198, and $235,476, respectively, payable at the rate of $23,932 and $24,062 monthly including interest at an annual rate of 4.74% and 5% respectively, through October of each year. At March 31, 2022 and June 30, 2021, the loan balance was $164,905, and $95,306, respectively. For the three and nine months ended March 31, 2022, the Company incurred interest expense of $2,502 and $3,445, respectively. For the three and nine months ended March 31, 2021, the Company incurred interest expense of $2,516 and $3,282, respectively.

Note 8 - Equity Transactions

On September 9, 2021, the Company entered into a COVID-19 License Agreement to use, promote, offer for sale, import, export, sell and distribute drugs that treat Covid-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. Pursuant to such license agreement, the Board of Directors authorized the issuance of 100,000 fully vested shares of the Company's Series A preferred stock as a license milestone payment and recorded an expense of $0 and $935,088 for the three and nine months ended March 31, 2022.

On September 14, 2021, the Board of Directors and Dr. Anil Diwan, President and Chairman of the Board agreed to the extension of Dr. Diwan's employment agreement for a period of one year from July 1, 2021 through June 30, 2022 under the same general terms and conditions. The Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares shall be vested in quarterly installments of 2,551 shares on September 30, 2021, December 31, 2021, March 31, 2022 and June 30, 2022 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $27,246 and $81,738 for the three and nine months ended March 31, 2022, respectively. The balance of $27,244 will be recognized as the remaining 2,551 shares vest and service is rendered for the year ended June 30, 2022.

For the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 1,727 and 2,501, respectively of fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of $12,155 and $23,920, respectively for the three and nine months ended March 31, 2022 related to these issuances.

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

Date	Shares	Value
07/31/2021	10,333	$ 111,012
08/31/2021	129	1,718
09/30/2021	100,129	936,984
10/31/2021	129	2,166
11/30/2021	129	1,895
12/31/2021	129	2,060
01/31/2022	129	1,336
02/28/2022	129	1,008
03/01/2022	1,340	8,888
03/31/2022	129	923
	112,705	$ 1,067,990

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:

a. The common stock price for the nine months ended March 31, 2022 was in the range $1.67 to $7.86. 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.

b. 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.

c. 32.2% discount for lack of marketability (based upon a call put analysis): 144.7% to 149.1% historical volatility, 0.57% to 0.51% risk free rate applied to the converted common stock.

During the nine months ended March 31, 2022, the Scientific Advisory Board was granted in August 2021 fully vested warrants to purchase 572 shares of common stock with an exercise price of $4.65 per share expiring in August 2025, in November 2021 fully vested warrants to purchase 572 shares of common stock with an exercise price of $5.92 per share expiring in November 2025, and in February 2022 fully vested warrants to purchase 572 shares of common stock with an exercise price of $2.69 per share expiring in February 2026. The fair value of the warrants was $785 for the three months ended March 31, 2022 and $3,781 for the nine months ended March 31, 2022 and was recorded as consulting expense.

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	86.0-91.4 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	0.615-1.870 %

For the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 11,632 and 24,134, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of $27,000 and $81,000, respectively, for the three and nine months ended March 31, 2022, which is reflective of the fair value on the dates of issuance.

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For the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 4,788 and 11,600, respectively, fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of $11,250 and $41,250 for the three and nine months ended March 31, 2022, which is reflective of the fair value on the dates of issuance.

For both the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 3,572 of fully vested shares of its common stock for employee compensation. The Company recorded an expense of $6,768 for both the three and nine months ended March 31, 2022 which was the fair value on the date of issuance.

Note 9 - Stock Warrants and Options

Stock Warrants

Stock Warrants	Number of Shares	Weighted Average Exercise Price per share ($)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($)
Outstanding and exercisable at June 30, 2021	9,146	$ 10.80	2.00	$ 1,943
Granted	1,716	4.42	3.63	—
Expired	(1,716)	25.93	—	—
Outstanding and exercisable at March 31, 2022	9,146	$ 6.77	1.93	$ —

Of the above warrants 572 expire in fiscal year ending June 30, 2022, 2,286 expire in fiscal year ending June 30, 2023, 2,286 warrants expire in the fiscal year ending June 30, 2024, 2,286 warrants expire in the fiscal year ending June 30, 2025, and 1,716 warrants expire in the fiscal year ending June 30, 2026.

Stock Options

Stock Options	Number of Shares	Weighted Average Exercise Price per share ($)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($)
Outstanding and exercisable at June 30, 2021	5,000	$ 10.00	.16	$ —
Granted	—	—	—	—
Expired	5,000	10.00	—	—
Outstanding and exercisable at March 31, 2022	—	—	—	—

The options expired on August 31, 2021.

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.

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Employment Agreements

The Company and Dr. Diwan, President and Chairman of the Board of Directors, entered into an extension of employment agreement effective July 1, 2018 for a term of three years. Dr. Diwan's will be paid an annual base salary of $400,000. Additionally, Dr. Diwan was awarded a grant of 26,250 shares of the Company's Series A preferred stock. 8,750 shares vested equally on June 30, 2019, 2020 and 2021. On September 14, 2021, the Board of Directors and Dr. Anil Diwan, agreed to the extension of Dr. Diwan's employment agreement for a period of one year from July 1, 2021 through June 30, 2022 under the same general terms and conditions. On September 14, 2021 the Company granted Dr. Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares will be deemed vested in quarterly installments following the grant date and fully vested on June 30, 2022.

On March 3, 2010, the Company entered into an employment agreement with Dr. Jayant Tatake to serve as Vice President of Research and Development. The employment agreement provides for a term of four years with a base salary of $150,000. In addition, the Company issued 1,340 shares of Series A preferred stock and 1,786 shares of common stock upon entering into the agreement, and will issue an additional 1,340 shares of Series A preferred stock and 1,786 shares of common stock on each anniversary date of the agreement. The shares of Series A preferred stock were issued in recognition of Dr. Tatake's work towards the achievement of several patents by the Company. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

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

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

License Agreements

The Company is dependent upon its license agreements with TheraCour (See Notes 1 and 4). If the Company lost the right to utilize any of the proprietary information that is the subject of the TheraCour license agreement on which it depends, the Company will incur substantial delays and costs in development of its drug candidates. On November 1, 2019, the Company entered into a 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, 2021. 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 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 are currently working on taking these two COVID-19 lead drug candidates into human clinical trials. We believe that the essential preclinical work including GLP Safety/Toxicology studies is substantially complete for taking these drugs into human evaluation. We are working on required regulatory submissions for initiating human clinical trials of our COVID-19 drug candidates at present. We have begun cGMP-compliant manufacturing operations for the production of a large batch of the drug substance and the drug products NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies to be used in human clinical trials for COVID-19. Clinical trial protocol for evaluation of safety and preliminary evaluation of efficacy upon oral administration of NV-CoV-2 has been defined and agreed with certain consultants already. We are now in the final stages of preparing the documents for submission of a clinical trial application.

We have also begun an enteric adenovirus program in response to the recent build-up of severe hepatitis cases in children. Several cases of severe hepatitis of unknown cause in children requiring hospitalizations, with 14% of cases requiring liver transplants, and up to 5% fatalities have occurred across the world, with more than 100 cases in the USA alone. This new disease is thought to be caused by an enteric version of Adenovirus, possibly Adenovirus 41 (hAdV-F41) , although there is no consensus on this yet (https://www.cnn.com/2022/05/06/health/hepatitis-kids-cdc-update/index.html). We have begun the process of developing an antiviral assay for screening of active nanoviricides drugs against this virus. After the antiviral assay is developed, we plan on screening our existing nanoviricides drugs first to determine if there are any viable drug candidates that can attack this adenovirus. Previously, we have developed drug candidates that were highly active against adenoviral epidemic keratoconjunctivitis (EKC), with excellent results in animal studies. EKC is caused by group B human adenoviruses, whereas hAdV-F41 is a group F virus with different structure as well as tissue tropism. Adenoviruses are non-enveloped viruses. We believe we were successful in developing nanoviricides with high activity against the EKC-causing adenovirus possibly because the fibers of the virus that carry attachment site may get uprooted upon a nanoviricide attack, and possibly the nanoviricide lipid interior may be able to "coat" the hydrophobic portions of the surface proteins that make up the virus particle. There are no approved drugs for adenoviral EKC, adenoviral enteric infections or adenoviral hepatitis at present.

After developing viable drug candidates against COVID-19 in 2020, we focused substantially on the COVID-19 drug development, which, we believe, is about to enter the human clinical development phase. We plan on undertaking further clinical advancement of our other lead drug candidate, NV-HHV-101 skin cream for the treatment of shingles, after the COVID-19 program completes initial human clinical studies. The essential preclinical work including GLP Safety/Toxicology studies of NV-HHV-101 was 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 we plan to advance further towards clinical drug candidates as we progress further. Thus, we have a strong and broad pipeline that is expected to continue to result in highly effective drug candidates against a number of viral diseases.

NanoViricides is one of a few biopharma companies that has its own cGMP-compliant manufacturing facility. We intend to produce our drug substances, and in many cases, our drug products as well, for clinical trials in this facility. We have the capability to produce sufficient drugs for about 1,000 patients in a single batch of production, depending upon dosage. This production capacity is anticipated to be sufficient for first-in-human use 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-101 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 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.

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This broad-spectrum capability is highly sought after as the effectiveness of vaccines as well as antibody drugs is waning with each evolution of new virus variants. The US FDA has revoked the emergency use authorization (EUA) of two different antibody drug cocktails that received EUA early on because of loss of effectiveness against the current Omicron variants and sub-variants.

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, 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.

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.

Our COVID-19 drug candidates successfully entered core safety pharmacology studies required prior to commissioning human clinical trials around October/November, 2019. These studies have been successfully completed and we have received the GLP Safety/Toxicology reports from the external CRO in August 2021. We have completed development of clinical trial protocols for safety and preliminary efficacy evaluation of NV-CoV-2 upon oral administration. We are working on further activities that would be necessary for filing of an IND with the U.S. Food and Drug Administration (“FDA”) or equivalent regulatory filings for entering into human clinical trials in other countries.

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Since completing the IND-enabling safety/toxicology studies,we have 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 believe 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.

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. Of the available antivirals, only Remdesivir has shown significantly high activity in severe disease. However, it suffers from rapid bodily metabolism and toxicity, as well as the fact that it requires daily infusions. Molnuprivir (Merck, Ridgeback), an oral drug, has received emergency use approval (EUA) by the US FDA but the Indian Council for Medical Research (ICMR) has advised against its use in their protocol for treatment of SARS-CoV-2 patients, citing its mutagenicity, toxicity, potential carcinogenicity, potential teratogenicity, and a poor risk-benefit profile. Paxlovid(R) (Pfizer) has received an EUA from the US FDA but is not yet widely available. It is a combination of two drugs, nirmatrelvir, a SARS-CoV-2 main protease inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. It has several drug-drug-interaction limitations on its use. It shortcomings are now becoming apparent. For example, it appears to be acting as a virostatic, not able to cure the disease in many patients. Thus, patients after completing Paxlovid course of treatment are experiencing rebound of the coronavirus infection, which is being investigated at present. EUAs for two monoclonal antibody cocktails (one from Regeneron and one from Eli Lilly) were revoked recently by the US FDA because of poor efficacy against Omicron variant and sub-variant. Another monoclonal antibody, Sotrovimab (GSK/Vir) has an active EUA at present but is in short supply. Molnupiravir, Paxlovid as well as Sotrovimab are approved only for the treatment patients with high risk of severe disease, while they are presenting with mild-to-moderate COVID-19. None of these antivirals are approved for use in hospitalized patients or in patients requiring oxygen therapy, except Remdesivir.

Oral drugs are sought after for the treatment of mild to moderate COVID-19 disease. We have successfully developed oral syrup and oral gummies ("Chewable Gel") formulations of our lead drug candidate NV-CoV-2 against COVID-19 (see below).

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.

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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. Of note, SARS-CoV-1 was shown to have 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 more severely and causing higher risk of fatalities, it is called ADE. The antibodies in the patient may be because of a prior natural infection, vaccination, or therapeutic usage. 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.

In addition to NV-CoV-2, we 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 despite approvals of several additional antivirals as of now.

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.

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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, we have been working diligently on designing, testing, and advancing drug candidates against SARS-CoV-2.

During the nine months ended March 31, 2021, we have been preparing for clinical trials of our COVID-19 drug candidates NV-CoV-2 and NV-CoV-2-R. We have completed improvements in manufacturing of the drug substance for NV-CoV-2. We are in the process of establishing packaging operations at our cGMP-capable facility in Shelton, CT. With these improvements, NanoViricides will be 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). We have completed development of a clinical protocol for safety and preliminary efficacy evaluation of NV-CoV-2 in human clinical trials. We started the process for setting up the scale of manufacturing needed for the clinical trial batch size. We have begun manufacture of cGMP compliant drug products NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies for anticipated human clinical trials.

We are in the process of preparing the dossiers for submission to regulatory agencies and related activities.

On September 15, 2020, we reported in a press release that we have nominated a clinical candidate for COVID-19, with additional back-up candidates that we continue to work on advancing further. We have previously reported that our developmental drug candidates have shown effectiveness against multiple coronaviruses in cell culture studies, and have shown strong effectiveness in animal studies against a human coronavirus that uses the same human receptor (ACE2) as SARS-CoV-2, namely h-CoV-NL63. There are reports that common colds coronavirus infection has led to protection from SARS-CoV-2 infection. This protection is most likely associated with infection by hCoV-NL63, because this is the only common cold virus that uses the same human receptor as SARS-CoV-2. Thus we believe our results are significant as they have demonstrated a broad-spectrum anti-coronavirus effectiveness, and, additionally, strong effectiveness in animal model that indicates that our drug candidates should be effective against SARS-CoV-2. Studies involving SARS-CoV-2 require BSL3/BSL4 facilities. Performing studies in BSL3/4 facilities is inherently slow, and requires dependence on high containment laboratory schedules and access. We, therefore, developed animal models and cell culture studies that can be conducted in BSL2 facilities. This enabled our rapid drug development.

The broad-spectrum anti-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 we develop 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.

On November 11, 2020, we announced that we have engaged Calvert Labs to perform core safety pharmacology studies that are generally required for filing an Investigational New Drug (IND) application with the FDA prior to being able to begin human clinical studies.

On or about February 8, 2021, we reported in a press release that our broad-spectrum anti-coronavirus drug candidate for the treatment of COVID-19 infections was found to be well tolerated in safety pharmacology studies required for progressing to human clinical trials.

We reported that our anti-coronavirus drug candidate NV-CoV-2 was found to be safe in the GLP safety pharmacology studies performed by an external contract research organization (CRO) in both rat and non-human primate (NHP) models. Additionally, multiple injections of NV-CoV-2 were also well tolerated in an extensive non-GLP study in rats that was performed by AR Biosystems, Inc., Florida.

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On March 2, 2021, we reported in a press release that both of our anti-coronavirus drug candidates, namely, NV-CoV-2 and NV-CoV-2-R, were found to be highly effective in comparison to remdesivir against two distinctly different coronaviruses in our new cell culture studies. Remdesivir is one of the most effective drugs in cell culture studies against coronaviruses. Therefore our finding that NV-CoV-2 was highly effective and comparable to remdesivir in activity in these cell culture studies was pleasantly surprising. Even more striking was the finding that NV-CoV-2-R exceeded the effectiveness of remdesivir itself in these cell culture studies. These results indicate that NV-CoV-2 and NV-CoV-2-R could be some of the strongest weapons in the fight against coronaviruses and the current COVID-19 global pandemic.

On March 9, 2021, we reported in a press release that our pan-coronavirus COVID-19 drug candidates NV-CoV-2 and NV-CoV-2-R were found to be highly effective in pre-clinical antiviral animal studies, consistent with their previously reported effectiveness in cell culture studies against infection by human coronaviruses.

On September 22, 2021, we reported in a press release that remdesivir was indeed being protected from metabolism improving upon both its safety and effective drug level in the form of NV-CoV-2-R, i.e. due to encapsulation in NV-CoV-2.

On October 11, 2021 we reported in a press release that our pan-coronavirus COVID-19 drug candidate NV-CoV-2 was effective against SARS-CoV-2 in a pseudovirion cell culture study.

On November 15, 2021 we reported in a press release additional safety data on NV-CoV-2. In particular, NV-CoV-2 has been found to be an extremely safe, non-mutagenic, non-allergenic, and non-immunogenic drug in relevant animal models and in vitro studies.

NV-CoV-2 and NV-CoV-2-R Drug Formulations for Oral, Injectable, Infusion, and Direct Lung Inhalation Reported on November 15, 2021

We have developed formulations of both NV-CoV-2 and NV-CoV-2-R to meet the needs of different levels of disease severity and different types of patients.

On November 15, 2021 we reported in the same press release that we have successfully developed oral syrup and oral gummies ("chewable gel") formulations of NV-CoV-2. The oral gummies formulation may have advantages in terms of drug bioavailability over oral pills, because of partial sublingual absorption that avoids the gastrointestinal tract. We believe that both the oral gummies and oral syrup formulations would be very attractive to patients, especially children, and older patients, over oral pills. These formulations would be for the benefit of symptomatic non-hospitalized patients. Additionally, the simplicity of administration is expected to enable their prophylactic use as well.

We also reported that we have previously developed an injectable formulation of NV-CoV-2 that we believe may not require infusion, allowing treatment of severe cases without hospitalization. This is an important unmet need for reducing strain on hospital systems during waves of the global COVID-19 pandemic.

Previously, we have developed formulations for infusion for both NV-CoV-2 and NV-CoV-2-R, to treat severely ill hospitalized patients.

We have also very recently developed formulations of both NV-CoV-2 and NV-CoV-2-R for direct inhalation into lungs using a simple nebulizer. This inhalation formulation is developed to benefit very severely ill patients with significant lung pathology. Direct inhalation of the drug would result in highest possible levels of the drug to be achieved in lungs thereby maximizing antiviral effect, and minimizing lung viral load. This is expected to help minimize lung damage, enabling the patient to recover rapidly.

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.

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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 second year.

Additional details of the studies referenced above are cited below:

Pre-clinical GLP Safety Pharmacology Studies Reported on February 8, 2021

In a GLP neuro-pulmonary safety pharmacology study in rats, the following conclusion was drawn: The intravenous administration of NV-CoV-2 at doses of 25, 50 and 100 mg/kg did not affect respiratory function in rats.

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

These results were consistent with a more extensive, multiple injection non-GLP safety and tolerability study in Sprague-Dawley male and female rats. In this non-GLP study, NV-CoV-2 was injected intravenously (via tail vein) on each of days 0, 1, 2, 3, 4, and 5. Two different doses were used: 320mg/kg BW per injection, and 160 mg/kg BW per injection. Clinical observations, body weight, urine, blood chemistry, post-mortem findings, and organ histology were studied. In all parameters, NV-CoV-2 was well tolerated at both dosages throughout the study.

Pre-clinical Cell Culture Efficacy Study Reported on March 2, 2021

The Company studied the effectiveness of NV-CoV-2, NV-CoV-2-R and remdesivir against two unrelated human coronaviruses: h-CoV-229E (229E), and h-CoV-NL63 (NL63). Of these NL63 uses the same ACE2 human cell receptor to gain entry into cells as do all variants of SARS-CoV-2 and SARS-CoV-1. Additionally, human pathology of NL63 infection closely mimics that of SARS-CoV-2, albeit with limited disease severity. NL-63 is being used as a model for anti-SARS-CoV-2 drug development in various labs including ours (reviewed in: A. Chakraborty and A. Diwan (2020). “NL63: A Better Surrogate Virus for studying SARS- CoV-2”. Integer Mol Med, 2020, vol.7, pp 1-9, doi: 10.15761/IMM.1000408.). In contrast, 229E uses the cell surface receptor APN for entry rather than ACE2, and causes common colds. Thus, NL63 and 229E are unrelated human coronaviruses.

Pre-clinical Efficacy Study in Lethally Infected Animals Reported on March 9, 2021

We developed a BSL2 lethal coronavirus lung infection rat model that mimics the lung pathology of COVDI-19 in humans. We used human coronavirus NL63 (h-CoV-NL63 or simply NL63) as a surrogate for SARS-CoV-2 in this model. NL63 is known to cause severe lower respiratory tract infections in young children leading to hospitalization. The symptoms are generally less severe than SARS-CoV-2 but are similar. In most cases, hCoV-NL63 causes relatively mild disease, often associated with croup, bronchiolitis, and lower respiratory tract disease in children, and is considered to cause some of the common colds in adults. Thus, the clinical manifestation of hCoV-NL63 infection in pediatric patients is similar to that of SARS-CoV-2, although much less severe. SARS-CoV-2 causes clinically similar milder forms of disease in most patients, but moderate to severe disease requiring hospitalizations in about 15-20% of infected persons. These similarities imply that hCoV-NL63 should be a reasonable model virus for antiviral cell culture and animal studies in BSL2 environment in the course of antiviral drug development for SARS-CoV-2.

NV-CoV-2 and NV-CoV-2-R were found to be highly effective against a fully lethal direct-lung coronavirus infection in rats based on multiple indicators:

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

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

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

Since the press release was issued, additional studies on histopathology of organs and blood chemistry from this experiment have been completed and there were no adverse findings.

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

We studied the effectiveness of these drugs against the human coronaviruses h-CoV-NL63 (NL63) that uses the same ACE2 human cellular protein as receptor to gain entry into cells as do all variants of SARS-CoV-2 and SARS-CoV-1. Additionally, the human pathology of NL63 infection closely mimics that of SARS-CoV-2, albeit with limited disease severity. NL63 is a circulating human coronavirus that can be used in BSL2 labs. NL-63 is therefore being used as a model for anti-SARS-CoV-2 drug development in various labs including ours.

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

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

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

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

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

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Significant Improvement in the Safety and Metabolism of Remdesivir Due to Encapsulation In NV-CoV-2 Reported on September 22, 2021

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

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

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

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

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

NV-CoV-2 was Effective against SARS-CoV-2, Reported on October 11, 2021

NV-CoV-2 was found to be effective against SARS-CoV-2 in a standard cell culture pseudovirion assay, demonstrating that the drug indeed has broad-spectrum pan-coronavirus activity. With these results, we have now demonstrated that NV-CoV-2 is highly effective in cell cultures against SARS-CoV-2, human coronavirus NL-63, and human coronavirus 229E, all very different human coronaviruses. This pan-coronavirus activity implies that the drug NV-CoV-2 should remain active in spite of evolution of variants of SARS-CoV-2 in the field, a highly sought-after characteristic to combat the current global pandemic.

A strong SARS-CoV-2 infection inhibition activity of NV-CoV-2 was observed in this pseudovirion study. Pseudovirion assay is a standard method for evaluating virus entry-inhibitors in BSL2 laboratories and is primarily used for viruses that would otherwise require high security BSL3 or BSL4 laboratories. In this study, SARS-CoV-2-pseudovirion virus particles were made that carry a green fluorescent protein (GFP)

producer mRNA inside, and use the SARS-CoV-2 S1 protein on their surface to bind to ACE2 receptor protein on cells. They were incubated with NV-CoV-2 (test article), or a known neutralizing antibody (positive control), or just the vehicle buffer (negative control). Then these solutions were separately used to infect ACE2 positive cells and the cultures were incubated. Only the infected cells produced GFP and were visualized by green fluorescence in microscopy.

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In this well-known assay, NV-CoV-2 was as effective as the neutralizing antibody in reducing the virus infection.

Additionally, the pseudovirion study also demonstrated that NV-CoV-2 neutralizes the virus particles themselves, outside of the cells, validating our design mechanism.

NV-CoV-2 Additional Safety Data, Reported on November 15, 2021

NV-CoV-2 has been found to be an Extremely Safe and Non-mutagenic Drug, as described below:

We reported in a press release on November 15, 2021 that NV-CoV-2 has been found to be 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. It 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.

We also reported that NV-CoV-2 has been found to be non-mutagenic in a standard GLP Ames Test. This is important as molnupiravir, a heavily touted drug against COVID-19, is known to be mutagenic. Concerns have been raised about molnupiravir's potential for generating more pathogenic variants of SARS-CoV-2 as well as for long term effect on the patient taking it.

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.

The non-immunogenicity, non-allergenicity, and lack of hypersensitivity or adverse reactions at injection site seen in animal models with single and repeated injections leads us to postulate that it may be possible to give a therapeutic dose of NV-CoV-2 in humans via a simple slow-push injection rather than an infusion. If this proves out in clinical trials, it would enable treating moderate cases without hospitalizing the patients. This is an important unmet need that would help significantly reduce the severe and intense load on hospitals and health-care workers that occurs during the waves of the global COVID-19 pandemic.

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.

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.

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We have received final audited reports on most of the GLP studies already. We are now in the process of preparing submission documents for regulatory submissions. Additionally, we are actively seeking opportunities to engage appropriate sites for human clinical trials, both in the USA and abroad.

Clinical Trial Drug Substance and Drug Product Manufacture

We have initiated production of a large batch of the drug substances for NV-CoV-2 and of NV-CoV-2-R under cGMP-compliant conditions for human clinical trials. NanoViricides is one of a few biopharma companies with the strong advantage that it has its own cGMP-capable manufacturing facility. This has made possible rapid translation from synthesis for non-clinical studies to large scale clinical batch production in a very short timeframe. Our cGMP-capable facility is capable of producing approximately 4kg of the COVID-19 drug candidate per batch. We anticipate that this would be sufficient for human clinical trials, and possibly for initial introduction under Compassionate Use, Emergency Use Authorization or similar regulatory approval.

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.

Clinical Trial Preparation

The COVID-19 human clinical trials landscape in the USA became heavily crowded because of the guidelines that enabled any drug that had previously gone through Phase I to be repurposed for COVID-19 clinical trial, with a justifiable rationale, not necessitating antiviral drug development. Large pharma companies were not impacted in their capabilities of developing and taking antivirals against COVID-19 into clinical trials, but smaller companies, such as ours that are developing novel antivirals have been severely affected. Further, given the high rate of vaccination in the USA, and due to the very large number of clinical trials already under way, it is likely to be very difficult to engage into clinical trials for our novel coronavirus drug candidates in the United States. There appears to be several months of lead time before Phase 1 clinical trials of a novel drug can be initiated, because of the capacity saturation and hoarding effects in the clinical trials marketplace. As of December 31, 2021, the US FDA CTAP Dashboard snapshot lists 670+ drug development programs in planning stages, 470+ clinical trials including INDs reviewed by the FDA (https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap#dashboard). With this workload, the timelines for review are expected to be extended. We are therefore working on non-USA clinical trial services.

We are therefore looking at sites outside USA, even as we continue our efforts for engaging sites within the USA. All of these factors have introduced significant uncertainties in the timeline for the execution of our COVID-19 clinical trials program as a risk factor.

As stated earlier, 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 believe we are now close to completing the clinical trial plan, clinical trial application documents, as well as most of the agreements. We will be able to announce the resulting collaborations once the formal steps are completed.

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

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COVID-19 Competitive Landscape

Because of the "Operation Warp Speed" program in the USA, and other international programs that accelerated vaccine developments in both private sector and public-private partnerships, several vaccines against the original strain of the SARS-CoV-2 have become available. Significant speed-up in regulatory agencies, and experts teaming together to solve problems rapidly, as well as very high levels of funding enabled these developments.

However, it is now well recognized that antiviral drug development, especially novel pan-coronavirus or broad-spectrum drugs development was neither supported nor accelerated at various levels, both in the USA as well as internationally. Instead, fast-tracking was enabled for re-purposing of existing drugs and moving them into clinical trials against SARS-CoV-2. This has led to failures of several such programs, as well as an explosion in the number of drug development efforts and the number of clinical trials. Fast tracking was also enabled for antibody drugs, which are known to be highly specific and known to fail when variants emerge.

There are 15 COVID-19 drugs that have received Emergency Use Authorization (EUA) of which only one drug that has received full approval (Remdesivir) from the FDA (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs). In addition, there are at least three vaccines licensed in the USA and several more are in use internationally. Apart from Remdesivir and antibodies, there are only 2 drugs with direct antiviral effect that have received an EUA, namely, oral nucleoside analog Molnupiravir (Merck/Ridgeback), and Oral protease inhibitor, Paxlovid™ (Pfizer).

Molnuprivir (Merck, Ridgeback) completed a clinical trial for oral use in SARS-CoV-2-infected patients with mild symptoms. The clinical data showed only about 48% reduction in hospitalization in spite of therapy being started very early. Unfortunately, molnupiravir has significant mutagenic properties. The possibility of additional potentially dangerous variants arising upon its use has been raised by renowned scientists. In addition, the possibility of long term harm to the person using molnupiravir due to its mutagenic nature has also been raised. Earlier, molnupiravir was found to be not effective in hospitalized patients, a setting in which previously Remdesivir (Gilead) was shown to reduce hospitalization stay and disease impact on the patient. The clinical cumulative dosage course of molnupiravir is 8g indicated for mild disease, whereas that of Remdesivir is 1.1g indicated for hospitalized patients with moderate to severe disease. Remdesivir is given as an infusion, limiting its use to hospitalized patients. The Indian Council of Medical Research (ICMR) national task force focused on COVID-19 will opt to not recommend the antiviral drug molnupiravir in their clinical management protocol for COVID-19 despite the approval of molnupiravir by India's drug regulatory body—the Drugs Controller General of India (DCGI), citing that it does not have much benefit in the treatment of coronavirus infection and that there were major safety concerns. (https://rupreparing.com/news/2022/1/14/india-icmr-rejects-mercks-molnupiravir-as-antiviral-for-covid-19not-effective-amp-material-safety-concerns ; see also https://trialsitenews.com/top-research-chief-for-india-mercks-molnupiravir-has-major-safety-concerns/).

Pfizer's oral drug, Paxlovid™ (PF-07321332 a/k/a nirmatrelvir in combination with ritonavir) has received an EUA from the US FDA in December, 2021. Comparing the clinical trials press releases issued by Pfizer for Paxlovid and by Merck for Molnupiravir, we find that Paxlovid showed clinical effect superior to molnupiravir (about 89% reduction in hospitalization for paxlovid as opposed to 48% for molnupiravir) in similar patient pools (recently infected patients with symptoms and having at least one health issue that would indicate significant risk of severe disease.

Neither Molnupiravir nor Paxlovid oral drugs were approved for patients with advanced disease. Their worldwide acceptance demonstrates the unmet need for effective therapeutics against SARS-CoV-2. Moreover, generation of virus mutants that escape the drug is known to occur in the case of both of these classical types of drugs that target specific proteins at specific locations. We believe that there is a much

lower probability of generation of escape mutants against NV-CoV-2 (as compared to the classical types of drugs) (1) because it is designed to create a multi-point attack on the virus thereby completely disrupting the virus structure, and (2) because of the observed broad-spectrum activity of NV-COV-2 against multiple types of distinctly different coronaviruses including SARS-CoV-2.

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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$^{(R)}$ 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.

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

Previously, on March 2, 2021 in an “At-the-Market” Offering, the Company sold 814,242 shares of common stock at an average price of $7.83 under the Sales Agreement with B. Riley Securities, Inc. The net proceeds to the Company from the offering were approximately $6.1 million after deducting underwriting discounts and commissions and other offering expenses.

As of March 31, 2022 we had approximately $15.6 million in cash and cash equivalents and $8.8 million of property and equipment, net of accumulated depreciation. Our current liabilities are approximately $0.4 million. Stockholder’s equity was approximately $24.8 million at March 31, 2022.

During the nine-month period ended March 31, 2022, we used approximately $4.5 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 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 we have sufficient funds in hand for initial human clinical trials for at least one of our drug candidates at this time.

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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.

Thereafter, we intend to focus on NV-HHV-101, and develop this drug through initial human clinical trials. We anticipate that, as the NV-HHV-101 drug (skin cream) for Shingles indication goes into human clinical testing, we would develop clinical candidates for topical 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.

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-101 – The Company's Lead Candidate in the HerpeCide™ Program, with First Indication as a Skin Cream for the Treatment of Shingles Rash

NV-HHV-101 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-101 drug candidate, although final clinical candidates are in pre-clinical optimization stage for both of these indications as of now.

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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-101 would have significant impact in reducing PHN incidence rates. We anticipate extending the NV-HHV-101 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.

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 rapid success of translating the research scale production of several grams drug substance in early CY-2018 to kg-scale cGMP manufacture in early CY-2019 was a result of the tremendous subject matter expertise of the team. External contract manufacturing organizations would likely have required at least three years to scale up these complex products, based on certain discussions we have had.

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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-101 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-101 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.

The anti-VZV drug development program moved rapidly towards clinical candidate declaration stage because of several factors, namely (a) that it was simply the existing HSV-1 drug program in which the existing candidates were re-tested for effectiveness against VZV, (b) that we have had a highly successful collaboration with Dr. Moffat Lab at SUNY Syracuse with rapid turnaround times, and (c) the drug candidates were found to be highly effective against VZV in these studies.

While the Company has been focused on cGMP production, scale-up, and establishment of required characterization and analytical tools, we have brought down our cash expenditure rate significantly by reducing our workforce and by stopping work on all other programs except the HerpeCide program and the Covid–19 program.

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.

Initially, we plan on performing clinical trials based on VZV related biomarkers and clinical pathology, which we believe would be sufficient for a first indication for approval of the drug for treatment of shingles by the FDA. Sales of an effective drug against shingles with this limited indication are projected to reach several hundreds of millions of dollars. We plan on performing observations regarding PHN in these clinical trials so that an informed PHN clinical trial may be performed later to extend the drug indication.

We have developed strong chemical manufacturing process controls that enable us to produce the backbone polymers with highly restricted and reproducible molecular size range. In fact, we have achieved highly reproducible and scalable processes that have yielded the same polymer molecular sizes across production scales from 10g to 500g. In other words, we are now able to control the length of the backbone polymer to within one monomer unit, irrespective of production scale, at least up to about 1 kg scale.

We believe that this is a remarkable and possibly unmatched achievement in the field of nanomedicines. We have scaled up the production of the polymer backbone “nanomicelle” to multiple-kilogram scales, and do not anticipate any manufacturing constraints at present. We have also achieved kilogram-scale manufacture of the ligand in NV-HHV-101, and have further scaled up production of the nanoviricide NV-HHV-101, which is chemical conjugate of the ligand to the nanoviricide, in a well defined manner to kilogram scale. Additionally we have scaled up formulation of the resulting drug substance into the skin cream to multi-kilogram scales. The production of the drug substance and the drug product is achieved in a cGMP compatible fashion at our own facility.

Our polymer backbone itself is designed based on the route of administration. In the case of the shingles drug candidate, as well as for HSV-1 cold sores, and for HSV-2 genital ulcers, the route is dermal topical application.

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The ligands currently in use for the nanoviricide drug candidates against VZV shingles were actually developed using computer models of HSV binding to its cellular receptor, and not against VZV itself. Our program shifted to advance a VZV candidate as our first indication due to various considerations that led to the prioritization of the different drug indications. The Company identified certain advantages that would enable earlier entry into clinical trials for the shingles candidates. The shingles drug development program has been moving rapidly primarily because of the quick turnaround time and high responsiveness of the Dr. Moffat Lab at SUNY Syracuse, our critical collaborator for human skin effectiveness studies of our drug candidates.

One of the advantages of the shingles program is that the pre-clinical drug development is performed directly in a human skin model, bypassing any animal model, providing significant confidence that a human clinical studies outcome would parallel the preclinical study outcome. VZV does not infect animals other than humans.

Thus, we have made significant and substantial progress in the reporting quarter towards the goal of filing our first IND application, and we continue to build on this progress.

In addition to VZV, we are also developing dermal topical drugs against HSV-1 cold sores and HSV-2 genital ulcers. Dr. Brandt's Lab at CORL, the University of Wisconsin, Madison, WI, is validating animal models for the study and evaluation of relative efficacies of different treatments for HSV-1 infection in mice as well as for HSV-2 infection in mice. The goal of these developments is to develop animal models that would be able to discriminate an experimental drug that is more effective than the current standard of care drugs, from the standard of care. At present the existing animal models show maximal effectiveness with the standard of care and therefore cannot discriminate a drug that might be superior. If their animal models are successful in differentiating effectiveness of different drug candidates, then we will be able to evaluate our drug candidates for the treatment of HSV-1 cold sores as well as for the treatment of HSV-2 genital ulcers, in addition to the VZV testing being performed.

Acute Retinal Necrosis is characterized by severe ocular inflammation, retinal necrosis, and a high incidence of retinal detachment (RD) leading to visual loss and blindness. This disease is caused by members of the herpesvirus family, including, herpes simplex virus-2 (HSV-2), varicella zoster virus (VZV), and herpes simplex virus (HSV-1). An estimated 50,000 new and recurrent cases of ocular herpes per year are reported in the United States alone, and in a small proportion of the patients, the disease escalates to v-ARN. We anticipate that ocular herpes or v-ARN may qualify for an orphan disease indication.

We have recently reported that we have extended the contracts with both the Moffat Lab, UMC, SUNY Syracuse, as well as the Brandt Lab, CORL, UW, Madison to continue to perform more advanced studies in preparation of an IND for shingles topical treatment and for v-ARN intravitreal treatment, respectively.

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.

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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). Thereafter we plan on undertaking the development of suitable materials for intravitreous 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.

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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.

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.

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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.

Our nanoviricides in the HerpeCide™ program at present are designed as topical treatment for the breakout of shingles or herpes sores. Our animal studies results are very significant considering that topical acyclovir in the form of a cream as well as an ointment, are approved for the treatment of cold sores. We believe our strong anti-herpes nanoviricide® drug candidates are capable of reaching approval as a drug for topical use against herpes cold sores, based on these datasets. Further drug development is necessary towards the goal of drug approval.

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.

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 Phase1/2 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.

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Management Discussion - Current Drug Development Strategy

During the reported quarter, we have focused on development of a drug against SARS-CoV-2 that causes the COVID-19 spectrum of diseases. 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.

The Company believes that its anti-coronavirus drug program could result in a cure for SARS-CoV-2, based on attacking both viral replication and the viral reinfection cycles. We are developing a next generation nanoviricide in this program that is capable of attacking the virus particle and also is designed to encapsulate and deliver another drug to block the intracellular virus replication.

The Company believes that it's 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.

The Company believes that it will be able to expand its 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). This would lead to a very large number of therapeutic indications beyond the four or five indications we are currently targeting.

The Company thus continues to expand its portfolio of opportunities, while also making progress towards the clinical trials stage.

Previously, in the FluCide™ program, the Company has 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, the Company's 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. The Company intends to reactivate these programs upon appropriate collaborations or funding. The Company has also demonstrated preliminary successes in developing drug candidates against Dengue viruses, and Ebola virus, among others.

The Company intends to re-engage its anti-influenza drug candidates upon sufficient financing or upon achieving grants or collaborations for the same. We are developing Injectable FluCide™ for hospitalized patients with severe influenza as our first, broad-spectrum anti-influenza drug candidate. We have demonstrated the very first effective orally available nanomedicine, namely oral FluCide™ for outpatients with influenza. The development of Oral FluCide is expected to follow behind Injectable FluCide. Development of an anti-Influenza drug candidate has been estimated to be an extremely expensive process with a long drug development timeframe. This is because of the large number of virus types and subtypes that change rapidly within and over seasons. The Company at present does not have the resources to engage into a full-fledged anti-Influenza drug development program. Additionally, Xofluza®, a new drug with a novel mechanism of action (an endonuclease inhibitor) was very recently approved in the USA (Roche/Genentech). While it reduced viral load significantly in clinical trials, it did not have a significant effect on the time course of the clinical pathology of influenza infection in the clinical trials that led to its approval. Xofluza is approved for uncomplicated influenza. Information on its usage and effectiveness in the field in the current influenza seasonal cycle in the USA is not yet available. All of the current influenza drugs, including Xofluza have resulted in mutated influenza viruses that are drug-resistant.

Thus, an effective therapy for patients hospitalized with severe influenza continues to be an unmet need. In addition, a single injection treatment of non-hospitalized patients would be a viable drug if it provides superior benefits to existing therapies.

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Due to our limited resources, we have now assigned lower development priorities to our other drug candidates in our pipeline such as DengueCide™ (a broad spectrum nanoviricide designed to attack all types of dengue viruses and expected to be effective in the Severe Dengue Disease syndromes including Dengue Hemorrhagic Fever (DHS) and Dengue Shock Syndrome (DSS)) and HIVCide™ (a potential "Functional Cure" for HIV/AIDS).

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 than ever 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 and satisfy that said drug product is within our own defined specifications. 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.

At present, we plan on moving operations to our cGMP-capable manufacturing suite as the operational steps are developed to the level needed for moving them into this facility. This requires the development of draft-level Standard Operating Procedures, training, and drill-through of operations. We will also need to establish a Quality Assurance and Quality Control Department. Our current staff is busy developing our pre-clinical HerpeCide programs. Given our limited financing, we have not been able to attract the necessary talent for replacing the lost staff and for building out additional resources for QA/QC. We are working with available staff, training them further in cGMP requirements and operations, as well as in QA/QC. This inherently leads to serialization of efforts, and can lead to extending the timeline. We have been working diligently to meet our goals in the shortest timeframe possible given these constraints.

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.

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We employ the same team that developed the small-scale synthesis chemistry for translation of those chemical syntheses into clinical-scale 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 avoided 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, we have 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.

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 and HSV-2 in our lab. This 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 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.

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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 engaged Biologics Consulting Group, Inc., to help us with the FDA regulatory submissions. We are also engaged with Australian Biologics Pty, Ltd to help us with clinical trials and regulatory approvals in Australia. We believe that cGMP-like manufactured product is acceptable for entering human clinical trials in Australia.

We have contracted NorthEast BioLab, Hamden CT, to conduct the bio-analytical studies and facilitate the toxicokinetic analyses of NV-HHV-101. 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-101 in blood samples from the general safety and toxicology studies that are required for IND.

We also engaged MB Research Labs, Spinnerstown, PA, to conduct the studies to assess the dermal sensitization and ocular irritation potential of the drug candidate. These initial studies involve two separate types of studies: 1) assess the direct potential of the drug candidate to induce skin sensitization after repeated treatment of the skin (contact dermal sensitization); and 2) assess the potential of the drug candidate to cause ocular irritation following potential exposure. The ocular irritation test (EpiOcular™ Eye Irritation Test, EIT) is a non-animal test in compliance with multi-national regulatory guidelines. Additional IND-enabling studies are in progress. Upon completion of all of these required studies, the Company anticipates filing an IND with the FDA to advance NV-HHV-101 into human clinical trials for topical dermal treatment of the shingles rash as the initial indication.

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

We have continued to achieve significant milestones in our drug development activities. Our lead program, NV-HHV-101 skin cream for the treatment of shingles rash, is in advanced pre-clinical stage, as we await final reports from external collaborators to produce and file the IND application with the FDA. 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 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, NanoViricides 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. The Company was not required to make any upfront payments to TheraCour and agreed to the following milestone payments to TheraCour; the issuance of 75,000 shares of the Company's Series A preferred stock upon the grant of an

IND Application; $1,500,000 in cash upon completion of Phase I Clinical Trials; $2,500,000 in cash upon completion of Phase II clinical trials; and $5,000,000 in cash upon completion of Phase III clinical trials.

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On September 9, 2021, the Company entered into a world-wide, exclusive, sub-licensable, license ("Covid-19 License Agreement") to use, promote, offer for sale, import, export, sell and distribute drugs that treat Covid-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement. The Company was not required to make any upfront cash payments to TheraCour and agreed to the following milestone payments to TheraCour: (i) the issuance of 100,000 shares of the Company's Series A preferred stock within 30 days upon execution of this agreement; (ii) the issuance of 50,000 shares of the Company's Series A preferred stock upon the approval of the Company's 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.

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. In addition, unless there is an event of default, in which case the license would revert to TheraCour, the licenses are held in perpetuity by NanoViricides for worldwide use. The licenses are also exclusively provided to NanoViricides for the licensed products so NanoViricides is the only party that can further sublicense the resulting drugs to another party, if it so desires. 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, in the case of the VZV license a failure to make a milestone payment within 90 days or a failure to use its commercially reasonable efforts to obtain FDA approval for 24 consecutive months.

A fundamental Patent Cooperation Treaty ("PCT") patent application, on which the nanoviricides® technology is based, has resulted in additional issued patents in Europe and Korea. As with issuances in other countries including the United States, these patents have been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The corresponding original "pi-polymer" international application, namely, PCT/US06/01820, was filed under the PCT system in 2006. Several other patents have already been granted previously in this patent family in various countries and regions, including Australia, ARIPO, Canada, China, Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, OAPI, Philippines, Singapore, Vietnam, South Africa, and the USA. Prosecution in several other countries continues. In May 2012, the US Patent (No. 8,173,764) was granted for "Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers." The US patent term is expected to last through October 1, 2028, including anticipated extensions in compensation for time spent in clinical trials. This US Patent has been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The disclosed structures enable self-assembling, biomimetic nanomedicines. Estimated expiry dates for these patents range nominally from 2027 to 2029 with various extensions accounting for delays in clinical trials. Additional issuances are expected in Europe, and in several other countries around the world.

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In addition to this basic PCT application that covers the "pi-polymer" structure itself, another PCT application, PCT/US2007/001607, that discloses making antiviral agents from the TheraCour family of polymers and such structures is in various stages of prosecution in several countries, and has already issued in at least seven countries and regions. The counterparts of the international PCT application have issued as a granted patent in Australia, Japan, China, ARIPO, Mexico, New Zealand, OAPI, Pakistan, and, South Africa to date. Additional issuances are expected in Europe, USA, and in several other countries around the world. This patent application covers antivirals based on the TheraCour polymeric micelle technologies, their broad structures and compositions of matter, pharmaceutical compositions, methods of making the same, and their uses. The nominal expiry dates are expected to range from 2027 to 2029.

More than 61 patents have been issued globally on the basis of the two international PCT patent families that cover the fundamental aspects of our platform technology. Additional patent grants are expected to continue as the applications progress through prosecution processes. All of the resulting patents have substantially broad claims.

A new patent application regarding coronavirus drug candidates has been filed under the PCT on June 25, 2021, and is automatically licensed by us under the Covid-19 License Agreement. Our anti-COVID drugs are based on polymeric micelle nanomedicine technologies developed by TheraCour and its affiliate, AllExcel, Inc.("Allexcel"). The inventors at AllExcel have filed a broad PCT patent application that forms the basis of our two lead drug candidates, namely, NV-CoV-2 and NV-CoV-2-R. The new patent application covers the new technologies, compositions, formulations, processes, manufactured products, and methods of use, among other specifics. This patent application was filed on June 25, 2021, application number PCT/US2007/001607, entitled "Self-Assembling Amphiphilic Polymers As Anti-Covid-19 Agents". Its nominal expiry date would be 20 years, after filing and if issued, i.e. June 24, 2041, and could be extended in certain countries under regulatory extensions to as late as into the year 2043, providing a significant commercial runway.

The patents are issued to the inventors Dr. Anil R. Diwan, PhD, Jayant G. Tatake, PhD, and Ann L. Onton, all of whom are among the founders of NanoViricides, Inc. The patents have been assigned to Allexcel, the Company at which the groundbreaking work was performed. AllExcel, Inc. has contractually transferred this intellectual property to TheraCour.

Patents and other proprietary rights are essential for our operations. If we have a properly designed and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, 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 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 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.

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 we intend 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.

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We may obtain patents for our compounds many years before we obtain marketing approval for them. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions, based on delays experienced in marketing products due to regulatory requirements. There is no assurance we would be able to obtain such extensions. The Company controls the research and work TheraCour performs on its behalf and no costs may be incurred without the prior authorization or approval of the Company.

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

On April 20, 2010, the United States Patent and Trademark Office granted trademark registration number 3,777,001 to the Company for the standard character mark "nanoviricides" (the "Mark") for International Class 5, pharmaceutical preparation for the treatment of viral diseases.

Analysis of Financial Condition, and Result of Operations

As of March 31, 2022, we had cash and cash equivalents of $15,572,134, prepaid expenses of $337,182 and net property and equipment of $8,804,720. Accounts payable and accrued expenses were $221,826, inclusive of account payables to a related party of $73,587. The accounts payable–related party is net of a two month advance of $491,000. Our liabilities included a third party short term loan payable of $164,905 at March 31, 2022. Stockholders' equity was $24,757,846 at March 31, 2022.

In comparison, as of June 30, 2021, we had $20,516,677 in cash and cash equivalents, prepaid expenses of $307,102 and $9,084,901 of net property and equipment. Our liabilities at June 30, 2021 were $351,146 including a third party short term loan payable of $95,306, accounts payable of $200,016 payable to third parties and accounts payable to TheraCour of $31,539.

During the nine -month period ended March 31, 2022, we used approximately $4.5 million in cash toward operating activities. During the nine-month period ended March 31, 2021, we used approximately $6.0 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 that as a result of the March 2, 2021 “At the Market” Offering, 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. Management believes we will have to raise additional capital to fund and perform additional projected work, including further required clinical trials of the first drug candidate towards approval, as well as engaging in further IND-enabling development and subsequent anticipated IND filings of human clinical trials of additional 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 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.

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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.

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 March 31, 2022.

Revenues – The Company is currently a non-revenue producing entity.

Research and Development Expenses – Research and development expenses for the three months ended March 31, 2022 decreased $209,103 to $1,255,074 from $1,464,177 for the three months ended March 31,2021. Research and development expenses for the nine months ended March 31, 2022 increased $82,854 to $4,613,302 from $4,530,448 for the nine months ended March 31, 2021.The decrease in the cost of research and development expenses for the three months ended March 31, 2022 is due to a decrease in outside lab expenses. The increase in the cost of research and development expenses for the nine months ended March 31, 2022 is due to a milestone payment 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 of an exclusive license agreement for the sale of drugs to treat Covid-19 infections using TheraCour's technology, and offset by a decrease in outside lab expenses.

General and Administration Expenses – General and administrative expenses for the three months ended March 31, 2022 decreased $110,557 to $532,801 from $643,358 for the three months ended March 31, 2021. General and administrative expenses for the nine months ended March 31, 2022 decreased $431,878 to $1,707,514 from $2,139,392 for the nine months ended March 31, 2021. The decrease in general and administrative expenses during the nine months ended March 31, 2022 compared to the prior period resulted primarily from decreases in professional fees and in operating expenses in general.

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

Net Loss – For the three months ended March 31, 2022, the Company had a net loss of $(1,792,644) or $(0.16) per share compared to a net loss of $(2,108,030) or $(0.19) per share for the three months ended March 31, 2021. For the nine months ended March 31, 2022, the Company had a net loss of $(6,326,866) or $(0.55) per share compared to a net loss of $(6,749,317) or $(0.63) per share for the nine months ended March 31, 2021. The decrease in the net loss for the nine months ended March 31, 2022 is attributable to a decrease in outside lab expenses and professional fees and operating expenses in general, offset by a

milestone payment of 100,000 shares of the Company's Series A preferred stock, with a fair value of approximately $935,000, issued in September 2021, to TheraCour upon execution of an exclusive license agreement for the sale of drugs to treat Covid-19 infections using TheraCour's technology.

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Liquidity and Capital Reserves

The Company had cash and cash equivalents of $15,572,134, and prepaid expenses of $337,182 as of March 31, 2022 and accounts payable, loan payable, and accrued expenses were $386,731, inclusive of accounts payable of $73,587 to a related party. The accounts payable–related party is net of a two month advance of $491,000. 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 $120,712,179 at March 31, 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 a Sales Agreement with the Sales Agents, pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agents, shares of common stock having an aggregate offering price of up to $50 million. On March 2, 2021 the Company sold 814,242 shares of common stock at an average price of approximately $7.83 per share. The net proceeds to the Company from the offering was approximately $6.1 million after placement agent fees and other estimated offering expenses.

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 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 our 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 emergence of widespread health emergencies due to COVID-19 have led to regional quarantines, shutdowns, shortages, disruptions of supply chains, and economic instability. The impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted at this time. Though the Company has not experienced a direct financial impact, if the financial markets and/or the overall economy are impacted for an extended period, the Company's ability to raise funds, in the future, may be materially adversely affected.

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.

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Off Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements during the nine months ended March 31, 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.

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 March 31, 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 December 31, 2021 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, 2021. 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 March 31, 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 March 31, 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

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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.

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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.

For the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 1,727 and 2,501, respectively of fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of $12,155 and $23,920, respectively for the three and nine months ended March 31, 2022 related to these issuances.

During the nine months ended March 31, 2022, the Scientific Advisory Board was granted in August 2021 fully vested warrants to purchase 572 shares of common stock with an exercise price of $4.65 per share expiring in August 2025, in November 2021 fully vested warrants to purchase 572 shares of common stock with an exercise price of $5.92 per share expiring in November 2025 and in February 2022 fully vested warrants to purchase 572 shares of common stock with an exercise price of $2.69 per share expiring in February 2025. The fair value of the warrants was $786 for the three months ended March 31, 2022 and $3,782 for the nine months ended March 31, 2022 and was recorded as consulting expense.

For the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 11,632 and 24,134, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of $27,000 and $81,000, respectively, for the three and nine months ended March 31, 2022.

For the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 4,788 and 11,600, respectively, fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of $11,250 and $41,250 for the three and nine months ended March 31, 2022.

For both the three and nine months ended March 31, 2022, the Company's Board of Directors authorized the issuance of 3,572 of fully vested shares of its common stock for employee compensation. The Company recorded an expense of $6,768 for both the three and nine months ended March 31, 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.

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ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

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ITEM 6. EXHIBITS

Exhibit No.	Description
31.1	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Executive Officer
31.2	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
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: May 16, 2022	/s/ Anil R. Diwan Name: Anil R. Diwan Title: President, Chairman of the Board (Principal Executive Officer)
Dated: May 16, 2022	/s/ Meeta Vyas Name: Meeta Vyas Title: Chief Financial Officer (Principal Financial Officer)