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

FORM 10-Q

QUARTERLY REPORT UNDER SECTION 1320 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended March 31, 2024

Commission File Number: ***001-36081***

NANOVIRICIDES, INC.

(Exact name of Company as specified in its charter)

Delaware	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 14, 2024 there were approximately 11,814,000 shares of common stock of the registrant issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NanoViricides, Inc.
Condensed Balance Sheets

	March 31, 2024 (Unaudited)	June 30, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,257,240	$ 8,149,808
Prepaid expenses	258,548	295,486
Total current assets	3,515,788	8,445,294
Property and equipment, net	7,602,835	8,106,647
Intangible assets, net	327,376	333,578
OTHER ASSETS		
Service agreements	18,908	14,361
Total assets	$ 11,464,907	$ 16,899,880
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 341,394	$ 157,056
Accounts payable – related parties	213,148	233,434
Accrued expenses	258,795	143,760
Total current liabilities	813,337	534,250
Other non-current liability – related party	—	1,500,000
Total liabilities	813,337	2,034,250
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A convertible preferred stock, $0.00001 par value, 10,000,000 shares designated, 892,238 and 547,674 shares issued and outstanding, at March 31, 2024 and June 30, 2023, respectively	9	5
Common stock, $0.00001 par value; 150,000,000 shares authorized, 11,813,867 and 11,698,497 shares issued and outstanding, at March 31, 2024 and June 30, 2023, respectively	118	116
Additional paid-in capital	147,670,351	145,946,258
Accumulated deficit	(137,018,908)	(131,080,749)
Total stockholders' equity	10,651,570	14,865,630
Total liabilities and stockholders' equity	$ 11,464,907	$ 16,899,880

See accompanying notes to the condensed financial statements

NanoViricides, Inc.
Condensed Statements of Operations
(Unaudited)

	For the Three Months Ended March 31,		For the Nine Months Ended March 31,	
	2024	2023	2024	2023
OPERATING EXPENSES				
Research and development	$ 1,214,661	$ 1,196,094	$ 4,255,205	$ 3,479,463
General and administrative	693,742	614,647	1,869,545	1,787,632
Total operating expenses	1,908,403	1,810,741	6,124,750	5,267,095
LOSS FROM OPERATIONS	(1,908,403)	(1,810,741)	(6,124,750)	(5,267,095)
OTHER INCOME (EXPENSE)				
Interest income	53,927	107,937	236,399	249,453
Interest expense	—	—	(49,808)	(938)
Other income (expense), net	53,927	107,937	186,591	248,515
NET LOSS	$ (1,854,476)	$ (1,702,804)	$ (5,938,159)	$ (5,018,580)
Net loss per common share- basic and diluted	$ (0.16)	$ (0.15)	$ (0.51)	$ (0.43)
Weighted average common shares outstanding- basic and diluted	11,779,579	11,636,041	11,747,978	11,612,735

See accompanying notes to the condensed financial statements

NanoViricides, Inc.
Condensed Statement of Changes in Stockholders' Equity
For the nine months ended March 31, 2024
(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, 2023	547,674	$ 5	11,698,497	$ 116	$ 145,946,258	$ (131,080,749)	$ 14,865,630
Series A preferred stock issued for employee stock compensation	10,591	—	—	—	9,617	—	9,617
Common stock issued for consulting and legal services rendered	—	—	39,103	1	50,599	—	50,600
Warrants issued to Scientific Advisory Board	—	—	—	—	159	—	159
Common stock issued for Directors fees	—	—	7,947	—	11,250	—	11,250
Net loss	—	—	—	—	—	(1,968,746)	(1,968,746)
Balance, September 30, 2023	558,265	$ 5	11,745,547	$ 117	$ 146,017,883	$ (133,049,495)	$ 12,968,510
Series A preferred stock issued for employee stock compensation	387	—	—	—	9,358	—	9,358
Series A preferred stock issued upon conversion of related party promissory note	331,859	4	—	—	1,499,996	—	1,500,000
Common stock issued for consulting and legal services rendered	—	—	23,379	—	27,000	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	147	—	147
Common stock issued for Directors fees	—	—	9,717	—	11,250	—	11,250
Forgiveness of interest on related party debt	—	—	—	—	49,808	—	49,808
Net loss	—	—	—	—	—	(2,114,937)	(2,114,937)
Balance, December 31, 2023	890,511	$ 9	11,778,643	$ 117	$ 147,615,442	$ (135,164,432)	$ 12,451,136
Series A preferred stock issued for employee stock compensation	1,727	—	—	—	14,189	—	14,189
Common stock issued for employee compensation	—	—	1,786	—	2,340	—	2,340
Common stock issued for consulting and legal services rendered	—	—	23,613	1	26,999	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	131	—	131
Common stock issued for Directors fees	—	—	9,825	—	11,250	—	11,250
Net loss	—	—	—	—	—	(1,854,476)	(1,854,476)
Balance, March 31, 2024	892,238	$ 9	11,813,867	$ 118	$ 147,670,351	$ (137,018,908)	$ 10,651,570

NanoViricides, Inc.
Condensed Statement of Changes in Stockholders' Equity
For the nine months ended March 31, 2023
(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, 2022	484,582	$ 5	11,592,173	$ 116	$ 145,574,080	$ (122,492,176)	$ 23,082,025
Series A preferred stock issued for employee stock compensation	10,591	—	—	—	13,864	—	13,864
Common stock issued for consulting and legal services rendered	—	—	12,710	—	27,000	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	480	—	480
Common stock issued for Directors fees	—	—	5,154	—	11,250	—	11,250
Net loss	—	—	—	—	—	(1,570,642)	(1,570,642)
Balance, September 30, 2022	495,173	$ 5	11,610,037	$ 116	$ 145,626,674	$ (124,062,818)	$ 21,563,977
Series A preferred stock issued for employee stock compensation	387	—	—	—	13,055	—	13,055
Common stock issued for consulting and legal services rendered	—	—	17,366	—	27,000	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	223	—	223
Common stock issued for Directors fees	—	—	7,173	—	11,250	—	11,250
Net loss	—	—	—	—	—	(1,745,134)	(1,745,134)
Balance, December 31, 2022	495,560	$ 5	11,634,576	$ 116	$ 145,678,202	$ (125,807,952)	$ 19,870,371
Series A preferred stock issued for employee stock compensation	1,727	—	—	—	17,233	—	17,233
Common stock issued for employee compensation	—	—	3,572	—	4,822	—	4,822
Common stock issued for consulting and legal services rendered	—	—	19,983	—	27,000	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	183	—	183
Common stock issued for Directors fees	—	—	8,340	—	11,250	—	11,250
Net loss	—	—	—	—	—	(1,702,804)	(1,702,804)
Balance, March 31, 2023	497,287	$ 5	11,666,471	$ 116	$ 145,738,690	$ (127,510,756)	$ 18,228,055

See accompanying notes to the condensed financial statements

NanoViricides, Inc.
Condensed Statements of Cash Flows
(Unaudited)

	For the Nine Months Ended	
	March 31, 2024	March 31, 2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,938,159)	$ (5,018,580)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	33,164	44,152
Common shares issued as compensation and for services	140,690	119,572
Warrants granted to Scientific Advisory Board	437	886
Depreciation	562,209	552,445
Amortization	6,202	6,202
Changes in operating assets and liabilities:		
Prepaid expenses	36,938	69,904
Service Agreement	(4,547)	23,257
Accounts payable	184,338	4,735
Accounts payable - related party	(20,286)	29,484
Accrued expenses	164,843	(3,524)
NET CASH USED IN OPERATING ACTIVITIES	(4,834,171)	(4,171,467)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(58,397)	(149,146)
NET CASH USED IN INVESTING ACTIVITIES	(58,397)	(149,146)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of Loan Payable	—	(94,788)
NET CASH (USED IN) INVESTING ACTIVITIES	—	(94,788)
NET CHANGE IN CASH AND CASH EQUIVALENTS	(4,892,568)	(4,415,401)
Cash and cash equivalents at beginning of period	8,149,808	14,066,359
Cash and cash equivalents at end of period	$ 3,257,240	$ 9,650,958
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	$ —	$ 938
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Fair value of Series A Preferred shares issued upon conversion of related party convertible promissory note	$ 1,500,000	$ —
Forgiveness of interest on related party debt	$ 49,808	$ —

See accompanying notes to the condensed financial statements

NANOVIRICIDES, INC.
March 31, 2024
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1 – Organization and Nature of Business

NanoViricides, Inc. (the "Company") is a clinical stage nano-biopharmaceutical company specializing in the discovery, development, and commercialization of drugs to combat viral infections using its unique and novel nanomedicines technology. NanoViricides possesses its own state of the art facility that supports research and development and drug discovery, drug candidate optimization, cGMP-compliant drug substance manufacturing, cGMP-compliant manufacturing and packaging of drug products for human clinical trials, and early commercialization. The Company has several drugs in various stages of development. The Company's lead drug candidate NV-387, formulated as the drug product NV-CoV-2, has recently completed Phase 1a/1b clinical trial for the assessment of human safety and tolerability upon increasing single and multiple dosings. This Phase 1a/1b clinical trial is sponsored by our licensee and collaborator in India, Karveer Meditech Private Limited (KMPL). NV-CoV-2 contains the nanoviricide active pharmaceutical ingredient (API) called NV-387.

Additionally, the Company has previously developed a clinical drug candidate, NV-HHV-1 formulated as skin cream, for the treatment of Shingles. The Company plans on taking NV-HHV-1 into human clinical trials, and further develop the HerpeCide™ program after clinical trials of NV-387. In the HerpeCide program alone, the Company has drug candidates against at least five indications at different stages of development. The Company's drug candidates against HSV-1 "cold sores" and HSV-2 "genital herpes" are in advanced pre-clinical studies and are expected to follow the shingles drug candidate into human clinical trials. In addition, the Company has drugs in development against all Influenzas including Bird Flu H5N1 in its FluCide™ program, as well as drug candidates against HIV/AIDS, Dengue, Ebola/Marburg, and other viruses.

The Company's drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc., a related party substantially owned by Dr. Anil Diwan, ("TheraCour"), to which the Company has broad, exclusive licenses. The licenses are to entire fields and not to specific compounds. In all, the Company has exclusive, worldwide licenses for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV-1 and HSV-2), Influenza and Asian Bird Flu Virus, Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis virus, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes (restated), Varicella Zoster Virus ("VZV") infections (i.e. Shingles and Chickenpox), and SARS-CoV-2 infections. In all cases, the discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, and 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. Milestone payments were made or are specified in certain of the license agreements, details of which have been disclosed at the time the agreements were entered into. The Company negotiates and licenses specific verticals of therapeutic applications from TheraCour if promising drug candidates are found in early research and development against a virus target. TheraCour has not denied any such licenses when requested.

The Company's business plan is based on developing the drug candidates into regulatory approvals, and partnering and sub-licensing for commercialization of the drugs whenever possible.

The Company has out-licensed NV-CoV-2 and NV-CoV-2-R for further clinical drug development and commercialization in the territory of India to KMPL, a company of which Dr. Anil Diwan is a passive investor and advisor. KMPL sponsored NV-CoV-2 for human clinical trials and obtained regulatory approvals in India. KMPL retained a local clinical research organization (CRO) to conduct the clinical trials. The Phase1a/1b human clinical trial of NV-CoV-2 began in India on June 17, 2023. The clinical trial drug products, NV-CoV-2 Oral Syrup, and NV-CoV-2 Oral Gummies, were manufactured at the Company's Shelton campus, and then shipped to and received by KMPL. Under the agreement with KMPL, the Company will pay for the expenses of the clinical trials, and in return will benefit from having the data and reports made available for regulatory filings in other territories of the world. Upon commercialization, the Company will receive royalties from KMPL equal to 70% of sales less costs to unaffiliated third parties.

Note 2 - Liquidity

The Company's condensed 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 condensed financial statements, the Company has an accumulated deficit at March 31, 2024 of approximately $137.0 million, a net loss of approximately $5.9 million and net cash used in operating activities of approximately $ 4.8 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, 2024, the Company had available cash and cash equivalents of approximately $3.3 million. Management believes that the Company's existing resources, including availability under its $2 million line of credit will not be sufficient to fund the Company's planned operations and expenditures for at least 12 months from the date of the filing of this Form 10-Q. As a result substantial doubt exists about the Company's ability to continue as a going concern.

The ability of the Company to continue as a going concern is dependent upon controlling its overall expenses and identifying and securing additional financing. Management has considered several options for financing the net working capital deficit as well as to obtain additional funds that will be needed for future human clinical trials. Management believes that the Company will be achieving several important milestones, including release of the Phase I clinical trial report, a pre-IND application for use of NV-387 in RSV infections as an antiviral, and clinical trial applications (including US FDA IND) for use of NV-387 to treat RSV and other important respiratory diseases, in the ensuing year. Management believes that as it achieves these milestones, the Company would likely experience improvement in the liquidity of the Company's stock, and would improve the Company's ability to raise funds on the public markets at terms that may be more favorable to the terms presently offered to the Company. Management believes that it has on-going access to the capital markets under an "At-The-Market" (ATM) agreement with EF Hutton that became active in April 2024. Management believes that the Company's stock is currently substantially undervalued in contrast to its asset value, based on the potential of NV-387 alone. Management believes that as the Company's investor outreach program expands and bears fruit, this deviation should be lessened, enabling the Company to access public markets for equity funding at reasonable valuations. In addition, Management has already begun soliciting funds by mortgaging its existing fully owned campus and cGMP manufacturing facilities in Shelton, CT, in order to free up a portion of the fixed capital for use as liquid working capital. However, there is no guarantee that the Company will be able to raise funds on terms acceptable to it, or at all.

In addition, Management continues to adjust its planned expenditures, activities, and programs, in accordance with budgetary constraints and in accordance with its expectations of obtaining additional financing. Management is also taking steps for seeking to license NV-387 to potential partners. Such licenses, if effected, would likely result in an initial payment at signing, milestone payments as the program advances, and royalty payments from future sales. The Company does not currently have a licensed partner other than KMPL and there is no guarantee that the Company can enter into such licensing agreement that provides substantial cash value to the Company.

There can be no assurance that the Company will be able to raise the necessary capital or that it will be on acceptable terms. Similarly, there can be no assurance that the Company can enter into licensing agreement(s) that provide(s) substantial cash value to the Company. The accompanying unaudited financial statements do not include any adjustments that may result from the outcome of these uncertainties.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation – Interim Financial Information

The accompanying unaudited interim condensed 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 condensed 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 condensed 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, 2023 filed with the SEC on October 13, 2023.

The June 30, 2023 year-end balance sheet data in the accompanying interim condensed financial statements was derived from the audited financial statements.

For a summary of significant accounting policies, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2023 filed on October 13, 2023.

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 Three Months Ended March 31, 2024	For the Three Months Ended March 31, 2023	For the Nine Months Ended March 31, 2024	For the Nine Months Ended March 31, 2023
Warrants	7,148	8,290	7,148	8,290

The Company has 892,238 shares of Series A preferred stock outstanding as of March 31, 2024. Only in the event of a "change of control" of the Company is 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, 2024, the number of potentially dilutive shares of the Company's common stock into which these Series A preferred shares can be converted into is 3,122,834, and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

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 through TheraCour, and Director
TheraCour Pharma, Inc. ("TheraCour")	An entity owned and controlled by Dr. Anil R. Diwan
Karveer Meditech, Pvt., Ltd ("KMPL")	An entity of which Dr. Anil R. Diwan is a passive investor and advisor without operating control.

	For the three months ended		For the nine months ended	
	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
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	$ 2,500	$ —	$ 16,265	$ 29,369

	As of	
	March 31, 2024	June 30, 2023
Account Payable – Related Party-TheraCour		
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 month's invoice to be applied as a prepayment towards expenses. Accounts payable due TheraCour at March 31, 2024 and June 30, 2023 were $213,148 and $233,434, respectively. The June 30, 2023 accounts payable was offset by a two month advance of $500,000 to TheraCour. On February 12, 2024 the Company requested and TheraCour agreed to suspend the existing license requirement to maintain an advance with TheraCour equal to two months of projected TheraCour invoices which is recalculated quarterly. The suspension will remain in effect until such time as the Company is able to raise sufficient capital. The existing available advance of $500,000 was applied towards payment of current TheraCour invoices.	$ 213,148	$ 233,434

	March 31, 2024	June 30, 2023
Accounts Payable- Related Party-KMPL		
The Company has out-licensed NV-CoV-2 and NV-CoV-2-R for further clinical drug development and commercialization in the territory of India to KMPL, a company of which Dr. Anil R. Diwan is a passive investor and advisor. KMPL sponsored NV-CoV-2 for human clinical trials and obtained regulatory approvals in India. KMPL has retained a local clinical research organization (CRO) to conduct the clinical trials. The Phase1a/1b human clinical trial of NV-CoV-2 began in India on June 17, 2023. Under the agreement with KMPL, the Company agreed to pay for the expenses of the clinical trials, and in return will benefit from having the data and reports made available for regulatory filings in other territories of the world. Upon commercialization, the Company will receive royalties from KMPL equal to 70% of sales net of costs to unaffiliated third parties. Accounts payable to KMPL at March 31, 2024 and June 30, 2023 were:	$ —	$ —

	For the three months ended		For the nine months ended	
	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
Research and Development Costs - Related Party				
Development fees and other costs charged by TheraCour pursuant to the license agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at March 31, 2024 and June 30, 2023.	$ 588,763	$ 622,016	$ 1,910,098	$ 1,867,974

	For the three months ended		For the nine months ended	
	March 31, 2024	March 31, 2023	March 31, 2024	March 31, 2023
Clinical Trial Costs - Related Party				
Clinical trial related and other costs charged by KMPL pursuant to the license between KMPL and the Company were $77,435 and $442,845 for the three and nine months ended March 31, 2024. As of March 31, 2024 and June 30, 2023, $227,435 and $100,000 of such costs were accrued by the Company pursuant to the license agreement between the Company and KMPL. The amounts were recorded within accrued expenses in the accompanying condensed balance sheets.	$ 77,435	$ —	$ 442,845	$ —

License Milestone Fee – Related Party

On September 9, 2021, the Company entered into a COVID-19 License Agreement with TheraCour to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. Pursuant to such license agreement, the Board of Directors authorized the issuance of 100,000 fully vested shares of the Company's Series A preferred stock as a license milestone payment and recorded an expense to research and development of $935,088 for the year ended June 30, 2022. On April 20, 2023, the Company was notified that the Company's licensee, KMPL was authorized to enter into Phase 1a/1b clinical trials of its COVID, NV-CoV-2 Oral Syrup and its NV-CoV-2 Oral Gummies after satisfying the conditions of a conditional authorization received on or about January 27, 2023. Pursuant to the COVID-19 License Agreement a milestone payment of 50,000 fully vested shares of the Company's Series A preferred stock was issued as a license milestone payment and recorded as an expense to research and development of approximately $157,000 for the year ended June 30, 2023 representing the fair value of the shares on the date of grant. On June 19, 2023, the Company was notified that the Company's licensee, KMPL had commenced volunteer recruitments for Phase 1a/1b clinical trials of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies. Pursuant to the COVID-19 License Agreement a milestone payment of $1,500,000 became due 5 days thereafter and was recorded as a non-current liability and research and development expense at June 30, 2023.

On July 19, 2023, the Company entered into an agreement with TheraCour, to accept the Company's unsecured convertible promissory note (the "Note") in payment of the milestone award. The Note accrues simple interest at the rate of 12% per annum and is due and payable on January 19, 2025, the maturity date. The principal of the Note is convertible, at TheraCour's option, into 331,859 shares of the Company's Series A preferred stock, par value $0.00001 at the conversion price, specified as the fair value of the Series A shares on July 19, 2023 in the terms and conditions contained within the Note. On October 27, 2023 TheraCour exercised its right to convert the principal of the Note into 331,859 shares of the Company's Series A preferred stock. Furthermore, TheraCour cancelled all of the accrued interest on the Note totaling $49,808 which has been reported as a capital transaction credit to additional paid in capital on the accompanying condensed statements of changes in stockholders' equity. Total interest incurred under the Note for the three and nine months ended March 31, 2024 was $0 and $49,808, respectively.

On February 13, 2024, the Company and TheraCour amended the COVID-19 License Agreement (the "Amendment"). The Amendment provides that the as yet unearned and unremitted cash awards specified in the COVID-19 License Agreement for milestone payments shall not be due and payable until the Company achieves a Revenue Event which shall mean, but not be limited to, the receipt of revenue by the Company generated from, but not limited to, sources such as (1) research and development grants, government contracts, non-profit organizations and other sources to the extent that the amount of Recognized Revenue (as defined in the Amendment) is only considered to be the profit portion of Revenue Event, if any; (2) licensing of third-party development partnerships to the extent Recognized Revenue is considered to include only the profit or retained earnings portion received from such deals (and exclude any at-cost-reimbursements); (3) drug commercialization wherein recognized revenue shall be the amount of gross profit (i.e., net sales less cost of net sales); or (4) other sources of revenue such as gross profits from private contract work. Additionally, the Amendment provides that no more than 50% of the Recognized Revenue shall be applied for remitting such consideration at the time of payment. Further the Amendment clarifies that financing raised by the Company from sale of equity, mortgage or debt transactions, and such other instruments shall not be regarded as Recognized Revenue.

Line of Credit - Related Party

On November 13, 2023, the Company's President and CEO, Dr. Anil R. Diwan, entered into a Line of Credit Agreement whereby Dr. Diwan agreed to provide a standby Line of Credit to the Company in the maximum amount of $2,000,000. All amounts outstanding under the Line of Credit, including principal, accrued interest and other fees and charges, will be due and payable on December 31, 2025. Amounts drawn down under the Line of Credit shall bear interest at a fixed rate of 12%. Advancements under the Line of Credit will be collateralized by an Open End Mortgage Deed on the Company's real property at 1 Controls Drive, Shelton, Connecticut and a Chattel Mortgage (U.C.C - 1 filing) against the Company's equipment and fixtures. Any draw down under the Line of Credit requires the approval of the Company's Board of Directors. On February 12, 2024 the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil R. Diwan, signed an Extension Agreement which extended the maturity of the Company's Line of Credit from December 31, 2024 to December 31, 2025. There were no other amendments to the original Line of Credit. The Company has not drawn against the Line of Credit facility as of March 31, 2024.

Note 5 - Property and Equipment

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

	March 31, 2024	June 30, 2023
GMP Facility	$ 8,168,045	$ 8,168,045
Land	260,000	260,000
Office Equipment	63,056	60,347
Furniture and Fixtures	5,607	5,607
Lab Equipment	6,371,415	6,315,727
Total Property and Equipment	14,868,123	14,809,726
Less Accumulated Depreciation	(7,265,288)	(6,703,079)
Property and Equipment, Net	$ 7,602,835	$ 8,106,647

Depreciation expense for the three months ended March 31, 2024 and 2023 was $ 187,889 and $186,255, respectively, and for the nine months ended March 31, 2024 and 2023 was $562,209 and $552,445, respectively.

Note 6 – Intangible Assets

Intangible assets, net consists of the following:

	March 31, 2024		Total	June 30, 2023		Total
	Finite Lived Intangible Assets	Indefinite Lived Intangible Assets	March 31, 2024	Finite Lived Intangible Assets	Indefinite Lived Intangible Assets	June 30, 2023
Intangible Assets	$ 153,393	$ 305,561	$ 458,954	$ 153,393	$ 305,561	$ 458,954
Less Accumulated Amortization	(131,578)	—	(131,578)	(125,376)	—	(125,376)
Intangible Assets, Net	$ 21,815	$ 305,561	$ 327,376	$ 28,017	$ 305,561	$ 333,578

Amortization expense amounted to $2,067 and $2,067 for the three months ended March 31, 2024 and 2023, respectively, and for the nine months ended March 31, 2024 and 2023 were $6,202 and $6,202, respectively.

NanoViricides, Inc.'s intangible assets include acquired licenses and capitalized patent costs representing legal fees associated with filing patent applications. Intangible assets with finite lives, licenses and patent costs, are amortized using the straight- line method over the estimated economic lives of the assets, which range from seventeen to twenty years. The Company's intangible assets with finite lives are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

Intangible assets determined to have indefinite useful lives, primarily patent costs, are not amortized but are tested for impairment annually, or more frequently if events or changes in circumstances indicate the asset may be impaired. The Company accounts for patent costs in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") ASC 350-30, *General Intangibles Other than Goodwill*. The Company will begin amortizing the patent costs when they are brought to the market or otherwise commercialized.

The Company does assess the recoverability of intangible assets with indefinite lives annually in the fourth quarter of each fiscal year, or more often if indicators warrant, by determining whether the fair value of each of the intangible assets, as a unit, supports its carrying value. In accordance with ASC 350, each year the Company may assess qualitative factors to determine whether it is more likely than not that the fair value of each license is less than its carrying amount as a basis for determining whether it is necessary to complete quantitative impairment assessments.

Note 7 – Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2024	June 30, 2023
Personnel and compensation costs	$ 22,360	$ 39,060
Consultant	9,000	4,700
Clinical trial costs due to KMPL-related party	227,435	100,000
	$ 258,795	$ 143,760

Note 8 - Equity Transactions

On October 6, 2023, the Company and Dr. Anil Diwan executed an extension of his employment agreement for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares shall be vested in quarterly installments of 2,551 shares on September 30, 2023, December 31, 2023, March 31, 2024 and June 30, 2024 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $8,125 and $24,374, respectively for the three and nine months ended March 31, 2024. The balance of $8,125 will be recognized as the remaining 2,551 shares vest and service is rendered for the remaining three months ended June 30, 2024.

For the three and nine months ended March 31, 2024, 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 $6,064 and $8,791, respectively for the three and nine months ended March 31, 2024 related to these issuances.

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 fair value of the Series A Convertible preferred stock at each issuance was estimated based upon the price of the Company's common stock after an application for a reasonable discount for lack of marketability.

For the three and nine months ended March 31, 2024, the Company's Board of Directors authorized the issuance of 1,786 fully vested shares of its common stock with a restrictive legend for employee compensation. The Company recorded an expense of $2,340 for the three and nine months ended March 31, 2024, which is reflective of the fair value of the common stock on the date of issuance.

In August 2023, the Scientific Advisory Board was granted fully vested warrants to purchase 286 shares of common stock with an exercise price of $1.63 per share expiring in August 2027 and in November 2023 fully vested warrants to purchase 286 shares of common stock with an exercise price of $1.55 per share expiring in November 2027 and in February 2024 fully vested warrants to purchase 286 shares of common stock with an exercise price of $ 1.44 per share expiring in February 2028. The fair value of the warrants was $131 for the three months ended March 31, 2024 and $ 437 for the nine months ended March 31, 2024 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 assumptions:

Expected life (year)	4
Expected volatility	50.55-54.02 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	4.3-4.6 %

For the three and nine months ended March 31, 2024, the Company's Board of Directors authorized the issuance of 23,613 and 86,095, respectively, fully vested shares of its common stock with a restrictive legend for consulting and legal services. The Company recorded expense of $27,000 and $104,600, respectively, for the three and nine months ended March 31, 2024, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and nine months ended March 31, 2024, the Company's Board of Directors authorized the issuance of 9,825 and 27,489, fully vested shares of its common stock with a restrictive legend for director services, respectively. The Company recorded an expense of $11,250 and $33,750 for the three and nine months ended March 31, 2024, which is reflective of the fair value of the common stock on the dates of issuance.

Note 9 - Common Stock Warrants

Common 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, 2023	8,004	$ 4.96	1.79	$ —
Granted	858	1.58	3.63	—
Expired	(1,714)	5.73	—	—
Outstanding and exercisable at March 31, 2024	7,148	$ 4.37	1.69	$ —

Of the outstanding warrants at March 31, 2024, 572 expire in fiscal year ending June 30, 2024, 2,287 expire in fiscal year ending June 30, 2025, 2,287 warrants expire in the fiscal year ending June 30, 2026, 1,144 warrants expire in the fiscal year ending June 30, 2027 and 858 warrants expire in the fiscal year ending June 30, 2028.

Note 10 - Commitments and Contingencies

Legal Proceedings

From time to time, the Company is subject to various legal proceedings arising in the ordinary course of business, including proceedings for which the Company has insurance coverage. There are no pending legal proceedings against the Company to the best of the Company's knowledge as of the date hereof and to the Company's knowledge no action, suit or proceeding has been threatened against the Company that it believes will have a material adverse effect to its business, financial position, results of operations, or liquidity.

Employment Agreements

On October 6, 2023, the Company and Dr. Diwan, the Company's President and Chief Executive Officer, executed an extension of his employment agreement for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares will be deemed partially vested in quarterly installments following the grant date and fully vested on June 30, 2024.

On August 21, 2023, the Company's Board of Directors approved the extension of the agreement with Meeta Vyas, Chief Financial Officer of the Company. On October 6, 2023, Company and Meeta Vyas signed an extension of the agreement for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms and conditions as the current agreement, except that she will be additionally compensated for up to 50% of all medical insurance costs, not to exceed $ 2,500 per month.

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.

On March 27, 2023 the Company entered into a License Agreement with KMPL wherein the Company granted to KMPL a limited, non-transferable, exclusive license for the use, sale, or offer of sale in India of the Company's two clinical test drug candidates titled as NV-CoV-2 and NV-CoV-2-R for the treatment of COVID in patients in India. KMPL has engaged in further drug development in India including sponsoring of drug candidates for human clinical trials in India and has acted as clinical trials manager for such clinical trials. KMPL shall provide NanoViricides with all reports of the clinical trials and the Company can use such reports for further advancement of the drug candidates with regulatory authorities outside India. In consideration, KMPL will be reimbursed by the Company for all direct and indirect costs incurred for the clinical trials and development activities with a customary clinical trials manager fee of thirty percent (30%) of such costs and applicable taxes. Upon commercial sales of any resulting approved drugs, KMPL will pay the Company a royalty of seventy (70%) percent of the final invoiced sales to unaffiliated third parties.

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 condensed 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, 2023. Readers should carefully review the risk factors disclosed in the Company's, Form 10-K and other documents filed by the Company with the SEC.

As used in this report "Safety" "Efficacy" "Effectiveness" and related terms refer to the results of the Company's research studies and these statements have not been evaluated by regulatory bodies including the US FDA that have the authority for the purpose of commercial use of the drugs.

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

PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This 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", "NanoViricides", "we," or "us") was incorporated in Nevada on April 1, 2005, and redomiciled to Delaware effective May 30, 2023. Our corporate offices are located at 1 Controls Drive, Shelton, Connecticut 06484 and our telephone number is (203) 937-6137. Our Website is located at http://www.Nanoviricides.com. We do not incorporate by reference into this Quarterly Report the information on or accessible through our website, and you should not consider it part of this Quarterly Report.

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

We are a clinical stage company developing (a) host-mimetic, and (b) direct-acting, nanomachines capable of dismantling the virus without assistance from the human immune system. As a host-mimetic, viruses cannot escape a nanoviricide drug by generating mutants and variants in the field, because all variants still require the same signature host features that our drugs mimic. In contrast, vaccines, antibodies and small chemical drugs are readily escaped by viruses as mutations occur, rendering these medical countermeasures ineffective. This was repeatedly observed in the recent COVID pandemic. As a direct-acting antiviral, a nanoviricide drug is not expected to interfere with human bodily systems or enzymes, which is expected to result in significant levels of safety, unlike most of the antiviral drugs. Any viral infection that causes significant pathology does so by virtue of host immune system disrepair, either pre-existing, or caused by the virus itself. Therefore, nanoviricides can be expected to be superior to approaches such as vaccines and antibodies that require a good functional host immune system for antiviral response.

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

Our first drug candidate, NV-CoV-2, administered orally, has recently completed Phase 1a/1b human clinical trial for the evaluation of safety and tolerability in healthy subjects. NV-387 is the active ingredient in this drug product. There were no reported adverse events, and the drugs were well-tolerated even at the highest level of dosing given multiple times in this trial.

We plan to further develop this drug, NV-387, as an ultra-broad-spectrum antiviral medication to treat a number of viral infections including Coronaviruses (SARS-CoV-2, MERS-CoV, seasonal coronaviruses, hCoV-NL63), Respiratory Syncytial Virus (RSV), Influenza viruses, other respiratory infections, possibly thus covering all of the “tripledemic” viruses and more with this single drug. We also plan to further develop NV-387 for the treatment of biodefense viruses such as Smallpox/Mpox. This ultra-broad-spectrum antiviral activity of NV-387 is supported by multiple highly lethal animal studies of infections by different viruses.

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

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

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

We are also developing several other virus-family-specific drug candidates. Of these, NV-HHV-1, developed as a skin cream for the treatment of Shingles rash, has completed non-clinical safety/pharmacology studies required for a U.S. Food and Drug Administration (“FDA”) Investigational New Drug (“IND”) submission. We believe that the NV-HHV-1 skin cream, when approved, can also be additionally indicated to treat HSV-1 “cold sores” and HSV-2 “genital ulcers” based on successful animal studies. Further, we are also developing an oral drug for the systemic treatment of most of the herpesvirus family related infections, including HSV-1 “cold sores” that is based on the same active ingredient as NV-HHV-1. Further, we have drug candidates in HIVCide™ program that have shown substantial antiviral activities in animal studies warranting further clinical development. We have several other drug candidates others at different preclinical drug development stages in our pipeline for the treatment of other viral infections including Dengue viruses, Ebola viruses, etc.

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

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

We plan on seeking non-dilutive grant and contracts funding for our drug candidates that are responsive to bio-defense and pandemic-preparedness objectives.

There is no guarantee that we will be successful in partnering our drug candidates or obtaining non-dilutive funding for furtherance of our drug development programs. To date, we have financed our drug development programs using equity-based financing from the sale of our shares in private and public instruments including registered direct offerings as well as “At the Market” (ATM) offerings

NV-387, A First-of-a-Kind, Novel, Ultra-Broad-Spectrum Antiviral Nanomedicine

NV-387 was designed to be and has been found to be an ultra-broad-spectrum antiviral, reminiscent of antibiotics. So far it has been evaluated for antiviral activity in animal models of Coronavirus, RSV, Smallpox, and Influenza infections. In all cases the studies demonstrated positive results for NV-387 treatment that matched or exceeded corresponding available therapeutics or positive controls.

1. Coronaviruses: NV-387 was found to effectively reduce the cytopathic effects caused by coronaviruses in cell culture studies without cellular toxicity. It was also found to suppress infection of cells by SARS-CoV-2 pseudovirion as much as a control antibody. NV-387 was found to significantly increase the lifespan of rats infected lethally into the lungs with the coronavirus hCoV-NL63, a model virus stand-in for SARS-CoV-2. Further, the increase in lifespan upon NV-387 I.V. administration was substantially greater than that obtained with Remdesivir I.V. administration. Additionally, NV-387 given orally also increased the lifespan by more than that seen with remdesivir IV administration.

2. RSV: Oral dosing with NV-387 led to full survival of mice lethally infected with RSV/A2 leading to severe lung disease, whereas the only available drug against RSV, namely ribavirin, showed a limited increase in lifespan. Ribavirin is a highly toxic drug and is given only as a last resort. Two vaccines have recently been approved for protection of persons 60+ years old from RSV infection (Arexvy®, GSK, and Abrysvo®, Pfizer). Abrysvo was recently approved for use in pregnant women for protection of infants. A new antibody, nirsevimab (Beyfortus®) was approved for protection of newborn children at risk of RSV disease, but not for treatment. There is no approved drug for the treatment of RSV infection, other than the last resort drug, ribavirin that has limited effectiveness.

3. Smallpox/Mpox: Oral dosing with NV-387 led to an increase in lifespan of mice lethally infected with ectromelia virus (a cousin and model stand-in for smallpox/mpox viruses) into lungs that was comparable to treatment with tecovirimat (TPOXX®, SIGA). We also found that in a lethal intradigital footpad infection of mice with ectromelia virus, oral NV-387 treatment led to lifespan improvement comparable to oral tecovirimat treatment. This model is relevant to the skin-abrasion mode of MPox transmission that was found to be dominant in the recent MPox pandemic, and is also found to be operative in the current Congo MPox epidemic. Tecovirimat, approved for Smallpox treatment under the FDA “Animal Rule”, is currently stockpiled under the US Strategic National Stockpile.

4. Influenza: Oral dosing with NV-387 led to a substantially increased lifespan of mice lethally infected with Influenza A/H3N2 compared to the increase in lifespan afforded by treatment with Oseltamivir (Tamiflu®, Roche), Peramivir (Biocryst), or Baloxavir (Xofluza®, Shionogi, Roche), approved drugs against influenza viruses.

Knowing the broad-spectrum nature of NV-387, we anticipate that NV-387 would possess clinically relevant antiviral activity against the HPAI (Highly Pathogenic Avian Influenza) viruses including H5N1 “Bird Flu”.

Oseltamivir-resistant mutants are known and have spread across the world. Resistance to oseltamivir also generates resistance to Peramivir because the two drugs share the same mechanism of action. Baloxavir clinical trial demonstrated generation of resistant influenza viruses in 2.2% of treated patients. Thus, an escape-resistant drug that we believe NV-387 is, is sorely needed in the face of potential prospects of a resistant bird flu or influenza epidemic.

Given that, in each of these studies, we have compared the results of treatment with NV-387 with those of approved drugs, and believe that the NV-387 treatment is superior. We believe that NV-387 has strong prospects for regulatory approval in each of these indications.

Novel Orthogonal Nanoviricide Mechanism Has Many Benefits

Additionally, the NV-387 putative mechanism of action is orthogonal and complementary to that of the existing therapeutics, enabling combination therapy with the existing drugs in the market. NV-387 acts on the free virus outside cells blocking infection of new cells by destroying the virus. Existing antiviral therapeutics (except antibodies and entry inhibitors) act on the replication cycle of the virus (ex.: remdesivir, acyclovir, ribavirin, cidofovir, brincidofovir) inside cells, or exiting of the virus (ex.: oseltamivir, peramivir, tecovirimat) from inside cells. Thus combining the action outside the cells of NV-387 with the action inside the cells (or at exit) of these existing agents is expected to lead to complete blockage of any virus thus resulting in a rapid and complete cure. Combining multiple drugs also leads to reduction in emergence of viral resistance, as has been scientifically proven already.

Nanoviricides Can Encapsulate Small Chemicals as Guests, Enabling Improved Pharmacokinetics and thus Activity of the Guest

Further, NV-387 also acts as a unique and novel drug delivery vehicle, similar in action to exosomes. Thus, encapsulation of remdesivir in NV-387 enabled oral delivery of NV-387 and the activity of the resulting drug, NV-387-Rp, given orally in lethally infected animals, was found to be superior to that of each of NV-387 and remedesivir (Veklury®, Gilead).

We have also developed our own, patent-pending replication inhibitor antiviral agents that can be encapsulated in NV-387 for improved antiviral activity in animal models, with the objective of curing long-term (long COVID) and lifelong (HSV-1, HSV-2, VZV, others) viral infections.

Broad and Long Pipeline for Sustained Commercial Success and Cures of Viral Infections

RSV is an important disease particularly for infants and children under six years of age, as well as for older persons and immunocompromised patients. A recent report by Growth Plus Reports estimated the global respiratory syncytial virus (RSV) therapeutics market to grow from $1.8 Billion in 2022 at a CAGR of 18.9%, reaching $ 8.73 billion by 2031 (https://finance.yahoo.com/news/respiratory-syncytial-virus-rsv-therapeutics-093200835.html?guccounter=1).

Influenza market size is expected to increase from approximately $3.6 billion in 2021, increasing at a CAGR of 8.5% over 2019-2032, according to Delve Insight (https://www.prnewswire.com/news-releases/influenza-a-market-to-witness-robust-expansion-at-a-cagr-of-8-5-in-the-united-states-during-the-study-period-20192032-assesses-delveinsight-301717394.html).

The global Herpes Simplex Virus treatment market size was estimated at $2.47 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 8.1% from 2024 to 2030, according to Grand View Research (https://www.grandviewresearch.com/industry-analysis/herpes-simplex-virus-treatment-market-report).

We believe that we have developed a strong pipeline of drug candidates that, we anticipate, will yield new drug candidates over a very long timeframe into the future, and, we expect, will enable cures of many currently non-curable viral diseases.

Clinical Development Program: NV-387 Phase I Clinical Trial

In the Phase 1a/1b human clinical trial, even at the highest dose level, dosed multiple times, NV-387 was found to be well tolerated, and there were no reported adverse events of the drug when given orally.

This clinical trial finding is consistent with the findings that the evaluation of safety of NV-387 in pre-clinical studies demonstrated a No-Observed-Adverse-Effects-Level (NOAEL) at 1,200 mg/Kg, and the Maximum Tolerable Dose level (MTD) at 1,500 mg/Kg in rats, which are very positive numbers. Further, NV-387 was found to be non-mutagenic, non-immunogenic, non-allergenic, and non-genotoxic in pre-clinical studies.

We therefore anticipate that NV-387 can be given to patients across all patient population, in age from infants to seniors, including immunocompromised persons, patients with co-morbidities, and others, when approved. This is in contrast to available antiviral therapeutics that, limited by their toxicity and metabolic effects, cannot be given to many pools of patients.

The Phase 1a/1b clinical trial was sponsored in India by the drug sponsor Karveer Meditech Private Limited (KMPL), and conducted by the Clinical Research Organization (CRO), PristynCR. KMPL is a licensee and collaborator of NanoViricides, Inc., as described in more detail under “Collaborations” further below. The trial was conducted under ICH GCP guidelines as required in India. We believe that this clinical trial will be acceptable for submission to the US FDA.

Further Clinical Development of NV-387 Towards Drug Approvals: Multiple Indications for NV-387 Against Different Viral Infections Enable Maximizing Return on Investments While Fulfilling Unmet Medical Needs

KMPL intends on initiating a Phase II clinical trial in India shortly after the Phase I report become available. We are in discussions with subject matter experts in India regarding the best indication to go with in Phase II, with RSV and Influenza as some of the choices.

We also plan on initiating a Phase IIa clinical trial of NV-387 for the treatment of RSV infection under the US FDA (see further below). We are in the process of developing a Pre-IND application to the US FDA for this purpose. Our overall objective of the program is to evaluate NV-387 for commercialization as a treatment of infants to young children. We believe that our Phase IIa clinical trial design will enable us to proceed to a Phase II/III registration clinical trials in infants and young children with RSV infection. We believe that this is an unmet medical need.

Each year in the United States, RSV leads to approximately 2.1 million outpatient (non-hospitalization) visits among children younger than five years old, resulting in 58,000-80,000 hospitalizations among children younger than 5 years old, and 100–300 deaths in children younger than five years old, according to the CDC (https://www.cdc.gov/rsv/research/index.html).

Additionally, we anticipate that NV-387 would be expected to be eligible for the development of Poxvirus therapeutics under the FDA "Animal Rule". The Animal Rule program requires well-controlled GLP studies in specific animal poxvirus infection models as replacement of the Phase II/III human clinical trials, and expanded Phase I human clinical trials to elucidate safety of the drug in human use. We plan to seek non-dilutive government funding for this indication.

Multiple indications of NV-387 enable us to maximize return on investments. The Phase I safety and tolerability clinical trial would be generally applicable across all indications. All of IND-enabling non-clinical studies would also be reused, with the addition of animal model antiviral activity studies for the specific indication. The Chemistry, Manufacture, and Controls for the drug substance would remain substantially the same and potentially the drug product sections also could be reused.

Multiple Formulations Enable Treatment of All Segments of Patient Population with Varying Disease Severity, from Mild to Moderate to Severe and Hospitalized

We have successfully developed NV-387 formulations for different severities of viral diseases, and with different patient populations in mind. These include:

(i) Oral "Gummies" for adults and older children. Oral gummies have an advantage over tablets in that the drug dissolves slowly in the mouth and does not require swallowing. Older adults as well as children with certain respiratory infections are known to have difficulty swallowing.

(ii) Oral Syrup. In infants and younger children, the drug must be "titrated" on the basis of body weight or a similar parameter. A syrup form is best suited for this purpose.

(iii) Solution for Injection, Infusion or Inhalation. For hospitalized patients with severe disease, injections and infusions are better suited to provide immediate antiviral action. A simple inhalation of the same solution using a standard available nebulizer enables direct delivery to lower respiratory system where the virus is causing lung damage that can lead to lung failure and potentially death.

Unique, Novel Design Leading to Broad-Spectrum Activity of NV-387

NV-387 has such broad-spectrum activity because it is designed to mimic the attachment receptors to which viruses bind before infecting a cell. The family of attachment receptors mimicked by NV-387 is called Sulfated Proteoglycans (S-PG). This family includes glycosaminoglycans ("GAG"s), and proteoglycans containing heparan sulfate (HSPG), dermatan sulfate (DSPG), chondroitin sulfate (CSPG), and keratan sulfate (CSPG), among others.

Over 90% of known pathogenic viruses bind to one or more of these S-PG class attachment receptors. These viruses include Coronaviruses, Paramyxoviruses (RSV - Respiratory Syncytial Virus, and HMPV- human Metapneumovirus), Dengue Viruses, Chickengunya Virus, Herpesviruses, Human Papillomavirus (HPV), HIV, Hendra and Nipah Viruses, Ebola and Marburg Viruses, and Poxviruses, among others (Cagno V, Tseligka ED, Jones ST, Tapparel C. Heparan Sulfate Proteoglycans and Viral Attachment: True Receptors or Adaptation Bias? Viruses. 2019 Jul 1;11(7):596. doi: 10.3390/v11070596. PMID: 31266258; PMCID: PMC6669472). Thus, a large number of virus families use these S-PG family attachment receptors to concentrate next to cells and thereby efficiently infect cells, with different virus families having preferences to one or more of such attachment factors.

We believe our unique and successful mimicking of S-PG is responsible for the observed broad-spectrum activity of NV-387. NV-387 is an example of NanoViricides Platform Modality #1 implementation discussed in our Form 10-K Annual report filed with the SEC on October 13, 2023.

The NanoViricides Platform Technology has an important advantage in that no matter how much a virus changes in the field, it is unlikely to escape the nanoviricide drug, because the nanoviricide drug is designed to mimic the very features that the virus uses to bind to and enter cells. These specific molecular signature features on the cellular side do not change even as the virus mutates, and nanoviricides are designed to mimic these host-side features. In contrast viruses readily escape antibodies as drugs, as well as vaccine-induced immunity as they evolve in the field, as is well known from the COVID-19 pandemic as well as Influenza pandemics and the continuing HIV/AIDS pandemic.

A safe and effective antiviral drug that the virus would not escape by mutations or field evolution is the holy grail of antiviral drug development. We believe that the NanoViricides Platform technology meets this challenge.

Further details of the NanoViricides Platform Technology, the various Modalities of its implementation, and the extensive drug candidate developments that we have undertaken, have been discussed in our Annual Report filed with the SEC on October 13, 2023.

cGMP-Compliant Manufacture of Nanoviricide Drug Candidates in Our Own Facility

NanoViricides is one of a few biopharma companies that has its own cGMP-compliant manufacturing facility. We have designed and developed a cGMP-capable drug substance and drug product manufacturing facility at our headquarters in Shelton, CT. The manufacturing facility comprises a Scale-Up Suite, Clean Room Suites (Class 1000 and Class 100) for Manufacture of the Drug Substances, and Formulation and Packaging Suites for our Drug Products.

We believe our capabilities in manufacturing clinical drug products are now well established. We have manufactured multi-Kg scale clinical supply of drug substances as well as the oral drug products for NV-CoV-2 at our own facility, from synthesis all the way to fill-finish-labeling and packaging, simplifying and expediting the cGMP-compliant manufacturing operations.

Our team has successfully and rapidly translated from the research scale production of several grams drug substance to Kg-scale cGMP-compliant manufacture for two different drug candidates, namely NV-HHV-1 and NV-CoV-2, in three different formulations, namely skin cream, oral syrup, and oral gummies, in a very short time span. This includes manufacture of the active ingredients (drug substances), the formulated drug products, and packaged drug products for clinical trials usage.

Manufacturing nanomedicines, especially under cGMP conditions, has been identified as a major risk, and has led to failure of several nanomedicines programs. NanoViricides co-founder Dr. Anil Diwan and our 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.

We have thus demonstrated that we have unique expertise in the industry of performing cGMP-compliant manufacture of multiple 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 is a very significant milestone on the way of NanoViricides becoming a fully-integrated pharma company.

Our production capacity is anticipated to be more than sufficient for Phase I, Phase II and Phase III human clinical trials for all of our drugs in development.

We believe that our drug manufacturing capacity is sufficient for initial market entry for our anti-RSV drug when approved.

Our in-house cGMP production capability has resulted in and is expected to continue to result in significant cost savings across all our drug development programs.

NanoViricides is Fully Equipped for Rapid Antiviral Drug Development from Discovery to cGMP Drug Product Delivery for Clinical Trials; Which Makes NanoViricides a “FIPCO”

In addition to the manufacturing facility, we have on site specialized nanomedicines characterization facility with advanced instrumentation including Wyatt Dynamic Light Scattering instruments, Mass Spectrometry Equipment with “Multiple Reaction Monitoring (MRM)” capability, and others.

We also have onsite full-fledged chemistry laboratories to enable drug design, discovery, small scale synthesis, testing, and scale-up of drug candidates worthy of further development.

We also have our own BSL2 Virology Lab for initial evaluation of our drug candidates in cell culture and other in vitro studies.

Thus we are a “Fully-Integrated-Pharmaceutical Company” (FIPCO) unlike most biopharma companies that do not possess the full suite of drug discovery, synthesis, testing, characterization, scale-up, as well as drug substance and drug product manufacture capabilities in house.

High Probability of Success in Clinical Trials for Drugs Based on NanoViricides Platform Technology

We are now a clinical stage innovative drug development company, advancing from the research and development (“R&D”) stage into regulatory development of our drug candidates towards commercialization. We have been executing rapidly and efficiently, as well as in a cost-effective and productive manner, resulting in successful completion of the Phase I Safety and Tolerability clinical trial of our drug candidate, NV-CoV-2 (API NV-387). We believe that this successful completion with no reported adverse events, is a very important milestone because NV-387 can now advance into Phase II efficacy clinical trials for multiple antiviral indications. Further, this success validates our entire platform technology as being capable of producing drug candidates that are capable of successfully completing Phase I safety and tolerability studies.

In addition, our pre-clinical lethal virus infection animal model studies provide us the confidence that the drug candidates we advance into Phase II efficacy clinical trials would have a very high likelihood of success. This is because in these animal studies, the animal model plays the role of a “test tube” where the virus can proliferate, and our drugs are designed to directly attack the virus without interfering with functions of the host animal. Additionally, we design the studies to provide clear readout in terms of survival lifespan that can be used for ranking the activity of each tested drug, including already approved drugs where available.

We de-risk drug development heavily in the early stages so that failure at clinical stage would be minimized. We believe our success rate of drug approval would be substantially better than industry averages because of the features of our nanoviricides platform technology and the de-risking strategies we employ in drug development.

The NanoViricides Platform Technology: (i) Solving the Problem of Drug Escape by Virus Variants

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

Our 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. Thus our platform technology is inherently designed to combat the issue of viruses escaping drugs by generation of variants.

We mimic the feature on the cellular protein at which the virus binds, and, using molecular modeling, design small molecules that act as “ligands” to bind to the virus surface glycoproteins as though the virus was binding to that cellular protein itself. This host-side chemical signature that the virus uses for infecting cells does not change even as the virus mutates, evolves and generates variants. We chemically synthesize the optimal ligands, and separately attach them to the polymeric micelle scaffold to generate a number of initial “nanoviricide” drug candidates to screen against the virus. Consequently, the nanoviricide is designed to “look like” the cell membrane with copious amounts of sites for the virus to bind to. When initial interaction of a few ligands with the virus particle takes place, the “metstable” nanoviricide micelle is anticipated to shift its shape, inverting itself onto the virus particle promoted by the “lipid-lipid mixing effect” driven by the lipid chains normally on the interior of a nanoviricide micelle and the lipid membrane that is on the virus surface. Such an attack on the virus particle is expected to de-stabilize the virus particle and uproot the surface glycoproteins it uses for fusing with a cell. As a result, the virus would no longer be capable of infecting a cell. This process would result in complete blockage of the “Re-Infection Cycle” of the virus if successful. We call this mechanism “Re-Infection Inhibition”. This mechanism goes beyond the simple neutralization of the virus by antibodies, which requires the human immune system to further take care of the resulting virus-antibody complex. This mechanism also goes beyond the simple blocking of virus entry by small chemical entry inhibitors, which would require extremely high concentrations of the inhibitor to effect complete blockage of each virus particle based on mass-action considerations.

The nanoviricide polymeric micelle is expected to be able to completely coat the virus particle. This is unlike the antiviral antibodies as well as small molecule entry inhibitors that can only partially block the virus particle whereby the virus would still remain capable of infecting a cell. Additionally, antibodies only tag the virus for recognition by the patient’s immune system for clearance. In contrast, a nanoviricide is designed to complete the task of dismantling the machinery of the virus that enables it to infect cells.

In the case of NV-CoV-2, during drug discovery and development process, in addition to employing the ACE2 virus entry protein as our engineering bio-mimicry target, we also performed biomimetic engineering that used the sulfated proteoglycans that all coronaviruses attach to and concentrate at the cell surface, then during drug discovery and development process. We believe this enables them to bind to their cognate receptors (such as ACE2 for SARS-CoV-1, SARS-CoV-2, and hCoV-NL63; DPP-IV for MERS, etc.) and gain entry into the cell. This second approach provides substantially broader antiviral spectrum than using a specific cognate cellular protein that the virus uses for entry. NV-CoV-2 is a result of this broad-spectrum approach of using sulfated proteoglycan mimetic ligands.

Mimicking the attachment receptor families may lead to extremely broad-spectrum drug candidates. We call this implementation NanoViricides Platform Technology Modality #1. NV-387 is an example of this Modality #1, namely, Broad-Spectrum Antiviral Re-infection Inhibitors.

Mimicking the cognate receptor would lead to a narrower range but can be anticipated to have greater efficacy compared to mimicking the attachment receptor families. We call mimicking the cognate receptor the NanoViricides Platform Technology Modality #2, or Specific Antiviral Re-Infection Inhibitors.

The NanoViricides Platform Technology: (ii) Promising Potential Cures for Infections by Non-latency Viruses

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 (i.e. block the “Re-Infection Cycle”), and (b) simultaneously block the reproduction of the virus that has already gone inside a cell (i.e. block the “Replication Cycle”). Together, this strategy of a two-pronged attack against the virus, both inside the cell and outside the cell, and thus blocking the complete lifecycle of the virus, can be expected to result in a cure for coronaviruses and other viruses that do not become latent. We call this implementation, namely encapsulation of other active ingredients within the polymeric micelle of the virus-targeted nanoviricide (which can be based on either Modality #1 or Modality #2), the NanoViricides Platform Technology Modality #3.

As an example of the Modality #3, we have developed NV-387-g-R, which comprises NV-387 that encapsulates Remdesivir, a known broad-spectrum antiviral drug that is already approved for COVID treatment of hospitalized patients. Although approved, the clinical effectiveness of Remdesivir is limited by its bodily metabolism. It is well-known that this drug is highly active in cell culture studies, but the clinical results do not match the expectations corresponding to its cell culture effectiveness. We developed NV-387-g-R to overcome this issue and we have demonstrated that encapsulation within NV-387 successfully improves the PK/PD (pharmacokinetics and pharmacodynamics) profile of Remdesivir. The increased circulating lifetime and also concentration of intact Remdesivir should improve its effectiveness. Additionally, NV-387-g-R affords the synergistic effects of attacking the virus lifecycle by two orthogonal mechanisms, going well beyond the effects of Remdesivir alone. In NV-387-g-R, one component, NV-387, is designed to block the “Re-Infection Cycle”, and the encapsulated guest component, Remdesivir is known to block the “Replication Cycle”. Thus NV-387-g-R is designed to block the entire lifecycle of many viruses, not just coronaviruses.

This total attack on the complete 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 demonstrated this capability in the case of NV-387-g-R, as discussed above, wherein encapsulation of Remdesivir within the polymeric micelles of NV-387 protects the former drug from bodily metabolism in animal studies. This allows higher concentrations of the guest drug to be reached and simultaneously extends the effectiveness time period in comparison to the standard Veklury® (Gilead) formulation. The resulting drug, NV-387-g-R has not only significantly improved characteristics for its Remdesivir component, but additionally provides the novel re-infection blocking mechanism of NV-387; together enabling complete block of the viral lifecycle, which would potentially result in a cure. (Chakraborty A, Diwan A, Chiniga V, Arora V, Holkar P, Thakur Y, et al. (2022) Dual effects of NV-CoV-2 biomimetic polymer: An antiviral regimen against COVID-19. PLoS ONE 17(12): e0278963. https://doi.org/10.1371/journal. pone.0278963.)

The NanoViricides Platform Technology: (iii) Routes of Administration Include Oral Route

It is generally believed that nanomedicines as a class would not have good bio-availability if taken orally. We believe that this biased opinion has unnecessarily resulted in curbing potential innovation to overcome the issue of oral bioavailability.

In fact, we have found in pre-clinical animal studies that both NV-387 and NV-387-g-R were highly effective when given orally in combating a lethal lung infections that models the severe SARS-CoV-2 disease as seen with the delta variant. In comparing the effect on combating the infection by oral treatment versus injectable treatment, we believe that the bioavailability of the oral dosage forms is substantially good, and in the range of many approved oral drugs. In addition, the API NV-387 was found to be highly effective when given orally in the case of lethal lung RSV infection animal model, a lethal smallpox-emulating ectromelia footpad infection mouse model, a lethal smallpox-emulating ectromelia lung infection mouse model, as well as a lethal Influenza A/H3N2 lung infection mouse model, further substantiating the oral bio-availability of NV-387.

These findings have enabled us to develop oral formulations of NV-387 for human clinical trials. We have successfully developed orally active formulations of our NV-387 in an oral syrup form, as well as an oral gummies (“Chewable Soft Solids”) form. We believe that for mild to moderate viral infection disease, for pediatric, and for geriatric patients, the oral syrup and gummies forms would be highly advantageous over tablets, capsules, injections, infusions, or lung inhalations.

The injectable formulation of NV-387 is expected to be valuable in the treatment of severe cases. Out-patient single dose injection treatment may be feasible if the effectiveness of NV-387 in human clinical trials matches that observed in pre-clinical animal studies. Further, this injectable formulation is designed to be deliverable also as an aerosol by a simple hand-held nebulizer device directly into the lungs. Such inhalation, as an aerosol, is expected to provide greater benefits to more severe patients by providing high concentration of the drug locally in the lungs where the RSV, SARS-CoV-2, and Influenza viruses cause the most damage in severe cases. The Solution for Injection, Infusion and Inhalation of NV-387 would also be very important in pediatric as well as hospitalized cases.

We believe that the strong antiviral activity we have observed in cell culture studies and in lethal virus infection animal studies, in comparison to approved drugs is a positive indication of clinical success and potential regulatory approval of NV-387 for the different viral infection indications we are seeking.

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 flexible and tailorable Nanoviricide

Platform technology. The technology also enables us to develop nasal sprays and bronchial aerosols. We plan to develop the appropriate formulations as necessary.

A Note on Nomenclature of NanoViricides Candidates:

“g” denotes that the next component is encapsulated as a guest within the preceding nanoviricide. Thus NV-387-g-R refers to Remdesivir encapsulated as a guest within NV-387. Similarly NV-387-g-Rp refers to a pro-drug of Remdesivir (denoted Rp) is encapsulated as a guest within NV-387.

“m” denotes that the next component is mixed in with the preceding nanoviricide. Thus NV-387-m-T refers to NV-387 and Tecovirimat mixed together in a formulation method.

Developments During the Reported Period

During the nine months ended March 31, 2024, (i) we have successfully completed the Phase 1a/1b clinical trial of NV-387 with no adverse events; (ii) we have expanded our manufacturing capacity of nanoviricides drugs in anticipation of multiple clinical trials, and (iii) we have continued to further understand the spectrum of antiviral activity of NV-387 towards obtaining information for regulatory advancement against different antiviral indications.

Manufacturing Capacity Increase in Preparation of Drug Supply for Phase II Clinical Trials

In the previous quarter, we have approximately doubled our production batch size and capacity for NV-387 manufacture. We believe that this capacity will be sufficient for Phase II/III clinical trials for RSV. The production program for Phase II clinical supply is expected to be commissioned soon.

The Phase 1a/1b Human Clinical Trial of NV-CoV-2 (API NV-387), a Broad-Spectrum Antiviral Drug, in Healthy Subjects, is Completed Successfully with No Adverse Events

On January 29, 2024, we reported that the healthy subjects part of the Phase 1a/1b human clinical trial of NV-CoV-2, under the sponsorship of KMPL, our licensee and collaborator, was completed.

All subjects were successfully discharged. There were no discontinuations. All dosage levels at all dosing instances were well-tolerated and there were no adverse events. Thus the drug NV-387 was found to be safe for both single dosing and for repeat dosing even at amounts as high as 40 mg/Kg, including a first “loading” dose at 80 mg/Kg.

Additionally, the pharmacokinetics human plasma samples from these SAD and MAD healthy human subjects were shipped from India under appropriate conditions and have been received by the bioanalytical lab in the USA. We are now awaiting the human PK data and report.

The internal audit of the clinical data has been completed. The Drug Safety Monitoring Board has provided their input that the drug can be advanced into further Phase II clinical trials.

Once the PK analyses and statistical analyses are completed, the drug sponsor KMPL and the CRO will complete a final report of the Phase I clinical trial.

In the non-clinical studies leading to the Phase 1a/1b clinical trial, NV-387 has been found to be non-immunogenic, non-allergenic, non-mutagenic, as well as non-genotoxic in various pre-clinical animal model studies. No adverse effects were reported in GLP Safety-Toxicology studies in multiple animal models including non-human primates (NHP, Cynomolgus monkeys). The NOAEL (No-Observed-Adverse-Events-Level) was 1,200 mg/Kg and MTD (Maximum Tolerable Dose) was 1,500 mg/Kg in rats, which are very high numbers (high is numbers are positive).

The results of the Phase 1a/1b clinical trial are consistent with these non-clinical findings, with no adverse events reported.

Thus NV-387 can now be advanced into Phase II human clinical trials against the different antiviral indications within its antiviral activity spectrum.

Update on Our COVID Program

The original plan for the Phase 1a/1b clinical trial was to include COVID patients in Phase 1b-COVID cohorts to obtain initial indications of efficacy and dosage requirement. The healthy subjects portion of the clinical trial, which is the traditional Phase I clinical trial involving the evaluation of single-ascending-dose and multiple-ascending dose of the investigational medical product in healthy subjects was completed in December, 2023. Thereafter, efforts to find COVID patients were continued, and an additional clinical site was added during February 2024. In spite of this, the lack of obtaining PCR-positive COVID patients eligible for enrollment into the clinical trial became the obstacle to this trial. Our diligent efforts to identify COVID-19 participants for the clinical trial have been met with a notable absence of positive cases at the designated clinical trial site(s). Therefore, the Phase 1a/1b clinical trial was closed in April 2024, concluding the study as a traditional Phase I study.

We note that we do not have any information regarding the activity of NV-387 (drug product NV-CoV-2) in COVID from this clinical trial because no COVID patients could be found for enrollment in the study. We believe that NV-387 has strong, clinically relevant, activity in treatment of COVID based on our pre-clinical studies that directly evaluated the activity of NV-387 in comparison with remdesivir, an approved drug for the treatment of COVID, and found that the activity of NV-387 was substantially superior to that of remdesivir.

We have been in discussion with subject matter experts in the U.S. as well regarding potential clinical trials towards approval of NV-387 for COVID indication. While COVID still continues to be significant globally, the prospect of conducting meaningful clinical trials in COVID patients has become substantially difficult. Long COVID remains an important disease in the U.S. However, it is multi-factorial, and conducting meaningful clinical trials is even more difficult than with COVID patients, and could result in lengthy and expensive clinical trial designs, not within the capabilities of small companies like us.

Therefore, while we fully believe that (i) NV-387 has demonstrated strong pan-coronavirus antiviral activity and therefore (ii) NV-387 is a viable clinical drug candidate for COVID treatment, (iii) NV-387 could be substantially superior to available drugs such as remdesivir and Paxlovid, and (iv) NV-387 would be available to the entire patient population while the available drugs have severe limitations, regrettably, we have determined that we cannot take NV-387 forward for COVID indication with our limited resources.

If resources become available for clinical trial of NV-387 for a subset of Long COVID patients with residual virus found in sensitive assays, then we would consider seeking to advance clinical trials to develop NV-387 for the Long COVID indication as this is currently an unmet medical need.

NV-387 Has Multiple Antiviral Indications Beyond COVID Towards Regulatory Approvals

Knowing that NV-387 is designed to be broad-spectrum, over the previous nine months we have continued to work towards understanding the broad spectrum of antiviral activity of the API NV-387.

Of the potential indications, we have decided to focus our resources on advancing NV-387 into clinical trials towards approval for RSV infection in pediatric patients, an unmet medical need.

The results of the NV-387 Phase 1a/1b clinical trial indicate that NV-387 can be used: (i) across all ages from pediatrics to seniors; (ii) irrespective of co-morbidities such as diabetes, other pre-existing diseases, or immune compromised status of the individual; and (iii) at all levels of disease severity, from mild/moderate to severe to very severe (hospitalized patients).

We believe that this capability of NV-387 is analogous to the success of antibiotics against bacteria.

In contrast, currently available antiviral drugs have substantial limitations on the patient populations that they can be used in. For example, of the two remaining approved drugs for treatment of COVID, Paxlovid which is given orally, is not indicated for the treatment of COVID in patients without a risk factor for progression to severe COVID-19, whereas Remdesivir can only be used in hospitalized cases. Similarly ribavirin, indicated for RSV infection and other viral infections, is only indicated as a last resort because of severe toxicities. Other antivirals such as Cidofovir, Brincidofovir, etc. also have limitations due to toxicities.

NanoViricides Broad-Spectrum Antiviral Drug NV-387 Was Found To Have Strong Antiviral Activity Against RSV Lethal Lung Infection Leading to Full Survival of Lethally Infected Animals, Indicating A High Success Probability for Regulatory Approval After Appropriate Clinical Trials

On July 11, 2023 we reported that NV-387 was found to possess strong antiviral activity in an animal model of lethal lung pneumonia caused by RSV infection. Importantly, both oral and intravenous administrations of NV-387 were effective almost matching the effectiveness of the toxic drug Ribavirin. We believe that there is currently no safe and effective drug approved for RSV.

In the reported quarter, we performed an additional RSV infection study with increased dosing of NV-387 as well as increased dosing of ribavirin. In this study, NV-387 oral treatment led to *complete survival* of lethally RSV infected mice, whereas the untreated or vehicle-treated mice died in seven days and the ribavirin treated mice survived only 14 days. Thus we believe that NV-387 is potentially a highly valuable drug for the treatment of RSV infection. To our knowledge, there are currently no drugs approved for the treatment of RSV infection, other than ribavirin that is given as last resort due to its extreme toxicity.

On the basis of these studies, we have determined to advance NV-387 into clinical trials towards approval of NV-387 for RSV infection in pediatrics because we believe that this is currently an unmet medical need.

Pre-IND Application for Treatment of RSV Infection with NV-387 is in Preparation

In the reported quarter, we have begun to assemble a pre-IND application to the US FDA for NV-387 in RSV infection. Simultaneously, we are also working on developing an IND application for a Phase II clinical trial of NV-387 in RSV infection. We plan on using the non-clinical data, the CMC data, as well as the data from Phase I clinical trial to support our application. It is likely that the US FDA may require additional non-clinical data, and may require modifications to our outline of Phase II clinical protocol.

RSV causes severe infections primarily in infants and young children, persons over age of 60 and immune-compromised persons. Each year in the United States, an estimated 58,000–80,000 children younger than 5 years old are hospitalized due to RSV infection. Globally, RSV is a common cause of childhood acute lower respiratory infection (ALRI, which includes pneumonia) and a major cause of hospital admissions in young children. Globally in 2015, 33 million episodes of RSV-ALRI, resulted in about 3.2 million hospital admissions, and 59,600 in-hospital deaths in children younger than five years. About 45% of hospital admissions and in-hospital deaths due to RSV-ALRI occur in children younger than 6 months.

Two vaccines have recently been approved for RSV prophylaxis. Arexvy (GSK), and Abrysvo (Pfizer) were approved in May 2023 for use in adults over 60 years of age and both reduced severity of RSV infection. There are currently no vaccines approved for infants and children.

To our knowledge, there are no safe and effective therapeutics for RSV to date. Ribavirin, a highly toxic drug, is conditionally approved only for patients with high risk of progressively severe RSV disease, due to significant side effects including hemolytic anemia and kidney failure. Synagis (palivizumab), and recently approved Beyfortus (nirsevimab) are antibodies approved only for prophylactic use in children and infants at high risk of severe RSV infection, but neither is approved for treatment of RSV infection, which remains an unmet medical need.

NV-387 Was Found To Have Strong Antiviral Activity In Lethal Infection Animal Model of Influenza A/H3N2 Infection, Suggesting that Its Antiviral Spectrum Could Extend to Influenza A Viruses, Potentially Including the Highly Pathogenic Influenza A (HPAI) Such as Bid Flu, H5N1

We have recently performed a lethal lung infection study of mice infected with Influenza A/H3N2 treated with NV-387 comparing with three approved drugs: Oseltamivir (Tamiflu®, Roche), Peramivir (Rapivab®, Biocryst), and Baloxivir (Xofluza®, Shionogi, Roche). In this study, NV-387 Oral treatment led to a survival lifespan of 15 days, compared to 10 days with Oseltamivir Oral treatment, 11 days with Peramivir I.V. treatment, and 11 days with Baloxivir Oral treatment, while the vehicle-treated and untreated (infected) animals survived only 8 days. Thus the antiviral activity of NV-387 given orally was substantially superior to all three of the approved anti-influenza drugs, namely Tamiflu, Rapivab, and Xofluza.

Given the broad-spectrum of antiviral activity of NV-387 against viruses in many different virus families, we believe that its effectiveness against H3N2 is indicative of potential antiviral activity against most if not all Influenza A viruses.

We believe, based on structural information, that the H5 hemagglutinin of H5N1 bird flu virus may be even more susceptible to NV-387 attack than the H3 hemagglutinin of the H3N2 virus. This is because H5 contains a long polybasic site sequence, which has biochemical affinity from electrostatic interactions with the antiviral ligand in NV-387. This antiviral ligand is a sulfated proteoglycan mimetic.

Based on this information, we believe that it is very likely that NV-387 may have strong antiviral activity against the bird flu H5N1 virus, although further work is needed in this regard.

To date H5N1 bird flu virus has caused only sporadic infections in humans that have been zoonotic in origin, most previous ones being from poultry to humans, while recently cases from cattle to human transmission have recently occurred. H5N1 has caused increasing spread in wild bird and poultry populations, and now has taken hold in several herds of dairy cattle, and caused a cattle-to-human transmission recently. Recent reports by CDC indicate that the current H5N1 dairy virus has not incorporated mutations necessary for successful human infection and for human-to-human transmission. In addition, pasteurization of milk is found to destroy the infectivity of the H5N1 virus, although its genomic RNA may still turn the RT-PCR test positive. At present the potential risk for a human pandemic from H5N1 is considered low.

This H5N1 was also found to be sensitive to oseltamivir. However, the influenza viruses in particular are known to change rapidly by mutations, recombinations, as well as re-assortments; the last one enabled by the multi-segmented nature of the virus genome. Eight RNA segments together make up its genome, and in a co-infection of two different influenza A viruses, interachange i.e. reassortment of these segments can take place leading to new variants. Public health officials are closely watching H5N1.

We note that all three approved influenza drugs oseltamivir, peramivir and baloxivir are known to be prone to viral escape by mutations. In contrast, NV-387 as a host-mimetic is highly unlikely to be escaped by the susceptible viruses.

We therefore believe that NV-387 could be advanced as a viable anti-influenza drug with a novel mechanism of action. We plan on seeking non-dilutive financial support for this endeavor.

If such an Influenza pandemic does happen in the near future, we believe NV-387 could be the go-to drug for treatment of H5N1 infection, provided that further studies demonstrate antiviral activity of NV-387 against H5N1 itself. In case of an emergency, NV-387 could be readily advanced into an efficacy clinical trial since it has completed the Phase I Safety and Tolerability clinical trial successfully with no reported adverse events.

NV-387 Was Found To Have Strong Antiviral Activity In Lethal Infection Animal Models Used In Drug Development for MPox and Smallpox Virus Infections In Humans

On November 14, 2023, we reported on the on-going smallpox-emulating animal model studies of efficacy of NV-387 treatment. This study emulates the skin-to-skin transfer of the virus as in sexual transmission, such as that in the current Clade 1 MPox virus epidemic in the DR Congo; Clade 1 MPox is more deadly than the Clade 2 MPox that became a small pandemic recently (https://www.sciencefocus.com/news/monkey-pox-new-strain , May 5, 2024).

In this study, we found that oral NV-387 treatment demonstrated antiviral activity equivalent to that of the approved drug tecovirimat (TPOXX®, SIGA Pharmaceuticals) in a lethal model comprising intra-digital infection by the ectromelia virus into the footpads of mice, resulting in a 14-days survival in both treatments, as opposed to 8 days survival of vehicle-treated or untreated animals, based on the on-going work on this project. Moreover, combined treatment with both NV-387 and tecovirimat resulted in a significantly improved survival of 17 days in this study.

In addition, during the reported quarter, we have completed an additional lethality animal study wherein animals were infected with ectromelia virus into the lungs directly. This study emulates infection from aerosolized dispersion of the virus, as may be expected in a bioterrorism scenario.

In this study, we found that NV-387 alone treated animals survived 16 days, tecovirimat alone treated animals survived 17 days, and NV-387 plus tecovirimat treated animals survived 19 days, whereas vehicle-treated animals died in 8 days. This lung infection study substantiates the results of the footpad infection study that (i) NV-387 has comparable antiviral activity as tecovirimat, and

(ii) NV-387 plus tecovirimat has much stronger antiviral activity than either drug alone.

Tecovirimat is the drug approved for smallpox under “animal rule” and is stockpiled by the Biomedical Advanced Research and Development Authority (BARDA). It was mobilized from the stockpile during the recent MPox epidemic. BARDA is interested in development of additional poxvirus therapeutics as per a recent Broad-Agency Announcement (BAA). There is significant interest in the development of a smallpox therapeutic that works well by itself, as well as in combination with the known drug, tecovirimat. Tecovirimat has a low barrier of escape, a single mutation in one protein can enable the virus to escape this drug, adding to the significance of additional smallpox drug development.

Therefore we believe that NV-387 is a viable clinical candidate to be developed by itself for the treatment of poxvirus infections under the US FDA “Animal Rule”. In addition, we believe that the combination of NV-387 and tecovirimat could reduce the potential for escape resistant generation against tecovirimat, as is known with other drug combination studies against viruses.

Further, having a single drug, NV-387, that can tackle (i) the pandemic-potential Influenza viruses, (ii) the bioterrorism-threat Smallpox, (iii) the pandemic potential Mpox virus, (iv) RSV, and (v) pandemic potential Coronaviruses could save the US Strategic National Stockpile significant sums of money, rather than the current approach of developing one or more drugs against each of these viruses.

We believe that it may be possible for us to obtain non-dilutive grants and contracts based funding for the development of NV-387 as a therapeutic for poxviruses under the FDA “Animal Rule” provision, which requires specific animal model studies as substitutes for Phase II/III human clinical efficacy studies, and an extended Phase I human safety study.

In July, 2023, SIGA announced that it has received new procurement orders of approximately $138 million for TPOXX from the U.S. government. Previous acquisitions of TPOXX have totaled close to a billion dollars, indicating the significant commercial value for a Smallpox/Mpox drug.

Thus, NV-387 addresses an unmet medical need for broad-spectrum antiviral drug against multiple threats. In addition to the above reported work, we have been working on a number of background tasks that feed into the regulatory pathway.

Our press release regarding NV-387 activity against Influenza A/H3N2 in comparison to other approved Influenza drugs was published on May 6, 2024 via AccessWire.

Our press release regarding NV-387 activity against a lethal lung infection animal model of smallpox/Mpox in comparison to the toxic drug ribavirin was published on May 8, 2024 via AccessWire.

Our press release regarding NV-387 activity against a lethal lung infection animal model of smallpox/Mpox in comparison to the approved drug tecovirimat was published on May 14, 2024 via AccessWire.

Our Other Drug Development Programs

NV-HHV-1, Our Drug Candidate for Treatment of Shingles Rash

Previously, we have developed a clinical drug candidate NV-HHV-1 and formulated it as a skin cream for the treatment of Shingles. We plan on undertaking clinical trials of NV-HHV-1 after NV-387 RSV Phase II clinical trials. We have performed cGMP-like manufacture of both the active pharmaceutical ingredient (the API in NV-HHV-1 i.e. NV-360), and the fully formulated skin cream (the drug product candidate), at our own facilities at ~1Kg scale (API basis) with attendant significant time, project management, and cost savings as opposed to going to an external contract manufacturer. Approximately 10Kg of fully formulated drug product was manufactured. We believe this scale is sufficient for the requirements of Phase I and Phase II human clinical trials of NV-HHV-1.

Previously, NV-HHV-1 was found to have antiviral activity against HSV-1 as well as HSV-2 in animal models. The antiviral ligand in NV-HHV-1 is designed to mimic the host protein HVEM (HerpesVirus Entry Mediator) that almost all herpesvirus family viruses use for cell entry as a cognate receptor. We plan on pursuing indications of NV-HHV-1 skin cream formulation for the treatment of (i) Shingles rash (VZV), (ii) Chickenpox rash (VZV), (iii) HSV-1 “cold sores”, and (iv) HSV-2 “genital ulcers”.

We are also developing a systemic drug for the treatment of herpesvirus family infections, based on the same API NV-360 that we believe will be superior to acyclovir related drugs, the current workhorse drugs for HSV-1 and HSV-2. While acyclovir and related drugs are also given for severe shingles, they do not work very well. This is because these drugs require first phosphorylation by the viral Thymidinylate Kinase (v-TK) enzyme, which is not very active in VZV.

Other Pre-clinical Drug Programs

We also have drug candidates against HIV that have shown antiviral activity in cell culture studies as well as in SCID-hu-Thy-Liv mouse model studies. We plan on undertaking further development of the HIV drug in partnership because of the expensive nature of the development.

Additionally, we have developed drug candidates in the past against several other viral infections including Influenza viruses, H5N1 bird flu virus (successful cell culture studies using two different H5N1 strains in Vietnam), Adenoviral epidemic kerato-conjunctivitis (EKC) (successful animal study in rabbits). We also have drug development programs to treat Dengue viruses and Ebola/Marburg viruses.

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

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 indications in the evaluation of safety of our broad-spectrum antiviral drug candidate NV-387 as well as that of NV-360, our herpesvirus family specific antiviral drug candidate to date in non-clinical studies including IND-enabling safety pharmacology studies. Further, NV-387 has successfully completed Phase 1 human clinical trial with no adverse events, indicating an excellent level of safety. The final determination of safety and efficacy of a drug rests with the regional drug regulatory authority such as the US FDA, EU EMEA, India CDSCO/DCGI, UK MHRA and others.

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 NV-387 with the goal of the treatment of pediatric RSV infection with urgency. Further, we continue to perform pre-clinical investigations to expand the usage of NV-387 as an antiviral drug against other viruses to improve return on investment, ROI. Additionally, we are also performing topical drug development against several indications related to infections by herpes family viruses.

Our Campus in Shelton, CT

Our campus at Shelton, CT, is fully operative. With our R&D discovery labs, analytical labs, the bio labs for virology R&D, the process scale-up production facility, and the cGMP-capable manufacturing facility established at our Shelton campus, we are in a strong position to move our drug development programs into the clinic rapidly.

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. It comprises reactors and process vessels on chassis or skids, ranging from 250mL to 75L capacities, as needed. Many of the reactors and vessels have been designed by us for specific tasks related to our unique manufacturing processes. Additionally, we have clinical scale filling and packaging equipment for oral syrup and oral gummies (semi-solids) formulations, that was custom-designed and fabricated in the U.S.

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 have added a suite for cGMP-compliant Oral Drug Product Formulation, Fill, and Packaging. We manufactured and delivered the clinical NV-CoV-2 oral syrup and oral gummies (semi-solids) drug products in this suite using equipment that we had custom-designed and fabricated in the U.S.

We plan to produce multiple batches of a drug product. At the appropriate time as required we plan to register the facility as a cGMP manufacturing facility with the FDA.

Our BSL-2 Certified Virology Lab

We have significantly enhanced our internal anti-viral cell culture testing capabilities at our Shelton campus. Our Virology Research Lab suite has a BSL-2 (Biological Safety Level 2) certification from the State of Connecticut. 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 drug candidates against Coronaviruses, SARS-CoV-2 Pseudovirions, VZV, HSV-1, HSV-2, Influenza viruses, among others in this lab. Recently, we have added assays for screening of drug candidates against BSL2-Orthopoxviruses, Enteroviruses, and RSV. Our BSL-2 Virological capability has been instrumental in our rapid development of potential drug candidates for further investigation towards human clinical trials. We believe that having developed the internal capabilities for cell culture testing of our ligands and nanoviricides against a variety of viruses has substantially strengthened and accelerated our drug development programs.

NanoViricides Business Strategy in Brief

We intend to perform the regulatory filings and own all the regulatory licenses for the drugs we are currently developing. We will develop these drugs in part via subcontracts to TheraCour, the exclusive source for these nanomaterials. We plan to market these drugs either on our own or in conjunction with marketing partners. We also plan to actively pursue co-development, as well as other licensing agreements with 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. Such licensing and/or co-development agreements may shape the manufacturing and development options that we may pursue. There can be no assurance that we will be able to enter into co-development or other licensing agreements.

We have kept our 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.

As a risk factor, we have 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 plan to take NV-387 into Phase II/III clinical trials for treatment of RSV infections. We plan on obtaining non-dilutive funding for the drug development poxvirus program. We plan on seeking partnerships on these programs as they mature further.

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 Phase II clinical trials of our NV-387 drug candidate for RSV.

As a risk factor, we recognize that the FDA may require additional studies to be done before approving the IND for any of our programs. 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 NV-387 in human clinical studies for the treatment of RSV infection. 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 additional studies as necessary 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 immuno-compromised patients, among others, provided that appropriate levels of funding is available. We believe that adding further indications would significantly expand market penetration and improve return on investment for our drugs.

Collaborations, Agreements and Contracts

On March 27, 2023, we entered into a License Agreement (the "Agreement") with Karveer Meditech Private Limited, India ("KMPL"), whereby we granted to KMPL a limited, non-transferable, exclusive license for the development and commercialization and further use, sale, or offer of sale of the Licensed Product(s) NV-CoV-2 and NV-CoV-2-R (the "Two Clinical Test Drug Candidates") in the Territory of India, and as part of the drug evaluation and development, KMPL agreed to sponsor the clinical test drug candidates for Phase I and Phase II clinical trials and act as clinical trials manager. The Company shall have rights to the data generated by KMPL in the clinical trials for use in other jurisdictions, and KMPL shall provide the Company with applicable reports and data. The license conveyed pursuant to the Agreement shall have no set term, and will continue for the period during which KMPL uses the Company's proprietary technologies. In return, the Company will reimburse KMPL for all direct and indirect costs incurred for the clinical trials, as well as a customary fee of 30% of such costs. Further pursuant to the Agreement, KMPL shall pay the Company 70% of any invoiced commercial net sales of either or both of the Two Clinical Test Drug Candidates to unaffiliated third parties; there will be no minimum royalties, nor any license maintenance fees. KMPL is a related party in that Dr. Anil Diwan, our President, co-founder, and Executive Chairman, is also a co-founder and passive investor in KMPL.

KMPL retained a local clinical research organization (CRO), PristynCR, and together they had successfully obtained required regulatory permissions to conduct clinical evaluation of NV-CoV-2 as a COVID treatment in India, on or about January 30, 2023. Previously, on September 15, 2021, we signed a Master Services Agreement with KMPL in which KMPL declared its intent to license NV-COV-2 and NV-CoV-2-R for commercialization in India, and undertook the responsibility to obtain necessary licenses and regulatory approvals as would be needed for the clinical evaluation and commercialization of the drugs in India. No binding licensing activity took place under that earlier agreement. Subsequently KMPL proceeded to develop and file the required regulatory documents including a clinical trials application with the regulatory authority in India. KMPL has retained a local clinical research organization (CRO) for the purpose of developing such documents and planning and executing the clinical trials. We helped KMPL with assembling the necessary datasets and information.

Around June, 2023, KMPL and PristynCR began the Phase 1a/1b clinical trial of NV-CoV-2. The healthy subjects part of the SAD and MAD clinical trial cohorts was completed recently.

We have not engaged any other new collaborators during the reported quarter.

Patents, Proprietary Rights: Intellectual Property – Recent events

NanoViricides' platform technology and programs are based on the TheraCour® nanomedicine technology of TheraCour, which TheraCour licenses from AllExcel. NanoViricides holds a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex Virus (HSV-1 and HSV-2), Varicella-Zoster Virus (VZV), Influenza and Asian Bird Flu Virus, Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Ebola/Marburg viruses, and certain Coronaviruses. We intend to obtain a license for poxviruses, enteroviruses, RSV and other viruses that we engage into research for, if the initial research is successful. TheraCour has not denied any licenses requested by us to date. Our business model is based on licensing technology from TheraCour Pharma Inc. for specific application verticals of specific viruses, as established at the Company's foundation in 2005.

In September 2021, we 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. These licenses are not limited to underlying patents, but also include the know-how, trade secrets, and other important knowledge base that is utilized for developing the drugs and making them successful. In addition, these extremely broad licenses are not limited to some specific chemical structures, but comprise all possible structures that we could deploy against the particular virus, based on these technologies. Further, the licenses are held by NanoViricides for worldwide use. These are described in our Form 10-K filed on October 13, 2023.

COVID Related Drugs: Patent Coverage and Lifetime

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

We have licenses to key patents, patent applications and rights to proprietary and patent-pending technologies related to our compounds, products and technologies, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

Table 1: Update on recent Intellectual Property, Patents, and Pending Patents Licensed by the Company

PCT/US21/39050 - SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTI-COVID-19 AGENTS	Applied: June 25, 2021	Ca. 2043 (estimated)	PCT Application filed.	TheraCour Pharma, Inc. [Exclusive License].
PCT/US22/35210 – SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTI-COVID-19 AGENTS (**)	Applied: June 28, 2022	Ca. 2043 (estimated)	PCT Application filed,	TheraCour Pharma, Inc. [Exclusive License].

**: The PCT application PCT/US22/35210 was filed with request for priority of PCT/US21/39050.

Analysis of Financial Condition, and Result of Operations

As of March 31, 2024, we had cash and cash equivalents of $3,257,240, prepaid expenses of $258,548 and net property and equipment of $7,602,835. Accounts payable and accrued expenses were $813,337, inclusive of accounts payables to related parties of $213,148 and accrued expenses to a related party of $227,435. On February 12, 2024 the Company requested and TheraCour agreed to suspend the existing license requirement to maintain an advance with TheraCour equal to two months of projected TheraCour invoices. The suspension will remain in effect until such time as the Company is able to raise sufficient capital. The existing available advance of $500,000 was applied towards payment of current TheraCour invoices. Stockholders' equity was $10,651,570 at March 31, 2024. In comparison, as of June 30, 2023, we had $8,149,808 in cash and cash equivalents, prepaid expenses of $295,486 and $8,106,647 of net property and equipment. Our liabilities at June 30, 2023 were $534,250 including accounts payable of $157,056 payable to third parties and accounts payable to TheraCour of $233,434, net of a two month advance of $500,000, and accrued expenses of $143,760 including an accrued expense of $100,000 to a related party, and a non-current liability of $1,500,000 due to a related party for a milestone payment.

During the nine month period ended March 31, 2024, we used approximately $4.8 million in cash in operating activities. During the nine month period ended March 31, 2023, we used approximately $4.2 million in cash in operating activities.

Research and Development Costs

We do not maintain separate accounting line items for each project in development. We maintain aggregate expense records for all research and development conducted. Because at this time all of our projects share a common core material, we allocate 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 the reported quarter, we have focused almost exclusively on our COVID program drug candidates.

Results of Operations

Revenues The Company is a biopharmaceutical company and did not have any revenue for the nine month periods ended March 31, 2024 and 2023.

Research and Development Expenses – Research and development expenses for the three months ended March 31, 2024 increased $18,567 to $1,214,661, from $1,196,094 for the three months ended March 31, 2023. Research and development expenses for the nine months ended March 31, 2024 increased $775,742 to $4,255,205 from $3,479,463 for the nine months ended March 31, 2023. The increase in research and development expenses for the three and nine months ended March 31, 2024 is due to an increase in outside lab expenses and clinical trial costs.

General and Administration Expenses – General and administrative expenses for the three months ended March 31, 2024 increased $79,095 to $693,742 from $614,647 for the three months ended March 31, 2023. General and administrative expenses for the nine months ended March 31, 2024 increased $81,913 to $1,869,545, from $1,787,632 for the nine months ended March 31, 2023. The increase in general and administrative expenses for the three and nine months ended March 31, 2024 is due an increase in professional fees.

Interest Income – Interest income for the three months ended March 31, 2024 decreased $54,010 to $53,927 from $107,937 for the three months ended March 31, 2023. Interest income for the nine months ended March 31, 2024 decreased $13,054 to $236,399 from $249,453 for the nine months ended March 31, 2023. The decrease in interest income for the three and nine months ended March 31, 2024 is due to a lower interest bearing balance during the period compared to the prior.

Interest Expense – Interest expense for the three months ended March 31, 2024 and 2023 was $0. Interest expense increased $48,870 to $49,808 for the nine months ended March 31, 2024 from $938 for the nine months ended March 31, 2023. The increase in interest expense for the nine months ended March 31, 2024 is a result of interest expense charged pursuant to the milestone payment note with TheraCour. The interest charged pursuant to the milestone payment note was cancelled by TheraCour on October 27, 2023. The cancellation of the note interest reduced accrued expenses and increased additional paid in capital by $49,808.

Net Loss – For the three months ended March 31, 2024, the Company had a net loss of $(1,854,476) or $(0.16) per share compared to a net loss of $(1,702,804) or $(0.15) per share for the three months ended March 31, 2023. For the nine months ended March 31, 2024, the Company had a net loss of $(5,938,159) or $(0.51) per share compared to a net loss of $(5,018,580) or $(0.43) per share for the nine months ended March 31, 2023. The increase in the net loss for the three and nine months ended March 31, 2024 is attributable to the items discussed above.

Liquidity and Capital Reserves

As of March 31, 2024 we had $3,257,240 in cash and cash equivalents.

The Company's condensed 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 condensed financial statements, the Company has an accumulated deficit at March 31, 2024 of approximately $137.0 million and a net loss of approximately $5.9 million and net cash used in operating activities of approximately $4.8 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, 2024, the Company had available cash and cash equivalents of approximately $3.3 million. Management believes that the Company's existing resources, including availability under its $2 million line of credit will not be sufficient to fund the Company's planned operations and expenditures for at least 12 months from the date of the filing of this Form 10-Q. As a result substantial doubt exists about the Company's ability to continue as a going concern.

The ability of the Company to continue as a going concern is dependent upon controlling its overall expenses and identifying and securing additional financing. Management has considered several options for financing the net working capital deficit as well as to obtain additional funds that will be needed for future human clinical trials. Management believes that we will be achieving several important milestones, including release of the Phase I clinical trial report, a pre-IND application for use of NV-387 in RSV infections as an antiviral, and a clinical trial applications (including US FDA IND) for use of NV-387 to treat RSV and other important respiratory diseases, in the ensuing year. Management believes that as it achieves these milestones, there would be improvement in the liquidity of the Company's stock, and that would improve our ability to raise funds on the public markets at terms that may be more favorable to the terms we are offered at present. Management believes that it has on-going access to the capital markets under an "At-The-Market" (ATM) agreement with EF Hutton that became active around April 15, 2024. Management believes that the Company's stock is currently substantially undervalued in contrast to its asset value, based on the potential of NV-387 alone. Management believes that as our investor outreach program expands and bears fruit, this deviation should be lessened, enabling access to public markets for equity funding at reasonable valuations. In addition, Management has already begun soliciting funds by mortgaging its existing fully owned campus and cGMP manufacturing facilities in Shelton, CT, in order to free up a portion of the fixed capital for use as liquid working capital. These facilities were recently valued at $12 to $15 Million by industry experts. However, there is no guarantee that we will be able to raise funds on reasonable terms acceptable to us, or at all.

In addition, Management continues to adjust its planned expenditures, activities, and programs, in accordance with budgetary constraints and in accordance with its expectations of obtaining additional financing. Management is also taking steps for seeking to license NV-387 to potential partners. Such licenses, if effected, would result in an initial payment at signing, milestone payments as the program advances, and royalty payments from future sales. We do not currently have a licensed partner other than KMPL and there is no guarantee that we can enter into such licensing agreement that provides substantial cash value to us. KMPL has enabled clinical trials of NV-387, our lead drug candidate, in India.

Management is actively exploring additional required funding through debt or equity financing pursuant to its plan. There is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us to fund continuing operations. Management believes that as a result of the management plan, our existing resources and access to the capital markets will allow us to fund planned operations and expenditures. To cover the shortfall, we intend to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies in addition to equity-based financing. There can be no assurance that we will be able to obtain such additional capital resources or that such financing will be on terms that are favorable to us. We believe that the management plan, our existing resources and access to the capital markets will permit us to fund planned operations and expenditures. However, we cannot provide assurance that our plans will not change or that changed circumstances will not result in the depletion of the capital resources more rapidly than we currently anticipate. The accompanying unaudited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

We do not anticipate any major capital costs going forward in the near future. We intend to seek collaborations to develop NV-387 drug further towards approvals by FDA as well as international regulatory authorities. We believe that we have several important milestones that we will be achieving in the current year. Management believes that as it achieves these milestones, our ability to raise additional funds in the public markets would be enhanced. There can be no assurance that we will be able to raise the necessary capital or that it will be on acceptable terms.

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

Off Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements during the nine months ended March 31, 2024.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a smaller reporting company as defined by 17.C.F.R. and are not required to provide information under this item.

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, 2024, 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 March 31, 2024 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, 2023. Management's responsibility is to oversee that the Company is capable of developing accurate and timely financial information. The Company will continue to reinforce additional procedures ensuring that Form 10-K and 10-Q are prepared and reviewed on a timely and accurate basis.

Changes in Internal Control Over Financial Reporting

There were no material changes in our system of internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the quarter ended March 31, 2024 that has materially affected, or is likely to materially affect, our internal control over financial reporting. As noted below, we have implemented 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 provides oversight to the Company's efforts for ensuring appropriate internal control over financial reporting including, but not limited to, remediation of the aforesaid material weakness and identifying and testing for potential internal control weaknesses in the financial reporting process to assure reliability and accuracy. While the Company has implemented additional layers of review of its Form 10-Q through the establishment of the financial reporting controls committee, it was not able to fully remediate the material weakness with respect to the timeliness component. The Company will continue to work to improve its timeliness in review and issuance of its future annual filings.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, the Company may be a party to legal proceedings in the ordinary course of our business in addition to those described below. The Company does 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 1A. RISK FACTORS

We are a smaller reporting company as defined by 17 C.F.R. and are not required to provide information under this item.

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

On October 6, 2023, the Company and Dr. Anil Diwan executed an extension of his employment agreement for a period of one year from July 1, 2023 through June 30, 2024 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares shall be vested in quarterly installments of 2,551 shares on September 30, 2023, December 31, 2023, March 31, 2024 and June 30, 2024 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $8,125 and $24,374, respectively for the three and nine months ended March 31, 2024. The balance of $8,125 will be recognized as the remaining 2,551 shares vest and service is rendered for the remaining three months ended June 30, 2024.

For the three and nine months ended March 31, 2024, 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 $6,064 and $8,791, respectively for the three and nine months ended March 31, 2024 related to these issuances.

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 fair value of the Series A Convertible preferred stock at each issuance was estimated based upon the price of the Company's common stock after an application for a reasonable discount for lack of marketability.

For the three and nine months ended March 31, 2024, the Company's Board of Directors authorized the issuance of 1,786 fully vested shares of its common stock with a restrictive legend for employee compensation. The Company recorded an expense of $2,340 for the three and nine months ended March 31, 2024, which is reflective of the fair value of the common stock on the date of issuance.

The Scientific Advisory Board was granted in August 2023 fully vested warrants to purchase 286 shares of common stock with an exercise price of $1.63 per share expiring in August 2027 and in November 2023 fully vested warrants to purchase 286 shares of common stock with an exercise price of $1.55 per share expiring in November 2027 and in February 2024 fully vested warrants to purchase 286 shares of common stock with an exercise price of $1.44 per share expiring in February 2028. The fair value of the warrants was $131 for the three months ended March 31, 2024 and $437 for the nine months ended March 31, 2024 and was recorded as consulting expense.

For the three and nine months ended March 31, 2024, the Company's Board of Directors authorized the issuance of 23,613 and 66,095, respectively, fully vested shares of its common stock with a restrictive legend for consulting and legal services. The Company recorded expense of $27,000 and $104,600, respectively, for the three and nine months ended March 31, 2024, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and nine months ended March 31, 2024, the Company's Board of Directors authorized the issuance of 9,825 and 27,489, fully vested shares of its common stock with a restrictive legend for director services, respectively. The Company recorded an expense of $11,250 and $33,750 for the three and nine months ended March 31, 2024, which is reflective of the fair value of the common stock on the dates of issuance.

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. None of the foregoing securities as well as common stock issuable upon conversion or exercise of such securities, have been registered under the Securities Act or any other applicable laws and are deemed restricted securities, and unless so registered may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

(a) None.

(b) Corporate Governance

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

(c) Insider Trading Arrangements and Policies

During the period covered by this Quarterly Report on Form 10-Q, no director or officer of the Company " adopted" or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" as each term is defined in Item 408(a) of Regulation S-K.

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)

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 14, 2024

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

Dated: May 14, 2024

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

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Anil Diwan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of NanoViricides, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 14, 2024

By: */s/ Anil Diwan*
Name: Anil Diwan
Title: President, Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Meeta Vyas, certify that:

1. I have reviewed this quarterly report on Form 10-Q of NanoViricides, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 14, 2024

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of NanoViricides, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof, I, Anil Diwan, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The quarterly report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

2. The information contained in the quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 14, 2024

By: */s/ Anil Diwan*
Name: Anil Diwan
Title: President, Chairman
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-Q or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.1 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of NanoViricides, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof, I, Meeta Vyas, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The quarterly report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and

2. The information contained in the quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 14, 2024

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

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-Q or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.2 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.