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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 December 31, 2023

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 February 14, 2024 there were approximately 11,779,000 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

	December 31, 2023 (Unaudited)	June 30, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,245,374	$ 8,149,808
Prepaid expenses	72,442	295,486
Total current assets	5,317,816	8,445,294
Property and equipment, net	7,746,092	8,106,647
Intangible assets, net	329,443	333,578
OTHER ASSETS		
Service agreements	8,859	14,361
Total assets	$ 13,402,210	$ 16,899,880
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 266,663	$ 157,056
Accounts payable – related parties	504,039	233,434
Accrued expenses	180,372	143,760
Total current liabilities	951,074	534,250
Other non-current liability – related party	—	1,500,000
Total liabilities	951,074	2,034,250
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A convertible preferred stock, $0.00001 par value, 10,000,000 shares designated, 890,511 and 547,674 shares issued and outstanding, at December 31, 2023 and June 30, 2023, respectively	9	5
Common stock, $0.00001 par value; 150,000,000 shares authorized, 11,778,643 and 11,698,497 shares issued and outstanding, at December 31, 2023 and June 30, 2023, respectively	117	116
Additional paid-in capital	147,615,441	145,946,258
Accumulated deficit	(135,164,431)	(131,080,749)
Total stockholders' equity	12,451,136	14,865,630
Total liabilities and stockholders' equity	$ 13,402,210	$ 16,899,880

See accompanying notes to the condensed financial statements

Nanoviricides, Inc.
Condensed Statements of Operations
(Unaudited)

	For the Three Months Ended December 31,		For the Six Months Ended December 31,	
	2023	2022	2023	2022
OPERATING EXPENSES				
Research and development	$ 1,573,879	$ 1,170,710	$ 3,040,544	$ 2,283,369
General and administrative	610,877	663,284	1,175,803	1,172,985
Total operating expenses	2,184,756	1,833,994	4,216,347	3,456,354
LOSS FROM OPERATIONS	(2,184,756)	(1,833,994)	(4,216,347)	(3,456,354)
OTHER INCOME (EXPENSE)				
Interest income	83,134	88,954	182,472	141,516
Interest expense	(13,315)	(94)	(49,808)	(938)
Other income (expense), net	69,819	88,860	132,664	140,578
NET LOSS	$ (2,114,937)	$ (1,745,134)	$ (4,083,683)	$ (3,315,776)
Net loss per common share- basic and diluted	$ (0.18)	$ (0.15)	$ (0.35)	$ (0.29)
Weighted average common shares outstanding- basic and diluted	11,745,906	11,610,303	11,732,349	11,601,335

See accompanying notes to the condensed financial statements

NanoViricides, Inc.
Condensed Statement of Changes in Stockholders' Equity
For the six months ended December 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, 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	$ 146,017,882	$ (133,049,494)	$ 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	$ 147,615,441	$ (135,164,431)	$ 12,451,136

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

	Series A Preferred Stock: Par $0.001		Common Stock: Par $0.001				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 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

See accompanying notes to the condensed financial statements

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

	For the Six Months Ended	
	December 31, 2023	December 31, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,083,683)	$ (3,315,776)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	18,975	26,919
Common shares issued as compensation and for services	100,100	76,500
Warrants granted to Scientific Advisory Board	306	703
Depreciation	374,320	366,190
Amortization	4,135	4,135
Changes in operating assets and liabilities:		
Prepaid expenses	223,044	245,476
Other assets	5,502	15,930
Accounts payable	109,607	(18,669)
Accounts payable - related party	270,605	159,027
Accrued expenses	86,420	6,185
NET CASH USED IN OPERATING ACTIVITIES	(2,890,669)	(2,433,380)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(13,765)	(89,845)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of loan payable	—	(94,788)
NET CASH (USED IN) FINANCING ACTIVITIES	—	(94,788)
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,904,434)	(2,618,013)
Cash and cash equivalents at beginning of period	8,149,808	14,066,359
Cash and cash equivalents at end of period	$ 5,245,374	$ 11,448,346
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.
December 31, 2023
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 for the treatment of COVID, NV-CoV-2, is in Phase1a/1b human clinical trials sponsored by our licensee and collaborator in India, Karveer Meditech Private Limited (KMPL). This candidate has shown effectiveness and safety in pre-clinical studies. The healthy subjects part of the Phase 1a/1b clinical trial was successfully completed recently with no adverse events in both single dose escalation studies and multiple dose escalation studies. NV-CoV-2 mechanism of action is orthogonal and complementary to that of the existing therapeutics, enabling combination therapy with the existing drugs in the market. Further, the active pharmaceutical ingredient (API) of NV-CoV-2, namely NV-387, was found to be active against Respiratory Syncytial Virus (RSV) in a lethal pre-clinical lung infection study. Therefore NV-387, a broad-spectrum antiviral, may be eligible for a Phase II clinical trial for RSV as well as Coronavirus infections after completing the current Phase 1 study. In addition, the Company reported on November 14, 2023 that NV-387 was found to be effective in a lethal animal model emulating smallpox disease, namely lethal intradigital footpad infection by ectromelia virus in mice. Smallpox therapeutics are important for biodefense purposes.

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-CoV-2 (NV-387) that are expected to move rapidly from current Phase 1a/1b to Phase 2. 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 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 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, as well as process development and related work will be performed by TheraCour, a related party substantially owned by Dr. Anil Diwan, 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 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, sponsored by KMPL, 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 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 December 31, 2023 of approximately $135.1 million and a net loss of approximately $4.0 million and net cash used in operating activities of approximately $ 2.9 million for the six 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 December 31, 2023, the Company had available cash and cash equivalents of approximately $5.2 million.

Since the onset of the COVID-19 pandemic, the Company has focused its efforts primarily on a single lead program to minimize cost outlays, namely, taking the COVID drug candidate against SARS-CoV-2 into human clinical trials. The same drug candidate, with the Active Pharmaceutical Ingredient (API) NV-387, demonstrated effectiveness against RSV, indicating that its broad-spectrum antiviral activity is not limited to coronaviruses. The prior lead program for a shingles drug will follow the regulatory development of the NV-387 drug program. The Company believes that it has several important upcoming milestones, including Phase 1a/1b human clinical trials for the Company's broad-spectrum, pan-coronavirus drug NV-CoV-2, that is now in progress. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced. However, there is no guarantee that the Company will be able to raise funds on terms acceptable to it, or at all.

Management believes that the Company's existing resources, including availability under its $ 2 million line of credit will be sufficient to fund the Company's planned operations and expenditures for at least 12 months from the date of the filing of this Form 10-Q. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company will need to raise additional capital to fund its long-term operations and research and development plans including human clinical trials for its various drug candidates until it generates revenue that reaches a level sufficient to provide self-sustaining cash flows. There can be no assurance that the Company will be able to raise the necessary capital or that it will be on acceptable terms. The accompanying condensed 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 condensed 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 December 31, 2023	For the Three Months Ended December 31, 2022	For the Six Months Ended December 31, 2023	For the Six Months Ended December 31, 2022
Warrants	7,433	8,820	7,433	8,576

The Company has 890,511 shares of Series A preferred stock outstanding as of December 31, 2023. 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 December 31, 2023, the number of potentially dilutive shares of the Company's common stock into which these Series A preferred shares can be converted into is 3,116,789, 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 six months ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
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	$ 5,474	$ 3,493	$ 13,765	$ 29,369

	As of	
	December 31, 2023	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 months invoice to be applied as a prepayment towards expenses. Accounts payable due TheraCour at December 31, 2023 and June 30, 2023 were $831,227 and $733,434, respectively, which were each offset by a two month advance of $ 500,000.	$ 331,227	$ 233,434

	December 31, 2023	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 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 to unaffiliated third parties. Accounts payable to KMPL at December 31, 2023 and June 30, 2023 were:	$ 172,812	$ —

	For the three months ended		For the six months ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
Research and Development Costs Related Party				
Development fees and other costs charged by to 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 December 31, 2023 and June 30, 2023	$ 682,258	$ 633,247	$ 1,321,335	$ 1,245,958

	For the three months ended		For the six months ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
Clinical Trial Costs - Related Party				
Clinical trial related and other costs charged by KMPL pursuant to the license between KMPL and the Company were approximately $150,000 and $365,000 for the three and six months ended December 31, 2023. As of December 31, 2023 and June 30, 2023 approximately $150,000 and $100,000 of such costs were accrued by the Company pursuant to the license agreement between the Company and KMPL. The amounts has been recorded within accrued expenses in the accompanying condensed balance sheets.	$ 150,000	$ —	$ 365,000	$ —

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.

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 promissory Note. On October 27, 2023 TheraCour exercised its right to convert the principal of the July 19, 2023 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 approximately $50,000 which has been reported as a capital transaction credit to additional paid in capital on the accompanying condensed statements of changes in stockholder's equity. Total interest incurred under the Note for the three and six months ended December 31, 2023 was $13,000 and $50,000, respectively.

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 are 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. The Company has not drawn against the facility as of December 31, 2023.

Note 5 - Property and Equipment

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

	December 31, 2023	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	6,326,783	6,315,727
Total Property and Equipment	14,823,491	14,809,726
Less Accumulated Depreciation	(7,077,399)	(6,703,079)
Property and Equipment, Net	$ 7,746,092	$ 8,106,647

Depreciation expense for the three months ended December 31, 2023 and 2022 was $ 187,262 and $184,855, respectively, and for the six months ended December 31, 2023 and 2022 was $374,320 and $366,190, respectively.

Note 6 – Intangible Assets

Intangible assets, net consists of the following:

	December 31, 2023		Total	June 30, 2023		Total
	Finite Lived Intangible Assets	Indefinite Lived Intangible Assets	December 31, 2023	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	(129,511)	—	(129,511)	(125,376)	—	(125,376)
Intangible Assets, Net	$ 23,882	$ 305,561	$ 329,443	$ 28,017	$ 305,561	$ 333,578

Amortization expense amounted to $2,068 and $2,068 for the three months ended December 31, 2023 and 2022, respectively, and for the six months ended December 31, 2023 and 2022 were $4,135 and $4,135, 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:

	December 31, 2023	June 30, 2023
Personnel and compensation costs	$ 23,872	$ 39,060
Consultant	6,500	4,700
Clinical trial costs due to KMPL	150,000	100,000
	$ 180,372	$ 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 $8,124 and 16,248, respectively for the three and six months ended December 31, 2023. The balance of $16,250 will be recognized as the remaining 5,102 shares vest and service is rendered for the remaining six months ended June 30, 2024.

For the three and six months ended December 31, 2023, the Company's Board of Directors authorized the issuance of 387 and 774, respectively of fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of $1,234 and $2,727, respectively for the three and six months ended December 31, 2023 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.

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. The fair value of the warrants was $ 147 for the three months ended December 31, 2023 and $306 for the six months ended December 31, 2023 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	51.93-54.02 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	4.5-4.6 %

For the three and six months ended December 31, 2023, the Company's Board of Directors authorized the issuance of 23,379 and 62,482, 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 $77,600, respectively, for the three and six months ended December 31, 2023, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and six months ended December 31, 2023, the Company's Board of Directors authorized the issuance of 9,717 and 17,664, fully vested shares of its common stock with a restrictive legend for director services, respectively. The Company recorded an expense of $11,250 and $22,500 for the three and six months ended December 31, 2023, 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	572	1.59	3.75	—
Expired	(1,143)	4.26	—	—
Outstanding and exercisable at December 31, 2023	7,433	$ 4.81	1.71	$ —

Of the outstanding warrants at December 31, 2023, 1,143 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 572 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.

Note 11 – Subsequent Events

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 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 facility as of December 31, 2023.

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 will be applied towards payment of TheraCour invoices.

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.

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, 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 with our first drug in Phase 1a/1b clinical trial and several additional drug candidates in various stages of pre-clinical development, including IND-preparation stage and late stage IND-enabling non-clinical studies. We have no customers, products or revenues to date, and may never achieve revenues or profitable operations. We continue to add to our existing portfolio of products through our internal discovery and clinical development programs and also seek to do so through an in-licensing strategy.

An Overview of Our Drug Pipeline

We have several drugs in our pipeline. Our lead clinical stage drug is NV-CoV-2 for the treatment of COVID and potentially the residual virus cases of "long COVID". NV-387, our broad-spectrum antiviral nanoviricide agent, is the active pharmaceutical ingredient (API) in NV-CoV-2. We have found that NV-387 is also effective against RSV infection in an animal model. There is no licensed drug for the treatment of RSV infection at present. Additionally, NV-387 was found to be as effective as the approved drug tecovirimat (TPOXX®, SIGA) in an animal model that is used for drug development for Smallpox and Mpox infections.

A safe and effective antiviral drug with such an extensive broad-spectrum activity across multiple, distinct, virus families is an unmet medical need. We believe this development is akin to the development of antibiotics to treat bacterial infections and could be as revolutionary towards the treatment of viral infections.

While broad-spectrum antivirals such as Remdesivir, Ribavirin, Cidofovir, etc. are known, all of them suffer from extensive and varied dose-limiting toxicities, and thereby present limitations on eligible patient populations as well as on clinical effectiveness.

In contrast, NV-387 has been found to be safe in the Phase 1a/1b on-going human clinical study even at the highest dose level, with no adverse events. This is consistent with the finding that it was extremely safe in pre-clinical studies. As an example of its safety, the No-Observed-Adverse-Effects-Level (NOAEL) is found to be 1,200 mg/Kg, and the Maximum Tolerable Dose level (MTD) is 1,500 mg/Kg in rats. 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.

Additionally, the strong effectiveness of NV-387 is demonstrated in pre-clinical animal model studies. Our lethal animal studies are designed to demonstrate improvement in survival as a quantitative indicator of relative effectiveness of different drugs. The animal essentially serves as a “test-tube” in which the virus infects and replicates in the cells eventually leading to severe diseases and a fatal outcome.

In the case of RSV, NV-387 oral and intravenous treatments were both almost as effective as Ribavirin, the highly toxic last resort drug, in a lethal lung RSV infection animal model. There is currently no approved, safe drug for the treatment of RSV infection. RSV is an important and sometimes fatal disease of infants, children, seniors, and immunocompromised persons. The market size for RSV therapeutics was worth $1.8 billion in 2022, and is expected to grow at a CAGR of 18.9%, reaching $8.73 billion by 2031, according to Growthplus Reports, June 2023[1].

In the case of coronavirus infections, NV-387 oral and intravenous treatments were both significantly more effective than the approved drug Remdesivir, in animal model studies of coronavirus NL-63 lethal lung infection in rats. HCoV-NL-63 serves as a BSL2 model for the SARS-CoV-2 virus drug development, and has similar lower-lung pathology as the severe SARS-CoV-2 variant delta.

In the case of Mpox/Smallpox virus infections, NV-387 oral treatment was as effective as the approved drug tecovirimat (TPOXX®, SIGA) in a lethal model comprising intra-digital infection by the Ectromelia virus into the footpads of mice. Moreover, a formulation combining NV-387 and Tecovirimat, that we developed and call NV-387-m-T, led to a significantly greater survival rate. NV-387 acts by a different mechanism than tecovirimat. Also, viruses are unlikely to escape NV-387 by mutations or changes as they evolve in the field, because of the very design of the drug. In contrast, a single point mutation is known to result in a tecovirimat-resistant orthopoxvirus. Thus, we believe, there is a strong case for developing NV-387 as a drug for the treatment of Smallpox and Mpox. Smallpox therapeutics are of interest for biodefense, and tecovirimat is currently being stockpiled by the US Government Strategic National Stockpile (USG-SNS) of drugs against important threat agents. USG-SNS recently requisitioned an additional approximately $150 million worth of doses of TPOXX.

We believe that upon completion of the Phase 1a/1b human clinical trials of NV-CoV-2, the NV-387 oral formulations will be eligible for (i) Phase II/III clinical trials for RSV, (ii) Phase II clinical trials for COVID, and (iii) Phase II clinical trials for “Long COVID” associated with residual virus. We are currently in discussions with field experts regarding the strategy of prioritization for further development of NV-387 towards approval.

[1] https://finance.yahoo.com/news/respiratory-syncytial-virus-rsv-therapeutics-093200835.html?soc_src=social-sh&soc_trk=ma

We anticipate that NV-387 formulations 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.

NV-387 has such broad-spectrum activity because it is designed to mimic the attachment receptors to which over 90% of viruses bind before infecting a cell. We are currently engaged in expanding the spectrum of activity of NV-387. NV-387 is an example of NanoViricides Platform Modality #1 implementation.

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 simple 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.

We have previously developed NV-HHV-1 as a skin cream formulation for the treatment of Shingles rash caused by the Varicella Zoster Virus (VZV) that also causes Chickenpox in children and immune-compromised adults. NV-HHV-1 has gone through pre-clinical safety/pharmacology and efficacy studies as required for an IND-filing. We plan on advancing this drug into clinical trials after advancing the NV-387 based drug programs into clinical trials. NV-HHV-1 uses a small chemical ligand that was designed by us using rational drug design to mimic the herpesvirus entry mediator (HVEM, aka CD270) where the HSV glycoproteins bind to HVEM. Thus it mimics a "cognate receptor" of the virus, and is an example of NanoViricides Platform Modality #2 implementation, which is expected to yield higher activity against a specific virus family than related Modality #1 nanoviricides.

We are also developing, on our own, NV-387-R, an active pharmaceutical ingredient ("API") that is a potential cure for all viruses against which NV-387 and Remdesivir are both active, based on the broad-spectrum, orthogonal, activities of its two ingredients, NV-387 and Remdesivir. NV-387 attacks the virus "Re-Infection" part and Remdesivir attacks the "Replication" part of the virus lifecycle. Blocking these two parts simultaneously would be expected to cure the viral infection for viruses that do not cause latent infections. Remdesivir is the well-known antiviral drug from Gilead. We have demonstrated that the pharmacokinetic properties of Remdesivir are considerably improved upon encapsulation within the NV-387 polymeric micelles[2]. NV-387-R is an example of NanoViricides Platform Modality #3 implementation, which is expected to yield cures for a large variety of virus families.

Developing broad-spectrum antivirals such as NV-387, NV-HHV-1, and NV-387-R enables us to maximize the utility and benefits from these drugs and also minimize capital expenditures and thus maximize the return on investments.

Moreover, we have built a portfolio of pre-clinical stage drug candidates against a number of diseases. Of these, our HerpeCide drug program is the most advanced. We believe we have drug candidates based on NV-HHV-1 that have shown strong benefits in pre-clinical studies for the treatment of HSV-1 and HSV-2 infections. We are also working on many other programs of antiviral drug developments including HIV, Influenza, Dengue viruses, Ebola and Marburg viruses, to name a few.

[2] Ashok Chakraborty., et al. "Encapsulation of Remdesivir in Nanoviricide's Platform Technology Based NV-CoV-2 Polymer Protects the Drug and Improves Its Pharmacokinetics". EC Pharmacology and Toxicology 10.2 (2022): 108-118.

We now have a panel of a number of antiviral drugs that we keep adding to and that we can rapidly screen for any new virus to discover a potentially highly active drug possibly in a much shorter time frame than what was needed for our COVID drug development.

We believe our capabilities in manufacturing clinical drug products are now well established. Further, we have developed, and plan on adding to, our internal regulatory expertise. Thus, we believe our capabilities in effective antiviral drug development are now substantially improved.

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 advancing our first drug candidate, NV-CoV-2 into human clinical trials. We believe that taking our first drug candidate through Phase 1a/1b human clinical trials is a very important milestone in that it essentially validates our entire platform technology as being capable of producing drug candidates worthy of human clinical trials, and potentially of success in those clinical trials.

Our Pan-Coronavirus Drug Candidates: NV-CoV-2 (API NV-387) In Clinical Trials

Our lead drug candidate NV-CoV-2 (API NV-387) is a broad-spectrum, pan-coronavirus drug for the treatment of COVID. NV-CoV-2 entered into Phase Ia/Ib human clinical trials around mid-June, 2023, sponsored by our licensee and collaborator in India, Karveer Meditech, Private Ltd (KMPL) (see below).

NV-CoV-2 contains the API NV-387, which is a "nanoviricide" with a mechanism of action that is orthogonal and complementary to that of the existing therapeutics (see below).

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

We have successfully developed NV-387 formulations for different severities of the disease, including (i) NV-CoV-2 Oral "Gummies" and (ii) NV-CoV-2 Oral Syrup, to treat mild to moderate disease, and (iii) NV-CoV-2 for Injection, Infusion or Inhalation for hospitalized patients with severe disease including the direct-lung-inhalation for severe lower lung disease, thus covering the entire disease severity spectrum. These same formulations are applicable to additional indications of NV-387, including RSV, Smallpox, Mpox, and others.

The clinical trials program for NV-387 has started with the evaluation of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies in adults, which we plan to extend to pediatric populations upon successful results. Clinical trials of the Injectable Formulation of NV-387 are expected to follow thereafter. We will continue to report on these objectives via press releases as meaningful advancements take place.

Additionally, we are also developing NV-387-R as an ultra-broad-spectrum antiviral drug that is designed to block the complete lifecycle of a wide variety of distinct families of viruses and therefore it is anticipated to be a potential cure for all such virus infections (see below). NV-387-R comprises NV-387 with Remdesivir encapsulated in the belly of the polymeric micelles of NV-387.

We believe that once the Phase I studies of NV-CoV-2 are completed, both NV-387 and NV-387-R will be eligible for Phase II studies for a number of antiviral indications, not limited to COVID. Remdesivir® (Gilead) is currently the only fully approved drug for treatment of COVID, but is limited to the treatment of hospitalized patients only and requires infusion therapy. At present we are continuing to develop NV-387-R independently of Gilead.

Both NV-CoV-2 and NV-CoV-2-R (API NV-387-R) have demonstrated pan-coronavirus, broad-spectrum effectiveness in pre-clinical studies. This broad-spectrum effectiveness indicates that SARS-CoV-2 variants that are continuously generated in the field are quite unlikely to escape either of these two drug candidates.

In contrast, we note that all of the existing antibodies and cocktails with emergency use approvals, including Evusheld, have lost effectiveness and have lost their emergency use authorizations (EUA) against the current SARS-CoV-2 Omicron variants.

Paxlovid has limited application as it has been found to be effective only in adults over 65 years of age with co-morbidities, and its composition further limits its usefulness due to side effects and interactions with other drugs commonly taken by persons with co-morbidities. Molnupiravir is a known mutagen and its use is not recommended or severely restricted by international health authorities.

Remdesivir is the only FDA approved drug for treating COVID, but it is only approved for hospitalized patients; it requires long, daily infusions, and clinically it has shown only marginal improvements, with reduction in hospital stay of a few days.

Thus, we believe NV-CoV-2 is poised to meet the unmet medical need of a highly effective and safe drug to treat COVID, and potentially long COVID with residual virus, that would be useable in all segments of patient populations, from children to otherwise healthy patients to older patients and patients with co-morbidities.

Exploring Additional Applications of NV-387 to Maximize Return on Investments and to Fulfill Unmet Medical Needs

NV-387 is designed to mimic a common “attachment factor” family that we refer to as the “Sulfated Proteoglycans (S-PG)”, to which a large number of viruses bind as the first step in infecting a cell (reviewed in[3]). We loosely include a number of sulfated proteoglycan types in this “S-PG class”. They differ in exact structures but share a number of commonalities. 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, Poxviruses, among others. 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 anticipated that the active pharmaceutical ingredient of NV-CoV-2, namely NV-387, would have significantly broader spectrum of antiviral effectiveness than the coronavirus family alone, based on its design. Previously, during COVID drug development, we found that NV-387 has a broad-spectrum anti-coronavirus activity that included all of the tested seasonal coronaviruses and SARS-CoV-2 in pre-clinical studies. Therefore, we anticipated that NV-387 may be sufficiently effective to warrant clinical development against a number of additional S-PG-utilizing virus families.

To date, we have tested NV-387 for effectiveness in animal models of RSV and of Poxviruses, and we have found it to be highly effective in both cases, warranting further clinical development as a treatment for RSV as well as for Smallpox, in addition to Coronaviruses.

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 having a safe and effective ultra-broad-spectrum antiviral agent such as NV-387 in hand could help combat future viral infection epidemics before they expand. This strategy should form a backbone of pandemic preparedness strategy, rather than reliance on vaccines and antibodies that have now been proven to be of limited durable utility.

NV-387 further offers an additional strategy for developing antivirals, that of enhancing and supplementing activity of known drugs by virtue of encapsulation within the polymeric micelles of NV-387. We have demonstrated this capability successfully with the development of NV-387-R. This encapsulation strategy is applicable to other viruses as well and may result in potential cures for viruses that do not become latent in the body.

Once NV-387 successfully undergoes Phase 1 Safety Clinical Trials, further applications of NV-387 to treat other viral infections would be eligible to directly proceed to Phase 2 Efficacy Clinical Trials in many cases, subject to regulatory approvals. This would save us a substantial amount of time and money investment to bring additional drugs against other viruses based on this platform forward towards approval, significantly improving the return on investment.

[3] 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.

The COVID Pandemic is changing and NV-CoV-2 is Expected to Fulfill the Unmet Medical Need of this New Scenario

The pandemic has changed in character from each distinct wave being of a single dominant variant to nearly continuous disease prevalence with multiple circulating variants at the same time, and newer variants rising to dominance every few months. The variants have become progressively more communicable and contagious in time. Although the observed severity of the disease has decreased due to multiple factors including the built up population immunity from prior exposure to the virus variants and vaccinations, SARS-CoV-2 continues to be an important health threat, with weekly 4,000 deaths during the current (December-January 2024) COVID wave in the USA alone.

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

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

Thus, the world is not well prepared for the SARS-CoV-2 waves and the continuing public health threat, except for the fact that natural immunity and prior vaccine-boosted immunity may afford protection that did not exist when the pandemic first arose. The therapeutics and preventatives tools available today are generally known to be inadequate, as summarized above. As the populations get “used to” living with the virus, the societal tools of masking, social distancing, and clean hygiene have mostly fallen off due to the encumbrances they pose. The extremely high infectiveness of the current Omicron variants implies that even these societal tools would have limited effect unlike with the earlier alpha and delta waves of SARS-CoV-2 wherein lockdowns may have averted substantial spread and thus morbidity and mortality.

A large percentage of COVID patients have been experiencing “long COVID” [4], wherein various disease manifestations extend into many months to even years. In the long COVID syndrome, nasal swabs do not indicate virus presence, but using highly sensitive tests, it has been shown that a substantial percentage of long COVID cases do have circulating SARS-CoV-2 virus or its antigens present in small quantities. There are significant uncertainties in the numbers of long COVID patients, and among them, the ones who are still carrying residual virus, because of issues with data collection, methodologies, and limitations regarding reporting and testing. It has also been recently shown that the incidence of long COVID is somewhat reduced in patients that have used the antiviral drug Paxlovid® to treat their COVID infection[5], indicating the need for a more effective antiviral drug for minimizing long COVID, and also possibly treating long COVID cases with residual virus. At present there is no therapeutic available for treating even the long COVID cases with manifest virus presence. We believe that NV-CoV-2 is capable of fulfilling this unmet medical need.

We are targeting NV-CoV-2 to fulfill an important medical need for COVID treatment that remains unmet even today. There is no antiviral COVID drug available yet that can be used for the treatment of all segments of patient population. Equally noteworthy, there is no antiviral COVID drug available yet that can be expected to continue to work even as new variants of the SARS-CoV-2 keep evolving and spreading in the field. We plan on developing the same drug for the treatment of RSV as well, given the successful results in the RSV animal model. Of the three major seasonal threats of respiratory infections, NV-387 is found to be capable of tackling coronavirus infections and RSV infections. Influenza virus uses a different attachment/entry receptor, namely sialylated glycoproteins, and we have corresponding drugs in development under our FluCide™ program, which we plan to accelerate depending upon available resources.

[4] Shaw, J. “The Causes of Long COVID”, Harvard Magazine, https://www.harvardmagazine.com/2022/09/feature-long-covid.
[5] M Yan Xie, Taeyoung Choi, and Ziyad Al-Aly, “Nirmatrelvir and the Risk of Post-Acute Sequelae of COVID-19”, MedRxiv preprint doi: https://doi.org/10.1101/2022.11.03.22281783; version posted November 5, 2022.

NanoViricides is Fully Equipped for Rapid Antiviral Drug Development from Discovery to cGMP Drug Product Delivery for Clinical Trials

NanoViricides is one of a few biopharma companies that has its own cGMP-compliant manufacturing facility. 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 production capacity is anticipated to be more than sufficient for Phase I, Phase II and Phase III human clinical trials for our anti-coronavirus and anti RSV drugs in development, as well as for the anticipated clinical trials of NV-HHV-1 skin cream for the treatment of shingles, and any other anticipated clinical trials that we may engage into. This in-house cGMP production capability is expected to result in significant cost savings across all our programs.

Manufacturing nanomedicines, especially under cGMP conditions, has been identified as a strong risk, and has led to failure of several nanomedicines programs. NanoViricides co-founder Dr. Anil Diwan and 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. The team has successfully and rapidly translated from the research scale production of several grams drug substance to Kg-scale cGMP-compliant manufacture for two different drug candidates, namely NV-HHV-1 and NV-CoV-2, in three different formulations, namely skin cream, oral syrup, and oral gummies, in a very short time span. This includes manufacture of the active ingredient (drug substance), the formulated drug products, and packaged drug products for clinical trials usage.

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.

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 very 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. Thus 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. Thus 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 [6]

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, namelyencapsulation 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-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-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[4]. The increased circulating lifetime and also concentration of intact Remdesivir should improve its effectiveness. Additionally, NV-387-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-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-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-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-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.

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-CoV-2 and NV-CoV-2-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 as well as a lethal smallpox-emulating ectromelia footpad infection mouse model, further substantiating the oral bio-availability observed in the coronavirus study results.

These findings have enabled us to develop oral formulations of NV-CoV-2 for human clinical trials. We have successfully developed orally active formulations of our COVID drug candidates, in an oral syrup form, as well as an oral gummies (“Chewable Soft Solids”) form. We believe that for mild to moderate disease, for pediatric, and older patients, the oral syrup and gummies forms would be highly advantageous over tablets, capsules, injections, infusions, or lung inhalations.

[6] 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 injectable formulation of NV-CoV-2 (API 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-CoV-2 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 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 SARS-CoV-2 viruses cause the most damage. Injectable, Infusion and Inhalation formulation of NV-387 would also be very important for the treatment of RSV infections, especially for severe infections in pediatric cases.

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

We 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.

Developments During the Reported Period

During the six months ended December 31, 2023, we have focused on expansion of the indications of the broad-spectrum antiviral API, NV-387, which is in Phase 1a/1b clinical trials for the indication of Coronavirus infections.

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

Importantly, in the reported 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 clinical trials for COVID or Phase II/III clinical trials for RSV. The production program for Phase II clinical supply is expected to be commissioned soon.

NanoViricides Broad-Spectrum Antiviral Drug NV-387 Was Found To Be Effective Against RSV Lethal Lung Infection

On July 11, 2023 we reported that NV-387 was found to be effective 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. There is currently no safe and effective drug approved for RSV. The market size for RSV therapeutics is estimated by GrowthPlus to grow at a CAGR of 18.9%, reaching $8.73 billion by 2031, representing a significant commercial opportunity.

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 5 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 no vaccines currently approved for infants and children.

However, 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.

We anticipate that NV-387 formulations for treatment of RSV infection would be eligible for Phase 2/3 human clinical trials upon completion of the Phase 1a/1b clinical trials of NV-CoV-2 (which contains NV-387).

The Phase 1a/1b Human Clinical Trial of NV-CoV-2 (API NV-387), a Broad-Spectrum Antiviral Drug, is Progressing Successfully

On August 21, 2023, we reported that the Phase 1a/1b human clinical trial of NV-CoV-2, under the sponsorship of KMPL, our licensee and collaborator, is progressing successfully. In the single-ascending-dose (SAD) part, i.e. Phase 1a part, 26 of the expected 36 human volunteer subjects have been dosed and completed the study. In addition, in the multiple-ascending-dose (MAD) part, i.e. Phase 1b-Healthy Subjects part, 26 of the expected 36 healthy subjects have completed the study successfully. No adverse events or serious adverse events were found in the SAD or MAD studies to date, in either the NV-CoV-2 Oral Syrup or the NV-CoV-2 Oral Gummies administration cohorts. The drugs are believed to be safe and well tolerated. Thereafter, a scheduled interim audit of the trial operations by the clinical trial sponsor, KMPL, was successfully completed and recruitment of the remaining subjects has resumed.

COVID waves are expected to continue because of novel variants appearing constantly. However, with the built-up immunity from prior SARS-CoV-2 exposures and infections with several variants, as well as the earlier vaccinations, the fatality rates are expected to remain low. Nevertheless, the COVID waves continue to cause an adverse economic impact worldwide that is substantially greater than that caused by influenza viruses.

NV-387 Was Found To Be Effective In A Lethal Infection Animal Model That Is 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. We reported that oral NV-387 treatment was as effective as 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. 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.

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 2/3 human clinical efficacy studies, and an extended Phase 1 human safety study.

SIGA announced in July 2023 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-CoV-2 (NV-387) addresses an unmet medical need for broad-spectrum, safe and effective 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. Further, we have re-initiated the FluCide™ program this quarter with a limited engagement, while focusing our primary work on advancing the regulatory development of NV-387, and expansion of indications of NV-387.

Healthy Subjects Part of the Phase 1a/1b Human Clinical Trial of NV-CoV-2 (API NV-387), a Broad-Spectrum Antiviral Drug, is Completed Successfully

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, has completed. All subjects have been successfully discharged. There were no discontinuations. All dosage levels at all dosing instances were well tolerated. 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 80mg/Kg. The data are undergoing internal audit. After this, the data will be provided for biostatistical analysis.

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.

The healthy subjects part of the clinical trial will now undergo data-lock procedures and thereafter biostatistical analyses will be conducted. The final report will become available afterwards.

Previously 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 leading to the clinical trials. 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 indicate excellent safety.

The strong safety and tolerability of NV-387 demonstrated in human clinical trial implies that it 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). This capability of NV-387 is analogous to the highly successful 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-19 in patients without a risk factor for progression to severe COVID-19, whereas Remdesivir can only be used in hospitalized cases.

The second part of the Phase 1a/1b clinical trial is the treatment of COVID patients suffering from mild to moderate disease. Recruitment has been challenging because COVID cases arise in waves. We believe that the recent COVID wave in India is providing an opportunity to conduct the clinical trial part involving the treatment of COVID patients with NV-CoV-2. We are in talks with our licensee and the drug sponsor in India, KMPL, and the CRO, PristynCR, to evaluate suitable sites for the performance of this part of the clinical trial. This part is designed to evaluate the safety and tolerability of NV-CoV-2 in COVID patients, and to obtain information on the effective dosing level(s) to select for the subsequent Phase II/III clinical trials.

Subsequent Events

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 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 facility as of December 31, 2023.

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.

This amendment has a significant positive impact for our cash budgets. The effect of this amendment is that we can continue the clinical development program of NV-387 without any cash payment impact from milestones met during the progress.

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-CoV-2 clinical trials. We have performed cGMP-like manufacture of both the active pharmaceutical ingredient (API NV-HHV-1, the nanoviricide against VZV), 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.

Other Pre-clinical Drug Programs

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

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 safety of our injectable SARS-CoV-2 drug candidates, as well as of the Shingles skin cream drug candidate. This leads us to believe that the nanomicelle backbones of these drug candidates that were evaluated in preliminary safety studies should be safe in most if not all routes of administration.

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

We are currently focused on the development of an anti-coronavirus drug with urgency. Further, we are performing pre-clinical investigations to expand the usage of NV-387, the API of NV-CoV-2 in developing antiviral drugs 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.

Financial Status

As of December 31, 2023 the Company had approximately $5.2 million in cash and cash equivalents and approximately $7.7 million of property and equipment, net of accumulated depreciation. Our current liabilities are approximately $1.0 million. Stockholder’s equity was approximately $12.5 million at December 31, 2023.

During the six month period ended December 31, 2023, the Company used approximately $2.9 million in cash toward operating activities. The available cash, and cash available under our Line of Credit, is sufficient for more than twelve months of operations at the current rate of expenditures from the date of filing of this Quarterly Report on Form 10-Q. As our COVID and shingles drug programs mature into human clinical trials, our expenditures are anticipated to increase due to the costs of the clinical trials. We estimate that we have sufficient funds in hand, and the availability of a standby Line of Credit, for completion of initial human clinical trials of NV-CoV-2 at this time. We estimate that we will need additional funding to continue further development of our drug candidates through later stages of human clinical trials if we do not form a collaborative licensing or partnership agreement with a party that would provide such funding such as Big Pharma.

We do not anticipate any major capital costs going forward in the near future. We intend to seek collaborations to develop the COVID 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 the Company will be able to raise the necessary capital or that it will be on acceptable terms.

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 USA.

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 USA.

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 on completing the on-going Phase 1a/1b clinical trials of NV-CoV-2 (API NV-387) in India. Thereafter we plan to take NV-CoV-2 into Phase 2/3 clinical trials for at least two indications, namely COVID and RSV infections, possibly as part of a single, multi-arm, clinical trial. 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 clinical trials of our NV-CoV-2 drug candidate.

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 COVID, RSV or both. 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.

Recently, KMPL and PristynCR were able to get a special permission from the regulatory authorities to conduct the COVID Patients treatment part of the Phase 1a/1b clinical trial at a different clinical trial site. They have completed site feasibility studies on multiple

sites where COVID patients started increasing due to a recent wave in the region of South India. They have finalized a clinical site. The COVID patient part of the clinical trial is expected to start recruitment and dosing soon. KMPL acts as the clinical trial manager and drug sponsor.

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 most current Annual Report.

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 December 31, 2023, we had cash and cash equivalents of $5,245,374, prepaid expenses of $72,442 and net property and equipment of $7,746,092. Accounts payable and accrued expenses were $951,074, inclusive of accounts payables to related parties of $504,039 and accrued expenses to a related party of $150,000. The accounts payable–related parties is net of a two month advance of $500,000. Stockholders' equity was $12,451,136 at December 31, 2023. 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 six month period ended December 31, 2023, we used approximately $2.9 million in cash in operating activities. During the six month period ended December 31, 2022, we used approximately $2.4 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 six month period ended December 31, 2023.

Research and Development Expenses – Research and development expenses for the three months ended December 31, 2023 increased $403,169 to $1,573,879 from $1,170,710 for the three months ended December 31, 2022. Research and development expenses for the six months ended December 31, 2023 increased $757,175 to $3,040,544 from $2,283,369 for the six months ended December 31, 2022. The increase in research and development expenses for the three and six months ended December 31, 2023 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 December 31, 2023 decreased $52,407 to $610,877 from $663,284 for the three months ended December 31, 2022. General and administrative expenses for the six months ended December 31, 2023 increased $2,818 to $1,175,803 from $1,172,985 for the six months ended December 31, 2022. The decrease in general and administrative expenses for the three months ended December 31, 2023 is due to a general decrease in general

and administrative expenses. The increase in general and administrative expense for the six months ended December 31, 2023 is due to an increase in professional fees.

Interest Income – Interest income for the three months ended December 31, 2023 decreased $5,820 to $83,134 from $88,954 for the three months ended December 31, 2022. Interest income for the six months ended December 31, 2023 increased $40,956 to $182,472 from $141,516 for the six months ended December 31, 2022. The decrease in interest income for the three months ended December 31, 2023 is due to a lower interest bearing balance during the period. The increase in interest income for the six months ended December 31, 2023 is due to higher interest rates during the current six month period compared to the prior.

Interest Expense – Interest expense increased $13,221 to $13,515 for the three months ended December 31, 2023 from $94 for the three months ended December 31, 2022. Interest expense increased $48,870 to $49,808 for the six months ended December 31, 2023 from $938 for the six months ended December 31, 2022. The increase in interest expense for the three and six months ended December 31, 2023 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 expense and increased additional paid in capital by $49,808.

Net Loss – For the three months ended December 31, 2023, the Company had a net loss of $(2,114,937) or $(0.18) per share compared to a net loss of $(1,745,134) or $(0.15) per share for the three months ended December 31, 2022. For the six months ended December 31, 2023, the Company had a net loss of $(4,083,683) or $(0.35) per share compared to a net loss of $(3,315,776) or $(0.29) per share for the six months ended December 31, 2022. The increase in the net loss for the three and six months ended December 31, 2023 is attributable to an increase in outside lab expenses and clinical trial costs.

Liquidity and Capital Reserves

We had cash and cash equivalents of $5,245,374 as of December 31, 2023. Since inception, we have expended substantial resources on research and development. Consequently, we have sustained substantial losses. We have an accumulated deficit of $135,164,431 at December 31, 2023. Such losses are expected to continue for the foreseeable future and until such time, if ever, that we are able to attain sales levels sufficient to support its operations. There can be no assurance that we will achieve or maintain profitability in the future. Further, we anticipate several important milestones to occur in the ensuing year starting with preliminary results from the Phase 1a/1b clinical trial of NV-CoV-2 (API NV-387). Management believes that assuming these milestones are achieved, the Company would likely experience improvement in the liquidity of the Company's stock, and would eventually improve the Company's ability to raise funds on the public markets at terms that may be more favorable to the terms we are offered at present. There can be no assurance that we will be to raise funds on terms acceptable to the Company, or at all. There can be no assurance that we will be able to enter into co-development or other licensing agreements.

We believe that cash on hand as of December 31, 2023, and cash available under our Line of Credit, will be sufficient to fund the planned operations and expenditures for at least the next twelve months from the issuance of these condensed financial statements. However, we will need to raise additional capital to fund our long-term operations and research and development plans including human clinical trials for the various drug candidates until we generate revenue that reaches a level sufficient to provide self-sustaining cash flows. To cover the shortfall, management intends 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.

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

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

Off Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements during the six months ended December 31, 2023.

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 December 31, 2023, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2023 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 must 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 December 31, 2023 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 27, 2023, TheraCour Pharma, Inc. exercised its right to convert a $1,500,000 convertible note into 331,859 shares of the Company's Series A preferred stock, par value $0.00001 per share (the "Series A Shares").

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 Shares. 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 Shares of $8,124 for the three months ended December 31, 2023. The balance of $16,250 will be recognized as the remaining 5,102 shares vest and service is rendered for the remaining six months ended June 30, 2024.

For the three and six months ended December 31, 2023, the Company's Board of Directors authorized the issuance of 387 and 774, respectively of fully vested Series A shares for employee compensation. The Company recorded expense of $1,233 and $2,726, respectively for the three and six months ended December 31, 2023 related to these issuances.

There is currently no market for the Series A shares 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 shares 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 shares 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.

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. The fair value of the warrants was $147 for the three months ended December 31, 2023 and $306 for the six months ended December 31, 2023 and was recorded as consulting expense.

For the three and six months ended December 31, 2023, the Company's Board of Directors authorized the issuance of 23,379 and 62,482, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of $27,000 and $77,600, respectively, for the three and six months ended December 31, 2023, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and six months ended December 31, 2023, the Company's Board of Directors authorized the issuance of 9,717 and 17,664, fully vested shares of its common stock with a restrictive legend for director services, respectively. The Company recorded an expense of $11,250 and $22,500 for the three and six months ended December 31, 2023, 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: February 14, 2024	/s/ Anil R. Diwan Name:Anil R. Diwan Title: President, Chairman of the Board (Principal Executive Officer)
Dated: February 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.

February 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.

February 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 December 31, 2023, 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.

February 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 December 31, 2023, 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.

February 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.