

## Submission Header Summary

Element	Value
Submission Type	10-Q
Contact Information	
Name	EDGAR Advantage Service Team
Phone Number	800-688-1933
Filer Information	
CIK	0001379006
CCC	*****
Issuer Stock Exchanges	
Stock Exchange	NYSE
Period Date	03-31-2023
Shell Company	false
Emerging Growth Company	false
Accelerated Filer Status	Non-Accelerated Filer
Smaller Reporting Company	true
Notifications	
Email Address	purple_team2@ToppanMerrillLLC.com

## Document Sequence

Count	Output File Name	Source File Name	Document Type	Description	PDF Action
1	nnvc-20230331x10q.htm	nnvc_20230331_10Q	10-Q	10-Q	
2	nnvc-20230331xex31d1.htm	nnvc_Ex31_1	EX-31.1	EX-31.1	
3	nnvc-20230331xex31d2.htm	nnvc_Ex31_2	EX-31.2	EX-31.2	
4	nnvc-20230331xex32d1.htm	nnvc_Ex32_1	EX-32.1	EX-32.1	
5	nnvc-20230331xex32d2.htm	nnvc_Ex32_2	EX-32.2	EX-32.2	
6	nnvc-20230331.xsd		EX-101.SCH	EX-101.SCH	
7	nnvc-20230331_cal.xml		EX-101.CAL	EX-101.CAL	
8	nnvc-20230331_def.xml		EX-101.DEF	EX-101.DEF	
9	nnvc-20230331_lab.xml		EX-101.LAB	EX-101.LAB	
10	nnvc-20230331_pre.xml		EX-101.PRE	EX-101.PRE	

[Table of Contents](#)

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

**FORM 10-Q**

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

For the quarterly period ended March 31, 2023

Commission File Number: 001-36081

**NANOVIRICIDES, INC.**

(Exact name of Company as specified in its charter)

NEVADA

76-0674577

(State or other jurisdiction)  
of incorporation or organization)

(IRS Employer Identification No.)

**1 Controls Drive**

**Shelton, Connecticut 06484**

(Address of principal executive offices and zip code)

(203) 937-6137

(Company's telephone number, including area code)

Indicate by check mark whether the Company (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the Company is a larger accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

Yes  No

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

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

As of May 15, 2023 there were approximately 11,666,000 shares of common stock of the registrant issued and outstanding.

[Table of Contents](#)

NanoViricides, Inc.  
FORM 10-Q  
INDEX

<a href="#">PART I FINANCIAL INFORMATION</a>	3
<a href="#">Item 1. Financial Statements</a>	3
<a href="#">Condensed Balance Sheets at March 31, 2023 (Unaudited) and June 30, 2022</a>	3
<a href="#">Condensed Statements of Operations for the Three and Nine Months Ended March 31, 2023 and 2022 (Unaudited)</a>	4
<a href="#">Condensed Statements of Changes in Stockholders' Equity for the Nine Months Ended March 31, 2023 and 2022 (Unaudited)</a>	5
<a href="#">Condensed Statements of Cash Flows for the Nine Months Ended March 31, 2023 and 2022 (Unaudited)</a>	7
<a href="#">Notes to the Condensed Financial Statements (Unaudited)</a>	8
<a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	18
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	33
<a href="#">Item 4. Controls and Procedures</a>	33
<a href="#">PART II OTHER INFORMATION</a>	34
<a href="#">Item 1. Legal Proceedings</a>	34
<a href="#">Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</a>	34
<a href="#">Item 3. Defaults Upon Senior Securities</a>	34
<a href="#">Item 4. Mine Safety Disclosures</a>	35
<a href="#">Item 5. Other Information</a>	35
<a href="#">Item 6. Exhibits and Reports on Form 8-K</a>	36
<a href="#">Signatures</a>	37
<a href="#">Certifications</a>	

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NanoViricides, Inc.  
 Condensed Balance Sheets

	March 31, 2023	June 30, 2022
	(Unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 9,650,958	\$ 14,066,359
Prepaid expenses	280,117	350,021
Total current assets	<u>9,931,075</u>	<u>14,416,380</u>
Property and equipment, net	8,290,895	8,694,194
Intangible assets, net	335,646	341,848
<b>OTHER ASSETS</b>		
Service agreements	19,183	38,925
Security deposits	—	3,515
Other assets	19,183	42,440
Total assets	<u>\$ 18,576,799</u>	<u>\$ 23,494,862</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 62,695	\$ 57,960
Accounts payable – related party	243,881	214,397
Loan payable	—	94,788
Accrued expenses	42,168	45,692
Total current liabilities	<u>348,744</u>	<u>412,837</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Series A convertible preferred stock, \$0.001 par value, 10,000,000 shares designated, 497,287 and 484,582 shares issued and outstanding, at March 31, 2023 and June 30, 2022, respectively	497	485
Common stock, \$0.001 par value; 150,000,000 shares authorized, 11,666,471 and 11,592,173 shares issued and outstanding, at March 31, 2023 and June 30, 2022, respectively	11,666	11,592
Additional paid-in capital	145,726,648	145,562,124
Accumulated deficit	<u>(127,510,756)</u>	<u>(122,492,176)</u>
Total stockholders' equity	<u>18,228,055</u>	<u>23,082,025</u>
Total liabilities and stockholders' equity	<u>\$ 18,576,799</u>	<u>\$ 23,494,862</u>

*See accompanying notes to the condensed financial statements*

[Table of Contents](#)

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

	For the Three Months Ended		For the Nine Months Ended	
	2023	2022	2023	2022
<b>OPERATING EXPENSES</b>				
Research and development	\$ 1,196,094	\$ 1,255,074	\$ 3,479,463	\$ 4,613,302
General and administrative	614,647	532,801	1,787,632	1,707,514
Total operating expenses	1,810,741	1,787,875	5,267,095	6,320,816
<b>LOSS FROM OPERATIONS</b>	(1,810,741)	(1,787,875)	(5,267,095)	(6,320,816)
<b>OTHER INCOME (EXPENSE)</b>				
Interest income	107,937	—	249,453	—
Interest expense	—	(4,789)	(938)	(6,050)
Other (expense) income, net	107,937	(4,789)	248,515	(6,050)
<b>LOSS BEFORE INCOME TAX PROVISION</b>	(1,702,804)	(1,792,664)	(5,018,580)	(6,326,866)
<b>INCOME TAX PROVISION</b>	—	—	—	—
<b>NET LOSS</b>	\$ (1,702,804)	\$ (1,792,664)	\$ (5,018,580)	\$ (6,326,866)
Net loss per common share- basic and diluted	\$ (0.15)	\$ (0.16)	\$ (0.43)	\$ (0.55)
Weighted average common shares outstanding- basic and diluted	11,636,041	11,540,296	11,612,735	11,527,069

*See accompanying notes to the condensed financial statements*

[Table of Contents](#)

**NanoViricides, Inc.**  
**Condensed Statement of Changes in Stockholders' Equity**  
**For the nine months ended March 31, 2023**  
**(Unaudited)**

	Series A Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2022	484,582	\$ 485	11,592,173	\$ 11,592	\$ 145,562,124	\$ (122,492,176)	\$ 23,082,025
Series A preferred stock issued for employee stock compensation	10,591	10	—	—	13,854	—	13,864
Common stock issued for consulting and legal services rendered	—	—	12,710	13	26,987	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	480	—	480
Common shares issued for Directors fees	—	—	5,154	5	11,245	—	11,250
Net loss	—	—	—	—	—	(1,570,642)	(1,570,642)
Balance, September 30, 2022	495,173	\$ 495	11,610,037	\$ 11,610	\$ 145,614,690	\$ (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	17	26,983	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	223	—	223
Common shares issued for Directors fees	—	—	7,173	7	11,243	—	11,250
Net loss	—	—	—	—	—	(1,745,134)	(1,745,134)
Balance, December 31, 2022	495,560	\$ 495	11,634,576	\$ 11,634	\$ 145,666,194	\$ (125,807,952)	\$ 19,870,371
Series A preferred stock issued for employee stock compensation	1,727	2	—	—	17,231	—	17,233
Common stock issued for consulting and legal services rendered	—	—	19,983	20	26,980	—	27,000
Common stock issued for employee compensation	—	—	3,572	4	4,818	—	4,822
Warrants issued to Scientific Advisory Board	—	—	—	—	183	—	183
Common shares issued for Directors fees	—	—	8,340	8	11,242	—	11,250
Net loss	—	—	—	—	—	(1,702,804)	(1,702,804)
Balance, March 31, 2023	497,287	\$ 497	11,666,471	\$ 11,666	\$ 145,726,648	\$ (127,510,756)	\$ 18,228,055

*See accompanying notes to the financial statements*

[Table of Contents](#)

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

	Series A Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2021	371,490	\$ 372	11,515,170	\$ 11,515	\$ 144,284,593	\$ (114,385,313)	\$ 29,911,167
Series A preferred stock issued for employee stock compensation	10,591	10	—	—	32,880	—	32,890
Series A preferred stock issued for license agreement	100,000	100	—	—	934,988	—	935,088
Common stock issued for consulting and legal services rendered	—	—	6,509	6	26,994	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	1,352	—	1,352
Common shares issued for Directors fees	—	—	3,524	4	14,996	—	15,000
Net loss	—	—	—	—	—	(2,613,068)	(2,613,068)
Balance, September 30, 2021	482,081	\$ 482	11,525,203	\$ 11,525	\$ 145,295,803	\$ (116,998,381)	\$ 28,309,429
Series A preferred stock issued for employee stock compensation	387	—	—	—	33,367	—	33,367
Common stock issued for consulting and legal services rendered	—	—	5,993	6	26,994	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	1,644	—	1,644
Common shares issued for Directors fees	—	—	3,288	3	14,997	—	15,000
Net loss	—	—	—	—	—	(1,921,134)	(1,921,134)
Balance, December 31, 2021	482,468	\$ 482	11,534,484	\$ 11,534	\$ 145,372,805	\$ (118,919,515)	\$ 26,465,306
Series A preferred stock issued for employee stock compensation	1,727	2	—	—	39,399	—	39,401
Common stock issued for consulting and legal services rendered	—	—	11,632	12	26,988	—	27,000
Common stock issued for employee compensation	—	—	3,572	3	6,765	—	6,768
Warrants issued to Scientific Advisory Board	—	—	—	—	785	—	785
Common shares issued for Directors fees	—	—	4,788	5	11,245	—	11,250
Net loss	—	—	—	—	—	(1,792,664)	(1,792,664)
Balance, March 31, 2022	484,195	\$ 484	11,554,476	\$ 11,554	\$ 145,457,987	\$ (120,712,179)	\$ 24,757,846

*See accompanying notes to the financial statements*



[Table of Contents](#)

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

	For the Nine Months Ended	
	March 31, 2023	March 31, 2022
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (5,018,580)	\$ (6,326,866)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	44,152	105,658
Preferred shares issued pursuant to license agreement	—	935,088
Common shares issued as compensation and for services	119,572	129,018
Warrants granted to Scientific Advisory Board	886	3,781
Depreciation	552,445	529,167
Amortization	6,202	6,202
Changes in operating assets and liabilities:		
Prepaid expenses	69,904	204,118
Other assets	23,257	(45,702)
Accounts payable	4,735	(77,029)
Accounts payable - related party	29,484	42,048
Accrued expenses	(3,524)	967
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(4,171,467)</b>	<b>(4,493,550)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(149,146)	(248,986)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payment of loan payable	(94,788)	(164,599)
Deferred financing costs	—	(37,408)
<b>NET CASH (USED IN) FINANCING ACTIVITIES</b>	<b>(94,788)</b>	<b>(202,007)</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(4,415,401)</b>	<b>(4,944,543)</b>
Cash and cash equivalents at beginning of period	14,066,359	20,516,677
Cash and cash equivalents at end of period	\$ 9,650,958	\$ 15,572,134
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>		
Interest paid	\$ 938	\$ 3,488
<b>Non-Cash Financing and Investing Activities:</b>		
Directors and Officers Insurance financed through loan	\$ —	\$ 234,198

*See accompanying notes to the condensed financial statements*

[Table of Contents](#)

**NANOVIRICIDES, INC.**  
**March 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 about to enter into Phase1a/1b human clinical trials sponsored by our licensee and collaborator in India, Karveer Meditech, Pvt. Ltd (see below). It has shown strong effectiveness and safety in pre-clinical 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.

The Company has also initiated additional drug programs to expand the repertoire of drugs based on NV-387, the active pharmaceutical ingredient contained in the COVID drug product NV-CoV-2. These programs include drug development for the treatment of MPOX virus infection (mpox and smallpox family of viruses) and for the treatment of Respiratory Syncytial Virus (RSV) infection. The Company anticipates that by leveraging NV-387 developments, the regulatory process for resulting drug candidates, if any, would be substantially faster than for de novo development.

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. 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. (“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), VZV infections, 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.

[Table of Contents](#)

The Company has licensed NV-CoV-2 and NV-CoV-2-R for further clinical drug development and commercialization in the territory of India to Karveer Meditech, Private. Limited. ("Karveer"), a company of which Dr. Anil R. Diwan is a passive investor, and Board Member without possessing operating control. Karveer has sponsored NV-CoV-2 for human clinical trials and has obtained regulatory approvals in India. Karveer has retained a local Clinical Research Organization (CRO) to conduct the clinical trials. NV-CoV-2, is about to enter into Phase1a/1b human clinical trials in India, sponsored by Karveer. We are awaiting notification of start of the clinical trial from Karveer. The drug products, NV-CoV-2 Oral Syrup, and NV-CoV-2 Oral Gummies, were manufactured at the Company's Shelton campus, and have already been shipped to and received by Karveer. Under the agreement with Karveer, 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 Karveer 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 March 31, 2023 of approximately \$127.5 million and a net loss of approximately \$5.0 million and net cash used in operating activities of approximately \$4.2 million for the nine months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of March 31, 2023, the Company had available cash and cash equivalents of approximately \$9.7 million.

Since the onset of the COVID-19 pandemic, the Company has focused its efforts primarily on a single lead program to minimize cost outlays, namely, taking the COVID-19 drug candidate against SARS-CoV-2 into human clinical trials. The prior lead program for a shingles drug will follow the COVID-19 drug program.

The Company believes that it has several important milestones, including Phase I and Phase II clinical trials for the Company's broad-spectrum, pan-coronavirus drug NV-CoV-2, that should occur in the ensuing year. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced.

Management believes that the Company's existing resources will be sufficient to fund the Company's planned operations and expenditures for at least 12 months from the date of the filing of this Form 10-Q. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company will need to raise additional capital to fund its long-term operations and research and development plans including human clinical trials for its various drug candidates until it generates revenue that reaches a level sufficient to provide self-sustaining cash flows. The accompanying condensed financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

**Note 3 - Summary of Significant Accounting Policies**

*Basis of Presentation – Interim Financial Information*

The accompanying unaudited interim 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, 2022 filed with the SEC on October 13, 2022.

[Table of Contents](#)

The June 30, 2022 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, 2022 filed on October 13, 2022.

Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock and potentially outstanding shares of common stock during the period to reflect the potential dilution that could occur from common shares issuable through stock options, warrants and convertible preferred stock.

The following table shows the number of outstanding potentially dilutive common shares excluded from the diluted net loss per common share calculation, as they were anti-dilutive:

	Potentially Outstanding Dilutive Common Shares			
	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022	For the Nine Months Ended March 31, 2023	For the Nine Months Ended March 31, 2022
<b>Warrants</b>	8,290	9,146	8,290	9,146

The Company has 497,287 shares of Series A preferred stock outstanding as of March 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 March 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 1,704,505, 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 and Director
TheraCour Pharma, Inc. (“TheraCour”)	An entity owned and controlled by Dr. Anil R. Diwan
Karveer Meditech, Pvt., Ltd	An entity of which Dr. Anil R. Diwan is a passive investor, and Board member without operating control.

[Table of Contents](#)

	For the three months ended		For the nine months ended	
	March 31, 2023	March 31, 2022	March 31, 2023	March 31, 2022
<i>Property and Equipment</i>				
During the reporting period, TheraCour acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, at cost, to the Company	\$ —	\$ 39,324	\$ 29,369	\$ 120,041

	As of	
	March 31, 2023	June 30, 2022

*Account Payable – Related Party*

Pursuant to an Exclusive License Agreement with TheraCour, the Company was granted exclusive licenses for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. On November 1, 2019, the Company entered into the VZV Licensing Agreement with TheraCour. In consideration for obtaining these exclusive licenses, the Company agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of certain direct costs as a development fee and such development fees shall be due and payable in periodic installments as billed, (2) the Company will pay \$2,000 or actual costs each month, whichever is higher for other general and administrative expenses incurred by TheraCour on the Company's behalf, (3) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour and; (4) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. Accounts payable due TheraCour at March 31, 2023 and June 30, 2022 were \$708,881 and \$679,397, respectively, which were each offset by a two month advance of \$465,000.

	\$ 243,881	\$ 214,397
--	------------	------------

	For the three months ended		For the nine months ended	
	March 31, 2023	March 31, 2022	March 31, 2023	March 31, 2022
<i>Research and Development Costs Related Party</i>				

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 March 31, 2023 and June 30, 2022

	\$ 622,016	\$ 587,239	\$ 1,867,974	\$ 1,754,143
--	------------	------------	--------------	--------------

*License Milestone Fee – Related Party*

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

*License Agreement – Related Party*

[Table of Contents](#)

On March 27, 2023 the Company entered into a License Agreement with Karveer Meditech, Pvt., Ltd., India, (Karveer) wherein the Company granted to Karveer 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. Karveer 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. Karveer 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, Karveer 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 (30)% of such costs and applicable taxes. Upon commercial sales of any resulting approved drugs, Karveer will pay the Company a royalty of seventy (70)% percent of the final invoiced sales to unaffiliated third parties. No amounts are due to Karveer as of March 31, 2023.

**Note 5 - Property and Equipment**

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

	March 31, 2023	June 30, 2022
GMP Facility	\$ 8,168,045	\$ 8,149,416
Land	260,000	260,000
Office Equipment	57,781	57,781
Furniture and Fixtures	5,607	5,607
Lab Equipment	6,315,727	6,185,210
<b>Total Property and Equipment</b>	<b>14,807,160</b>	<b>14,658,014</b>
Less Accumulated Depreciation	(6,516,265)	(5,963,820)
<b>Property and Equipment, Net</b>	<b>\$ 8,290,895</b>	<b>\$ 8,694,194</b>

Depreciation expense for the three months ended March 31, 2023 and 2022 was \$186,255 and \$179,492, respectively, and for the six months ended March 31, 2023 and 2022 was \$552,445 and \$529,167, respectively.

**Note 6 – Intangible Assets**

Intangible assets, net consists of the following:

	March 31, 2023 Finite Lived Intangible Assets	March 31, 2023 Indefinite Lived Intangible Assets	Total March 31, 2023	June 30, 2022 Finite Lived Intangible Assets	June 30, 2022 Indefinite Lived Intangible Assets	Total June 30, 2022
Intangible Assets	\$ 153,393	\$ 305,561	\$ 458,954	\$ 153,393	\$ 305,561	\$ 458,954
Less Accumulated Amortization	(123,308)	—	(123,308)	(117,106)	—	(117,106)
<b>Intangible Assets, Net</b>	<b>\$ 30,085</b>	<b>\$ 305,561</b>	<b>\$ 335,646</b>	<b>\$ 32,287</b>	<b>\$ 305,561</b>	<b>\$ 341,848</b>

Amortization expense amounted to \$2,067 and \$2,067 for the three months ended March 31, 2023 and 2022, respectively, and for the nine months ended March 31, 2023 and 2022 were \$6,202 and \$6,202, respectively.

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

[Table of Contents](#)

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 – Loan Payable**

The Company financed its Directors and Officers liability insurance policies through BankDirect for the periods January 1, 2022 to December 31, 2022 and January 1, 2021 to December 31, 2021. The original loan balances as of January 1, 2022 and January 1, 2021 were \$234,198 and \$235,476, respectively, payable at the rate of \$23,932 and \$24,062 monthly including interest at an annual rate of 4.74% and 4.74%, respectively, through October of each year. At March 31, 2023 and June 30, 2022, the loan balance was \$0 and \$94,788, respectively. For the three and nine months ended March 31, 2023, the Company incurred interest expense of \$0 and \$938, respectively. For the three and nine months ended March 31, 2022, the Company incurred interest expense of \$2,502 and \$3,445, respectively. For the period January 1, 2023 to December 31, 2023 the Company did not finance its Directors and Officers liability insurance.

**Note 8 - Equity Transactions**

On September 14, 2022 the Company's Board of Directors approved the employment extension of Dr. Anil Diwan, President and Chairman of the Board. On October 6, 2022, the Company and Dr. Anil Diwan executed an extension of his employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares shall be vested in quarterly installments of 2,551 shares on September 30, 2022, December 31, 2022, March 31, 2023 and June 30, 2023 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$10,930 and \$32,790 for the three and nine months ended March 31, 2023, respectively. The balance of \$10,931 will be recognized as the remaining 2,551 shares vest and service is rendered for the three months ended June 30, 2023.

For the three and nine months ended March 31, 2023, the Company's Board of Directors authorized the issuance of 1,727 and 2,501, respectively of fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of \$6,303 and \$11,362, respectively for the three and nine months ended March 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 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$3.40 per share expiring in August 2026 and in November 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$2.09 per share expiring in November 2026 and in February 2023 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$1.79 per share expiring in February 2027. The fair value of the warrants was \$183 for the three months ended March 31, 2023 and \$886 for the nine months ended March 31, 2023 and was recorded as consulting expense.

[Table of Contents](#)

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	57.19-85.12 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.025-4.195 %

For the three and nine months ended March 31, 2023, the Company's Board of Directors authorized the issuance of 19,983 and 50,039, respectively, fully vested shares of the Company's common stock with a restrictive legend for consulting services. The Company recorded expense of \$27,000 and \$81,000, respectively, for the three and nine months ended March 31, 2023, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and nine months ended March 31, 2023, the Company's Board of Directors authorized the issuance of 8,340 and 20,667, respectively, fully vested shares of its common stock with a restrictive legend for director services. The Company recorded an expense of \$11,250 and \$33,750 for the three and nine months ended March 31, 2023, which is reflective of the fair value of the common stock on the dates of issuance.

**Note 9 - Common Stock Warrants**

	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
<b>Common Stock Warrants</b>				
Outstanding and exercisable at June 30, 2022	9,146	\$ 6.06	2.00	\$ 238
Granted	858	2.43	3.63	—
Expired	(1,714)	8.64	—	—
Outstanding and exercisable at March 31, 2023	8,290	\$ 5.16	1.84	\$ —

Of the outstanding warrants at March 31, 2023, 570 expire in fiscal year ending June 30, 2023, 2,287 expire in fiscal year ending June 30, 2024, 2,287 warrants expire in the fiscal year ending June 30, 2025, 2,288 warrants expire in the fiscal year ending June 30, 2026, and 858 warrants expire in the fiscal year ending June 30, 2027.

**Note 10 - Commitments and Contingencies**

Legal Proceedings

From time to time, we are subject to various legal proceedings arising in the ordinary course of business, including proceedings for which we have 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 we believe will have a material adverse effect to our business, financial position, results of operations, or liquidity.



[Table of Contents](#)

Employment Agreements

As discussed in Note 8, On September 14, 2022 the Company's Board of Directors approved the extension of Dr. Diwan's employment agreement, and on October 6, 2022, the Company and Dr. Diwan executed an extension of his employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares will be deemed partially vested in quarterly installments following the grant date and fully vested on June 30, 2023.

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 Karveer Meditech, Pvt., Ltd., India, (Karveer) wherein the Company granted to Karveer 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. Karveer 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. Karveer 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, Karveer 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, Karveer will pay the Company a royalty of seventy (70)% percent of the final invoiced sales to unaffiliated third parties. No amounts were owed to Karveer as of March 31, 2023.

[Table of Contents](#)

## 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, 2022. Readers should carefully review the risk factors disclosed in this Form 10-Q, Form 10-K and other documents filed by the Company with the SEC.

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

### PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

### Organization and Nature of Business

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

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

The Company is a clinical stage company with several drugs in various stages of clinical and pre-clinical development. To date, we do not have any commercialized products. 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. We have no customers, products or revenues to date, and may never achieve revenues or profitable operations.

### 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 ingredient in NV-CoV-2. We are also developing, on our own, NV-CoV-2-R, a drug that is a potential cure for all coronaviruses, based on the broad-spectrum activity of its two ingredients, NV-387 and Remdesivir. The latter is the well-known antiviral drug from Gilead which we have shown to be considerably improved upon encapsulation within NV-387.

[Table of Contents](#)

Additionally, we have completed safety/pharmacology studies of our drug to treat Shingles rash, NV-HHV-1, formulated as a skin cream, which we plan to advance into clinical trials following NV-CoV-2 and NV-CoV-2-R.

Further, we are exploring a breadth of additional applications of NV-CoV-2 and NV-CoV-2-R to other viral infections including respiratory viruses such as RSV (respiratory syncytial virus) and others, as well as mpox and smallpox family viruses, with dual importance for biodefense and public health, in order to maximize the utility and benefits from these two drugs and to 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.

Currently we are completely focused on clinical trials of NV-CoV-2 for the treatment of COVID and the expansion of the range of antiviral applications of its active ingredient, NV-387.

We believe that in the future, with appropriate support, we will be in a position to deliver a novel or in-pipeline antiviral drug to combat a future epidemic in a much shorter timeframe than what was possible for us in the COVID pandemic. We have demonstrated with NV-CoV-2 the rapid drug development capabilities of our platform technology, going from discovery to clinical drug product in about 18 months for our COVID developments, although engagement into clinical trials has taken a long time. This delay has been due to internal limitations on the number of Company personnel, financing, and internal regulatory function capabilities, factors that can be corrected with appropriate financial support.

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.

Our capabilities in manufacturing clinical drug product are now well established. Further, we have developed, and plan on adding to, our internal regulatory expertise. Thus, 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 into initial 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 In Clinical Trials

Our lead drug candidate NV-CoV-2 is a broad-spectrum, pan-coronavirus drug for the treatment of COVID. NV-CoV-2 is about to enter into Phase Ia/Ib human clinical trials sponsored by our licensee and collaborator in India, Karveer Meditech, Pvt. Ltd (see below). We await notification of the start of the clinical trials. NV-CoV-2 has shown strong effectiveness and safety in pre-clinical studies.

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

[Table of Contents](#)

We have successfully developed NV-CoV-2 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.

The clinical trials program for NV-CoV-2 is starting 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-CoV-2 are expected to follow thereafter. We will report on these objectives via press releases as meaningful advancements take place.

Additionally, we are also developing NV-CoV-2-R as a broad-spectrum, pan-coronavirus drug that is designed to block the complete lifecycle of coronaviruses and therefore is anticipated to be a potential cure for all coronavirus infections (see below). NV-CoV-2-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-CoV-2 and NV-CoV-2-R will be eligible for Phase II studies. 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-CoV-2-R independently of Gilead.

Both NV-CoV-2 and NV-CoV-2-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 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

We anticipate that the active pharmaceutical ingredient of NV-CoV-2, namely NV-387, may have significantly broader spectrum of antiviral effectiveness than the coronavirus family alone, based on its design. NV-387 has been found to have broad-spectrum activity against all of the tested seasonal coronaviruses and SARS-CoV-2 in pre-clinical studies. This activity is thought to be because NV-387 was designed to mimic a well-known feature on human cell surfaces, called “sulfated proteoglycans” that a large number of virus families bind to as the first step in infecting a cell (reviewed in <sup>1</sup>). Therefore, it can be anticipated that NV-387 may possess antiviral activity against many other virus families in addition to coronaviruses that warrants further clinical development against those virus families.

Antibiotics such as penicillin attack the bacterial surface and thereby kill the bacteria. Similarly, NV-387 is designed to 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 broad-spectrum, direct acting, antiviral agent to treat multiple different viral infections.

Having a safe and effective broad-spectrum antiviral agent such as NV-387 in hand would 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.

---

<sup>1</sup> 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.

[Table of Contents](#)

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-CoV-2-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.

To this end, we have undertaken pre-clinical studies of NV-387 against a number of other virus families of interest. As previously announced, due to the public health threat posed by mpox, we began working on poxvirus family therapeutics based on NV-387. Further, we are also working on Respiratory Syncytial Virus (RSV), and plan to work on other viruses that cause lung infections, such as parainfluenza virus, and human metapneumovirus. We plan to continue to add to this list with both internal and external efforts. Some of the other important viruses that are known to bind to sulfated proteoglycans include chickengunya virus (CHKV), human papillomavirus (HPV), Ebola and Marburg viruses (EBOV, MARV), Hendra and Nipah viruses, Rabies virus, Norovirus, and Rhinoviruses. There are no safe and effective treatments for most of these viruses at present and thus there is an unmet medical need for safe and effective antiviral drugs to combat their infections.

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

Even as U.S. President Joe Biden on April 10, 2023, signed a resolution to end the COVID-19 national emergency, SARS-CoV-2 continues to claim a substantial number of lives, with a decreasing trend from over 1,700 per the week of April 5, 2023 to 1,160 the week of April 19, 2023 and is still causing a substantial number of hospitalizations in the USA alone, in what is currently a “non-wave” period, as per CDC data tracker ([https://covid.cdc.gov/covid-data-tracker/#trends\\_weeklydeaths\\_select\\_00](https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00)). A new Omicron variant, XBB.1.16 has begun to gain ground in Asian countries, and cases have started rising in the USA as well, which can be projected to lead to another “wave” of SARS-CoV-2 infections in the next few months, based on the last two years of worldwide trends of waves progression (<https://www.usnews.com/news/health-news/articles/2023-04-21/cdc-xbb-1-16-or-arcturus-responsible-for-nearly-10-of-new-covid-19-cases>). In contrast to the COVID-19 national emergency, President Biden declared the end of the COVID-19 public health emergency on May 11, 2023.

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. 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. The SARS-CoV-2 virus with its continually evolving variants is now a continuously recurring phenomenon, like other seasonal viruses such as Influenzas.

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

We believe the world is woefully unprepared for a new SARS-CoV-2 wave and forever-arising new variants, except for the fact that natural immunity and prior vaccine-boosted immunity may afford some protection. The therapeutics and preventatives tools available

[Table of Contents](#)

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 are also falling 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.

Additionally, a large percentage of COVID patients have been experiencing “long COVID”<sup>2</sup>, 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 antigens from its 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<sup>3</sup>, indicating the need for a strong antiviral drug for minimizing long COVID, and also possibly treating long COVID cases with residual virus. However, 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.

The need for the broad-spectrum nanoviricide COVID drug NV-CoV-2 cannot be overstated in the current circumstances. 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.

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.

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 are manufacturing the clinical supply of drug substances as well as the oral drug products for NV-CoV-2 at our own facility, simplifying and expediting the cGMP-compliant manufacturing operations. 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 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, as our portfolio of drug products continues to expand with more drugs moving into the clinical trials stage. 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 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 now 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.

---

<sup>2</sup> Shaw, J. “The Causes of Long COVID”, Harvard Magazine, <https://www.harvardmagazine.com/2022/09/feature-long-covid>.

<sup>3</sup> M Yan Xie<sup>1,2</sup>, Taeyoung Choi<sup>1,2</sup>, 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.

[Table of Contents](#)

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. 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 “metastable” 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.

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, which then 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 second broad-spectrum approach of using sulfated proteoglycan mimetic ligands.

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

Additionally, we are the only company that, to the best of our knowledge, is developing antiviral treatments that are designed to (a) directly attack the virus and disable it from infecting human cells (i.e. block the “Re-Infection Cycle”), and (b) simultaneously block the reproduction of the virus that has already gone inside a cell (i.e. block the “Replication Cycle”). Together, this strategy of a two-pronged attack against the virus, both inside the cell and outside the cell, and thus blocking the complete lifecycle of the virus, can be expected to result in a cure for coronaviruses and other viruses that do not become latent.

[Table of Contents](#)

As an example of this strategy, we have developed NV-CoV-2-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-CoV-2-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<sup>4</sup>. The increased circulating lifetime and also concentration of intact Remdesivir should improve its effectiveness. Additionally, NV-CoV-2-R affords the synergistic effects of attacking the virus lifecycle by two orthogonal mechanisms, going well beyond the effects of Remdesivir alone. In NV-CoV-2-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-CoV-2-R is designed to block the entire lifecycle of 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-CoV-2-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-CoV-2-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.

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 Gel”) 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.

The injectable formulation of NV-CoV-2 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.

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.

---

<sup>4</sup> 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>



[Table of Contents](#)

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

**Developments During the Reported Period**

During the three months ended March 31, 2023, we have focused on the tasks required for the impending human clinical trials of NV-CoV-2 in India.

Our collaborator and licensee in India, Karveer Meditech Private Limited (“Karveer”) has obtained permission for clinical trials of NV-CoV-2 oral formulations that are intended for the treatment of mild to moderate patients. We completed a licensing agreement with Karveer on March 27, 2023 (see below, under “Collaborations”).

During the three months ended March 31, 2023, we (a) completed manufacturing of the drug substance NV-387 and (b) manufactured the drug products (i) NV-CoV-2-Oral Syrup and (ii) NV-CoV-2 Oral Gummies, all under cGMP-compliant manufacturing operations, in quantities sufficient for a number of required characterizations, including continuing stability studies, and the requirements of the anticipated clinical trials. We have established drug product formulation, filling, sealing, labeling and packaging operations for these oral drug products at our cGMP-compliant facility in Shelton, CT.

**Subsequent Events**

Subsequent to the reported period, on or about April 12, 2023 we shipped the drug products to Karveer, and Karveer received the shipment on or about April 19, 2023 in good condition after customs clearance. We have been advised that the clinical trial site training has been completed and that the clinical trial is about to begin as of this writing. We await notification from Karveer that the clinical trial has started.

Although we continued compiling and performing medical writings needed for developing regulatory applications for submission to the US FDA and other international regulatory agencies for human clinical trials of NV-CoV-2 in COVID patients, we had to put the NV-CoV-2 Injectables Clinical Trial Program on hold in order to fully focus on the cGMP manufacture of the drug products required for the human clinical trials of NV-CoV-2 in India. It is expected that the clinical trial protocol we have developed for these additional clinical trials may be modified by the Clinical Trial Provider contract research organization (CRO). We are in the process of due diligence for selecting a CRO for US IND or an international filing and performing such additional clinical trials at present. The CRO will need to complete the writing of the clinical protocol section of the IND or equivalent regulatory submission.

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

**Financial Status**

As of March 31, 2023 the Company had approximately \$9.7 million in cash and cash equivalents and \$8.3 million of property and equipment, net of accumulated depreciation. Our current liabilities are approximately \$0.3 million. Stockholder’s equity was approximately \$18.2 million at March 31, 2023.

During the nine month period ended March 31, 2023, the Company used approximately \$4.2 million in cash toward operating activities. The available cash is sufficient for more than twelve months of operations at the current rate of expenditures from the date of filing of this Quarterly Report on Form 10-Q. As our COVID and shingles drug programs mature into human clinical trials, our expenditures are anticipated to increase due to the costs of the clinical trials. We estimate that we have sufficient funds in hand for initial human clinical trials 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 believe we have sufficient cash as of March 31, 2023 to fund Phase 1 clinical trials in India for our lead Coronavirus drug, NV-CoV-2. We do not anticipate any major capital costs going forward in the near future. We intend to seek collaborations to develop the

[Table of Contents](#)

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.

**NanoViricides' Drug Programs – Additional Information**

NV-CoV-2: Our Lead Drug Candidate to Treat COVID-19 (SARS-CoV-2 Infection)

NV-CoV-2 refers to the drug products that contain NV-387 as the active pharmaceutical ingredient (API). NV-387 is the drug substance that is responsible for the effectiveness of the drug product NV-CoV-2. To avoid technical explanations, we are using the terms NV-CoV-2 and NV-387 generally interchangeably in the following paragraphs.

We have previously established that NV-387 (and thus NV-CoV-2) has broad-spectrum activity against many unrelated coronaviruses including SARS-CoV-2 in various assays. The broad-spectrum, pan-coronavirus activity of our drug candidates is important because it provides scientific rationale that as a virus mutates, it would not escape the NV-CoV-2 drug. In addition, we anticipate the drugs the Company develops should work against seasonal or commonly circulating coronaviruses as well as pandemic coronaviruses. Antibodies, in contrast tend to be highly specific and are known to fail when the virus mutates. Vaccines are also known to fail when a virus mutates.

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

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

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

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

We have upgraded our facilities to enable complete clinical drug product manufacture, which involves both formulation and packaging under cGMP-compliant processes. We are currently in the process of setting up the final drug product packaging at our facility for the oral drug products. We plan on having the fill-and-finish operations of injectable formulations performed by a third party CMO. We are in discussions with at least one vendor in this regard.

Internationally, virus variants have continued to emerge with resistance to drugs and vaccines. Scientists believe it is only a matter of time before escape variants against existing vaccines and therapeutics become commonplace. Thus, the need for therapeutics that the virus would not escape by mutations, such as the broad-spectrum, pan-coronavirus nanoviricides drug candidates, remains unmet.

[Table of Contents](#)

Exploring Additional Antiviral Applications of NV-387

As we progress NV-CoV-2 for COVID-19 therapeutics, we have also begun performing additional studies to assess the possibility of expanding the applicability of its active pharmaceutical ingredient (“API”), NV-387, for attacking and controlling other viral infections. The virus-recognition ligand in NV-387 is designed to mimic certain features of heparan-sulfate proteoglycans (HSPG) and related glycosaminoglycans (GAG). HSPG serve as the initial attachment and concentration site for a large number of viruses, and also may serve as cellular entry sites for some viruses. Most viruses additionally use certain cognate receptors for cell entry, such as ACE2 for SARS-CoV-2, SARS-CoV-1, hCoV-NL63; DPP-4 for MERS; CD4 and CCR5 or CXCR4 for HIV; nucleolin for RSV, etc. Notably, Orthopoxvirus (which includes mpox, smallpox, and murine ectromelia virus) mature virion particles bind to HSPG or the related Chondroitin sulfate. Respiratory Syncytial Virus (RSV) also binds to heparin. Thus NV-387 may have activity against mpox virus and/or RSV, two pathogens that are of significant interest. Additionally, we have shown that NV-387 improves the pharmacokinetic properties of other drugs, improving their activity, as in the case of remdesivir. Given these considerations, we have begun pre-clinical studies for mpox (formerly monkeypox) therapeutics development with the known drug tecovirimat as a guest drug in a murine animal model. Such studies if successful will significantly expand our pipeline with limited requirements for additional studies since NV-387 would have already undergone clinical studies in COVID-19 patients. This would provide substantially improved return on investment in the development of NV-387.

NV-HHV-1, Our Lead 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) 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.

**Our Campus in Shelton, CT**

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

[Table of Contents](#)

*Process Scale-Up Production Capability*

The process scale-up area is operational at kilogram to multi-kg scales for different chemical synthesis and processing steps now. It comprises reactors and process vessels on chassis or skids, ranging from 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.

In the previous quarter, we have modified an existing room into a cGMP-compliant Oral Drug Product Formulation, Fill, and Packaging room. In the reported quarter, we have established the clinical scale filling and packaging facilities for oral syrup and oral gummies (semi-solids) formulations using equipment that we had custom-designed and fabricated in the USA.

We plan to produce multiple batches of a drug product. If we are satisfied with the reproducibility of our processes, 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. We have achieved BSL-2 (Biological Safety Level 2) certification from the State of Connecticut for our Virology suite at the new campus. This suite comprises three individual virology workrooms, enabling us to work on several different viruses and strains at the same time. This facility is designed only for cell culture studies on viruses, and no animal studies can be conducted at any of our own facilities.

We have established several different types of assays for screening of candidates against Coronaviruses, SARS-CoV-2 Pseudovirions, as well as VZV, HSV-1, HSV-2, among others in this lab. In the previous quarter, we have added assays for screening of candidates against BSL2-Orthopoxviruses and Enteroviruses, and in the reported quarter we also added assays for screening of candidates against 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 it is 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.

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

[Table of Contents](#)

performed, additional work may become necessary or change in plans or workload may occur. Such changes may have an adverse impact on our estimated budget. Such changes may also have an adverse impact on our projected timeline of drug development.

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

We have previously completed IND-enabling studies for a drug candidate for the treatment of shingles rash caused by reactivation of the chickenpox virus (aka varicella-zoster virus, VZV). We plan on taking the shingles drug candidate into human clinical trials after clinical trials of our COVID-19 drug candidate.

As a risk factor, we recognize that the FDA may require additional studies to be done before approving the IND. Assuming that the FDA allows us to conduct human clinical studies as we intend to propose, we believe that this coming year's work plan will lead us to obtain certain information about the safety and efficacy of one of the drugs under development in human clinical studies. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further Phase II and Phase III human clinical studies, additional studies in animal models to obtain any necessary data regarding the pharmacokinetic and pharmacodynamic profiles of our drug candidates towards drug approval or licensure from regulatory agencies.

As a strategy, we plan to develop the same drug, once initial clinical trials towards a first approval of the drug are completed, for commercial approval for additional indications, such as pediatric applications, special case applications for certain classes of immune-compromised patients, among others, provided that appropriate levels of funding 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 ("Karveer"), whereby we granted to Karveer 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, Karveer 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 Karveer in the clinical trials for use in other jurisdictions, and Karveer 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 Karveer uses the Company's proprietary technologies. In return, the Company will reimburse Karveer 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, Karveer shall pay the Company 70% of any invoiced commercial 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. Karveer 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 Karveer. We believe that we have been able to harness significant savings in terms of both expenditures and time due to this relationship compared to if we had engaged with an unrelated commercial third party for the same purposes.

Karveer 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 Karveer in which Karveer 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 Karveer proceeded to develop and file the required regulatory documents including a clinical trials application with the regulatory authority in India. Karveer has retained a local clinical research organization (CRO) for the purpose of developing such documents and planning and executing the clinical trials. We helped Karveer with assembling the necessary datasets and information.

[Table of Contents](#)

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

**Patents, Trademarks, 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 “CoV 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.

[Table of Contents](#)

**Trademarks**

We have no registered trademarks.

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

As of March 31, 2023, we had cash and cash equivalents of \$9,650,958, prepaid expenses of \$280,117 and net property and equipment of \$8,290,895. Accounts payable and accrued expenses were \$348,744, inclusive of accounts payables to a related party of \$243,881. The accounts payable-related party is net of a two month advance of \$465,000. Stockholders' equity was \$18,228,055 at March 31, 2023. In comparison, as of June 30, 2022, we had \$14,066,359 in cash and cash equivalents, prepaid expenses of \$350,021 and \$8,694,194 of net property and equipment. Our liabilities at June 30, 2022 were \$412,837 including a third party short term loan payable of \$94,788, accounts payable of \$57,960 payable to third parties and accounts payable to TheraCour of \$214,397, net of a two month advance of \$465,000, and accrued expenses of \$45,692.

During the nine month period ended March 31, 2023, we used approximately \$4.2 million in cash toward operating activities. During the nine month period ended March 31, 2022, we used approximately \$4.5 million in cash toward operating activities.

**Research and Development Costs**

We do not maintain separate accounting line items for each project in development. We maintain aggregate expense records for all research and development conducted. Because at this time all of our projects share a common core material, we allocate expenses across all projects at each period-end for purposes of providing accounting basis for each project. Project costs are allocated based upon labor hours performed for each project. Far fewer man-hours are spent on the projects at low priority than the projects at high priority. In the reported quarter, we have focused almost exclusively on our COVID program drug candidates.

**Results of Operations**

**Revenues** The Company is a biopharmaceutical company and did not have any revenue for the nine month periods ended March 31, 2023 and 2022.

**Research and Development Expenses** – Research and development expenses for the three months ended March 31, 2023 decreased \$58,980 to \$1,196,094 from \$1,255,074 for the three months ended March 31, 2022. Research and development expenses for the nine months ended March 31, 2023 decreased \$1,133,839 to \$3,479,463 from \$4,613,302 for the nine months ended March 31, 2022. The decrease in research and development expenses for the three months ended March 31, 2023 is due to a decrease in external lab expenses. The decrease in the research and development expenses for the nine months ended March 31, 2023 is due to a decrease in external lab expenses, and a milestone payment during the nine months ended March 31, 2022 to a related party, TheraCour, upon execution of a COVID -19 License Agreement.

**General and Administration Expenses** – General and administrative expenses for the three months ended March 31, 2023 increased \$81,846 to \$614,647 from \$532,801 for the three months ended March 31, 2022. General and administrative expenses for the nine months ended March 31, 2023 increased \$74,118 to \$1,787,632 from \$1,707,514 for the nine months ended March 31, 2022. The increase in general and administrative expenses for the three- and nine- months ended March 31, 2023 is due to an increase in professional fees.

**Interest Income** – Interest income for the three months ended March 31, 2023 increased \$107,937 to \$107,937 from \$0 for the three months ended March 31, 2022. Interest income for the nine months ended March 31, 2023 increased \$249,453 to \$249,453 from \$0 for the nine months ended March 31, 2022. The increase in interest income for the three and nine months ended March 31, 2023 is due to an increase in interest rates during the three and nine month period ended March 31, 2023.

**Interest Expense** – Interest expense decreased \$4,789 to \$0 for the three months ended March 31, 2023 from \$4,789 for the three months ended March 31, 2022. Interest expense decreased \$5,112 to \$938 for the nine months ended March 31, 2023 from \$6,050 for the nine months ended March 31, 2022. The decrease in interest expense for the three and nine months ended March 31, 2023 is a result of the Company not financing its Directors and Officers Insurance Policies.

[Table of Contents](#)

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

**Net Loss** – For the three months ended March 31, 2023, the Company had a net loss of \$(1,702,804) or \$(0.15) per share compared to a net loss of \$(1,792,664) or \$(0.16) per share for the three months ended March 31, 2022. For the nine months ended March 31, 2023, the Company had a net loss of \$(5,018,580) or \$(0.43) per share compared to a net loss of \$(6,326,866) or \$(0.55) per share for the nine months ended March 31, 2022. The decrease in the net loss for the periods presented is attributable to the factors discussed above.

**Liquidity and Capital Reserves**

We had cash and cash equivalents of \$9,650,958 and prepaid expenses of \$280,117 as of March 31, 2023 and accounts payable and accrued expenses were \$348,744, inclusive of accounts payable of \$243,881 to a related party as of the same date. The accounts payable – related party is net of a two month advance of \$465,000. Since inception, we have expended substantial resources on research and development. Consequently, we have sustained substantial losses. We have an accumulated deficit of \$127,510,756 at March 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 believe that there are several important milestones that should occur in the ensuing year starting with entering a drug into our first clinical trials. 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.

We believe that cash on hand as of March 31, 2023 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 nine months ended March 31, 2023.



[Table of Contents](#)

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

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

**ITEM 4. CONTROLS AND PROCEDURES**

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the "SEC"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

As of March 31, 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 March 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, 2022. The material weakness in internal control over financial reporting resulted from the lack of timely and effective review of the Company's period-end closing process and adequate personnel and resources. Management has effected an assessment of its internal control over financial reporting and has taken steps to address this material weakness as described under the remediation plan.

*Changes in Internal Control Over Financial Reporting*

Other than what was described above, there were no material changes in our system of internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the quarter ended March 31, 2023 that has materially affected, or is likely to materially affect, our internal control over financial reporting. However, 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 has established a formal iterative review process which will provide oversight to the Company's efforts for ensuring appropriate and timely internal control over financial reporting including, but not limited to, remediation of the aforesaid material weakness and identifying and testing for potential internal control weakness in the financial reporting process to assure reliability and accuracy.

Management believes the foregoing efforts will remediate the material weakness identified above. As we continue to evaluate and work to improve our internal control over financial reporting, management may execute additional measures to address potential control deficiencies or modify the remediation plan described above and will continue to review and make necessary changes to the overall design of our internal controls.

[Table of Contents](#)

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

From time to time, 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

On September 14, 2022 the Company's Board of Directors approved the employment extension of Dr. Anil Diwan, President and Chairman of the Board. On October 6, 2022, the Company and Dr. Anil Diwan executed an extension of his employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares have vested in three quarterly installments of 2,551 shares on September 30, 2022, December 31, 2022, March 31, 2023 with the last installment of 2,551 shares due to vest on June 30, 2023, and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$10,930 and \$32,790 for the three and nine months ended March 31, 2023, respectively. The balance of \$10,931 will be recognized as the remaining 2,551 shares vest and service is rendered for the three months ended June 30, 2023.

For the three and nine months ended March 31, 2023, the Company's Board of Directors authorized the issuance of 1,727 and 2,501, respectively of fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of \$6,303 and \$11,362, respectively for the three and nine months ended March 31, 2023 related to these issuances.

The Scientific Advisory Board was granted in August 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$3.40 per share expiring in August 2026 and in November 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$2.09 per share expiring in November 2026 and in February 2023 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$1.79 per share expiring in February 2027. The fair value of the warrants was \$183 for the three months ended March 31, 2023 and \$886 for the nine months ended March 31, 2023 and was recorded as consulting expense.

For the three and nine months ended March 31, 2023, the Company's Board of Directors authorized the issuance of 19,983 and 50,059, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of \$27,000 and \$81,000, respectively, for the three and nine months ended March 31, 2023, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and nine months ended March 31, 2023, the Company's Board of Directors authorized the issuance of 8,340 and 20,667, fully vested shares of its common stock with a restrictive legend for director services, respectively. The Company recorded an expense of \$11,250 and \$33,750 for the three and nine months ended March 31, 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 the Common Stock issuable upon conversion or exercise of such securities, have been registered under the Securities Act or any other applicable securities laws and are deemed restricted securities, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

[Table of Contents](#)

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

[Table of Contents](#)

**ITEM 6. EXHIBITS**

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

[Table of Contents](#)

**SIGNATURES**

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

**NANOVIRICIDES, INC.**

Dated: May 15, 2023

/s/ Anil R. Diwan

Name: Anil R. Diwan

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

Dated: May 15, 2023

/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 condensed 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 condensed financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 15, 2023

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 condensed 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 condensed financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 15, 2023

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

Exhibit 32.1

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

In connection with the quarterly report of NanoViricides, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 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.

May 15, 2023

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

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

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

---



Exhibit 32.2

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

In connection with the quarterly report of NanoViricides, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 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.

May 15, 2023

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.

---