
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, 2025

Commission File Number: 001-36081

NANOVIRICIDES, INC.

(Exact name of Company as specified in its charter)

Delaware

76-0674577

(State or other jurisdiction)
of incorporation or organization)

(IRS Employer Identification No.)

1 Controls Drive

Shelton, Connecticut 06484

(Address of principal executive offices and zip code)

(203) 937-6137

(Company's telephone number, including area code)

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

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

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

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

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

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

Yes No

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

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

As of May 15, 2025 there were approximately 16,072,000 shares of common stock of the registrant issued and outstanding.

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PART I. FINANCIAL INFORMATION**Item 1. Financial Statements****NanoViricides, Inc.
Condensed Balance Sheets**

	<u>March 31, 2025</u>	<u>June 30, 2024</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,542,590	\$ 4,797,778
Prepaid expenses	184,716	172,742
Total current assets	<u>2,727,306</u>	<u>4,970,520</u>
Property and equipment, net	6,982,750	7,512,463
Intangible assets, net	319,106	325,308
OTHER ASSETS		
Service agreements	2,798	14,562
Total assets	<u>\$ 10,031,960</u>	<u>\$ 12,822,853</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 352,818	\$ 376,270
Accounts payable – related parties	813,477	720,039
Accrued expenses	32,616	262,467
Total current liabilities	<u>1,198,911</u>	<u>1,358,776</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A convertible preferred stock, \$0.00001 par value, 10,000,000 shares designated, 905,330 and 892,625 shares issued and outstanding, at March 31, 2025 and June 30, 2024, respectively	9	9
Common stock, \$0.00001 par value; 150,000,000 shares authorized, 16,071,950 and 13,144,055 shares issued and outstanding, at March 31, 2025 and June 30, 2024, respectively	160	131
Additional paid-in capital	155,578,860	150,838,832
Accumulated deficit	<u>(146,745,980)</u>	<u>(139,374,895)</u>
Total stockholders' equity	<u>8,833,049</u>	<u>11,464,077</u>
Total liabilities and stockholders' equity	<u>\$ 10,031,960</u>	<u>\$ 12,822,853</u>

See accompanying notes to the condensed financial statements

Nanoviricides, Inc.
Condensed Statements of Operations
(Unaudited)

	<u>For the Three Months Ended</u> <u>March 31,</u>		<u>For the Nine Months Ended</u> <u>March 31,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
OPERATING EXPENSES				
Research and development	\$ 1,282,251	\$ 1,214,661	\$ 4,371,693	\$ 4,255,205
General and administrative	966,905	693,742	3,104,349	1,869,545
	<u>2,249,156</u>	<u>1,908,403</u>	<u>7,476,042</u>	<u>6,124,750</u>
LOSS FROM OPERATIONS	(2,249,156)	(1,908,403)	(7,476,042)	(6,124,750)
OTHER INCOME (EXPENSE)				
Interest income	32,373	53,927	105,106	236,399
Interest expense	<u>—</u>	<u>—</u>	<u>(149)</u>	<u>(49,808)</u>
	<u>32,373</u>	<u>53,927</u>	<u>104,957</u>	<u>186,591</u>
Other income (expense), net				
	<u>32,373</u>	<u>53,927</u>	<u>104,957</u>	<u>186,591</u>
NET LOSS	<u><u>\$ (2,216,783)</u></u>	<u><u>\$ (1,854,476)</u></u>	<u><u>\$ (7,371,085)</u></u>	<u><u>\$ (5,938,159)</u></u>
Net loss per common share- basic and diluted	<u><u>\$ (0.14)</u></u>	<u><u>\$ (0.16)</u></u>	<u><u>\$ (0.50)</u></u>	<u><u>\$ (0.51)</u></u>
Weighted average common shares outstanding- basic and diluted	<u><u>16,026,318</u></u>	<u><u>11,779,579</u></u>	<u><u>14,761,896</u></u>	<u><u>11,747,978</u></u>

See accompanying notes to the condensed financial statements

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NanoViricides, Inc.
Condensed Statement of Changes in Stockholders' Equity
For the Nine Months Ended March 31, 2025
(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, 2024	892,625	\$ 9	13,144,055	\$ 131	\$ 150,838,832	\$ (139,374,895)	\$ 11,464,077
Proceeds from sale of common stock in connection with equity financings net of issuance costs of \$55,890	—	—	893,006	9	1,710,129	—	1,710,138
Series A preferred stock issued for employee stock compensation	10,591	—	—	—	14,408	—	14,408
Common stock issued for consulting and legal services rendered	—	—	19,713	—	34,500	—	34,500
Warrants issued to Scientific Advisory Board	—	—	—	—	229	—	229
Common stock issued for Directors fees	—	—	6,039	—	11,250	—	11,250
Net loss	—	—	—	—	—	(3,126,811)	(3,126,811)
Balance, September 30, 2024	903,216	\$ 9	14,062,813	\$ 140	\$ 152,609,348	\$ (142,501,706)	\$ 10,107,791
Proceeds from sale of common stock in connection with equity financings net of issuance costs of \$103,419	—	—	1,552,654	16	2,253,854	—	2,253,870
Series A preferred stock issued for employee stock compensation	387	—	—	—	14,005	—	14,005
Common stock issued for consulting and legal services rendered	—	—	18,470	—	27,000	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	154	—	154
Common stock issued for Directors fees	—	—	7,674	—	11,250	—	11,250
Net loss	—	—	—	—	—	(2,027,491)	(2,027,491)
Balance, December 31, 2024	903,603	\$ 9	15,641,611	\$ 156	\$ 154,915,611	\$ (144,529,197)	\$ 10,386,579
Proceeds from sale of common stock in connection with equity financings net of issuance costs of \$19,034	—	—	398,580	4	604,337	—	604,341
Series A preferred stock issued for employee stock compensation	1,727	—	—	—	18,376	—	18,376
Common stock issued for employee stock compensation	—	—	1,786	—	2,125	—	2,125
Common stock issued for consulting and legal services rendered	—	—	21,156	—	27,000	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	161	—	161
Common stock issued for Directors fees	—	—	8,817	—	11,250	—	11,250
Net loss	—	—	—	—	—	(2,216,783)	(2,216,783)
Balance, March 31, 2025	<u>905,330</u>	<u>\$ 9</u>	<u>16,071,950</u>	<u>\$ 160</u>	<u>\$ 155,578,860</u>	<u>\$ (146,745,980)</u>	<u>\$ 8,833,049</u>

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NanoViricides, Inc.
Condensed Statement of Changes in Stockholders' Equity
For the Nine Months Ended March 31, 2024

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

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

	<u>For the Nine Months Ended</u>	
	<u>March 31,</u> <u>2025</u>	<u>March 31,</u> <u>2024</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (7,371,085)	\$ (5,938,159)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	46,789	33,164
Common shares issued as compensation and for services	124,375	140,690
Warrants granted to Scientific Advisory Board	544	437
Depreciation	576,477	562,209
Amortization	6,202	6,202
Changes in operating assets and liabilities:		
Prepaid expenses	(11,974)	36,938
Other assets	11,764	(4,547)
Accounts payable	(23,452)	184,338
Accounts payable - related party	93,438	(20,286)
Accrued expenses	(229,851)	164,843
NET CASH USED IN OPERATING ACTIVITIES	<u>(6,776,773)</u>	<u>(4,834,171)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(46,764)	(58,397)
NET CASH USED IN INVESTING ACTIVITIES	<u>(46,764)</u>	<u>(58,397)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	4,568,349	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	<u>4,568,349</u>	<u>—</u>
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,255,188)	(4,892,568)
Cash and cash equivalents at beginning of period	4,797,778	8,149,808
Cash and cash equivalents at end of period	<u>\$ 2,542,590</u>	<u>\$ 3,257,240</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Fair value of Series A Preferred shares issued upon conversion of related party convertible promissory note	\$ —	\$ 1,500,000
Forgiveness of interest on related party debt	\$ —	\$ 49,808

See accompanying notes to the condensed financial statements

NANOVIRICIDES, INC.
December 31, 2023
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1 – Organization and Nature of Business

NanoViricides, Inc. (the “Company”) is a clinical stage nano-biopharmaceutical company specializing in the discovery, development, and commercialization of drugs to combat viral infections using its unique and novel nanomedicines technology platform. The Company’s platform is based on host-mimicry, and thereby has uniquely enabled development of broad-spectrum antiviral drugs that the viruses would be unable to escape, a critical unmet need in antiviral therapeutics. NanoViricides possesses its own 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.

NanoViricides, Inc. is domiciled under the laws of the State of Delaware, with its principal operations located in the State of Connecticut. The Company’s fiscal year begins on July 1st and ends on the next June 30th of the calendar year. The Company operates in one reportable business segment.

Note 2 – Liquidity and Going Concern

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, 2025 of approximately \$146.7 million and a net loss of approximately \$7.4 million and net cash used in operating activities of approximately \$6.8 million for the nine months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future.

Management believes that the Company’s cash and cash equivalents balance of approximately \$2.5 million, and the Company’s existing resources, including availability under its \$3 million line of credit will not be sufficient to fund the Company’s planned operations and expenditures for at least 12 months from the date of the filing of this Form 10-Q. As a result substantial doubt exists about the Company’s ability to continue as a going concern.

The Company believes that it has several important milestones, building on the successful Phase Ia/Ib human clinical trial for the Company’s broad-spectrum, antiviral drug NV-387 as described elsewhere, with further progress of NV-387 into Phase II clinical trials. We are anticipating the Phase Ia/Ib clinical study report (final report or CSR) to be received by us soon. We plan on submitting the CSR to the regulatory authorities in India, which would be a significant milestone in the regulatory progress of NV-387.

Additional milestones include filing of Clinical Trial Application (CTA) for Phase II clinical trial of NV-387 as treatment for MPox, execution of the Phase II clinical trial and attendant top-line readout, and the anticipated successful completion of the clinical trial. The Company anticipates that its Phase II clinical trial will be successful in demonstrating that NV-387 is effective and safe in the treatment of MPox infection, based on the known safety of NV-387 in both animal studies and the observations in Phase I human clinical trial, and the activity of NV-387 against lethal orthopoxvirus infection in animal models that simulate the dermal transfer of infection as well as direct lung infection. Further, the Company continues toward developing the Pre-IND and IND applications for a Phase IIa clinical trial of NV-387 for the treatment of RSV infection in adults, to be followed by a Phase IIb/III clinical trial of NV-387 for the treatment of RSV infection in hospitalized pediatric patients. To this end, the Company is also evaluating the possibility of a Phase IIa clinical trial of a RSV Infection Challenge in Humans. The Company executes its plans in a manner consistent with available resources, which can lead to reshuffling of priorities in its programs. Nevertheless, the Company has in the past and will continue to progress towards its goal of revolutionizing antiviral therapeutics.

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Management believes that as these various milestones are achieved, the Company would likely experience improvement in the liquidity of the Company's stock, and such improvement, if any, would enhance the Company's ability to raise funds on the public markets at terms that may be favorable to the terms offered at present.

Management is actively exploring additional required funding through non-dilutive grants and contracts, partnering, as well as debt or equity financing pursuant to its plan. There is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us to fund continuing operations.

Management believes that it has on-going access to the capital markets including the "At-The-Market" (ATM) agreement with D. Boral Capital (Formerly EF Hutton LLC), the Sales Agent.

There can be no assurance that the Company's plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company will need to raise additional capital to fund its long-term operations and research and development plans including human clinical trials for its various drug candidates until it generates revenue that reaches a level sufficient to provide self-sustaining cash flows. There can be no assurance that the Company will be able to raise the necessary capital or that it will be on acceptable terms. The accompanying 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, 2024 filed with the SEC on September 27, 2024.

The June 30, 2024 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, 2024 filed on September 27, 2024.

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.

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

	Potentially Outstanding Dilutive Common Shares			
	For the Three Months Ended	For the Three Months Ended	For the Nine Months Ended	For the Nine Months Ended
	March 31, 2025	March 31, 2024	March 31, 2025	March 31, 2024
Warrants	6,006	7,148	6,006	7,148

The Company has 905,330 shares of Series A preferred stock outstanding as of March 31, 2025. 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, 2025, the number of potentially dilutive shares of the Company’s common stock into which these Series A preferred shares can be converted into is 3,168,655 and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

Recently Issued Accounting Pronouncements

The Company considers the applicability and Impact of all Accounting Standard Updates (“ASU’s”). ASU’s not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the Company’s financial statements.

ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires public business entities (PBEs) to disclose, in interim and annual reporting periods, additional information about certain expenses in the notes to financial statements. The requirements of ASU 2024-03 apply to all public business entities. The ASU requires disaggregated disclosure of income statement expenses for public business entities (PBEs). The ASU does not change the expense captions an entity presents on the face of the income statement; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the footnotes to the financial statements. ASU 2024-03 is effective for all PBEs for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. While the Company is currently evaluating the adoption impact of this ASU on its financial statements, the preliminary assessment is that the adoption of this standard is not expected to have a material effect on the Company’s financial statements and the Company’s disclosures.

ASU 2023-09 Income Taxes (Topic 740) Improvements to Income Tax Disclosures. The amendments in this Update require that public business entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income [or loss] by the applicable statutory income tax rate). Additionally, the ASU requires all entities to disclose the amount of income taxes paid disaggregated by federal, state, and foreign taxes, as well as individual jurisdictions where income taxes paid are equal to or greater than 5 percent of total income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024. Early adoption is permitted and this ASU should be applied on a prospective basis. While the Company is currently evaluating the adoption impact of this ASU on its financial statements, the preliminary assessment is that the adoption of this standard is not expected to have a material effect on the Company’s financial statements and the Company’s disclosures.

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ASU 2023-07 Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The requirements of this update require disclosure of significant segments expenses and increase the frequency of segment reporting to interim periods. The ASU is effective for all public companies for fiscal years beginning after December 15, 2023 and for interim periods within fiscal periods beginning after December 15, 2024. Early adoption is permitted and is applicable to all periods presented in the financial statements unless retrospective application is impracticable. While the Company is currently evaluating the adoption impact of this ASU on its financial statements, the preliminary assessment is that the adoption of this standard is not expected to have a material effect on the Company's financial statements and the Company's disclosures.

Note 4 - Related Party Transactions

Related Parties

Related parties with whom the Company had transactions are:

<u>Related Parties</u>	<u>Relationship</u>
Dr. Anil Diwan	Chairman, President, CEO, significant stockholder through TheraCour, and Director
TheraCour Pharma, Inc. ("TheraCour")	An entity owned and controlled by Dr. Anil Diwan
Karveer Meditech, Pvt., Ltd ("KMPL")	An entity of which Dr. Anil Diwan is a passive investor and advisor without operating control.

Property and Equipment

During the reporting period, TheraCour acquired property and equipment on behalf of the Company from third party vendors and sold such property and equipment, at cost, to the Company

<u>For the three months ended</u>		<u>For the nine months ended</u>	
<u>March 31,</u>	<u>March 31,</u>	<u>March 31,</u>	<u>March 31,</u>
<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
\$ —	\$ 2,500	\$ 46,764	\$ 16,265

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	<u>As of</u>	
	<u>March 31,</u> <u>2025</u>	<u>June 30,</u> <u>2024</u>
<u>Account Payable – Related Party-TheraCour</u>		
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. On February 12, 2024, TheraCour and the Company agreed to suspend the license requirement for a two month advance until the Company raises sufficient capital, therefore there was no advance offset of the accounts payable due TheraCour at March 31, 2025 and at June 30, 2024.	<u>\$ 576,110</u>	<u>\$ 720,039</u>

Accounts Payable- Related Party-KMPL

KMPL has retained a local clinical research organization (CRO) to conduct the clinical trials. The Phase1 human clinical trial of NV-CoV-2 began in India on June 17, 2023. Under the agreement with KMPL, the Company agreed to pay for the expenses of the clinical trials, and in return will benefit from having the data and reports made available for regulatory filings in other territories of the world. In prior periods the amount due KMPL had been accrued and recorded in accrued expenses. At June 30, 2024, the aforesaid clinical trial related costs, as budgeted, of \$227,435 were recorded as accrued expense in the accompanying June 30, 2024 balance sheet. The aforesaid clinical trial related costs, at actual amounts, of \$237,367 have since been invoiced and recorded in accounts payable-related parties. Accounts payable to KMPL at March 31, 2025 and June 30, 2024 were:	<u>\$ 237,367</u>	<u>\$ —</u>
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	<u>For the three months ended</u>		<u>For the nine months ended</u>	
	<u>March 31,</u> <u>2025</u>	<u>March 31,</u> <u>2024</u>	<u>March 31,</u> <u>2025</u>	<u>March 31,</u> <u>2024</u>

Research and Development Costs Related Party:

Development fees and other costs charged by to TheraCour pursuant to the license agreements between TheraCour and the Company for the development of the Company’s drug pipeline. No royalties are due TheraCour from the Company at March 31, 2025 and June 30, 2024.	<u>\$ 630,315</u>	<u>\$ 588,763</u>	<u>\$ 1,904,774</u>	<u>\$ 1,918,231</u>
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Clinical Trial Costs Accrued - Related Party

Clinical trial related and other costs were accrued by Company pursuant to the license agreement between the Company and KMPL for the clinical trial related costs that have been incurred but not yet invoiced to the Company for Phase 1a/1b clinical trials in India as of June 30, 2024. The amount has been recorded within accrued expenses in the accompanying balance sheet as of June 30, 2024. The aforesaid clinical trial related costs of \$237,367 have since been invoiced and recorded in accounts payable-related party at March 31, 2025. See Accounts Payable- Related Party-KMPL above.

As of	
March 31, 2025	June 30, 2024
\$	\$
—	227,435

License Milestone Fee – Related Party

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

On July 19, 2023, the Company entered into an agreement with TheraCour, to accept the Company’s unsecured convertible promissory note (the “Note”) in payment of the milestone award. The Note accrues simple interest at the rate of 12% per annum and is due and payable on January 19, 2025, the maturity date. The principal of the Note is convertible, at TheraCour’s option, into 331,859 shares of the Company’s Series A preferred stock, par value \$0.00001 at the conversion price, specified as the fair value of the Series A shares on July 19, 2023 in the terms and conditions contained within the promissory Note. On October 27, 2023 TheraCour exercised its right to convert the principal of the July 19, 2023 Note into 331,859 shares of the Company’s Series A preferred stock. TheraCour cancelled all of the accrued interest on the Note totaling \$49,808 which has been reported as a capital transaction credit to additional paid in capital for the year ended June 30, 2024.

On February 12, 2024, the Company entered into an Amendment to the COVID License Agreement with TheraCour dated September 7, 2021, whereby any further cash milestone payments that would be earned upon milestone event would only become payable upon the Company having sufficient revenues, with only a portion of revenues to be used for satisfying such milestone payments.

Line of Credit - Related Party

On November 13, 2023, the Company’s President and CEO, Dr. Anil Diwan, entered into a Line of Credit Agreement, as amended February 12, 2024, whereby Dr. Diwan agreed to provide a standby Line of Credit to the Company in the maximum amount of \$2,000,000. All amounts outstanding under the Line of Credit, including principal, accrued interest and other fees and charges, will be due and payable on December 31, 2025. Amounts drawn down under the Line of Credit shall bear interest at a fixed rate of 12%. Advancements under the Line of Credit are collateralized by an Open End Mortgage Deed on the Company’s real property at 1 Controls Drive, Shelton, Connecticut and a Chattel Mortgage (U.C.C – 1 filing) against the Company’s equipment and fixtures. Any draw down under the Line of Credit requires the approval of the Company’s Board of Directors.

On September 23, 2024 and becoming effective as of September 20, 2024, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil Diwan, signed an Amendment Agreement which increased the available line of credit from \$2,000,000 to \$3,000,000, and extended the maturity of the Company's Line of Credit from December 31, 2025 to March 31, 2026. There were no subsequent amendments to the Line of Credit. The Company has not drawn against the Line of Credit facility as of March 31, 2025.

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Note 5 - Property and Equipment

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

	<u>March 31, 2025</u>	<u>June 30, 2024</u>
GMP Facility	\$ 8,168,045	\$ 8,168,045
Land	260,000	260,000
Office Equipment	77,425	63,056
Furniture and Fixtures	5,607	5,607
Lab Equipment	<u>6,501,973</u>	<u>6,469,578</u>
Total Property and Equipment	15,013,050	14,966,286
Less Accumulated Depreciation	<u>(8,030,300)</u>	<u>(7,453,823)</u>
Property and Equipment, Net	<u>\$ 6,982,750</u>	<u>\$ 7,512,463</u>

Depreciation expense for the three months ended March 31, 2025 and 2024 was \$189,114 and \$187,889, respectively, and for the nine months ended March 31, 2025 and 2024 was \$576,477 and \$562,209, respectively.

Note 6 – Intangible Assets

Intangible assets, net consists of the following:

	<u>March 31, 2025</u>		<u>Total March 31, 2025</u>	<u>June 30, 2024</u>		<u>Total June 30, 2024</u>
	<u>Finite Lived Intangible Assets</u>	<u>Indefinite Lived Intangible Assets</u>		<u>Finite Lived Intangible Assets</u>	<u>Indefinite Lived Intangible Assets</u>	
Intangible Assets	\$ 153,393	\$ 305,561	\$ 458,954	\$ 153,393	\$ 305,561	\$ 458,954
Less Accumulated Amortization	(139,848)	—	(139,848)	(133,646)	—	(133,646)
Intangible Assets, Net	<u>\$ 13,545</u>	<u>\$ 305,561</u>	<u>\$ 319,106</u>	<u>\$ 19,747</u>	<u>\$ 305,561</u>	<u>\$ 325,308</u>

Amortization expense amounted to \$2,068 and \$2,067 for the three months ended March 31, 2025 and 2024, respectively, and for the nine months ended March 31, 2025 and 2024 were \$6,202 and \$6,202, respectively.

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

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

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

Note 7 – Accrued Expenses

Accrued expenses consisted of the following:

	<u>March 31, 2025</u>	<u>June 30, 2024</u>
Personnel and compensation costs	\$ 26,616	\$ 23,532
Consultant	6,000	11,500
Clinical trial costs due to KMPL	—	227,435
	<u>\$ 32,616</u>	<u>\$ 262,467</u>

Note 8 - Equity Transactions

On April 15, 2024, the Company entered into a new ATM sales agreement with E.F. Hutton Securities (now D. Boral Capital), the Sales Agent, pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agent, shares of common stock having an aggregate offering price of up to \$50 million. From July 1, 2024 through March 31, 2025 the Company sold 2,844,240 shares of common stock at an average price of approximately \$1.67 per share. The shares were issued pursuant to a prospectus supplement dated May 5, 2023 and filed with the Securities and Exchange Commission on May 5, 2023 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-271706, which became effective on May 22, 2023). The net proceeds to the Company from the offering was approximately \$4,568,000 after placement agent fees and other estimated offering expenses.

The Company accounted for the proceeds of the ATM Offering, approximately, as follows:

Gross proceeds	\$ 4,746,300
Less: offering costs and expenses	178,300
Net proceeds from issuance of common stock	<u>\$ 4,568,000</u>

As of July 1, 2024 the Company and Dr. Anil Diwan entered into an extension of his employment agreement for a period of one year from July 1, 2024 through June 30, 2025 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, 2024, December 31, 2024, March 31, 2025 and June 30, 2025 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$37,374 for the nine months ended March 31, 2025. The balance of \$12,458 will be recognized as the remaining 2,551 shares vest and service is rendered for the remaining three months ended June 30, 2025.

For the three and nine months ended March 31, 2025, 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 \$5,918 and \$9,415, respectively for the three and nine months ended March 31, 2025 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.

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The Scientific Advisory Board was granted in August 2024 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$2.35 per share expiring in August 2028 and in November 2024 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$1.58 per share expiring in November 2028 and in February 2025 fully vested warrants to purchase 286 shares of common stock with exercise price of \$1.67 expiring in February 2029. The fair value of the warrants was \$161 for the three months ended March 31, 2025 and \$543 for the nine months ended March 31, 2025 and was recorded as consulting expense.

The Company estimated the fair value of the warrants granted to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following assumptions:

Expected life (year)	4
Expected volatility	52.55 - 54.18 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.85 - 4.29 %

For the three and nine months ended March 31, 2025, the Company's Board of Directors authorized the issuance of 21,156 and 59,339, respectively, fully vested shares of its common stock with a restrictive legend for consulting and legal services. The Company recorded expense of \$27,000 and \$88,500, respectively, for the three and nine months ended March 31, 2025, 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, 2025, the Company's Board of Directors authorized the issuance of 8,817 and 22,530, 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, 2025, which is reflective of the fair value of the common stock on the dates of issuance.

Note 9 - Common Stock Warrants

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price per share (\$)</u>	<u>Weighted Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (\$)</u>
Common Stock Warrants				
Outstanding and exercisable at June 30, 2024	6,862	\$ 3.64	1.67	\$ 399
Granted	858	1.87	3.62	—
Expired	(1,714)	5.70	—	—
Outstanding and exercisable at March 31, 2025	<u>6,006</u>	<u>\$ 2.79</u>	<u>1.67</u>	<u>\$ 62</u>

Of the outstanding warrants at March 31, 2025, 572 expire in fiscal year ending June 30, 2025, 2,288 expire in fiscal year ending June 30, 2026, 1,144 warrants expire in the fiscal year ending June 30, 2027, 1,144 warrants expire in the fiscal year ending June 30, 2028 and 858 warrants expire in the fiscal year ending June 30, 2029.

Note 10 - Commitments and Contingencies

Legal Proceedings

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

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Employment Agreements

As discussed in Note 8, as of July 1, 2024, the Company and Dr. Diwan, the Company's President and Chief Executive Officer, executed an extension of his employment agreement for a period of one year from July 1, 2024 through June 30, 2025 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, 2025.

As of July 1, 2024, the Company's Board of Directors approved the extension of the agreement with Meeta Vyas, Chief Financial Officer of the Company. The Company and Meeta Vyas signed an extension of the agreement for a period of one year from July 1, 2024 through June 30, 2025 under the same general terms and conditions as the current agreement.

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 7, 2021, the Company entered into a COVID-19 License Agreement to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed.

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

On February 12, 2024, the Company entered into an Amendment to the COVID License Agreement with TheraCour dated September 7, 2021, whereby any further cash milestone payments that would be earned upon milestone event would only become payable upon the Company having sufficient revenues, with only a portion of revenues to be used for satisfying such milestone payments.

On September 23, 2024 and effective as of September 20, 2024, the Company entered into a "Memorandum of Understanding for All Antivirals Drug Development" (the MoU) with TheraCour that granted to the Company, a limited, non-assignable, non-sublicensable, exclusive Right of First Refusal to License to any antiviral drugs in development or to be developed by TheraCour for research and development purposes only, for all as-yet unlicensed viral infection treatment indications. The MoU also clarified the roles and responsibilities of the Parties and essentially codified the process that the parties have adopted since inception. The MoU further codified the treatment of all future milestone payments arising from any current or future license agreements to TheraCour to be consistent with the principles adopted in the February 12, 2024 Amendment to the COVID-19 License Agreement.

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Note 11 – Subsequent Events

As of May 5, 2025, the Company was notified by our contract research organization (“CRO”) that we have received approval from the National Ethics Committee for Health (CNES) of the Ministry of Public Health (MSP), of the Democratic Republic of Congo (DRC), regarding the proposed Phase II clinical trial to evaluate safety and effectiveness of NV-387 for the treatment of patients with MPox disease caused by hMPXV infection. With this CNES approval, the said clinical trial proposal is cleared for further regulatory filing of a complete Clinical Trial Application (“CTA”).

The CNES approval clears the path for us to file the Clinical Trial Application to the regulatory agency, namely, the Ministry of Public Health, DRC, for full regulatory approval and start of the Phase II clinical trial.

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, 2024. Readers should carefully review the risk factors disclosed in the Company’s Form 10-K and other documents filed by the Company with the SEC.

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

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

PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Organization and Nature of Business

NanoViricides, Inc. (the “Company”, “NanoViricides”, “we,” or “us”) was incorporated in Nevada on April 1, 2005, and redomiciled to Delaware effective May 30, 2023. Our corporate offices are located at 1 Controls Drive, Shelton, Connecticut 06484 and our telephone number is (203) 937-6137. Our website is located at

<http://www.nanoviricides.com>. We do not incorporate by reference into this Quarterly Report the information on or accessible through our website, and you should not consider it part of this Quarterly Report.

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

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We are a clinical stage nano-biopharmaceutical company developing (a) host-mimetic, and (b) direct-acting, nanomachines capable of dismantling the virus without assistance from the human immune system.

As a host-mimetic, viruses cannot escape a nanoviricide drug by generating mutants and variants in the field, because all variants still require the same signature host features that our drugs mimic. In contrast, vaccines, antibodies and small chemical drugs are readily escaped by viruses because the viruses continuously change in the field, rendering these medical countermeasures ineffective. This was repeatedly observed during the COVID pandemic.

The host-mimicry nanoviricide platform has enabled development of extremely broad-spectrum antiviral drugs such as NV-387, as well as virus-type-specific drugs such as NV-HHV-1 (Herpesviridae) and NV-HIV-1 (HIV-1, 2 all mutants).

As a direct-acting antiviral, a nanoviricide drug is not expected to interfere with human bodily systems or enzymes, which is expected to result in significant levels of safety, unlike most of the antiviral drugs. Phase I human clinical trial of NV-387 was completed with no adverse events meeting or exceeding safety and tolerability objectives of the trial. In non-clinical IND-enabling studies NV-387 as well as NV-HHV-1 have been found to be extremely good in terms of their effects on animal physiology, clinical and blood chemistry, as well as no organ-specific negative findings. These clinical and non-clinical findings validate our nanoviricide platform as being capable of clinically relevant drug development.

Any viral infection that causes significant pathology does so by virtue of host immune system disrepair, either pre-existing, or caused by the virus itself. Therefore, nanoviricides can be expected to be superior to approaches such as vaccines and antibodies that require a good functional host immune system for antiviral response.

These distinctive features that set nanoviricides apart from the entire world of current antiviral approaches are made possible by our novel nanoviricide chemical nanomachine technology platform. After decades of development, this novel nanoviricide technology is now advancing through clinical stages towards regulatory approvals.

The Company's lead drug candidate, NV-387, is a broad-spectrum antiviral drug that has demonstrated strong activity in lethal lung infection animal model trials for the treatment of Coronaviruses, RSV, Influenza viruses as well as Smallpox and MPox, and the Company has predicted it to be active against all influenza viruses including bird flu H5N1 and H7N9, as well as against the Measles virus. All of these distinctly different viruses utilize HSPG (heparan sulfate proteoglycans) for cell infection; so do H5N1, H7N9, the highly pathogenic influenza viruses, and even the Measles virus.

The Company has initiated work towards evaluating the effectiveness of NV-387 in a humanized animal model of Measles virus infection.

The Company has initiated work to begin Phase II clinical trials to evaluate safety and effectiveness of NV-387 treatment in MPox patients (see below).

MPox caused by Clade 1 and 1b variants is currently a pandemic emergency in the African region covering multiple nations including Democratic Republic of Congo (DRC), Uganda, and nearby countries. A less pathogenic variant, MPox Clade 2, has spread across the globe and caused a widespread epidemic in May 2022 in the Western world that has now become endemic.

The Company is also in discussions with experts regarding a Phase II clinical trial for the evaluation of the effectiveness of NV-387 in the treatment of ARI and SARI of Viral origin (ARI = Acute Respiratory Infection and SARI = Severe Acute Respiratory Infection). The design of NV-387 suggests that it is likely to be active against most if not all respiratory viral infections (see below).

NV-387 is expected to be active against most if not all Highly Pathogenic Influenza viruses (HPAI) including H5N1 "Bird Flu" (or Avian Flu), and the Company plans to obtain non-dilutive funding to advance this drug for the H5N1 indication such as grants or contracts from government agencies.

In addition, the Company is planning clinical trials towards the approval of NV-387 for the treatment of RSV infection in pediatric patients in the US.

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NV-387 has completed a Phase I human clinical trial for safety and tolerability in healthy subjects that was sponsored by our licensee and collaborator in India, Karveer Meditech Private Limited (“KMPL”). As topline results of this clinical trial, there were no reported adverse events at all doses studied, and there were no drop-outs either, observations that are indicative that NV-387 was well tolerated by the healthy subjects in this clinical trial. These results of the Phase I clinical trial are consistent with the results of safety/tolerability studies in animals conducted in support of the clinical trial application. We are awaiting the final clinical trial study report from this clinical trial.

In addition to NV-387, the Company has previously developed a clinical drug candidate, NV-HHV-1 formulated as skin cream, for the treatment of Shingles. The Company plans to progress NV-HHV-1 into human clinical trials, and further develop the HerpeCide™ program after the Phase II clinical trial of NV-387 for RSV, MPox, ARI/SARI, and possibly for multiple other indications, including Influenzas. 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 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”), a related party substantially owned by Dr. Anil Diwan, to which the Company has broad, exclusive licenses. The licenses are to entire fields and not limited 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 (repeated), Varicella Zoster Virus (“VZV”) infections (i.e. Shingles and Chickenpox), and SARS-CoV-2 infections. Additionally, the Company has signed a Memorandum of Understanding (“MoU”) on September 23, 2024 to codify the process for all antiviral drug development with TheraCour. Despite the name (“MoU”), this is a legal agreement between the Parties that has formally assigned a right of first refusal (ROFR) for all antiviral drug developments from TheraCour to the Company.

This MoU expands the Company’s abilities to opportunistically and rapidly develop novel drugs to treat viral infections of public health importance, even for those viruses that do not exist today and cannot be predicted. The MoU has also formalized the process of development of drugs for unlicensed viral indications leading later to appropriate license agreements. There was no compensation paid to or due to TheraCour as a result of this MoU. The Parties have also agreed in this MoU that any cash milestone payments related to development activities, that are awardable, will become payable only upon the Company having sufficient revenue, thus extending the provisions previously incorporated in the Amendment to the COVID License Agreement, to all present and future license agreements.

In all cases, the discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, and the 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 has out-licensed NV-CoV-2 and NV-CoV-2-R for further clinical drug development and commercialization in the territory of India to KMPL, a company of which Dr. Anil Diwan is a passive investor and advisor. KMPL has sponsored the NV-CoV-2 (NV-387) into Phase Ia/Ib human clinical trial, to study the safety and tolerability of the NV-CoV-2 Oral Syrup and NV-CoV-2 Oral Gummies formulations of the API NV-387 in healthy human subjects, described earlier. The clinical trial drug products, NV-CoV-2 Oral Syrup, and NV-CoV-2 Oral Gummies, were manufactured at the Company’s Shelton campus. Under the agreement with KMPL, the Company will pay for the expenses of the clinical trials, and in return will benefit from having the data and reports made available for regulatory filings in other territories of the world. Upon commercialization, the Company will receive from KMPL a royalty of 70% calculated as the percentage of final invoiced sales less the cost of sales and goods sold to unaffiliated third parties.

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

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

NV-387, our most advanced drug candidate, administered orally, has successfully completed Phase I human clinical trial for the evaluation of safety and tolerability in healthy subjects. There were no reported adverse events, and the drugs were well tolerated even at the highest level of dosing given multiple times in this trial.

NV-387 was designed to be active against many viruses that affect humans. This is because NV-387 mimics a host-side feature of sulfated proteoglycans (“S-PG”). S-PG are a class of biochemicals that are used by most of the viruses as “Attachment Receptor(s)” before the viruses can infect cells and cause disease. S-PG class includes Heparan Sulfate Proteoglycans (HSPG), Chondroitin Sulfate, Dermatan Sulfate, and others. Over 90% of human pathogenic viruses are known to use HSPG as the first attachment site to cause infection into human cells. Thus, NV-387 is designed to have an extremely broad range of viruses against which it could be potentially clinically active.

NV-387 has been found to have strong activity in lethal animal models of several viral diseases. Its activity was evident from NV-387-treated animals demonstrating significant increase in survival lifetime, as well as protection of lungs and reduction of clinical pathologies caused by the different viruses we have tested to date.

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

Multiple indications of NV-387 enable us to maximize return on investments. The Phase I safety and tolerability clinical trial would be generally applicable across all indications. All of IND-enabling non-clinical studies would also be reused, with the addition of animal model antiviral activity studies for the specific indication. The Chemistry, Manufacture, and Controls for the drug substance would remain substantially the same and potentially the drug product sections also could be reused. All of this enables significant savings in time, material, labor, and costs shared across the multiple programs, resulting in a significant improvement in return on investments (ROI) as compared to a drug developed for a single indication.

NV-387 Has Successfully Completed Phase I Clinical Trial in Healthy Human Subjects

NV-387 in two different oral formulations has successfully completed a Phase Ia/Ib human clinical trial for safety and tolerability in healthy subjects that was sponsored by our licensee and collaborator in India, Karveer Meditech Private Limited (“KMPL”). All subjects were discharged and follow-up visits have been completed as of approximately the end of December 2023. As topline results of this clinical trial, there were no reported adverse events at all doses studied, and there were no drop-outs either, observations that are indicative of that NV-387 was well tolerated by the healthy subjects in this clinical trial. We are awaiting the final clinical trial study report from this clinical trial.

These results of the Phase I clinical trial are consistent with the results of safety/tolerability studies in animals conducted in support of the clinical trial application, wherein an extremely high level of safety of NV-387 was observed, as indicated by the NOAEL value of 1,200 mg/kg, and the MTD value of 1,500 mg/kg, when administered as a slow injection, in a standard rat model study (NOAEL = No Observed Adverse Event Level. MTD = Maximum Tolerable Dose).

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

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NV-387 Phase II Clinical Trials Preparation and Plans

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

A safe and effective antiviral drug, when approved, with an extensive broad-spectrum activity across multiple, distinct, virus families as observed for NV-387, is an unmet medical need. Currently available broad-spectrum antivirals such as remdesivir, ribavirin, cidofovir, etc. suffer from extensive and varied dose-limiting toxicities, and thereby present limitations on eligible patient populations as well as on clinical effectiveness.

NV-387 Phase II Clinical Trials Plans for Respiratory Viruses – A Single Drug to Combat “Tripleemics”

We are planning to advance NV-387 into Phase II human clinical trials to assess effectiveness of NV-387 treatment in a number of different viral diseases in humans as resources allow.

We plan to further develop NV-387, as an ultra-broad-spectrum antiviral medication to treat a number of viral infections including Respiratory Syncytial Virus (RSV), Influenza Viruses including Bird Flu H5N1 (all variants), Coronaviruses (SARS-CoV-2, MERS-CoV, Seasonal Coronaviruses, hCoV-NL63), as well as possibly other respiratory viral infections, thus covering all of the “tripleemic” viruses and more with this single drug.

NV-387 Phase II Clinical Trial for MPox Epidemic

We are working on starting Phase II clinical trials to evaluate safety and effectiveness of NV-387 treatment in MPox patients, in light of the continuing MPox Clade Ia/Ib pandemic in Central African region with increasing spill over cases into the rest of the world reported since April, 2025.

To this effect, the Company has engaged a Contract Research Organization (CRO) to help with conducting the MPox clinical trial of NV-387 in countries in the central African region. Trial sites have also been identified already. The Company is preparing a clinical trial application for the MPox Phase II clinical trial for submission to the appropriate regulatory agencies in DRC (Democratic Republic of Congo) and in Uganda. Recently, the Company has received approval from the regional ethics committee in the DRC for conducting a Phase II clinical trial to evaluate the effectiveness of NV-387 as a treatment for MPox infections.

MPox caused by Clade Ia and Ib variants is continuing as a pandemic emergency in the Central African region covering multiple nations including Democratic Republic of Congo (DRC), Uganda, and nearby countries. WHO declared MPox outbreak in 2024 a Public Health Emergency of International Concern (PHEIC) on August 14, 2024, and maintains that the outbreak status still meets the PHEIC definition ([https://www.who.int/news/item/17-03-2025-third-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-upsurge-of-mpox-2024](https://www.who.int/news/item/17-03-2025-third-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-upsurge-of-mpox-2024)). Clade Ib is more transmissible than Clade I and Clade II, and is also causing more pediatric infections (<https://www.who.int/news/item/14-08-2024-who-director-general-declares-MPox-outbreak-a-public-health-emergency-of-international-concern>).

A less pathogenic variant, MPox Clade II, particularly Clade IIB, has spread across the globe. The Clade II MPox virus caused a widespread epidemic in May 2022 in the Western world, and has now become endemic. It continues to cause cases in the USA every year as per May 2025 report of WHO on MPox outbreak global trends (https://worldhealthorg.shinyapps.io/mpx_global/).

Smallpox has always been considered a bioterrorism threat agent of highest priority, with MPox joining its ranks. The market size for a Smallpox/MPox drug can be estimated to be in the range of billions of dollars worldwide. Since the outbreak of MPox Clade Ib, which is both more transmissible and more pathogenic than the prior versions of this virus, globally public health protection agencies and governments have been concerned for pandemic preparation.

There is no drug currently available for the treatment of MPox. A drug, tecovirimat (TPOXX®, SIGA) was approved by US FDA under the “Animal Rule” for the treatment of Smallpox (and MPox). However, it failed in a large clinical

trial as a treatment of the MPox Clade 1/1b infections, with no statistical improvement observed in comparison to the standard of care (NIH/NIAID Press Release,

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August 15, 2024, at <https://www.nih.gov/news-events/news-releases/antiviral-tecovirimat-safe-did-not-improve-clade-i-MPox-resolution-democratic-republic-congo>). Even so, SIGA Technologies, Inc. had, for TPOXX, approximately \$146 million of outstanding procurement orders, out of which there was \$122 million of procurement orders from the U.S. Government alone in the third quarter ended September 2024, according to its financial report (SIGA press release dated November 7, 2024). Overall, SIGA has received procurement orders for tecovirimat from US Government alone for over \$250 million in 2023-2024, illustrative of the market size of an effective drug against poxviruses (www.siga.com, various press releases).

Notably, these procurements reflect replenishments and not initial stocking. The initial stocking orders would be substantially larger. This clearly illustrates the strong market size and demand for a Smallpox/MPox drug.

Smallpox is an important disease from biodefense perspective, and the US BARDA (Biomedical Advanced Research and Development Authority) has new drug development for smallpox as an important objective.

Thus, an effective MPox/Smallpox drug can be estimated to have global public health governmental markets reaching into billions of dollars because of the recognition of Smallpox as a bioterrorism threat agent, and the continuing spread of its cousin MPox that threatens a global pandemic that could be fueled by likely potential additional mutations in the virus as it simmers in Africa.

NV-387 has been found to possess strong activity against orthopoxvirus infection in animal model studies, making it a viable candidate for clinical trial as a treatment for MPox infection.

We believe NV-387 can meet the challenge of becoming an effective treatment for MPox infection that is currently ravaging in multiple nations in Central Africa.

NV-387 Potential Phase II Clinical Trial Positioning the Drug as an “Empiric Antiviral Therapy” that Could be Revolutionary

We are in discussions with experts regarding a Phase II clinical trial for the evaluation of the effectiveness of NV-387 in the treatment of ARI and SARI of Viral origin (ARI = Acute Respiratory Infection and SARI = Severe Acute Respiratory Infection.) We believe that for the very first time in the world, such clinical trial has become possible because the design of NV-387 suggests that it is likely to be active against most if not all respiratory viral infections.

About half of ARI and SARI cases are caused by viruses and most of the remaining are caused by bacteria. For a suspected bacterial infection, the physician can prescribe an antibiotic immediately upon presentation (called “Empiric Therapy”), and thereafter monitor, diagnose the causative bacterium, and modify therapy as necessary. Unfortunately, until now, there is no empiric therapy available for viral infections.

NV-387, if successful in the treatment of ARI and SARI, would presumably become the first ever antiviral that can be given as an empiric therapy by the physician immediately upon the patient presenting to the doctor. We believe this could be as revolutionary for the treatment of viral infections as the discovery of penicillin was for the treatment of bacterial infections.

The market size for a successful ARI/SARI clinical trial and potential subsequent emergency use and full registration of NV-387 upon completing the regulatory approval processes could open up tens of billions of dollars for NV-387 worldwide. Whenever a new effective therapy enters the market for a virus with no previous treatment or unsatisfactory prevalent treatments, the market size expands substantially, as has been historically witnessed for HIV/AIDS, Hepatitis C, HPV vaccine, and others.

Viral ARI and SARI are primarily caused by a number of different viruses that include all Coronaviruses (SARS-CoV-2 that led to COVID-19, SRAS-CoV-1, hCoV-NL63, hCoV-OC43 and others), all Influenza viruses including the H5N1, H7N9 and other Bird Flu viruses, RSV, human Metapneumoviruses (hMPV), and Para-Influenza Viruses (PIV).

Thus, this Phase II Clinical Trial Design for the evaluation of safety and effectiveness of NV-387 in viral ARI and SARI would be expected to provide important information for effectiveness of NV-387 against RSV, Influenza, hMPV, as well as Coronaviruses.

Notably, NV-387 was found to be active against all tested respiratory viral infections (lethal lung infections) in animal model studies, which included RSV, Influenza viruses, Coronaviruses, as well as MPox/Smallpox. hMPV is similar to RSV in terms of its infection process, suggesting that NV-387 could be effective against it.

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Additionally, NV-387 is expected to be active against many other viruses because of its design that mimics the human host-side sulfated proteoglycans that all of these viruses use for causing effective cell infection.

Measles Virus and NV-387 - A Drug to Respond to Current Measles Outbreak – Highly Likely to be Effective

Measles virus cases have been increasing in the USA year over year and in 2025 there have been over 935 confirmed cases and 3 deaths as of May 1, 2025 (<https://www.cdc.gov/measles/data-research/index.html>). The CDC has updated the Measles treatment overview fact sheet for health care providers to include recommendations for the use of vitamin A, antibiotics, and inhaled steroids, under the supervision of clinician, to treat measles.

There is no antiviral approved for the treatment of Measles virus, an urgent and unmet medical need. CDC fact sheet says that ribavirin is not approved for Measles, although it has been used in some patients, and that clinical data is lacking regarding its effectiveness. Ribavirin may be used only under an emergency use IND filing with the US FDA.

CDC notes that “MMR vaccination is the best way to prevent measles and its complications,” and that “those who cannot or prefer not to get vaccinated, risk of measles infection and severe illness.”

Vaccination rates for MMR vaccines in particular have fallen across the world, primarily because of loss of public faith in the communications regarding vaccines, compulsion during the COVID pandemic, as well supported belief that the side effects of vaccines have not been systematically captured and reported, and that, instead, there has been a strong bias in the health community to avoid associating side effects with the use of vaccines. The US Secretary of Health has begun revising the policies in order to perform more thorough evaluations of vaccines especially since vaccines are to be used in the entire population, unlike treatments that are used only in affected patients.

In particular, Measles is the most communicable disease known to man, and “herd immunity” that is required for elimination of Measles from the population, requires 95% of the population to be vaccinated. An increasing portion of the population is becoming incapable of generating full immunity upon vaccination because of immune system compromise, auto-immune diseases, severe allergies, chronic health issues such as diabetes and obesity, and advanced age. There is also personal reluctance for the risk that one’s own child may be affected by a major side effect even as documented rates of side effects are small. There are also communities with religious prohibition for using vaccines. Therefore, reaching 95% vaccination rate is becoming an ever distant goal.

New genotypes of the Measles virus are arising whereas Measles vaccine is based on an old genotype A.

Measles incidence rates are increasing worldwide. The need for an effective therapeutic cannot be over-emphasized.

NV-387 is anticipated to be effective against Measles virus. This is because of its broad-spectrum activity against viruses that use HSPG to infect cells. Measles virus belongs to the same class as RSV (paramyxoviruses), and uses HSPG for causing infection.

We believe that NV-387 has sufficient non-clinical and clinical data that it can be used in severe Measles cases under specific US FDA provisions related to investigator-initiated clinical trial in one or few patients that can provide preliminary information.

H5N1 and NV-387 - A Drug that the Virus Would Not Escape to Respond to Potential Pandemic

We plan on pursuing NV-387 as a treatment for Influenza virus infections. NV-387 was found to be superior in activity against Influenza A/H3N2 lethal lung infection in comparison to the three approved drugs oseltamivir (Tamiflu®, Roche), peramivir (Rapivab®, BioCryst), and baloxavir (Xofluza®, Shionogi/Roche) in an animal model.

We believe NV-387 would be effective against H5N1 bird flu as well. Also we believe NV-387 would be effective against influenza viruses resistant to available drugs. NV-387 is expected to be active against substantially all of the Highly Pathogenic Influenza viruses (HPAI) including H5N1 “Bird Flu” (or Avian Flu) because the HPAI viruses including H5N1 viruses possess in the HA protein a “polybasic” site that has high affinity to HSPG, which NV-387 mimics. The polybasic site is thought to be partly responsible for the high pathogenicity of these viruses. Thus these

H5N1/H5N9 viruses can be expected to be attacked by NV-387 perhaps even more strongly than the other Influenza viruses.

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The first fatality from H5N1 Bird Flu in the USA was announced on January 6, 2025 - an elderly Louisiana person with existing medical issues who died after fighting the virus for at least 20 days in the hospital. Just before this, a Canadian teenager girl survived a severe H5N1 infection suffering for almost 30 days with over 20 days in the hospital. In both cases, the virus was Influenza A H5N1 genotype D1.1 which is globally distributed in wild birds, and in open range bird flocks. Both cases were thought to have acquired infection from birds in the field.

In both cases, mutations in the H5 protein of the virus were found that increased the virus' ability to target the human receptor (E186D, Q222H, A134V, and N182K). Mutations were found in the H5 gene that clearly indicate that the virus can readily escape vaccines and antibody drugs. Additional mutations were also found in other important genes indicating that the virus could acquire resistance to existing drugs rapidly.

In this scenario, NV-387 stands apart in the field of antiviral countermeasures in that escape of virus even as it evolves is highly unlikely. This is because (i) NV-387 mimics the essential host-side feature that the virus requires for causing infection, and (ii) the activity spectrum of NV-387 is so broad, encompassing not just a single type of virus, but across many different types of viruses, that any small changes in a virus would be unlikely to enable the virus to escape NV-387.

This high propensity towards mutations in H5 can be expected to render vaccines and antibodies ineffective, as was experienced during the COVID pandemic.

Widespread H5N1 infection in dairy cows led California to declare a bird flu emergency in December 2024. This virus was different from the one that caused the fatality and is classified as Influenza A H5N1 genotype B3.13. The dairy cow H5N1 has infected over 60 persons, but has caused milder disease than the genotype D1.1.

Of increased concern, the more pathogenic D1.1 H5N1 virus has also been found in milk tests of certain dairy cow herds in Nevada in the USA in January/February 2025, raising the level of alert regarding the potential of its spread into humans.

In addition, another HPAI virus, H5N9, has been found to be circulating in ducks in California. It differs in the N protein from the H5N1 virus. At present none of these H5Nx viruses are known to transmit from human to human. However, continuous changes in the viral genome are thought to eventually lead to a virus that can effectively transmit from human to human, which could lead to a pandemic.

The market size for Influenza and Bird Flu is estimated at \$4.6 billion in 2024, growing to an estimated \$5.9 billion in three years, at a rate of 8.5% as reported by DelveInSight (https://www.delveinsight.com/report-store/influenza-a-infections-market?utm_source=cision&utm_medium=pressrelease&utm_campaign=spr). In case a pandemic occurs, reality may outrun such projections by magnitudes, as was seen with the COVID pandemic.

We plan to seek non-dilutive funding to advance NV-387 drug for the H5N1 indication, as well as for NV-387 as a treatment for COVID indication.

NV-387 Regulatory Development for the Treatment of Pediatric RSV Infection

In addition, we plan on Phase II clinical trial of NV-387 for the treatment of RSV infection, with the goal of developing a therapeutic for the treatment of pediatric patients, which is the greatest unmet need in RSV. RSV is an important disease particularly for infants and children under 6 years of age, as well as for older persons and immunocompromised patients. The market size for RSV is estimated at \$2.6 billion in 2024, growing to \$4.3 billion in three years, at a rate of 18.9% as reported by GrowthPlusReports (<https://www.growthplusreports.com/report/respiratory-syncytial-virus-rsv-therapeutics-market/8519>). There are two protective antibodies and two protective vaccines, approved in the U.S. but no drug for the treatment of RSV infection, other than the last resort toxic drug ribavirin.

We are in the process of developing a Pre-IND application regarding NV-387 as a treatment for pediatric RSV infections to the US FDA. Treatment of pediatric RSV infections is an unmet medical need.

RSV causes severe infections primarily in infants and young children, persons over age 60 and immune-compromised persons.

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Globally, RSV is a common cause of childhood acute lower respiratory infection (ALRI, which includes pneumonia) and a major cause of hospital admissions in young children. Globally in 2015, 33 million episodes of RSV-ALRI, resulted in about 3.2 million hospital admissions, and 59,600 in-hospital deaths in children younger than 5 years. About 45% of hospital admissions and in-hospital deaths due to RSV-ALRI occur in children younger than 6 months.

Two vaccines have recently been approved for protection of persons 60+ years old from RSV infection, namely, Arexvy® from GSK, and Abrysvo® from Pfizer. Both vaccines were demonstrated to only reduce the severity of RSV infection in vaccinated persons. Abrysvo was recently approved for use in pregnant women for protection of infants, despite significant side effects, indicative of the urgency for developing pediatric medical countermeasures against RSV infection.

Synagis (palivizumab), and the recently approved Beyfortus (nirsevimab) are antibodies approved only for prophylactic use in children and infants at high risk of severe RSV infection, but neither is approved for treatment of RSV infection.

There is no safe and effective therapeutic approved for the treatment of RSV infection to date, which remains an unmet medical need. Ribavirin, a highly toxic drug, is conditionally approved only for patients with high risk of progressively severe RSV disease, due to significant side effects including hemolytic anemia and kidney failure.

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

NV-HHV-1, Nanoviricide for the Treatment of Herpesvirus Infections (VZV – Chickenpox and Shingles, HSV-1, HSV-2).

In addition to NV-387, we have developed NV-HHV-1, a drug for the treatment of HSV-1 (“cold sores”), HSV-2 (“genital ulcers”), and VZV (“Shingles”, “chickenpox”) that mimics the host-side feature of the HVEM host protein that is required by all of these viruses for cell entry and infection. HVEM is the “HerpesVirus Entry Mediator” receptor on the cell surface. NV-HHV-1 formulated as skin cream has substantially completed IND-enabling studies for the treatment of Shingles rash. We plan to pursue clinical trials and regulatory approval of NV-HHV-1 after NV-387 undergoes a Phase II clinical trial.

We are also developing an oral drug for the systemic treatment of most of the herpesvirus family related infections, including HSV-1 cold sores, HSV-2 and VZV that is based on the same active ingredient as NV-HHV-1. Further, we have drug candidates in HIVCide™ program that have shown substantial antiviral activities in animal studies warranting further clinical development. We have previously worked on Ebola virus drug development, as well as Dengue virus drug development, which are at an early stage.

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

NanoViricides Further Technology Developments Curing Virus Infections and Business Strategy

In addition, with the goal of curing virus infections, we have developed novel platform technologies. Under these technologies, we have developed several additional drug candidates that are at different preclinical drug development stages in our pipeline.

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

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

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

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We plan to seek non-dilutive grant and contracts funding for our drug candidates that are responsive to bio-defense and pandemic-preparedness objectives, as well as objectives of importance to the health agencies such as RSV and Measles.

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

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

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

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

2. RSV: Oral dosing with NV-387 led to full survival of mice lethally infected with RSV/A2 to cause severe lung disease, whereas the only available drug against RSV, namely ribavirin, showed a limited increase in lifespan. The lethally RSV-infected animals in the NV-387-treated group showed no lung damage in lung histo-pathology study at all time points during the study, whereas animals in the ribavirin-treated group showed progressive pathology. There is no approved drug for the treatment of RSV infection, other than the last resort drug, ribavirin that has limited effectiveness.

Survival Lifespan of Lethally Infected Mice - Lung Infection with RSV A2			
Treatment	Survival, Days	Increase in Survival, Days	Increase in Survival, %
NV-387, Oral	22+ (Complete)	> 14	> 175%
Ribavirin, Oral	14	6	75%
Vehicle	8	0	0%

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

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

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Survival Lifespan of Lethally Infected Mice - Lung Infection with Ectromelia Virus			
Treatment	Survival, Days	Increase in Survival, Days	Increase in Survival, %
NV-387, Oral	15	7	88%
Tecovirimat, Oral	16	8	100%
NV-387 + Tecovirimat, Oral	19	11	138%
Vehicle	8	0	0%

NV-387 treated animals showed significant reduction in immune infiltration into lungs. Killer immune cells that migrate in response to infection can kill lung epithelial cells leading to lung damage. Lung mucus index was also significantly reduced upon NV-387 treatment. These effects indicate that NV-387 is beneficial in reducing lung disease pathology.

NV-387 Treatment Significantly Protected Lungs of Balb-c Mice Lethally Infected with Influenza A/H3N2 Virus		
Treatment	Lung Mucus Index	% Immune Cell Infiltration
NV-387, Intravenous	32	22%
NV-387, Oral	53	31%
Untreated Infected Control	138	68%

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

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

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

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

Novel Orthogonal Nanoviricide Mechanism Has Many Benefits

Additionally, the NV-387 putative mechanism of action is orthogonal and complementary to that of the existing therapeutics, enabling combination therapy with the existing drugs in the market. NV-387 acts on the free virus outside cells blocking infection of new cells by destroying the virus. Existing antiviral therapeutics (except antibodies and entry inhibitors) act on the replication cycle of the virus (ex.: remdesivir, acyclovir, ribavirin, cidofovir, brincidofovir) inside cells, or exiting of the virus (ex.: oseltamivir, peramivir, tecovirimat) from inside cells. Thus combining the action outside the cells of NV-387 with the action inside the cells (or at exit) of these existing agents is expected to lead to

complete blockage of any virus thus resulting in a rapid and complete cure. Combining multiple drugs also leads to reduction in emergence of viral resistance, as has been scientifically proven already.

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

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

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

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

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

- (i) Oral “Gummies” for adults and older children. Oral gummies have an advantage over tablets in that the drug dissolves slowly in the mouth and does not require swallowing. Older adults as well as children with certain respiratory infections are known to have difficulty swallowing.
- (ii) Oral Syrup. In infants and younger children, the drug must be “titrated” on the basis of body weight or a similar parameter. A syrup form is best suited for this purpose.
- (iii) Solution for Injection, Infusion or Inhalation. For hospitalized patients with severe disease, injections and infusions are better suited to provide immediate antiviral action. A simple inhalation of the same solution using a standard available nebulizer enables direct delivery to lower respiratory system where the virus is causing lung damage that can lead to lung failure and potentially death.

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

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

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

We believe our unique and successful mimicking of S-PG is responsible for the observed broad-spectrum activity of NV-387. NV-387 is an example of NanoViricides Platform Modality #1 implementation discussed in our Annual report filed with the SEC on September 27, 2024

Virus Escaping a Nanoviricide Drug is Unlikely

The NanoViricides Platform Technology has an important advantage in that no matter how much a virus changes in the field, it is unlikely to escape the nanoviricide drug, because the nanoviricide drug is designed to mimic the very features that the virus uses to bind to and enter cells. These specific molecular signature features on the cellular side do not change even as the virus mutates, and nanoviricides are designed to mimic these host-side features. In contrast viruses

readily escape antibodies as drugs, as well as vaccine-induced immunity as they evolve in the field, as is well known from the COVID-19 pandemic as well as Influenza pandemics and the continuing HIV/AIDS pandemic.

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

Further details of the NanoViricides Platform Technology, the various Modalities of its implementation, and the extensive drug candidate developments that we have undertaken, have been discussed in our Annual Report filed with the SEC on September 27, 2024.

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

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

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

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

Manufacturing nanomedicines, especially under cGMP conditions, has been identified as a major risk, and has led to failure of several nanomedicines programs. NanoViricides co-founder Dr. Anil Diwan and our team have employed considerations for cGMP manufacture of our nanomedicines right from the design, development and optimization of the drug candidates, the polymers and ligands that go into them, as well as the processes employed right from the small research scale to the initial process verification batches.

We have thus demonstrated that we have unique expertise in the industry of performing cGMP-compliant manufacture of multiple complex nanomedicine drugs, including cGMP manufacture of (a) drug substance from simple chemical starting materials, (b) the formulated drug product, and (c) the final packaged drug. This is a very significant milestone on the way of NanoViricides becoming a fully integrated pharma company.

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

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

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

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

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

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

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

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

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

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

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

Our non-clinical programs are designed to minimize the risk of failure of our drug candidates in clinical trials. Specifically, we perform evaluation of antiviral activity in lethal studies in direct comparison with known approved drugs if available, and choose drug candidates that show at least comparable or superior activity to the approved ones. We employ lethal infection studies so that the survival time is a clear indicator of the antiviral activity, and can be used to rank relative activity of drug candidates. We believe our success rate of drug approval would be substantially better than industry averages because of the features of our nanoviricides platform technology and the de-risking strategies we employ in drug development.

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

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

Our nanoviricides™ platform technology is based on biomimetic engineering that copies the features of the human cellular receptor of the virus. No matter how much the virus mutates, all virus variants bind to the same receptor in the same fashion. Thus our platform technology is inherently designed to combat the issue of viruses escaping drugs by generation of variants.

We mimic the feature on the cellular protein at which the virus binds, and, using molecular modeling, design small molecules that act as “ligands” to bind to the virus surface glycoproteins as though the virus was binding to that cellular protein itself. This host-side chemical signature that the virus uses for infecting cells does not change even as the virus mutates, evolves and generates variants. We chemically synthesize the optimal ligands, and separately attach them to the polymeric micelle scaffold to generate a number of initial “nanoviricide” drug candidates to screen against the virus. Thus the nanoviricide is designed to “look like” the cell membrane with copious amounts of sites for the virus to bind to. When initial interaction of a few ligands with the virus particle takes place, the “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. We call this mechanism “Re-Infection Inhibition”. This mechanism goes beyond the simple neutralization of the virus by antibodies, which requires the human immune system to further take care of the resulting virus-antibody complex. This mechanism also goes beyond the simple blocking of virus entry by small chemical entry inhibitors, which would require extremely high concentrations of the inhibitor to effect complete blockage of each virus particle based on mass-action considerations.

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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.

Mimicking the attachment receptor families may lead to extremely broad-spectrum drug candidates. We call this implementation NanoViricides Platform Technology Modality #1. NV-387 is an example of this Modality #1, namely, Broad-Spectrum Antiviral Re-infection Inhibitors. NV-387 is designed to mimic key features required by viruses of the host-side sulfated proteoglycans that viruses use as attachment receptors.

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

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

Additionally, we are the only company that, to the best of our knowledge, is developing antiviral treatments that are designed to (a) directly attack the virus and disable it from infecting human cells (i.e. block the "Re-Infection Cycle"), and (b) simultaneously block the reproduction of the virus that has already gone inside a cell (i.e. block the "Replication Cycle"). Together, this strategy of a two-pronged attack against the virus, both inside the cell and outside the cell, and thus blocking the complete lifecycle of the virus, can be expected to result in a cure for coronaviruses and other viruses that do not become latent. We call this implementation, namely encapsulation of other active ingredients within the polymeric micelle of the virus-targeted nanoviricide (which can be based on either Modality #1 or Modality #2), the NanoViricides Platform Technology Modality #3.

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

This total attack on the complete lifecycle of the virus is expected to result in the most effective drug candidates. It is now well accepted that multiple antivirals together produce better effectiveness than single ones individually. Our strategy goes beyond simply a mix of multiple antivirals. Our unique, shape-shifting nanomedicine technology leads to substantial improvement in the pharmacokinetic properties of the guest antiviral drug. We have demonstrated this capability in the case of NV-387-g-R, as discussed above, wherein encapsulation of remdesivir within the polymeric micelles of NV-387 protects the former drug from bodily metabolism in animal studies. This allows higher concentrations of the guest drug to be reached and simultaneously extends the effectiveness time period in comparison to the standard Veklury® (Gilead) formulation. The resulting drug, NV-387-g-R has not only significantly improved characteristics for its remdesivir component, but additionally provides the novel re-infection blocking mechanism of NV-387; together enabling complete block of the viral lifecycle, which would potentially result in a cure. (Chakraborty A, Diwan A, Chiniga V, Arora V, Holkar P, Thakur Y, et al. (2022) Dual effects of NV-CoV-2 biomimetic polymer: An antiviral regimen against COVID-19. PLoS One 17(12): e0278963. <https://doi.org/10.1371/journal.pone.0278963>.)

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

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

bioavailability.

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

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

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

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

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

A Note on Nomenclature of NanoViricides Candidates:

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

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

Developments During the Reported Period

We note that the Trump administration and the Secretary of Health are in the process of revising the overall HHS goals, budgets and staffing with a focus on health maintenance, chronic diseases, nutrition, and antiviral treatments, with reduced focus on vaccines.

We believe that the emphasis of the Secretary on antiviral drug treatments would be beneficial to our drug development programs.

During the three months ended March 31, 2025, we have focused on preparing regulatory documentation that will be necessary for primarily (i) a Phase II MPox clinical trial of NV-387, and (ii) a Phase II RSV clinical trial of NV-387.

Phase II Clinical Trial for the Treatment of MPox with NV-387

We are in the process of developing a Phase II clinical trial application for submission to a regulatory agency in the Central African region, for the treatment of MPox infection with NV-387. To this end we have retained a CRO to help us with the execution of the clinical trial.

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Our CRO has already engaged one clinical trial site as of this reporting, and we are working on an additional site.

Importantly, we have recently received an approval to proceed to a Phase II clinical trial for MPox from the Regional Ethics Committee in the Democratic Republic of Congo (DRC), based on the non-clinical data on safety and efficacy, as well as the safety and tolerability data from a draft report of the Phase I clinical trial of NV-387.

This clears the path for us to submit a Phase II Clinical Trial Application (CTA) for the use of NV-387 for the treatment of MPox disease (caused by MPXV infection) to the DRC regulatory agency.

We are now completely focused on preparing the Phase II MPox CTA for NV-387.

Further, we have continued to increase the scale of manufacture of NV-387 in our cGMP-compliant facility, effectively doubling the prior batch size, in preparation for supplying the drug products for the Phase II clinical trials. We believe this scale will be sufficient for a Phase II clinical trial for MPox or for a Phase II clinical trial for RSV. We will commission additional batches as we engage into additional clinical trials.

We are currently executing the production program for Phase II clinical supply of NV-387 drug products. We have improved the NV-387 drug product formulations with organoleptic considerations (i.e. taste, flavor, feel and smell). We have ordered additional custom equipment, made in the USA, for the gummies blister-pack filling and sealing operation that is expected to be delivered soon.

Treatment of Measles Virus Infection Using NV-387

During the reported quarter, we have initiated a program for the development of NV-387 as an antiviral treatment for Measles virus infection. We have acquired a Measles virus in our BSL2 Virology lab and we have grown it in cell cultures in a small quantity sufficient for initial animal studies.

We have completed designing an experiment for the evaluation of NV-387 as a treatment for Measles virus infection in an animal model. Measles virus is host restricted and requires the use of humanized hCD150 (h-SLAP) mice for this work. These mice are grown only on order and take several weeks for delivery. We have already commissioned this animal model study.

If the animal model study is successful, we plan on opening an IND with the US FDA for a Phase II clinical trial for the evaluation of NV-387 as a treatment of measles virus. We plan on seeking non-dilutive grant support for development of NV-387 as a treatment for Measles virus.

We already have the supporting data required for such an IND as summarized below.

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

A Phase I clinical trial of (i) NV-387 Oral Syrup and (ii) NV-387 Oral Gummies formulations to evaluate Safety and Tolerability in healthy human subjects was completed with the discharge and final visit of the last subject at the end of December, 2023. There were no reported adverse events, and there were no drop-outs in this clinical trial of 72 subjects. Thus, the drug NV-387, in both of the oral formulations studied, namely oral syrup and oral gummies (a soft solid form that dissolves in the mouth), is deemed to be safe and well tolerated and can be further advanced into Phase II clinical trials, as per communications with the Data Safety and Monitoring Board (DSMB) an independent expert review committee commissioned for this clinical trial. We are awaiting a final report of the clinical trial. This statement regarding safety and tolerability will be evaluated, after we submit the final Phase I report, by the regulatory agency.

The results of the Phase I clinical trial are consistent with our non-clinical findings.

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

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Update on Our COVID Program

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

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

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

Therefore, while we fully believe that (i) NV-387 has demonstrated strong pan-coronavirus antiviral activity in pre-clinical studies and therefore (ii) NV-387 is a viable clinical drug candidate for COVID treatment; (iii) NV-387 could be substantially superior to available drugs such as remdesivir and Paxlovid®; and (iv) NV-387 would be available to the entire patient population while the available drugs have severe limitations, regrettably, we have determined that we cannot take NV-387 forward for COVID indication with our limited resources. We will continue to seek non-dilutive resources such as government grants and contracts for the development of NV-387 for the treatment of COVID and potentially long COVID. We are also seeking to advance NV-387 for COVID and Long COVID indications via partnerships.

If resources become available for clinical trial of NV-387 for a subset of Long COVID patients with residual virus found in sensitive assays, then we would very much like to advance clinical trials to develop NV-387 for the Long COVID indication. This continues to be an unmet medical need.

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

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

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

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

This capability of NV-387 is analogous to the highly successful antibiotics against bacteria.

In contrast, currently available antiviral drugs have substantial limitations on the patient populations that they can be used in. For example, of the two remaining approved drugs for treatment of COVID, Paxlovid which is given orally, is not indicated for the treatment of COVID in patients without a risk factor for progression to severe COVID-19, whereas

remdesivir can only be used in hospitalized cases. Similarly ribavirin, indicated for RSV infection and other viral infections, is only indicated as a last resort because of severe toxicities. Other antivirals such as Cidofovir, Brincidofovir, etc. also have limitations due to toxicities.

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

Our press release regarding NV-387 activity leading to complete survival of animals in a lethal lung infection animal model of RSV in comparison to the toxic drug ribavirin was published on May 14, 2024 via AccessWire.

Our Other Drug Development Programs

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

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

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

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

Other Pre-clinical Drug Programs

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

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

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

Both the safety and effectiveness of any new drug has to be determined experimentally. The safety of a nanoviricide drug is expected to depend upon the safety of the nanomicelle portion as well as the safety of the antiviral ligand. We have observed excellent indications in the evaluation of safety of our broad-spectrum antiviral drug candidate NV-387 as well as that of NV-360, our herpesvirus family specific antiviral drug candidate to date in non-clinical studies including IND-enabling safety pharmacology studies. Further, NV-387 has successfully completed Phase 1 human clinical trial with no adverse events, indicating an excellent level of safety. The final determination of safety and efficacy of a drug rests with the regional drug regulatory authority such as the US FDA, EU EMEA, India CDSCO/DCGI, UK MHRA and others.

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

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Our Current Priorities – Measles, MPox, H5N1, and RSV

We are presently working on the Phase II clinical regulatory development of NV-387 as a treatment for MPox infection. If successful, this program is expected to enable us to tap into governmental programs for development and stockpiling of MPox and Smallpox treatments as preparedness against potential MPox pandemic and Smallpox bioterrorism events.

We have initiated work on evaluating NV-387 as a treatment for Measles virus infection in a relevant animal model. If successful, we believe this will enable us to apply for Phase II human clinical trials with the US FDA and seek non-dilutive grant funding for the same.

We continue to work on further development of NV-387 with the goal of the treatment of pediatric RSV infections.

We are also working on being prepared to respond to a H5N1 Bird Flu pandemic in humans, should it occur, with NV-387 for the treatment of bird flu.

COVID and Long COVID

We will continue to seek non-dilutive funding for further development of NV-387 as a treatment for COVID and Long COVID.

We plan on continuing to perform pre-clinical investigations to expand the usage of NV-387 as an antiviral drug against other viruses to improve return on investment, ROI.

Our Campus in Shelton, CT

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

Process Scale-Up Production Capability

The process scale-up area is operational at kilogram to multi-kg scales for different chemical synthesis and processing steps. It comprises reactors and process vessels on chassis or skids, ranging from 250mL to 100L capacities, as needed. Many of the reactors and vessels have been designed by us for specific tasks related to our unique manufacturing processes.

cGMP Production Capability

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

We also have a manufacturing suite for cGMP-compliant Oral Drug Product Formulation, Fill, and Packaging. We manufactured and delivered the clinical NV-387 oral syrup and oral gummies (semi-solids) drug products in this suite using equipment that we had custom-designed and fabricated in the U.S.

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

Our BSL-2 Certified Virology Lab

We have significantly enhanced our internal anti-viral cell culture testing capabilities at our Shelton campus. Our Virology Research Lab suite has a BSL-2 (Biological Safety Level 2) certification from the State of Connecticut. This suite comprises three individual virology workrooms, enabling us to work on several different viruses and strains at the

same time. This facility is designed only for cell culture studies on viruses, and no animal studies can be conducted at any of our own facilities.

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We have established several different types of assays for screening of drug candidates against Coronaviruses, SARS-CoV-2 Pseudovirions, VZV, HSV-1, HSV-2, Influenza viruses, RSV, Ectromelia virus (a stand-in for MPox and Smallpox viruses), among others in this lab. We are working on developing an H5N1 Bird Flu pseudovirion assay. We have begun working on the Measles virus during the reported quarter. Our BSL-2 Virological capability has been instrumental in our rapid development of potential drug candidates for further investigation towards human clinical trials. We believe that having developed the internal capabilities for cell culture testing of our ligands and nanoviricides against a variety of viruses has substantially strengthened and accelerated our drug development programs.

NanoViricides Business Strategy in Brief

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

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

As a risk factor, we have limited experience with pharmaceutical drug development. Thus, our budget estimates are not based on experience, but rather based on advice given by our associates and consultants. As such these budget estimates may not be accurate. In addition, the actual work to be performed is not known at this time, other than a broad outline, as is normal with any scientific work. As further work is performed, additional work may become necessary or change in plans or workload may occur. Such changes may have an adverse impact on our estimated budget. Such changes may also have an adverse impact on our projected timeline of drug development.

As we develop NV-387 further into Phase II clinical trials, we plan on seeking non-dilutive funding for the Measles, RSV, Smallpox/MPox, COVID and Long COVID, as well as Influenza and Bird Flu drug development programs as the opportunities arise. We plan on seeking partnerships for all of our drug development programs, as these programs mature further.

We have previously substantially 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 undertaking further development of our HerpeCide program into clinical trials after sufficient funding becomes available for re-engaging these programs.

As a risk factor, we recognize that the FDA may require additional studies to be done before approving the IND for any of our programs. Assuming that the FDA and other International regulatory agencies allow us to conduct human clinical studies as we intend to propose, we believe that the coming year's work plan will lead us to obtain certain information about the safety and efficacy NV-387 in human clinical studies for the treatment of MPox infection and possibly Measles infection. If our studies are not successful, we will have to perform additional clinical trials for NV-387 for other appropriate indications, and/or develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further additional studies as necessary towards drug approval or licensure from regulatory agencies.

We believe we have sufficient funds for undertaking the Phase II clinical trial for evaluation of NV-387 for the treatment of MPox in DRC. We plan on seeking additional funding for all of our drug programs from non-dilutive sources as well as raising equity-based financing as appropriate.

As a strategy, we plan to develop the same drug, once initial clinical trials towards a first approval of the drug are completed, for commercial approval for additional indications, such as pediatric applications, special case applications for certain classes of immuno-compromised patients, among others, provided that appropriate levels of funding is

available. We believe that adding further indications would significantly expand market penetration and improve return on investment for our drugs.

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Collaborations, Agreements and Contracts

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

In January 2025 we engaged a CRO to help us execute a Phase II clinical trial for the evaluation of NV-387 for the treatment of MPox in the Central African region.

Patents, Proprietary Rights: Intellectual Property – Recent events

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

In September 2021, we entered into a world-wide, exclusive, sub-licensable, license, COVID-19 License Agreement, to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour’s proprietary as well as patented technology and intellectual property. These licenses are not limited to underlying patents, but also include the know-how, trade secrets, and other important knowledge base that is utilized for developing the drugs and making them successful. In addition, these extremely broad licenses are not limited to some specific chemical structures, but comprise all possible structures that we could deploy against the particular virus, based on these technologies. Further, the licenses are held by NanoViricides for worldwide use. These are described in our most current Annual Report.

COVID Related Drugs: Patent Coverage and Lifetime

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

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

adequate protection or that pending patent applications will result in issued patents.

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

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

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

Analysis of Financial Condition, and Result of Operations

As of March 31, 2025, we had cash and cash equivalents of \$2,542,590, prepaid expenses of \$184,716 and net property and equipment of \$6,982,750. Accounts payable and accrued expenses were \$1,198,911, inclusive of accounts payables to related parties of \$813,477 and accrued expenses of \$32,616. Stockholders' equity was \$8,833,049 at March 31, 2025. In comparison, as of June 30, 2024, we had \$4,797,778 in cash and cash equivalents, prepaid expenses of \$172,742 and \$7,512,463 of net property and equipment. Our liabilities at June 30, 2024 were \$1,358,776 including accounts payable of \$376,270 payable to third parties and accounts payable to related parties of \$720,039, and accrued expenses of \$262,467, of which \$227,435 was due to a related party.

During the nine month period ended March 31, 2025, we used approximately \$6.8 million in cash toward operating activities. This was substantially greater than for the nine months ended March 31, 2024 primarily due to certain one-time costs related to investor outreach activities and certain required additional non-clinical studies to advance NV-387 into Phase II.

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 exclusively on our NV-387 drug development program. We have continued to work on development of documents for initiating a Phase II clinical trial for using NV-387 as a treatment for MPox infections in Central Africa, and on developing a Phase II clinical trial application for the development of NV-387 for the treatment of pediatric RSV infections in the U.S.

Results of Operations

Revenues The Company is a biopharmaceutical company and did not have any revenue for the nine month period ended March 31, 2025.

Research and Development Expenses – Research and development expenses for the three months ended March 31, 2025 increased \$67,590 to \$1,282,251 from \$1,214,661 for the three months ended March 31, 2024. Research and development expenses for the nine months ended March 31, 2025 increased \$116,488 to \$4,371,693 from \$4,255,205 for the nine months ended March 31, 2024. The increase in research and development expenses for the three and nine months ended March 31, 2025 is due to an increase in outside lab fees and clinical trial costs.

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General and Administration Expenses – General and administrative expenses for the three months ended March 31, 2025 increased \$273,163 to \$966,905 from \$693,742 for the three months ended March 31, 2024. General and administrative expenses for the nine months ended March 31, 2025 increased \$1,234,804 to \$3,104,349 from \$1,869,545 for the nine months ended March 31, 2024. The increase in general and administrative expenses for the three and nine months ended March 31, 2025 is due to an increase in professional fees associated with investor outreach.

Interest Income – Interest income for the three months ended March 31, 2025 decreased \$21,554 to \$32,373 from \$53,927 for the three months ended March 31, 2024. Interest income for the nine months ended March 31, 2025 decreased \$131,293 to \$105,106 from \$236,399 for the nine months ended March 31, 2024. The decrease in interest income for the three and nine months ended March 31, 2025 is due to a lower interest bearing balance during the period and lower interest rates during the current three and nine month period compared to the prior periods.

Interest Expense – There was no interest expense incurred during the three months ended March 31, 2025 and March 31 2024. Interest expense decreased \$49,659 to \$149 for the nine months ended March 31, 2025 from \$49,808 for the nine months ended March 31, 2024. The decrease in interest expense for the nine months ended March 31, 2025 is a result of cancellation of the milestone payment note with TheraCour during the nine month period ended March 31, 2024. The interest charged pursuant to the milestone payment note was cancelled by TheraCour on October 27, 2023. The cancellation of the note interest reduced accrued expense and increased additional paid in capital by \$49,808.

Net Loss – For the three months ended March 31, 2025, the Company had a net loss of \$(2,216,783) or \$(0.14) per share compared to a net loss of \$(1,854,476) or \$(0.16) per share for the three months ended March 31, 2024. For the nine months ended March 31, 2025, the Company had a net loss of \$(7,371,085) or \$(0.50) per share compared to a net loss of \$(5,938,159) or \$(0.51) per share for the nine months ended March 31, 2024. The increase in the net loss for the three and nine months ended March 31, 2025 is generally attributable to the factors discussed above.

Liquidity and Capital Resources

As of March 31, 2025 we had \$2,542,590 in cash and cash equivalents.

The Company's condensed financial statements have been prepared assuming that it will continue as a going concern, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the normal course of business. As reflected in the condensed financial statements, the Company has an accumulated deficit at March 31, 2025 of approximately \$146.7 million and a net loss of approximately \$7.4 million and net cash used in operating activities of approximately \$6.8 million for the nine months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of March 31, 2025, the Company had available cash and cash equivalents of approximately \$2.5 million. The Company's liabilities at March 31, 2025 were approximately \$1.2 million. Management believes that the Company's existing resources, including availability under its \$3 million line of credit will not be sufficient to fund the Company's planned operations and expenditures for at least 12 months from the date of the filing of this Form 10-Q. As a result substantial doubt exists about the Company's ability to continue as a going concern.

The ability of the Company to continue as a going concern is dependent upon controlling its overall expenses and identifying and securing additional financing. Management has considered several options for financing working capital as well as to obtain additional funds that will be needed for future human clinical trials. Management believes that we will be achieving several important milestones, including release of the Phase I clinical trial final report, a Phase II clinical trial application to evaluate safety and efficacy of NV-387 as a treatment for MPox, execution of this Phase II clinical trial, top-line results from the same, and further regulatory developments progressing NV-387 as cited elsewhere in this report, in the ensuing year. Management believes that as it achieves these milestones, there would be improvement in the liquidity of the Company's stock, and that would improve our ability to raise funds on the public markets at terms that may be more favorable to the terms we are offered at present. Management believes that it has on-going access to the capital markets under an "At-The-Market" (ATM) agreement with D. Boral Capital (Formerly EF Hutton LLC) that became active around April 5, 2024. Management believes that the Company's stock is currently

undervalued in contrast to its asset value, based on the potential of NV-387 alone. Management believes that as our investor outreach program expands and bears fruit, this deviation should be lessened, enabling access to public markets for equity funding at reasonable valuations. In addition, Management plans to solicit

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funds by mortgaging its existing fully owned campus and cGMP manufacturing facilities in Shelton, CT, in order to free up a portion of the fixed capital for use as liquid working capital. These facilities were recently valued at \$12 to \$15 million by industry experts. However, there is no guarantee that we will be able to raise funds on reasonable terms acceptable to us, or at all.

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

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

We do not anticipate any major capital costs going forward in the near future. We intend to seek collaborations to develop NV-387 drug further towards approvals by FDA as well as international regulatory authorities.

We do not have direct experience in taking a drug through human clinical trials at present. In addition, we depend upon external collaborators, service providers and consultants for much of our drug development work. Our estimates for external costs are based on various preliminary discussions and “soft” quotes from contract research organizations that provide pre-clinical and clinical studies support. The estimates are also based on certain time estimates for achievement of various objectives. If we miss these time estimates or if the actual costs of the development are greater than the early estimates we have at present, our drug development cost estimates may be substantially greater than anticipated now. In that case, we may have to re-prioritize our programs and/or seek additional funding.

Off Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements during the nine months ended March 31, 2025.

Excluding those sold under the ATM, all of the securities referred to above were issued without registration under the Securities Act of 1933, as amended (the “Securities Act”) in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. None of the foregoing securities as well as common stock issuable upon conversion or exercise of such securities, have been registered under the Securities Act or any other applicable laws and are deemed restricted securities, and unless so registered may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

ITEM 4. CONTROLS AND PROCEDURES

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the “SEC”). Disclosure controls and procedures include, without limitation, controls and procedures

designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns

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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, 2025, an evaluation was carried out under the supervision and with the participation of our management, including our President and our 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 President and our Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective as of March 31, 2025.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness, as of March 31, 2025, of our internal control over financial reporting based on the framework in 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of March 31, 2025.

Changes in Internal Control Over Financial Reporting

There were no material changes in our system of internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the three months ended March 31, 2025 that has materially affected, or is likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

There are no legal proceedings against the Company to the best of the Company's knowledge as of the date hereof and to the Company's knowledge, no action, suit or proceeding has been threatened against the Company.

ITEM 1A. RISK FACTORS

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

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

On April 15, 2024, the Company entered into a new ATM sales agreement with E.F. Hutton Securities (now D. Boral Capital), the Sales Agent, pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agent, shares of common stock having an aggregate offering price of up to \$50 million. From July 1, 2024 through March 31, 2025 the Company sold 2,844,240 shares of common stock at an average price of approximately \$1.60 per share. The shares were issued pursuant to a prospectus supplement dated May 5, 2023 and filed with the Securities and Exchange Commission on May 5, 2023 in connection with the Company's shelf registration statement on Form S-3, as amended (File No. 333-271706, which became effective on May 22, 2023). The net proceeds to the Company from the offering was approximately \$4,568,000 after placement agent fees and other estimated offering expenses.

The Company accounted for the proceeds of the ATM Offering, approximately, as follows:

Gross proceeds	\$ 4,746,300
Less: offering costs and expenses	<u>178,300</u>
Net proceeds from issuance of common stock	<u>\$ 4,568,000</u>

As of July 1, 2024 the Company and Dr. Anil Diwan entered into an extension of his employment agreement for a period of one year from July 1, 2024 through June 30, 2025 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, 2024, December 31, 2024, March 31, 2025 and June 30, 2025 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$37,374 for the nine months ended March 31, 2025. The balance of \$12,458 will be recognized as the remaining 2,551 shares vest and service is rendered for the remaining three months ended June 30, 2025.

For the three and nine months ended March 31, 2025, 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 \$5,918 and \$9,415, respectively for the three and nine months ended March 31, 2025 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.

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The Scientific Advisory Board was granted in August 2024 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$2.35 per share expiring in August 2028 and in November 2024 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$1.58 per share expiring in November 2028 and in February 2025 fully vested warrants to purchase 286 shares of common stock with exercise price of \$1.67 expiring in February 2029. The fair value of the warrants was \$161 for the three months ended March 31, 2025 and \$544 for the nine months ended March 31, 2025 and was recorded as consulting expense.

The Company estimated the fair value of the warrants granted to the Scientific Advisory Board on the date of grant using the Black-Scholes Option-Pricing Model with the following assumptions:

Expected life (year)	4
Expected volatility	52.55 - 54.18 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.85 - 4.29 %

For the three and nine months ended March 31, 2025, the Company's Board of Directors authorized the issuance of 21,156 and 59,339, respectively, fully vested shares of its common stock with a restrictive legend for consulting and legal services. The Company recorded expense of \$27,000 and \$88,500, respectively, for the three and nine months ended March 31, 2025, 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, 2025, the Company's Board of Directors authorized the issuance of 8,817 and 22,530, 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, 2025, which is reflective of the fair value of the common stock on the dates of issuance.

Excluding those sold under the ATM, all of the securities referred to above were issued without registration under the Securities Act of 1933, as amended (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. None of the foregoing securities as well as common stock issuable upon conversion or exercise of such securities, have been registered under the Securities Act or any other applicable laws and are deemed restricted securities, and unless so registered may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

(a) None.

(b) Corporate Governance

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

(c) Insider Trading Arrangements and Policies

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

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ITEM 6. EXHIBITS

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

SIGNATURES

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

NANOVIRICIDES, INC.

Dated: May 15, 2025

/s/ Anil R. Diwan

Name: Anil R. Diwan

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

Dated: May 15, 2025

/s/ Meeta Vyas

Name: Meeta Vyas

Title: Chief Financial Officer
(Principal Financial Officer)