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

**FORM 10-Q**

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

For the quarterly period ended December 31, 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 February 17, 2026 there were approximately 21,595,000 shares of common stock of the registrant issued and outstanding.

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[Table of Contents](#)

NanoViricides, Inc.  
FORM 10-Q  
INDEX

<a href="#">PART I FINANCIAL INFORMATION</a>	3
<a href="#">Item 1. Financial Statements</a>	3
<a href="#">Condensed Balance Sheets at December 31, 2025 and June 30, 2025 (Unaudited)</a>	3
<a href="#">Condensed Statements of Operations for the Three and Six Months Ended December 31, 2025 and 2024 (Unaudited)</a>	4
<a href="#">Condensed Statements of Changes in Stockholders' Equity for the Three and Six Months Ended December 31, 2025 and 2024 (Unaudited)</a>	5
<a href="#">Condensed Statements of Cash Flows for the Six Months Ended December 31, 2025 and 2024 (Unaudited)</a>	7
<a href="#">Notes to the Condensed Financial Statements (Unaudited)</a>	8
<a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	18
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	50
<a href="#">Item 4. Controls and Procedures</a>	50
<a href="#">PART II OTHER INFORMATION</a>	51
<a href="#">Item 1. Legal Proceedings</a>	51
<a href="#">Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</a>	51
<a href="#">Item 3. Defaults Upon Senior Securities</a>	52
<a href="#">Item 4. Mine Safety Disclosures</a>	53
<a href="#">Item 5. Other Information</a>	53
<a href="#">Item 6. Exhibits and Reports on Form 8-K</a>	54
<a href="#">Signatures</a>	55
Certifications	

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

	<u>December 31, 2025</u> (Unaudited)	<u>June 30, 2025</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 5,150,580	\$ 1,558,564
Prepaid expenses	145,985	112,146
Total current assets	<u>5,296,565</u>	<u>1,670,710</u>
Property and equipment, net	6,656,439	6,833,891
Intangible assets, net	312,904	317,039
<b>OTHER ASSETS</b>		
Service agreements	1,732	2,445
Total assets	<u>\$ 12,267,640</u>	<u>\$ 8,824,085</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 218,313	\$ 459,094
Accounts payable-related party	929,232	821,456
Accrued expenses	48,380	25,969
Total current liabilities	<u>1,195,925</u>	<u>1,306,519</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Series A convertible preferred stock, \$0.00001 par value, 10,000,000 shares designated, 916,695 and 905,717 shares issued and outstanding, at December 31, 2025 and June 30, 2025, respectively	9	9
Common stock, \$0.00001 par value; 150,000,000 shares authorized, 21,595,187 and 16,606,832 shares issued and outstanding, at December 31, 2025 and June 30, 2025, respectively	216	166
Additional paid-in capital	163,919,128	156,359,252
Accumulated deficit	<u>(152,847,638)</u>	<u>(148,841,861)</u>
Total stockholders' equity	<u>11,071,715</u>	<u>7,517,566</u>
Total liabilities and stockholders' equity	<u>\$ 12,267,640</u>	<u>\$ 8,824,085</u>

*See accompanying notes to the condensed financial statements*

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

	<u>For the Three Months Ended</u> <u>December 31,</u>		<u>For the Six Months Ended</u> <u>December 31,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
OPERATING EXPENSES				
Research and development	\$ 1,118,649	\$ 1,156,351	\$ 2,111,715	\$ 3,089,442
General and administrative	1,114,525	902,700	1,918,144	2,137,443
	<u>2,233,174</u>	<u>2,059,051</u>	<u>4,029,859</u>	<u>5,226,885</u>
Total operating expenses				
LOSS FROM OPERATIONS	(2,233,174)	(2,059,051)	(4,029,859)	(5,226,885)
OTHER INCOME (EXPENSE)				
Interest income	12,455	31,709	24,082	72,732
Interest expense	—	(149)	—	(149)
	<u>12,455</u>	<u>31,560</u>	<u>24,082</u>	<u>72,583</u>
Other income, net				
NET LOSS	<u>\$ (2,220,719)</u>	<u>\$ (2,027,491)</u>	<u>\$ (4,005,777)</u>	<u>\$ (5,154,302)</u>
Net loss per common share- basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.14)</u>	<u>\$ (0.22)</u>	<u>\$ (0.36)</u>
Weighted average common shares outstanding- basic and diluted	<u>19,850,080</u>	<u>14,572,042</u>	<u>18,466,253</u>	<u>14,132,159</u>

*See accompanying notes to the condensed financial statements*

[Table of Contents](#)

**NanoViricides, Inc.**  
**Condensed Statement of Changes in Stockholders' Equity**  
**For the three and six months ended December 31, 2025**  
**(Unaudited)**

	Series A Preferred Stock: Par \$0.00001		Common Stock: Par \$0.00001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2025	905,717	\$ 9	16,606,832	\$ 166	\$ 156,359,252	\$ (148,841,861)	\$ 7,517,566
Proceeds from sale of common stock in connection with equity financings net of issuance costs of \$44,275	—	—	824,535	9	1,245,310	—	1,245,319
Series A preferred stock issued for employee stock compensation	10,591	—	—	—	11,632	—	11,632
Common stock issued for consulting and legal services rendered	—	—	117,208	1	173,849	—	173,850
Warrants issued to Scientific Advisory Board	—	—	—	—	135	—	135
Common stock issued for Directors fees	—	—	7,504	—	11,250	—	11,250
Net loss	—	—	—	—	—	(1,785,058)	(1,785,058)
Balance, September 30, 2025	916,308	\$ 9	17,556,079	\$ 176	\$ 157,801,428	\$ (150,626,919)	\$ 7,174,694
Proceeds from sale of common stock in connection with equity financings net of issuance costs of \$21,965	—	—	440,453	4	663,798	—	663,802
Series A preferred stock issued for employee stock compensation	387	—	—	—	11,584	—	11,584
Proceeds from Registered Direct Offering of common stock and warrants net of Issuance costs of \$596,019 (see Note 8)	—	—	3,571,429	36	5,403,945	—	5,403,981
Common stock issued for consulting and legal services rendered	—	—	19,255	—	27,000	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	123	—	123
Common stock issued for Directors fees	—	—	7,971	—	11,250	—	11,250
Net loss	—	—	—	—	—	(2,220,719)	(2,220,719)
Balance, December 31, 2025	<u>916,695</u>	<u>\$ 9</u>	<u>21,595,187</u>	<u>\$ 216</u>	<u>\$ 163,919,128</u>	<u>\$ (152,847,638)</u>	<u>\$ 11,071,715</u>

*See accompanying notes to the financial statements*

[Table of Contents](#)

**NanoViricides, Inc.**  
**Condensed Statement of Changes in Stockholders' Equity**  
**For the six months ended December 31, 2024**  
**(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	<u>903,603</u>	<u>\$ 9</u>	<u>15,641,611</u>	<u>\$ 156</u>	<u>\$ 154,915,611</u>	<u>\$ (144,529,197)</u>	<u>\$ 10,386,579</u>

*See accompanying notes to the financial statements*

[Table of Contents](#)

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

	<b>For the Six Months Ended</b>	
	<b>December 31, 2025</b>	<b>December 31, 2024</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,005,777)	\$ (5,154,302)
Adjustments to reconcile net loss to net cash used in operating activities:		
Preferred stock issued as compensation	23,216	28,413
Common stock issued as compensation and for services	223,350	84,000
Warrants granted to Scientific Advisory Board	258	383
Depreciation	261,768	387,362
Amortization	4,135	4,134
Changes in operating assets and liabilities:		
Prepaid expenses	(33,839)	58,935
Other assets	713	8,817
Accounts payable	(240,781)	(124,413)
Accounts payable - related party	107,776	146,744
Accrued expenses	15,669	(225,881)
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b><u>(3,643,512)</u></b>	<b><u>(4,785,808)</u></b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	<u>(84,316)</u>	<u>(46,764)</u>
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b><u>(84,316)</u></b>	<b><u>(46,764)</u></b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Net proceeds from sale of common stock, net of issuance costs	1,909,121	3,992,846
Net proceeds from sale of common stock and common stock warrants, net of issuance costs	<u>5,410,723</u>	<u>—</u>
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b><u>7,319,844</u></b>	<b><u>3,992,846</u></b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>3,592,016</b>	<b>(839,726)</b>
Cash and cash equivalents at beginning of period	<u>1,558,564</u>	<u>4,797,778</u>
Cash and cash equivalents at end of period	<b><u>\$ 5,150,580</u></b>	<b><u>\$ 3,958,052</u></b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>		
<b>NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Cost related to sales of securities not paid	\$ 6,742	\$ 28,838

*See accompanying notes to the condensed financial statements*

**NANOVIRICIDES, INC.**  
**December 31, 2025**  
**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 December 31, 2025 of approximately \$152.8 million and a net loss of approximately \$4.0 million and net cash used in operating activities of approximately \$3.6 million for the six months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future.

As of December 31, 2025, the Company had available cash and cash equivalents of approximately \$5.2 million. The Company's liabilities at December 31, 2025 were approximately \$1.2 million including accounts payable of approximately \$218,000 payable to third parties, accounts payable to related parties of approximately \$929,000, and accrued expenses of approximately \$48,000. Management believes that the Company's cash and cash equivalents balance of approximately \$5.2 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.

During the three months ended December 31, 2025, the Company raised capital worth approximately \$664,000, net of offering expenses, from ATM sales of our common stock during the current period from October 1, 2025 through December 31, 2025. Additionally, we successfully raised capital worth approximately \$5.4 million net of expenses in a Registered Direct Offering of common stock, and a Private Placement of Series A 2-year and Series B 5.5 year common stock warrants, exercisable into common stock at \$1.75 and \$2.00, respectively, from a single investor.

The ability of the Company to continue as a going concern is dependent upon controlling its overall expenses and identifying and securing additional financing.

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. The Company is anticipating the Phase Ia/Ib clinical study report (final report or CSR) to be submitted soon. The Company plans on submitting the CSR to the regulatory authorities in India, which would be a significant milestone in the regulatory progress of NV-387.

## [Table of Contents](#)

Additional milestones include the start of 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.

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, 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 Item 2 (below) Management's Discussion and Analysis of Financial Condition and Results of Operations 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, 2025 filed with the SEC on September 29, 2025.

The June 30, 2025 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, 2025 filed on September 29, 2025.

#### *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.

Certain warrants issued in November 2025, as more fully described in Note 8, participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors, on the Company's common stock. For purposes of

[Table of Contents](#)

computing earnings per share (“EPS”), these warrants are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants for the three- and six-month periods ended December 31, 2025, as results of operations were a loss for the periods.

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

	<b>Potentially Outstanding Dilutive Common Shares</b>			
	<b>For the Three Months Ended December 31, 2025</b>	<b>For the Three Months Ended December 31, 2024</b>	<b>For the Six Months Ended December 31, 2025</b>	<b>For the Six Months Ended December 31, 2024</b>
<b>Warrants</b>	5,148	6,290	5,148	6,290
<b>Warrants (Participating Securities)</b>	7,142,858	—	7,142,858	—
<b>Total Warrants</b>	<u>7,148,006</u>	<u>6,290</u>	<u>7,148,006</u>	<u>6,290</u>

**Series A Preferred shares**

The Company has 916,695 shares of Series A preferred stock outstanding as of December 31, 2025. Only in the event of a “change of control” of the Company is each Series A preferred share convertible to 3.5 shares of its new common stock. A “change of control” is defined as an event in which the Company’s shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition of the Company or the Company’s intellectual property. In the absence of a change of control event, the Series A preferred stock is not convertible into common stock, and does not carry any dividend rights or any other financial effects. At December 31, 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 3,208,433, 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.

### Recently Adopted Accounting Standards

#### **Segment and geographic information**

The Company adopted ASU 2023-07, Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, as of January 1, 2024. This ASU requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker (“CODM”), an amount for other segment items by reportable segment with a description of its composition, and disclosure of the title and position of the CODM.

## [Table of Contents](#)

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the CODM, or decision making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment: life science. The life science segment consists of the development of clinical and preclinical product candidates for the development of the Company's proprietary anti-viral therapies. The Company's CODM is the President and Executive Chairman of the Board of Directors.

Segment revenue, profit or loss, significant segment expenses and other segment items - The accounting policies of the Company's single operating and reportable segment are the same as those described in this Summary of Significant Accounting Policies. The Company's method for measuring segment profitability includes net income (loss), which the CODM uses to assess performance and make decisions for resource allocation, consistent with the measurement principals for net income (loss) as reported on the Company's statement of operations. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company's statement of operations, and expenses are not regularly reviewed on a more disaggregated basis for purposes of assessing segment performance and deciding how to allocate resources.

### **Improvements to Income Tax Disclosures**

In December 2023, the FASB issued ASU 2023-09, "Improvements to Tax Disclosures" (Topic 740). The new guidance is intended to enhance the transparency and decision usefulness of income tax disclosures through changes to the rate reconciliation and the income taxes paid information disclosed. The ASU is effective retrospectively for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted this ASU as of July 1, 2025 and the impact on the financial statements is not material, beyond certain expanded disclosure.

### **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 transferred such property and equipment, at cost, to the Company

<u>For the three months ended</u>		<u>For the six months ended</u>	
<u>December 31,</u>	<u>December 31,</u>	<u>December 31,</u>	<u>December 31,</u>
<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
\$ —	\$ —	\$ 6,250	\$ 46,765

[Table of Contents](#)

	<u>As of</u>	
	<u>December 31, 2025</u>	<u>June 30, 2025</u>
<u>Accounts 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 as of December 31, 2025 and at June 30, 2025.	<u>\$ 691,865</u>	<u>\$ 584,089</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. Accounts payable to KMPL at December 31, 2025 and June 30, 2025 were:	<u>\$ 237,367</u>	<u>\$ 237,367</u>
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Research and Development Costs Related Party

	<u>For the three months ended</u>		<u>For the six months ended</u>	
	<u>December 31, 2025</u>	<u>December 31, 2024</u>	<u>December 31, 2025</u>	<u>December 31, 2024</u>
Development fees and other costs charged by TheraCour pursuant to the license agreements between TheraCour and the Company for the development of the Company’s drug pipeline. No royalties are due TheraCour from the Company at December 31, 2025 and June 30, 2025	<u>\$ 485,792</u>	<u>\$ 629,931</u>	<u>\$1,025,314</u>	<u>\$1,274,458</u>

[Table of Contents](#)

	As of	
	<u>December 31, 2025</u>	<u>June 30, 2025</u>
<i>Clinical Trial Costs Accrued - Related Party</i>		
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.	\$ —	\$ 9,932

*License Milestone Fee – Related Party*

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 R. Diwan, entered into a Line of Credit Agreement whereby Dr. Diwan agreed to provide a standby Line of Credit to the Company. Amounts drawn down under the Line of Credit shall bear interest at a fixed rate of 12%. Advancements under the Line of Credit will be collateralized by an Open End Mortgage Deed on the Company's real property at 1 Controls Drive, Shelton, Connecticut and a Chattel Mortgage (U.C.C – 1 filing) against the Company's equipment and fixtures. Any draw down under the Line of Credit requires the approval of the Company's Board of Directors.

On September 23, 2024, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil R. 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. On July 1, 2025, the Company, pursuant to Article 2.5 of the Company's Line of Credit Agreement with Dr. Anil R. Diwan, signed an Extension Agreement which extended the maturity of the Company's Line of Credit from March 31, 2026 to March 31, 2027.

There were no other amendments to the original Line of Credit. The Company has not drawn against the Line of Credit facility as of December 31, 2025.

**Note 5 - Property and Equipment**

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

	<u>December 31, 2025</u>	<u>June 30, 2025</u>
GMP Facility	\$ 8,246,111	\$ 8,168,045
Land	260,000	260,000
Office Equipment	77,425	77,425
Furniture and Fixtures	5,607	5,607
Lab Equipment	<u>6,518,423</u>	<u>6,512,173</u>
Total Property and Equipment	15,107,566	15,023,250
Less Accumulated Depreciation	(8,451,127)	(8,189,359)
Property and Equipment, Net	<u>\$ 6,656,439</u>	<u>\$ 6,833,891</u>

Depreciation expense for the three months ended December 31, 2025 and 2024 was \$131,016 and \$193,816, respectively, and for the six months ended December 31, 2025 and 2024 was \$261,768 and \$387,362 respectively.

[Table of Contents](#)

**Note 6 – Intangible Assets**

Intangible assets, net consists of the following:

	December 31, 2025		Total December 31, 2025	June 30, 2025		Total June 30, 2025
	Finite Lived Intangible Assets	Indefinite Lived Intangible Assets		Finite Lived Intangible Assets	Indefinite Lived Intangible Assets	
Intangible Assets	\$ 153,393	\$ 305,561	\$ 458,954	\$ 153,393	\$ 305,561	\$ 458,954
Less Accumulated Amortization	(146,050)	—	(146,050)	(141,915)	—	(141,915)
Intangible Assets, Net	<u>\$ 7,343</u>	<u>\$ 305,561</u>	<u>\$ 312,904</u>	<u>\$ 11,478</u>	<u>\$ 305,561</u>	<u>\$ 317,039</u>

Amortization expense amounted to \$2,068 and \$2,067 for the three months ended December 31, 2025 and 2024, respectively, and for the six months ended December 31, 2025 and 2024 were \$4,135 and \$4,134, respectively.

**Note 7 – Accrued Expenses**

Accrued expenses consisted of the following:

	December 31, 2025	June 30, 2025
Personnel and compensation costs	\$ 25,088	\$ 25,969
Consultant and other	23,292	—
	<u>\$ 48,380</u>	<u>\$ 25,969</u>

**Note 8 - Equity Transactions**

*ATM Offering*

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, 2025 through December 31, 2025 the Company sold 1,264,988 shares of common stock at an average price of approximately \$1.56 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 \$1,909,000 after placement agent fees and other estimated offering expenses.

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

Gross proceeds	\$ 1,975,361
Less: offering costs and expenses	66,240
Net proceeds from issuance of common stock	<u>\$ 1,909,121</u>

*Registered Direct Offering and Private Placement*

On November 10, 2025, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which the Company agreed to sell and issue to a single investor in a registered direct offering (the "Registered Direct Offering"): (i) 1,970,000 shares of common stock, par value \$0.00001 per share (the "Common Stock"), at an offering price of \$1.68 per share, and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,601,429 shares of Common Stock, at an offering price of \$1.67999 per Pre-Funded Warrant. Each Pre-Funded Warrant is exercisable for one share of Common Stock. The Pre-Funded Warrants have an exercise price of \$0.00001 per share, are immediately exercisable, and may be exercised at any time until exercised in full.



## [Table of Contents](#)

Also pursuant to the Securities Purchase Agreement, in a concurrent private placement offering (the “PIPE Offering,” and collectively with the Registered Direct Offering, the “Offering”), the Company agreed to sell and issue to the Investor detachable Series A Common Stock Purchase Warrants (the “Series A Warrants”) to purchase up to 3,571,429 shares of Common Stock and detachable Series B Common Stock Purchase Warrants (the “Series B Warrants,” and collectively with the Series A Warrants (the “Common Warrants”) to purchase up to 3,571,429 shares of Common Stock. The Series A Warrants will be exercisable beginning six months from the date of issuance at an exercise price of \$1.75 per share, and will expire two years from the date of issuance. The Series B Warrants will be exercisable beginning six months from the date of issuance at an exercise price of \$2.00 per share, and will expire five and one-half years from the date of issuance. The warrants meet the criteria for equity classification.

The Company generated gross proceeds of \$6,000,000 and net proceeds of \$5,403,981 from the Offering after deducting under writing discounts and commissions and other offering expenses. Additionally, on November 25, 2025 the Pre-Funded Warrants were exercised, the Company received \$16.01, the par value of the shares issued, and the Company issued 1,601,429 of the Company’s \$0.00001 par value common shares.

On December 15, 2025, the Company filed a Prospectus registering the common shares underlying Series A and B Common Warrants. The filing of the Preliminary Prospectus enables the registered shares of common stock to be issued upon the exercise of the Common Warrants.

The exercise price of the Pre-Funded and Common Warrants are subject to adjustment in the case of customary events such as stock dividends or other distributions on shares of common stock or any other equity or equity equivalent securities payable in shares of common stock, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock, and also, subject to limitations, upon any distribution of assets, including cash, stock or other property to our stockholders.

The Series A and Series B Warrants grant certain participation rights to the warrant holder. If the Company issues rights, warrants, or other purchase rights to common stockholders on a pro rata basis, the warrant holder can participate as if it already exercised the warrant in full. If the company declares any distribution to common stock holders, including, cash dividends stock dividends, spin-offs, property distributions, reorganizations or similar transactions, then the holder participates as if it held all warrant shares immediately before the record date. In the event of a fundamental transaction the holder can, generally, exercise the warrant, and receive the same consideration received by the common shareholders. These participation rights may be held in abeyance, or limited if they result in the holder exceeding beneficial ownership limitations as defined in the warrants.

### Stock-based Compensation

On July 1, 2025 the Company and Dr. Anil Diwan entered into an extension of his employment agreement for a period of one year from July 1, 2025 through June 30, 2026 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, 2025, December 31, 2025, March 31, 2026 and June 30, 2026 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$20,026 for the six months ended December 31, 2025. The balance of \$20,026 will be recognized as the remaining 5,102 shares vest and service is rendered for the remaining six months ended June 30, 2026.

For the three and six months ended December 31, 2025, the Company’s Board of Directors authorized the issuance of 387 and 774, respectively of fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of \$1,570 and \$3,189, respectively for the three and six months ended December 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.

The Scientific Advisory Board was granted in August 2025 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$1.79 per share expiring in August 2029 and in November 2025 fully vested warrants to purchase 286 shares of common

## [Table of Contents](#)

stock with an exercise price of \$1.63 per share expiring in November 2029. The fair value of the warrants was \$123 for the three months ended December 31, 2025 and \$258 for the six months ended December 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 ranges:

Expected life (year)	4
Expected volatility	42.5 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.615 %

For the three and six months ended December 31, 2025, the Company's Board of Directors authorized the issuance of 19,255 and 136,463, 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 \$200,850, respectively, for the three and six months ended December 31, 2025, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and six months ended December 31, 2025, the Company's Board of Directors authorized the issuance of 7,971 and 15,475, fully vested shares of its common stock with a restrictive legend for director services, respectively. The Company recorded an expense of \$11,250 and \$22,500 for the three and six months ended December 31, 2025, which is reflective of the fair value of the common stock on the dates of issuance.

### **Note 9 - Common Stock Warrants**

<u>Common Stock Warrants</u>	<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>
Outstanding and exercisable at June 30, 2025	5,720	\$ 2.62	1.70	\$ 4
Granted as compensation	572	1.71	3.75	—
Issued to investors	7,142,858	1.88	3.61	—
Expired	(1,144)	5.29	—	—
Outstanding and exercisable at December 31, 2025	<u>7,148,006</u>	<u>\$ 1.88</u>	<u>3.61</u>	<u>\$ —</u>

Of the outstanding warrants at December 31, 2025, 1,144 expire in fiscal year ending June 30, 2026, 3,572,573 expire in fiscal year ending June 30, 2027, 1,144 warrants expire in the fiscal year ending June 30, 2028, 1,144 warrants expire in the fiscal year ending June 30, 2029, 572 warrants expire in the fiscal year ending June 30, 2030, and 3,571,429 warrants expire in the fiscal year ending June 30, 2031.

### **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.



## [Table of Contents](#)

### Employment Agreements

As discussed in Note 8, as of July 1, 2025, 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, 2025 through June 30, 2026 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, 2026.

As of July 1, 2025, 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, 2025 through June 30, 2026 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 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.



[Table of Contents](#)

## **ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion should be read in conjunction with the information contained in the condensed financial statements of the Company and the notes thereto appearing elsewhere herein and in conjunction with the Management’s Discussion and Analysis of Financial Condition and Results of Operations set forth in the Company’s Annual Report on Form 10-K for the year ended June 30, 2025. 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 Food and Drug Administration (“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”.

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.

### Virus Escaping a Nanoviricide Drug is Unlikely

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.

## [Table of Contents](#)

### Nanoviricidases Drugs Are Designed So that They Can be Used in Potentially All Segments of Patient Population

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. Additionally, a nanoviricide is designed and constructed so that its components are biocompatible and metabolizable without toxicity.

Phase I human clinical trial of NV-387 to evaluate safety and tolerability in healthy subjects 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 development of safe and well tolerated drugs.

Such good safety and tolerability profile of nanoviricide drugs is expected to enable use of nanoviricide drugs in all segments of patient populations, potentially from infants to children to adolescents to healthy adults to geriatric patients.<sup>1</sup>

### Nanoviricidases Drugs Can be Used in Patients with Co-morbidities or Patients with Immune Compromise Status

A nanoviricide drug is designed to complete the task of destroying the virus particle, without requiring assistance from a functioning immune system of the patient. 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, nanoviricidases can be expected to be superior to approaches such as vaccines and antibodies that require a good functional host immune system for antiviral response. Vaccines require healthy immune system so that appropriate antibody-generating memory cells can be created, stored, and deployed in case of infection later. Antibodies used as drugs decorate the virus particle and require a healthy immune system to handle the virus-antibody complexes thus formed.

Since nanoviricide drugs are designed as chemical nanomachines that function without reliance on the patient's physiology, these drugs are expected to be useful even for patients with co-morbidities such as diabetes, heart disease, and others, as well as for immune-compromised patients including those with HIV/AIDS or "immune amnesia" such as resulting from measles or other prior infections.

These distinctive features that set nanoviricidases apart from the entire world of current antiviral approaches are made possible by our novel nanoviricide chemical nanomachine technology platform.

In contrast, almost all antivirals available today or in development with conventional methodologies have shortcomings of virus escape, limited eligible patient population, as well as limited responding patient population.

After decades of development, this novel nanoviricide technology is now advancing through clinical stages towards regulatory approvals.

### Broad and Expanding Drug Pipeline

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).

Nanoviricide drug development against other viruses would be rapid because of the modular drug development methodology of the nanoviricide platform in which the virus specific ligand is chemically attached to a standardized "cassette" polymeric micelle forming molecule to create the new drug.

<sup>1</sup> Specific non-clinical studies are required by regulatory agencies for allowing testing of a novel drug in (i) pediatric patients, (ii) newborns and infants, and (iii) women of reproductive age. We intend to perform these studies at appropriate regulatory stages of development of the nanoviricidases drugs as is customary.



## [Table of Contents](#)

### Large Market Sizes.<sup>2</sup>

NV-387 alone, because of its broad spectrum activity against Influenza, RSV, COVID, Smallpox, Mpox, Measles, and potentially many other viruses, is estimated to have market size of approximately \$23 Billion by 2030 based on available market estimates. Additionally, NV-HHV-1 could target a potential market size exceeding \$4 Billion by 2030, and NV-HHV-1 target market size is estimated at approximately \$13 Billion by 2030, based on external market reports.

### Revolutionary Broad-Spectrum Antiviral - Clinical Stage Lead Drug NV-387

Our clinical stage lead drug candidate, NV-387, is a broad-spectrum antiviral drug that has demonstrated strong activity in lethal lung viral infection animal model trials for the treatment of an extremely broad and wide variety of viruses.

These viruses include the “triple-threat” respiratory viral infections of (i) Coronaviruses, (ii) RSV, (iii) Influenza viruses; enabling us to envision that NV-387 would be likely effective against almost all respiratory viral infections, based on its design and its observed activity in animal models.

These robust results also provide us with confidence that NV-387 will be effective against any variant of bird flu H5N1 that may become successful in person-to-person transmission and thereby may cause an endemic or a pandemic. H5N1 is thought to be a single mutation away from acquiring these capabilities. H5N1 resistance to Tamiflu has emerged in the past, and would likely emerge again. Xofluza, a recently approved influenza drug, is readily escaped by Influenza viruses. Rapivab, an injectable drug that is in the same class as Tamiflu, is also escaped by viral mutations.

In contrast, NV-387 poses a very low likelihood of viral escape, if any. Moreover, orally given NV-387 was substantially superior to these approved drugs in a direct comparison in an animal model of lethal influenza infection.

We believe that as a single drug that can potentially treat almost any acute respiratory viral infection, NV-387 could be as revolutionary an antiviral drug as penicillin was as the anti-bacterial drug, if and when approved after clinical trials. If a patient presents with a suspected bacterial respiratory infection, the physician can immediately prescribe a broad-spectrum antibacterial treatment such as amoxicillin without waiting for test results. In contrast, at present if a patient presents with a suspected viral respiratory infection, there is no treatment available except for influenza and now COVID. Even in the case of influenza, the available drugs have limited effectiveness and need to be given within 48 hours of initial symptoms for best efficacy, as per prescribing information and literature. The COVID drug paxlovid has not shown efficacy in healthy adults, and has other limitations regarding eligibility of a patient as per prescribing information and literature.

In contrast, NV-387 could be prescribed to any patient with an acute respiratory viral infections, without further testing and with potentially no limitations on patient population, if approved for such use, assuming successful relevant clinical trials.

NV-387 was also found to be highly effective against orthopoxvirus infection animal models which provide support for moving it forward towards licensure for its use in the treatment of (iv) Smallpox (caused by Variola virus), an important bioterrorism threat; as well as for evaluation as a treatment for (v) MPox (caused by the Monkeypox virus, MPXV), an important emerging threat.

<sup>2</sup> These market size estimates are derived based on the following reports or press releases, among others:

(a). Influenza A Infections – Market Insight, Epidemiology and Market Forecast to 2032, DelveInsight, 2022, [https://www.delveinsight.com/report-store/influenza-a-infections-market?](https://www.delveinsight.com/report-store/influenza-a-infections-market?utm_source=cision&utm_medium=pressrelease&utm_campaign=spr)

[https://www.delveinsight.com/report-store/influenza-a-infections-market?utm\\_source=cision&utm\\_medium=pressrelease&utm\\_campaign=spr](https://www.delveinsight.com/report-store/influenza-a-infections-market?utm_source=cision&utm_medium=pressrelease&utm_campaign=spr)

(b). Respiratory Syncytial Virus (RSV) Therapeutics Market to 2031, GrowthPlusReports, 2023,

<https://www.growthplusreports.com/report/respiratory-syncytial-virus-rsv-therapeutics-market/8519>.

(c). Herpes Simplex Virus Treatment Market Size...Forecast to 2030, GrandviewResearch, 2024,

<https://www.grandviewresearch.com/industry-analysis/herpes-simplex-virus-treatment-market-report>.

(d) Infectious Disease Therapeutics Market Size... to 2030, GrandviewResearch, 2024,

<https://www.grandviewresearch.com/industry-analysis/infectious-disease-therapeutics-market>.



## [Table of Contents](#)

Further, the same drug NV-387 was found to be highly active against (vi) Measles virus in a humanized mouse model of lethal Measles virus infection.

### NV-387 is Broad-Spectrum by Design that Includes Specific Host Mimicry

The reason for such exceedingly broad-spectrum activity of NV-387 lies in the design of the drug. 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. In fact, it is well known that over 90-95% of human pathogenic viruses all utilize either HSPG or similar, related Sulfated Proteoglycans (“SPG”) as the initial attachment sites to be able to infect human cells. NV-387 mimics the key features of SPG that are required for the virus binding. No matter how much a virus mutates, it continues to use SPG for initial attachment.

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).

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”). This 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.

### NV-387, a Single Drug, Meets Many Unmet Medical Needs in Viral Diseases

At present,

- There is no approved drug for RSV, although three different antibodies have been approved for pre-exposure protection of infants from potential risk of RSV infection, and some vaccines have been approved for use in geriatric patients and adults at risk, as well as for pregnant women. While the market size is projected to be exceeding \$8 billion or so, the regulatory development timelines are long for RSV pediatric drug development.
- There is no approved drug for Influenza that can be reliably predicted to be not escaped by the next potential epidemic or pandemic Influenza virus, including H5N1. All approved influenza drugs are known to be readily escaped by Influenza variants.
- There is no approved drug for Measles.
- There is no approved drug for MPox.
- The Smallpox approved drugs (under FDA Animal Rule) have significant shortcomings, leaving the US practically unprepared for this bioterrorism scenario despite several billions of dollars in development and acquisitions.
- The approved drugs for Influenza are unlikely to meet the challenge of an H5N1 or highly pathogenic influenza virus epidemic, especially since the influenza virus changes readily in the field by multiple mechanisms including mutations, recombinations and reassortments. Mutations are small changes in the genomic RNA that are always occurring as the virus makes copies of itself. Recombinations occur when two different genomic strands exchange portions of their sequences generating a mixed or chimeric variant

genomic strand. Reassortment is specific to “segmented” viruses such as influenza wherein a new virus particle is assembled by taking the segments of RNA from two (or more) different influenza viruses that have co-infected a cell. Any of these changes can lead to viruses resistant to traditional drugs, vaccines, and antibodies. Pandemic influenza viruses usually are derived from multiple influenza viruses with such swapping or mixing of genetic code and mutations.

## [Table of Contents](#)

NV-387, based on relevant animal model studies, and based on safety and tolerability observed in a Phase I human clinical trial, can fulfill these glaring gaps in pandemic preparedness for current and emerging threats, as well as for potential bioterrorism threats.

Thus, NV-387, as a single drug, is responding to several unmet medical needs in viral infectious diseases at once.

### *Possible Rapid Regulatory Paths, Non-Dilutive Funding, and Potential Revenues for NV-387*

On February 3, 2026, the Company's filed and the FDA Office of Orphan Drugs received, applications for Orphan Drug Designation (ODD) of three drugs, namely (i) NV-387 for the treatment of Measles, (ii) NV-387 for the treatment of MPox, and (iii) NV-387 for the treatment of Smallpox. The Company has retained OnlyOrphansCote, LLC, ("OOC"), led by Dr. Timothy Cote, under a Master Services Agreement as of November 25, 2025, for the orphan drug related activities. Dr. Cote previously served as the Director of FDA Office of Orphan Drugs. OOC prepared and filed the ODD applications on behalf of the Company. FDA can take 90 to 120 days to respond to the ODD applications.

We believe that the potential relatively rapid regulatory path for NV-387 would be enabled by any of its indications that are eligible for "Orphan Drug" status in the USA. Generally speaking, an Orphan Drug is a drug for a disease that has less than 200,000 incidence rate annually, or for a specific bio-terrorism agent such as smallpox. Based on our animal model studies to date, we have identified three different treatment indications that are orphan drug indications for NV-387, namely: (i) NV-387 for the treatment of Measles, (ii) NV-387 for the treatment of MPox, and (iii) NV-387 for the treatment of smallpox. Orphan Drug Designation for these cases would enable several benefits.

Orphan drug benefits include frequent meetings with FDA for guidance, smaller clinical trials, a potential path for drug approval after a Phase II clinical trial that is performed under the US FDA, waivers of certain PDUFA fees payable to the US FDA, and certain R&D tax benefits, as well as a seven year exclusivity for marketing the drug for the licensed indication. These incentives, if they become available for further regulatory development of NV-387, would result in shorter time path and reduced financial requirements to gain regulatory approvals.

To this end, we are seeking "Orphan Drug Designation" for the above three diseases from the US FDA. The Company plans to take advantage of the increased FDA interactions for filing appropriate Pre-IND applications and IND applications with the US FDA.

Additionally, the annual drug product requirements for these orphan drugs, when approved, can be met by our existing cGMP manufacturing facilities at our main campus in Connecticut. This would enable rapid revenue generation, to the tune of several hundreds of millions of dollars a year, and would make the Company financially self-sufficient.

We believe that our MPox Phase II clinical trial in Democratic Republic of Congo (DRC), if successful, will likely enable a Phase II/III registration clinical trial for NV-387 as a treatment for MPox under the US FDA auspices, which may provide the shortest possible timeline for NV-387 licensure.

Additionally, success of this MPox Phase II clinical trial is likely to enable US Government funding from an agency such as Biomedical Advanced Research and Development Agency (BARDA) or the National Institutes of Health (NIH) for further development of the drug NV-387 as a treatment for the bioterrorism agent smallpox which is a closely related virus. Current FDA guidance for Smallpox drug development is based on the "Animal Rule" and does not require human clinical trials (which would be unethical and impossible to conduct), a licensure route that we believe NV-387 would be successful in, based on relevant animal model studies already conducted.

Such licensure, if obtained, could drive acquisition of the drug by the US government, worth hundreds of millions of dollars in revenues, and this could afford the fastest revenue path for the Company. As an example, Tecovirimat (TPOXX) acquisition contracts have been ranging at about \$150 million per year.



## [Table of Contents](#)

Measles has become an important emerging disease in the USA. While measles was declared eliminated in the USA in 2000, its resurgence has led to sustained transmission over the entire 2025 year with 2,230 cases, resulting in 11% hospitalizations, and 3 deaths, and it has continued unabated in the USA, with over 733 cases as of February 5, 2026, per CDC<sup>3</sup>. Effectively, US no longer has Measles elimination status<sup>4</sup>, and it has become an endemic disease in the USA. Measles vaccination rates have fallen in various geographic areas well below the 95% vaccination rate required for maintaining “herd immunity” or population immunity, keeping the virus from spreading. Vaccination rates with the Measles vaccine (usually given to children in 2 doses as a component of the triple MMR vaccine) are likely to continue to fall. Additionally, the Measles virus strain now in circulation is substantially different from the vaccine strain(s) that were derived from the 1968 era. While this old vaccine continues to be effective, its effectiveness may have started decreasing with breakthrough infection rates increasing, based on scientific literature<sup>5</sup>.

A single case of Measles leads to substantial disruption and economic losses. Measles typically affects school age or younger children, and a single case can lead to quarantining of a large portion of the school body and imposition of remote learning. We believe that if NV-387 is approved for Measles, quarantining can be avoided by treating the suspected contacts with small doses of the drug, and the spread can be eliminated by actually treating the patient with the drug, NV-387. We believe that our animal model studies in humanized mice have clearly demonstrated that NV-387 is a viable drug candidate for treatment as well as prophylaxis of Measles.

At present there is no approved drug for Measles.

We believe that non-dilutive funding for development of NV-387 as a drug is likely to become available from US Government agencies for smallpox as well as measles.

### *Phase II Clinical Trial of NV-387 as Treatment of MPox in the Democratic Republic of Congo (DRC), Africa*

We began working with the local regulatory agency in DRC, namely ACOREP, circa February 2025. After initial due diligence from them, the Ethics Committee of ACOREP agreed that NV-387 was worth evaluating as a treatment for MPox and gave us a go-ahead with a preliminary approval for a potential Phase II clinical trial in April, 2025. Since then we have been providing technical documents to ACOREP as parts of the clinical trial application, in what would be considered an informal “rolling review” of sorts. After all of the questions having been resolved, we received a final approval for starting a Phase II clinical trial from ACOREP at the end of October, 2025. This approval requires us to fulfill certain conditions and provide certain final documentation. We are currently working on completing these last set of requests (see below).

### *Phase II Clinical Trial of NV-387 as Treatment of Viral Acute and Severe-Acute Respiratory Infections (V-ARI and V-SARI) in India*

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). 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.

<sup>3</sup> [https://www.cdc.gov/measles/data-research/index.html#cdc\\_data\\_surveillance\\_section\\_10-measles-cases-in-2026](https://www.cdc.gov/measles/data-research/index.html#cdc_data_surveillance_section_10-measles-cases-in-2026).

<sup>4</sup> Technically, Measles elimination status of the USA continues until the 13 April 2026 meeting of Pan-American Health Organization (PAHO) which would then evaluate if the elimination status is effective. <https://apnews.com/article/us-measles-elimination-mexico-6f0bc8f7ef31d5ef82492e42ccb38e47>.

<sup>5</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC11209263/>.



## [Table of Contents](#)

### *US FDA Engagement and Regulatory Development Plan for NV-387*

Our objective is to bring the data from the clinical trials external to the USA and utilize it for further regulatory advancement of NV-387 against various indications under the US FDA. As discussed earlier, NV-387 has certain orphan disease as well as bioterrorism related indications. We believe some of these applications qualify for orphan drug designations. Therefore, we first plan to file the appropriate Orphan Drug Designations (ODD) for the following three treatments:

- NV-387 for the Treatment and Prophylaxis of MPox.
- NV-387 for the Treatment and Prophylaxis of Smallpox.
- NV-387 for the Treatment and Prophylaxis of Measles.

We believe that the ODD's will provide several benefits that would accelerate the NV-387 program towards regulatory licensure. These include frequent FDA meetings and rapid decision-making. Additionally, the economic benefits include certain tax credits for R&D costs, waiver of certain PDUFA fees, and a seven year exclusivity for marketing the drug for the licensed indication.

Assuming an ODD is granted, we plan on following up with further US FDA engagements by filing pre-IND applications:

- A Pre-IND for NV-387 for the Treatment and Prophylaxis of MPox.
- A Pre-IND for NV-387 for the Treatment and Prophylaxis of Smallpox.
- A Pre-IND for NV-387 for the Treatment and Prophylaxis of Measles.

We also plan to seek a Pediatric Investigation Plan ("PIP") Meeting with the US FDA at an appropriate time, particularly since Measles generally affects mostly children. RSV, another indication of NV-387, primarily affects neonates, infants and very young children. We plan on performing pediatric-use-related non-clinical studies in accordance with the FDA inputs.

We believe that the pre-IND Meeting for NV-387 for the Treatment and Prophylaxis of MPox will enable us to file an IND for a Phase II/III registrational clinical trial for licensure of the drug for MPox. We plan on leveraging the MPox Phase II clinical trial for this purpose.

We believe that the pre-IND Meeting for NV-387 for the Treatment and Prophylaxis of Smallpox will enable us to file an IND for a Phase II/III registrational clinical trial for licensure of the drug for Smallpox. We may be able to leverage the MPox Phase II clinical trial data as one of the model studies emulating smallpox infection.

At present there is no economic model or business case for development of a drug for Measles. We plan on engaging Measles drug development in full force if it is supported by non-dilutive grants and contracts funding. Measles may be eligible for a traditional tradeable Priority Review Voucher (PRV) issuance from the FDA. If so, the potential trade value of a PRV, currently at or above \$150 Million, would provide enticement for us to develop NV-387 for Measles.

We believe that the planned Phase II Viral ARI/SARI Clinical Trial will provide us with substantial actionable data on the safety and effectiveness of NV-387 in treating at least Influenza, RSV, COVID, and provide further information in the utility of NV-387 against many other respiratory viruses including hMPV, Enteroviruses, Adenoviruses, Rhinoviruses, etc.

We plan on being able to initiate an IND under the US FDA for use of NV-387 as the treatment of RSV in pediatric patients, based on the Phase II datasets.

### *NV-HHV-1 and the HerpeCide™ Program*

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 MPox, Measles, ARI/SARI, RSV, and possibly for multiple other indications, including Influenzas.



## [Table of Contents](#)

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.

### *Intellectual Property*

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 (restarted), 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.

### 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.

## [Table of Contents](#)

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.

### 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.



## [Table of Contents](#)

### 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.

### Monkeypox and Smallpox Background

Monkeypox is an emerging disease that has become endemic to Central and Western Africa. Potential epidemics across the world can occur as the virus spills over via travel and then takes hold in other regions.

Monkeypox virus (MPXV) is freely communicable between humans but requires close contact. MPXV is in the same type of viruses as the Smallpox virus (Variola) and the corresponding vaccine virus (Vaccinia). MPox disease caused by MPXV is far less severe and has a low case fatality rate compared to Smallpox (CFR MPXV Clade I ~9% to ~1.5%, Clade II <0.3%. CFR Variola ~30%).

MPox has led to two WHO declarations of Public Health Emergency of International Concern (PHEIC).

The first WHO PHEIC declaration was made in 2022 and lasted approximately one year. It was driven by the emergence of an epidemic of MPox Clade II in Western Africa and its further spread into European countries and then to the USA. MPox Clade II is now endemic in all of these regions.

The second WHO PHEIC declaration was made in August, 2024, and was closed in September, 2025, although the Africa CDC has continued the Public Health Emergency of Continental Security (PHECS) declaration of MPox because cases have continued and the outbreak has continued to spread into new regions and neighboring countries. This current outbreak is caused by MPox Clade Ia and Clade Ib. MPox Clade Ib in particular has substantially greater morbidity and higher case fatality rate (at about 1.5%) as compared to MPox Clade IIa or Clade IIb. Clade I also disproportionately affects children whereas Clade II remains primarily limited to adults, which is traceable to differences in the communicability of these two clades.

In the Western World, MPox Clade II has become endemic but has remained limited primarily to Men-having-Sex-with-Men (MSM) population, communicated by sexual contact. A smallpox vaccine called Jynneos was found to be effective in generating antibodies that protect against MPXV Clade II. CDC has recommended it in this MSM population as well as for immunocompromised persons with risky sexual behaviors and persons with HIV.

## [Table of Contents](#)

Recently three new MPox Clade I cases in unconnected persons were found in California that were not associated with travel to Africa, and community spread of MPox Clade I is suspected to be occurring in California, bringing the USA even closer to a potential epidemic from this MPox variant (<https://www.usatoday.com/story/news/health/2025/10/17/california-mpox-strain-cases/86748970007/>).

Thus, although the current threat level is low, MPox Clade I could result in becoming an endemic virus in the USA.

TPOXX (tecovirimat), a drug approved for Smallpox under the USA FDA Animal Rule, failed in clinical trials against MPox Clade II as well as MPox Clade I to show effectiveness more than the standard of care (NIH/NIAID Press Release, 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](http://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.

TEMBEXA (brincidofovir), another drug approved for Smallpox under the USA FDA Animal Rule, entered into a clinical trial called “MOSA” for MPox Clade I in DRC in January, 2025, under a multinational effort, and first cohort dosing began immediately. Initial results were expected around March 2025. There is no further public information regarding this trial, which may lead observant scientists to suspect that this treatment may have had results similar to what happened with the first three MPox patients that were treated with this drug under an Emergency Use Authorization in the UK. All three developed very high levels of hepatic enzymes leading to discontinuation of the drug, wherein at least one patient was described as “mild DILI (drug-induced-liver-injury)” in a Cochrane review<sup>1</sup>. The TEMBEXA prescribing information<sup>2</sup> has a “black box warning” that states that in an unrelated clinical trial this drug led to fatality rates greater than those in the control arm. Additionally, TEMBEXA is known to cause diarrhea, severe gastrointestinal adverse events, severe hepatic enzyme and bilirubin elevation adverse events, embryo-fetal toxicity, carcinogenicity, and may cause permanent male infertility. Further, medical monitoring is required upon dosing.

A physician must conclude that these listed adverse events exclude the use of the TEMBEXA drug to treat men and women of child-bearing age, pregnant women, developing infants and children (who are susceptible to liver injury), immuno-compromised patients, and other patients with co-morbidities that are at high risk of such adverse events. Additionally, it places the burden of medical monitoring, which is very difficult in epidemics. Clearly this drug is not suitable for mobilization in any bioterrorism event, or even in an epidemic scenario. Yet it has been procured in the US Strategic National Stockpile as a Smallpox treatment.

<sup>1</sup> Fox T, Gould S, Princy N, Rowland T, Lutje V, Kuehn R. “Therapeutics for treating mpox in humans.” Cochrane Database of Systematic Reviews 2023, Issue 3. CD015769. DOI:10.1002/14651858.CD015769.

<sup>2</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/214460s000,214461s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214460s000,214461s000lbl.pdf)

## [Table of Contents](#)

The above discussion clearly shows that the world needs a drug for Monkeypox (and for Smallpox) and currently available smallpox drugs have not met the challenge. We would like to raise the question here whether the drugs that did not succeed against a mild virus called Monkeypox would work against the very severe, high pathogenicity, high fatality virus, namely Smallpox, for which they have been licensed.

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.

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.

## [Table of Contents](#)

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 – Effective in Humanized Animal Model

Measles was eliminated in 2000 in the USA, the first country to do so, but has slowly re-emerged year over year. With over 1,680 confirmed cases in the USA in 2025 in continuing outbreaks, the USA is likely to lose its elimination status, and return to Measles becoming an endemic disease. In 2025 in the USA, 12% of Measles cases resulted in hospitalization, and 3 deaths have occurred as of November 4, 2025 (<https://www.cdc.gov/measles/data-research/index.html>).

Measles is endemic in the less developed world, but has become an increasingly emerging disease in last several years in the developed world as well. Even with an effective Measles vaccine, due to factors that include (i) increasing vaccine hesitancy, (ii) increasing rates of vaccine breakthrough possibly as the virus has drifted away from the 1968 vaccine strain, and (iii) increasing rates of population that do not fully benefit from vaccination because of issues with the individual's immune system, the USA has seen a resurgence of Measles year over year. Overall, in the Western World, Measles cases have been dramatically increasing in recent years, as seen in Canada, UK, and Europe<sup>3</sup>. Measles incidence rates are increasing worldwide.

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, and 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 required to be used in the entire population, unlike treatments that are used only in affected patients.

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

There is no antiviral drug approved for the treatment of Measles virus, an urgent and unmet medical need. 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. 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.

<sup>3</sup> The Measles vaccine, a live attenuated strain developed circa 1968, continues to be in use, even as the Measles virus itself has changed significantly. The vaccine was originally found to be 95% protective, which means 5% of the fully vaccinated persons could still get measles, called a “vaccine breakthrough” infection. At least 95% of the population needs to be vaccinated to confer “population immunity” or “herd immunity” which can be roughly defined as blocking person-to-person spread of the virus. This high percentage required is a result of the extremely contagious and persistent nature of the Measles virus. However, immune-compromised subjects do not benefit well from any vaccines. The percentage of such subjects that do not benefit fully from vaccination has been estimated at about 7-10% of the US population, and is rising due to chronic diseases, auto-immunity, inflammation, diabetes, obesity, as well as environmental factors that have led to increase in cancer rates in younger population in the USA. Analysis of post-elimination Measles cases in the USA have led to vaccine breakthrough rates estimated at 11-13% rather than the historically used value of 5% (J. Leung et al. Measles Cases in the US, 2001–2022 • CID 2025;80(3):663–72. <https://doi.org/10.1093/cid/ciae470>). 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. Thus, there is an urgent need for a Measles drug to treat persons that get sick.



## [Table of Contents](#)

A single case of Measles can lead to quarantine of an entire school, as well as isolation of associated adults. This causes broad-based disruption of educational activities. Vaccination campaign is the typical response upon finding a case. However, a vaccine takes at least two and up to four weeks for providing protective antibody response to the vaccinated person, during which time, the person continues to be at risk of the disease. And the sick one does not have an effective treatment.

Instead, if a drug becomes available, the sick person would be treated with the effective treatment. In addition, the contacts and persons at risk could be given the same drug albeit in smaller quantities as a prophylactic, which immediately provides protection against infection. There would be no need for school closures or excessive isolations once such a drug becomes available.

We believe NV-387 is such a drug that could be deployed both as a treatment and as a prophylactic for Measles, thereby taking away the social and educational disruption that Measles causes.

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

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.

## [Table of Contents](#)

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](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 of 60 and immune-compromised persons.

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.



## [Table of Contents](#)

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.

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.

[Table of Contents](#)

**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.

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%

[Table of Contents](#)

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.

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

**5. Measles:**

NV-387 was found to have direct antiviral effects against Measles virus in standard cell culture-based testing that measured increase in the extent of surviving infected cells upon treatment with the drug (i.e. “CPE” or Cytopathic Effects Assay).

Additionally, in a lethal Measles infection humanized animal model, NV-387 treatment led to a substantial increase in the number of survival days, to 17 days in NV-387-treated animals, from only 7.4 days in untreated animals, an increase of 130%, in a lethal lung infection of humanized mice by Measles virus.

Humanized mice were required for the animal model because Measles virus only infects humans, and specifically uses hSLAM as the cognate receptor for cell entry, while using the ubiquitous HSPG for congregation next to cells. The mice had human hSLAM (aka hCD150) gene knocked-in, and also had their interferon responses deleted (hSLAM+k.i., IfnAR-/- transgenic mice on C57BL/6 Background). NV-387 mimics the portions on HSPG that viruses bind to, including the Measles virus, and thereby is designed to attack and engulf the virus particle via lipid-lipid mixing and destroying the virus particle’s ability to infect cells.

## [Table of Contents](#)

The increased survival was correlated with several improvements in the animal health indicating control of viral infection:

- ✓ Slow disease progression, and mild to moderate levels of lung damage as observed in microscopic histopathology.
- ✓ Protection of lungs was also evident from the significant reduction in the level of lung plaques (damage to lung tissue) compared to untreated cases.
- ✓ Reduction in the level of lung-damaging lymphocytes and neutrophils attracted into the lungs (i.e. infiltration) was observed upon NV-387 treatment.

These observations indicated that NV-387 treatment led to beneficial effects that protected lungs as well as reduced overall systemic infection.

We have thus found that NV-387 has dual benefits of (i) directly reducing the virus itself, together with (ii) protecting systemic cellular damage, and in particular, protecting lungs from viral damage as well as self-inflicted damage from killer cells.

These benefits make NV-387 an unusual and highly desirable antiviral drug.

### Novel Orthogonal Nanoviricide Mechanism Has Many Benefits

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

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

Further, NV-387 also acts as a unique and novel drug delivery vehicle, similar in action to exosomes. Thus, encapsulation of remdesivir in NV-387 enabled oral delivery of NV-387 and the activity of the resulting drug, NV-387-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.



## [Table of Contents](#)

- (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.

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.

## [Table of Contents](#)

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.

### 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.



## [Table of Contents](#)

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.

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.



## [Table of Contents](#)

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

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

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

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

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

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

In fact, we have found in pre-clinical animal studies that 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.

## [Table of Contents](#)

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 December 31, 2025, we have focused on preparing regulatory documentation in accordance with the requirements for the Phase II MPox clinical trial of NV-387 in DRC under the regulatory agency ACOREP as requested by them. We have now submitted almost all of the documents constituting a clinical trial application, in a “rolling review”-like process to the DRC regulatory agency, ACOREP.

We completed manufacture of a pilot batch of the NV-387 oral gummies drug product (new formulation) and we have conducted required stability studies on the same.

We had previously completed manufacture of the NV-387 drug substance batch for the Phase II MPox clinical trial. As we engaged in this manufacturing batch, we have continued to increase the scale of manufacture of NV-387 in our cGMP-compliant facility, effectively doubling the prior batch size. We will commission additional batches as we engage into additional clinical trials.

Additionally, we have been engaged in efforts to obtain non-dilutive financings for the various applications of NV-387. This has resulted in a shift in our business plan towards tropical and rare diseases, emerging epidemics in the USA, and potential bioterrorism agents. We believe the new plan we have adopted is likely to result in regulatory licensure of NV-387 much more quickly than the regulatory pathway for a commercially important indication such as RSV or Influenza.

We are now executing substantially with an “Orphan First” focus, while continuing advancement of our non-orphan drug candidates along the way. Thus, we have focused on a Phase II clinical trial of MPox in DRC. Subsequently, we plan on regulatory advancement of NV-387 as a drug for the treatment of Measles. Along the way, we are also continuing to develop a Phase II clinical trial for the use of NV-387 as a treatment of acute respiratory viral infections.



## [Table of Contents](#)

### 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.

## [Table of Contents](#)

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.

#### Our Current Priorities – Measles, MPox, Smallpox, 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.

## [Table of Contents](#)

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.

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.

## [Table of Contents](#)

### **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.

### **Collaborations, Agreements and Contracts**

In November 2025 we engaged OnlyOrphansCote, LLC (OOC), under a Master Services Agreement to help us with strategy and execution of our orphan drug programs. Dr. Timothy Cote, Principal and Founder of OOC was previously Director of the US FDA Office of Orphan Drugs.



## [Table of Contents](#)

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.



[Table of Contents](#)

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

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

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

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

As of December 31, 2025, we had cash and cash equivalents of \$5,150,580, prepaid expenses of \$145,985 and net property and equipment of \$6,656,439. Accounts payable and accrued expenses were \$1,195,925, inclusive of accounts payables to related parties of \$929,232. Stockholders' equity was \$11,071,715 at December 31, 2025. In comparison, as of June 30, 2025, we had \$1,558,564 in cash and cash equivalents, prepaid expenses of \$112,146 and \$6,833,891 of net property and equipment. Our liabilities at June 30, 2025 were \$1,306,519 including accounts payable of \$459,094 payable to third parties and accounts payable to related parties of \$821,456.

During the six month period ended December 31, 2025, we used approximately \$3.6 million in cash toward operating activities. This was substantially less than the prior one year ago period 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 in the prior one year ago period.

During the six month period ended December 31, 2024, we used approximately \$4.8 million in cash toward operating activities.

Research and Development Costs

We do not maintain separate accounting line items for each project in development. We maintain aggregate expense records for all research and development conducted. Because at this time all of our projects share a common core material, we allocate expenses across all projects at each period-end for purposes of providing accounting basis for each project. Project costs are allocated based upon labor hours performed for each project. Far fewer man-hours are spent on the projects at low priority than the projects at high priority. In the reported quarter, we have focused 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 three and six month periods ended December 31, 2025 and 2024.

**Research and Development Expenses** – Research and development expenses for the three months ended December 31, 2025 decreased \$37,702 to \$1,118,649 from \$1,156,351 for the three months ended December 31, 2024. Research and development expenses for the six months ended December 31, 2025 decreased \$977,727 to \$2,111,715 from \$3,089,442 for the six months ended December 31, 2024. The decrease in research and development expenses for the three months ended December 31, 2025 is due to a decrease in outside lab fees and clinical trial costs. The decrease in

research and development expenses for the six months ended December 31, 2025 is due to a decrease in outside lab fees that were required for a Phase II Clinical Trial Application in 2024, and not required in 2025.

## [Table of Contents](#)

**General and Administration Expenses** – General and administrative expenses for the three months ended December 31, 2025 increased \$211,825 to \$1,114,525 from \$902,700 for the three months ended December 31, 2024. General and administrative expenses for the six months ended December 31, 2025 decreased \$219,299 to \$1,918,144 from \$2,137,443 for the six months ended December 31, 2024. The increase in general and administrative expenses for the three months ended December 31, 2025 is due to an increase in professional fees associated with investor outreach expense. The decrease in general and administrative expenses for the six months ended December 31, 2025 is due to a decrease in professional fees associated with investor outreach expense. From time to time the Company investor outreach strategies change, with occasional changes in expenditures.

**Interest Income** – Interest income for the three months ended December 31, 2025 decreased \$19,254 to \$12,455 from \$31,709 for the three months ended December 31, 2024. Interest income for the six months ended December 31, 2025 decreased \$48,650 to \$24,082 from \$72,732 for the six months ended December 31, 2024. The decrease in interest income for the three and six months ended December 31, 2025 is due to a lower interest bearing balance during the period and lower interest rates during the current three and six month period compared to the prior period.

**Interest Expense** – Interest expense decreased by \$149 to \$0 for the three months ended December 31, 2025 from \$149 for the three months ended December 31, 2024. Interest expense decreased by \$149 to \$0 for the six months ended December 31, 2025 from \$149 for the six months ended December 31, 2024.

**Net Loss** – For the three months ended December 31, 2025, the Company had a net loss of \$(2,220,719) or \$(0.11) per share compared to a net loss of \$(2,027,491) or \$(0.14) per share for the three months ended December 31, 2024. For the six months ended December 31, 2025, the Company had a net loss of \$(4,005,777) or \$(0.22) per share compared to a net loss of \$(5,154,302) or \$(0.36) per share for the six months ended December 31, 2024. The increase in the net loss for the three months ended December 31, 2025, and decrease in the net loss for the six months ended December 31, 2025 is generally attributable to the factors discussed above.

### **Liquidity and Capital Resources**

The Company's condensed financial statements have been prepared assuming that it will continue as a going concern, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the normal course of business. As reflected in the condensed financial statements, the Company has an accumulated deficit at December 31, 2025 of approximately \$152.8 million and a net loss of approximately \$4.0 million and net cash used in operating activities of approximately \$3.6 million for the six months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of December 31, 2025, the Company had available cash and cash equivalents of approximately \$5.2 million. The Company's liabilities at December 31, 2025 were approximately \$1.2 million. The Company raised approximately \$664,000, net of offering expenses, from ATM sales of our common stock during the current period from October 1, 2025 through December 31, 2025. Additionally, the Company successfully raised capital worth approximately \$5.4 million net of expenses in a Registered Direct Offering of common stock and a Private Placement of Series A 2-year and Series B 5.5 year common stock warrants, exercisable into common stock at \$1.75 and \$2.00, respectively, from a single investor. 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The ability of the Company to continue as a going concern is dependent upon controlling its overall expenses and identifying and securing additional financing.

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.

## [Table of Contents](#)

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 regulatory timelines for these three orphan diseases are likely to be substantially shorter than, say RSV, COVID, or Influenza drug development. This is because in the case of rare and orphan diseases, there are inherent limitations on the clinical trial recruitment due to the small number of available subjects, and the clinical protocols are designed to take this into account. Smaller number of subjects usually makes a clinical trial go faster, except in cases where the incidence rate of the disease cannot support the required recruitment level.

Additionally, 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 then plans to take advantage of the increased FDA interactions for filing appropriate Pre-IND applications and IND applications with the US FDA. We believe that the MPox Phase II if successful, will likely enable a Phase II/III licensure clinical trial under the US FDA auspices upon completion, which may provide the shortest possible timeline for NV-387 licensure.

Additionally, government funding for advanced regulatory development of NV-387 will be likely, especially for a new smallpox therapeutics.

Further, the regulatory timelines for these three orphan diseases are likely to be substantially shorter than, say RSV, COVID, or Influenza drug development. This is because in the case of rare and orphan diseases, there are inherent limitations on the clinical trial recruitment due to the small number of available subjects, and the clinical protocols are designed to take this into account. Smaller number of subjects usually makes a clinical trial go faster, except in cases where the incidence rate of the disease cannot support the required recruitment level.

The Company has planned a novel Phase II clinical trial for evaluating NV-387 as a first line, empiric therapy for any respiratory viral infection, in an adaptive, basket-style clinical trial design. We are in discussions to execute this clinical trial in India. In a single and relatively low cost clinical trial, we will be able generate substantial, statistically declarative information, regarding NV-387 as a treatment for (1) Influenza, (2) COVID, (3) RSV, (4) human MetaPneumovirus (hMPV), along with valuable information on effectiveness of NV-387 against many other respiratory infections including Adenoviruses, Enteroviruses, and others, depending upon the rates of incidence in the incoming patients. NV-387 can then progress towards licensure individually against RSV, Influenza, COVID, and other respiratory viruses under the US FDA and internationally.

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.

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, the Sales Agent.



## [Table of Contents](#)

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.

### ***Off Balance Sheet Arrangements***

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

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

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

### **ITEM 4. CONTROLS AND PROCEDURES**

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

As of December 31, 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 December 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 December 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 December 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 December 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.**

#### *Registered Direct Offering and Private Placement*

On November 10, 2025, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") pursuant to which the Company agreed to sell and issue to a single investor in a registered direct offering (the "Registered Direct Offering"): (i) 1,970,000 shares of common stock, par value \$0.00001 per share (the "Common Stock"), at an offering price of \$1.68 per share, and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,601,429 shares of Common Stock, at an offering price of \$1.67999 per Pre-Funded Warrant. Each Pre-Funded Warrant is exercisable for one share of Common Stock. The Pre-Funded Warrants have an exercise price of \$0.00001 per share, are immediately exercisable, and may be exercised at any time until exercised in full.

Also pursuant to the Securities Purchase Agreement, in a concurrent private placement offering (the "PIPE Offering," and collectively with the Registered Direct Offering, the "Offering"), the Company agreed to sell and issue to the Investor detachable Series A Common Stock Purchase Warrants (the "Series A Warrants") to purchase up to 3,571,429 shares of Common Stock and detachable Series B Common Stock Purchase Warrants (the "Series B Warrants,"), and collectively with the Series A Warrants (the "Common Warrants") to purchase up to 3,571,429 shares of Common Stock. The Series A Warrants will be exercisable beginning six months from the date of issuance at an exercise price of \$1.75 per share, and will expire two years from the date of issuance. The Series B Warrants will be exercisable beginning six months from the date of issuance at an exercise price of \$2.00 per share, and will expire five and one-half years from the date of issuance.

The Company generated gross proceeds of \$6,000,000 and net proceeds of \$5,403,981, from the Offering after deducting under writing discounts and commissions and other offering expenses. Additionally, on November 25, 2025 the Pre-Funded Warrants were exercised, the Company received \$16.01, the par value of the shares issued, and the Company issued 1,601,429 of the Company's \$0.00001 par value common shares.

On December 15, 2025, the Company filed a Prospectus registering the common shares underlying Series A and B Common Warrants. The filing of the Preliminary Prospectus enables the registered shares of common stock to be issued upon the exercise of the Common Warrants.

The exercise price of the Pre-Funded and Common Warrants are subject to adjustment in the case of customary events such as stock dividends or other distributions on shares of common stock or any other equity or equity equivalent securities payable in shares of common stock, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock, and also, subject to limitations, upon any distribution of assets, including cash, stock or other property to our stockholders.

#### *Stock-based Compensation*

On July 1, 2025 the Company and Dr. Anil Diwan entered into an extension of his employment agreement for a period of one year from July 1, 2025 through June 30, 2026 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

[Table of Contents](#)

September 30, 2025, December 31, 2025, March 31, 2026 and June 30, 2026 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$20,026 for the three months ended December 31, 2025. The balance of \$20,026 will be recognized as the remaining 5,102 shares vest and service is rendered for the remaining six months ended June 30, 2026.

For the three and six months ended December 31, 2025, the Company's Board of Directors authorized the issuance of 387 and 774, respectively of fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of \$1,570 and \$3,189, respectively for the three and six months ended December 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.

The Scientific Advisory Board was granted in August 2025 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$1.79 per share expiring in August 2029 and in November 2025 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$1.63 per share expiring in November 2029. The fair value of the warrants was \$123 for the three months ended December 31, 2025 and \$258 for the six months ended December 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 ranges:

Expected life (year)	4
Expected volatility	42.5 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.615 %

For the three and six months ended December 31, 2025, the Company's Board of Directors authorized the issuance of 19,255 and 136,463, 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 \$200,850, respectively, for the three and six months ended December 31, 2025, which is reflective of the fair value of the common stock on the dates of issuance.

For the three and six months ended December 31, 2025, the Company's Board of Directors authorized the issuance of 7,971 and 15,475, fully vested shares of its common stock with a restrictive legend for director services, respectively. The Company recorded an expense of \$11,250 and \$22,500 for the three and six months ended December 31, 2025, which is reflective of the fair value of the common stock on the dates of issuance.

**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.

[Table of Contents](#)

**ITEM 6. EXHIBITS**

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

**SIGNATURES**

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

**NANOVIRICIDES, INC.**

Dated: February 17, 2026

/s/ Anil R. Diwan

\_\_\_\_\_  
Name: Anil R. Diwan

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

Dated: February 17, 2026

/s/ Meeta Vyas

\_\_\_\_\_  
Name: Meeta Vyas

Title: Chief Financial Officer  
(Principal Financial Officer)