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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, 2022**

*Commission File Number: 001-36081*

**NANOVIRICIDES, INC.**

*(Exact name of Company as specified in its charter)*

NEVADA

76-0674577

(State or other jurisdiction)  
of incorporation or organization)

(IRS Employer Identification No.)

**1 Controls Drive**

**Shelton, Connecticut 06484**

(Address of principal executive offices and zip code)

(203) 937-6137

*(Company's telephone number, including area code)*

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

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

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

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

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

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

Yes  No

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

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

As of February 14, 2023, there were approximately 11,635,000 shares of common stock of the registrant issued and outstanding.

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FORM 10-Q  
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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NanoViricides, Inc.  
Condensed Balance Sheets**

	<u>December 31, 2022</u> (Unaudited)	<u>June 30, 2022</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 11,448,346	\$ 14,066,359
Prepaid expenses	104,545	350,021
Total current assets	<u>11,552,891</u>	<u>14,416,380</u>
Property and equipment, net	8,417,849	8,694,194
Trademark and patents, net	337,713	341,848
<b>OTHER ASSETS</b>		
Service agreements	26,510	38,925
Security deposits	—	3,515
Other assets	<u>26,510</u>	<u>42,440</u>
Total assets	<u>\$ 20,334,963</u>	<u>\$ 23,494,862</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 39,291	\$ 57,960
Accounts payable – related party	373,424	214,397
Loan payable	—	94,788
Accrued expenses	<u>51,877</u>	<u>45,692</u>
Total current liabilities	<u>464,592</u>	<u>412,837</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Series A convertible preferred stock, \$0.001 par value, 10,000,000 shares designated, 495,560 and 484,582 shares issued and outstanding, at December 31, 2022 and June 30, 2022, respectively	495	485
Common stock, \$0.001 par value; 150,000,000 shares authorized, 11,634,576 and 11,592,173 shares issued and outstanding, at December 31, 2022 and June 30, 2022, respectively	11,634	11,592
Additional paid-in capital	145,666,194	145,562,124
Accumulated deficit	<u>(125,807,952)</u>	<u>(122,492,176)</u>
Total stockholders' equity	<u>19,870,371</u>	<u>23,082,025</u>
Total liabilities and stockholders' equity	<u>\$ 20,334,963</u>	<u>\$ 23,494,862</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>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
OPERATING EXPENSES				
Research and development	\$ 1,170,710	\$ 1,261,308	\$ 2,283,369	\$ 3,358,228
General and administrative	663,284	659,268	1,172,985	1,174,713
	<u>1,833,994</u>	<u>1,920,576</u>	<u>3,456,354</u>	<u>4,532,941</u>
LOSS FROM OPERATIONS	(1,833,994)	(1,920,576)	(3,456,354)	(4,532,941)
OTHER INCOME (EXPENSE)				
Interest income	88,954	2,073	141,516	3,127
Interest expense	(94)	(2,631)	(938)	(4,388)
	<u>88,860</u>	<u>(558)</u>	<u>140,578</u>	<u>(1,261)</u>
LOSS BEFORE INCOME TAX PROVISION	(1,745,134)	(1,921,134)	(3,315,776)	(4,534,202)
INCOME TAX PROVISION	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
NET LOSS	<u>\$ (1,745,134)</u>	<u>\$ (1,921,134)</u>	<u>\$ (3,315,776)</u>	<u>\$ (4,534,202)</u>
Net loss per common share- basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.17)</u>	<u>\$ (0.29)</u>	<u>\$ (0.39)</u>
Weighted average common shares outstanding- basic and diluted	<u>11,610,303</u>	<u>11,525,304</u>	<u>11,601,335</u>	<u>11,520,291</u>

*See accompanying notes to the condensed financial statements*

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

	Series A Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2022	484,582	\$ 485	11,592,173	\$ 11,592	\$ 145,562,124	\$ (122,492,176)	\$ 23,082,025
Series A preferred stock issued for employee stock compensation	10,591	10	—	—	13,854	—	13,864
Common stock issued for consulting and legal services rendered	—	—	12,710	13	26,987	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	480	—	480
Common stock issued for Directors fees	—	—	5,154	5	11,245	—	11,250
Net loss	—	—	—	—	—	(1,570,642)	(1,570,642)
Balance, September 30, 2022	495,173	\$ 495	11,610,037	\$ 11,610	\$ 145,614,690	\$ (124,062,818)	\$ 21,563,977
Series A preferred stock issued for employee stock compensation	387	—	—	—	13,055	—	13,055
Common stock issued for consulting and legal services rendered	—	—	17,366	17	26,983	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	223	—	223
Common stock issued for Directors fees	—	—	7,173	7	11,243	—	11,250
Net loss	—	—	—	—	—	(1,745,134)	(1,745,134)
Balance, December 31, 2022	<u>495,560</u>	<u>\$ 495</u>	<u>11,634,576</u>	<u>\$ 11,634</u>	<u>\$ 145,666,194</u>	<u>\$ (125,807,952)</u>	<u>\$ 19,870,371</u>

**NanoViricides, Inc.**  
**Condensed Statement of Changes in Stockholders' Equity**  
**For the six months ended December 31, 2021**  
**(Unaudited)**

	Series A Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2021	371,490	\$ 372	11,515,170	\$ 11,515	\$ 144,284,593	\$ (114,385,313)	\$ 29,911,167
Series A preferred stock issued for employee stock compensation	10,591	10	—	—	32,880	—	32,890
Series A preferred stock issued for license agreement	100,000	100	—	—	934,988	—	935,088
Common stock issued for consulting and legal services rendered	—	—	6,509	6	26,994	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	1,352	—	1,352
Common stock issued for Directors fees	—	—	3,524	4	14,996	—	15,000
Net loss	—	—	—	—	—	(2,613,068)	(2,613,068)
Balance, September 30, 2021	482,081	\$ 482	11,525,203	\$ 11,525	\$ 145,295,803	\$ (116,998,381)	\$ 28,309,429
Series A preferred stock issued for employee stock compensation	387	—	—	—	33,367	—	33,367
Common stock issued for consulting and legal services rendered	—	—	5,993	6	26,994	—	27,000
Warrants issued to Scientific Advisory Board	—	—	—	—	1,644	—	1,644
Common stock issued for Directors fees	—	—	3,288	3	14,997	—	15,000
Net loss	—	—	—	—	—	(1,921,134)	(1,921,134)
Balance, December 31, 2021	<u>482,468</u>	<u>\$ 482</u>	<u>11,534,484</u>	<u>\$ 11,534</u>	<u>\$ 145,372,805</u>	<u>\$ (118,919,515)</u>	<u>\$ 26,465,306</u>

*See accompanying notes to the condensed financial statements*

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

	<u>For the Six Months Ended</u>	
	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (3,315,776)	\$ (4,534,202)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	26,919	66,257
Preferred shares issued pursuant to license agreement	—	935,088
Common shares issued as compensation and for services	76,500	84,000
Warrants granted to Scientific Advisory Board	703	2,996
Depreciation	366,190	349,675
Amortization	4,135	4,135
Changes in operating assets and liabilities:		
Prepaid expenses	245,476	165,198
Other assets	15,930	—
Accounts payable	(18,669)	(46,836)
Accounts payable - related party	159,027	135,409
Accrued expenses	6,185	(128)
NET CASH USED IN OPERATING ACTIVITIES	<u>(2,433,380)</u>	<u>(2,838,408)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	<u>(89,845)</u>	<u>(209,663)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of loan payable	(94,788)	(95,306)
Deferred financing costs	—	(37,408)
NET CASH (USED IN) FINANCING ACTIVITIES	<u>(94,788)</u>	<u>(132,714)</u>
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,618,013)	(3,180,785)
Cash and cash equivalents at beginning of period	14,066,359	20,516,677
Cash and cash equivalents at end of period	<u>\$ 11,448,346</u>	<u>\$ 17,335,892</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	\$ 938	\$ 943

*See accompanying notes to the condensed financial statements*

**NANOVIRICIDES, INC.**  
**December 31, 2022**  
**NOTES TO THE CONDENSED FINANCIAL STATEMENTS**  
**(Unaudited)**

**Note 1 – Organization and Nature of Business**

NanoViricides, Inc. (the “Company”) is a nano-biopharmaceutical research and development company specializing in the discovery, development, and commercialization of drugs to combat viral infections using its unique and novel nanomedicines technology. NanoViricides possesses its own state of the art facility that supports research and development and drug discovery, drug candidate optimization, cGMP-compliant drug substance manufacturing, cGMP-compliant manufacturing and packaging of drug products for human clinical trials, and early commercialization.

The Company has several drugs in various stages of development. The Company has a lead clinical candidate NV-CoV-2 for the treatment of SARS-CoV-2 infection (COVID-19) that has shown effectiveness and safety in pre-clinical studies. NV-CoV-2 mechanism of action is orthogonal and complementary to that of the existing therapeutics, enabling combination therapy with the existing drugs in the market.

The Company has also initiated additional drug programs for the treatment of Monkeypox (MPOX) virus infection and for the treatment of Enterovirus D68 (EV-D68) pediatric infection, that leverage the development of the clinical stage NV-387 active pharmaceutical ingredient contained in the drug product NV-CoV-2.

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

The Company’s drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. (“TheraCour”), to which the Company has broad, exclusive licenses. The licenses are to entire fields and not to specific compounds. In all, the Company has exclusive, worldwide licenses for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Virus (HSV-1 and HSV-2), Influenza and Asian Bird Flu Virus, Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis virus, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes (restated), VZV infections, and SARS-CoV-2 infections. In all cases, the discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour, a related party substantially owned by Dr. Anil Diwan, under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour. Milestone payments were made or are specified in certain of the license agreements, details of which have been disclosed at the time the agreements were entered into.

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

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### **Note 2 - Liquidity**

The Company's condensed financial statements have been prepared assuming that it will continue as a going concern, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the normal course of business. As reflected in the condensed financial statements, the Company has an accumulated deficit at December 31, 2022 of approximately \$126 million and a net loss of approximately \$3.3 million and net cash used in operating activities of approximately \$2.4 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, 2022, the Company had available cash and cash equivalents of approximately \$11.4 million.

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

On July 31, 2020, the Company entered into an At The Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc. and Kingswood Capital Markets, a division of Benchmark Investments, Inc. (each a "Sales Agent" and collectively, the "Sales Agents"), pursuant to which the Company may offer and sell, from time to time, through or to the Sales Agents, shares of common stock (the "Placement Shares"), having an aggregate offering price of up to \$50 million (the "ATM Offering"). Subject to the Company meeting certain requirements and market conditions, the Company could offer additional shares for sale under the ATM Sales Agreement. Sales of any placement shares will be made only upon instructions by the Company to the Sales Agents, and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. Actual sales will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Company's common stock, capital needs and determinations by the Company of the appropriate sources of funding for the Company. The Company is not obligated to make any sales of common stock under the Sales Agreement and the Company cannot provide any assurances that it will issue any shares pursuant to the Sales Agreement. To date the Company has sold 814,242 shares for approximately \$6.4 million under the ATM Sales Agreement none of which were sold during the six months ended December 31, 2022. Subject to the Company meeting certain requirements and market conditions, the Company could offer additional shares for sale under the ATM Sales Agreement.

The Company believes that it has several important milestones, including Phase 1 clinical trials for the Company's broad-spectrum, pan-coronavirus drug NV-CoV-2, that should occur in the ensuing year. Management believes that as it achieves these milestones, the Company's ability to raise additional funds in the public markets would be enhanced.

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

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

*Basis of Presentation – Interim Financial Information*

The accompanying unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission for Interim Reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete condensed financial statements. The unaudited interim condensed financial statements furnished reflect all adjustments (consisting of normal recurring accruals) that are, in the opinion of management, considered necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. The accompanying condensed financial statements and the information included under the heading “Management’s Discussion and Analysis or Plan of Operation” should be read in conjunction with the Company’s audited financial statements and related notes included in the Company’s Form 10-K for the fiscal year ended June 30, 2022 filed with the SEC on October 13, 2022.

The June 30, 2022 year-end balance sheet data in the accompanying interim condensed financial statements was derived from the audited financial statements.

For a summary of significant accounting policies, see the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2022 filed on October 13, 2022.

*Net Loss per Common Share*

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

The following table shows the number of potentially outstanding 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 <u>December 31, 2022</u></b>	<b>For the Three Months Ended <u>December 31, 2021</u></b>	<b>For the Six Months Ended <u>December 31, 2022</u></b>	<b>For the Six Months Ended <u>December 31, 2021</u></b>
<b>Warrants</b>	<u>8,820</u>	<u>9,146</u>	<u>8,576</u>	<u>9,146</u>

The Company has 495,560 shares of Series A preferred stock outstanding as of December 31, 2022. Only in the event of a “change of control” of the Company is each Series A preferred share is convertible to 3.5 shares of its new common stock. A “change of control” is defined as an event in which the Company’s shareholders become 60% or less owners of a new entity as a result of a change of ownership, merger or acquisition of the Company or the Company’s intellectual property. In the absence of a change of control event, the Series A preferred stock is not convertible into common stock, and does not carry any dividend rights or any other financial effects. At December 31, 2022, the number of potentially dilutive shares of the Company’s common stock into which these Series A preferred shares can be converted into is 1,734,460, and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

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**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 R. Diwan	Chairman, President, CEO, significant stockholder and Director
TheraCour Pharma, Inc. (“TheraCour”)	An entity owned and controlled by Dr. Anil R. Diwan

	<u>For the three months ended</u>	<u>For the six months ended</u>	<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>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>

Property and Equipment

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

\$	3,493	\$	61,563	\$	29,369	\$	80,717
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<u>As of</u>	
<u>December 31,</u>	<u>June 30,</u>
<u>2022</u>	<u>2022</u>

Account Payable – Related Party

Pursuant to an Exclusive License Agreement with TheraCour, the Company was granted exclusive licenses for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. On November 1, 2019, the Company entered into the VZV Licensing Agreement with TheraCour. In consideration for obtaining these exclusive licenses, the Company agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of certain direct costs as a development fee and such development fees shall be due and payable in periodic installments as billed, (2) the Company will pay \$2,000 or actual costs each month, whichever is higher for other general and administrative expenses incurred by TheraCour on the Company’s behalf, (3) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour and; (4) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. Accounts payable due TheraCour at December 31, 2022 and June 30, 2022 were \$838,424 and \$679,397, respectively, which were each offset by a two month advance of \$465,000.

\$	373,424	\$	214,397
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	<u>For the three months ended</u>	<u>For the six months ended</u>	<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>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>

Research and Development Costs Related Party

Development fees and other costs charged by to TheraCour pursuant to the license agreements between TheraCour and the Company for the development of the Company’s drug pipeline. No royalties are due TheraCour from the Company at December 31, 2022 and June 30, 2022

\$	633,247	\$	616,871	\$	1,245,958	\$	1,166,904
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*License Milestone Fee – Related Party*

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

**Note 5 - Property and Equipment**

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

	<u>December 31, 2022</u>	<u>June 30, 2022</u>
GMP Facility	\$ 8,168,045	\$ 8,149,416
Land	260,000	260,000
Office Equipment	57,781	57,781
Furniture and Fixtures	5,607	5,607
Lab Equipment	<u>6,256,426</u>	<u>6,185,210</u>
Total Property and Equipment	14,747,859	14,658,014
Less Accumulated Depreciation	<u>(6,330,010)</u>	<u>(5,963,820)</u>
Property and Equipment, Net	<u>\$ 8,417,849</u>	<u>\$ 8,694,194</u>

Depreciation expense for the three months ended December 31, 2022 and 2021 was \$184,855 and \$175,318, respectively, and for the six months ended December 31, 2022 and 2021 was \$366,190 and \$349,675, respectively.

**Note 6 - Trademark and Patents**

Trademark and patents, stated at cost, less accumulated amortization consisted of the following:

	<u>December 31, 2022</u>	<u>June 30, 2022</u>
Trademarks and Patents	\$ 458,954	\$ 458,954
Less Accumulated Amortization	<u>(121,241)</u>	<u>(117,106)</u>
Trademarks and Patents, Net	<u>\$ 337,713</u>	<u>\$ 341,848</u>

Amortization expense amounted to \$2,067 and \$2,067 for the three months ended December 31, 2022 and 2021, respectively, and for the six months ended December 31, 2022 and 2021 were \$4,135 and \$4,135, respectively.

**Note 7 – Loan Payable**

The Company financed its Directors and Officers liability insurance policies through BankDirect for the periods January 1, 2022 to December 31, 2022 and January 1, 2021 to December 31, 2021. The original loan balances as of January 1, 2022 and January 1, 2021 were \$234,198 and \$235,476, respectively, payable at the rate of \$23,932 and \$24,062 monthly including interest at an annual rate of 4.74% and 4.74%, respectively, through October of each year. At December 31, 2022 and June 30, 2022, the loan balance was \$0 and \$94,788, respectively. For the three and six months ended December 31, 2022, the Company incurred interest expense of \$94 and \$938, respectively. For the three and six months ended December 31, 2021, the Company incurred interest expense of \$95 and \$943, respectively.



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**Note 8 - Equity Transactions**

On September 14, 2022 the Company's Board of Directors approved the employment extension of Dr. Anil Diwan, President and Chairman of the Board. On October 6, 2022, the Company and Dr. Anil Diwan executed an extension of his employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares shall be vested in quarterly installments of 2,551 shares on September 30, 2022, December 31, 2022, March 31, 2023 and June 30, 2023 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$10,930 and \$21,860 for the three and six months ended December 31, 2022, respectively. The balance of \$21,861 will be recognized as the remaining 5,102 shares vest and service is rendered for the six months ended June 30, 2023.

For the three and six months ended December 31, 2022, 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 \$2,125 and \$5,059, respectively for the three and six months ended December 31, 2022 related to these issuances.

There is currently no market for the shares of Series A preferred stock and they can only be converted into shares of common stock upon a change of control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Series A preferred stock granted to various employees and others on the date of grant. The conversion of the shares is triggered by a change of control. The fair value of the Series A Convertible preferred stock at each issuance was estimated based upon the price of the Company's common stock after an application for a reasonable discount for lack of marketability.

The Scientific Advisory Board was granted in August 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$3.40 per share expiring in August 2026 and in November 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$2.09 per share expiring in November 2026. The fair value of the warrants was \$223 for the three months ended December 31, 2022 and \$703 for the six months ended December 31, 2022 and was recorded as consulting expense.

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

Expected life (year)	4
Expected volatility	60.09-85.12 %
Expected annual rate of quarterly dividends	0.00 %
Risk-free rate(s)	3.025-4.027 %

For the three and six months ended December 31, 2022, the Company's Board of Directors authorized the issuance of 17,366 and 30,076, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of \$27,000 and \$54,000, respectively, for the three and six months ended December 31, 2022, 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, 2022, the Company's Board of Directors authorized the issuance of 7,173 and 12,327, 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, 2022, which is reflective of the fair value of the common stock on the dates of issuance.



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**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, 2022	9,146	\$ 6.06	2.00	\$ 238
Granted	572	2.75	3.75	—
Expired	(1,142)	8.22	—	—
Outstanding and exercisable at December 31, 2022	<u>8,576</u>	<u>\$ 5.56</u>	<u>1.88</u>	<u>\$ —</u>

Of the outstanding warrants at December 31, 2022 1,142 expire in fiscal year ending June 30, 2023, 2,287 expire in fiscal year ending June 30, 2024, 2,287 warrants expire in the fiscal year ending June 30, 2025, 2,288 warrants expire in the fiscal year ending June 30, 2026, and 572 warrants expire in the fiscal year ending June 30, 2027.

**Note 10 - Commitments and Contingencies**

Legal Proceedings

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

Employment Agreements

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

License Agreements

The Company is dependent upon its license agreements with TheraCour (See Notes 1 and 4). If the Company lost the right to utilize any of the proprietary information that is the subject of the TheraCour license agreement on which it depends, the Company will incur substantial delays and costs in development of its drug candidates. On November 1, 2019, the Company entered into a VZV License Agreement with TheraCour for an exclusive license for the Company to use, promote, offer for sale, import, export, sell and distribute products for the treatment of VZV derived indications. Process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed.

On September 9, 2021, the Company entered into a COVID-19 License Agreement to use, promote, offer for sale, import, export, sell and distribute drugs that treat COVID-19 infections, using TheraCour's proprietary as well as patented technology and intellectual property. The discovery of ligands and polymer materials as well as formulations, the chemistry and chemical characterization, as well as process development and related work will be performed by TheraCour under the same compensation terms as prior agreements between the parties, with no duplication of costs allowed.



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

The following discussion should be read in conjunction with the information contained in the condensed financial statements of the Company and the notes thereto appearing elsewhere herein and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in the Company's Annual Report on Form 10-K for the year ended June 30, 2022. Readers should carefully review the risk factors disclosed in this Form 10-Q, Form 10-K and other documents filed by the Company with the SEC.

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

#### **PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

#### **Organization and Nature of Business**

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

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

We are a development stage company with several drugs in various stages of pre-clinical development, including IND-filing stage and late stage IND-enabling non-clinical studies. We have no customers, products or revenues to date, and may never achieve revenues or profitable operations.

We have several drugs in our pipeline. Of these, two drugs developed to combat the COVID-19 pandemics, namely NV-CoV-2 and NV-CoV-2-R, are our most advanced drug candidates. We believe that the essential preclinical work including GLP Safety/Toxicology studies has been completed for taking NV-CoV-2 into human clinical trials evaluation. We are working diligently towards the goal of filing an Investigational New Drug Application (IND) for NV-CoV-2 as soon as possible. We are also working towards the goal of starting clinical trials outside of the USA for this drug. We believe that once Phase I clinical trials of NV-CoV-2 are successful, both NV-CoV-2 and NV-CoV-2-R can enter Phase II and further clinical studies. We have successfully made oral formulations of NV-CoV-2 as both (i) NV-CoV-2 Oral "Gummies" and (ii) NV-CoV-2 Oral Syrup. In addition, we have developed the injectable formulation, (iii) NV-CoV-2 for Injection, Infusion or Inhalation. The other drug, NV-CoV-2-R comprises NV-CoV-2

with remdesivir encapsulated in the belly of the polymeric micelles. The clinical program is expected to start with evaluation of the NV-CoV-2 Oral Syrup and NV-CoV-2 Gummies in adults, with extension to pediatric populations upon success. Clinical trials of the

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Injectable Formulation of NV-CoV-2 are expected to follow thereafter. We will report on these objectives via press releases as meaningful advancements take place.

After developing viable drug candidates against COVID-19 in 2020 in a matter of a few months, the Company focused substantially on the COVID-19 drug development, resulting in two drug candidates that are shown to be extremely effective in pre-clinical studies compared to the currently most effective drug, remdesivir, namely NV-CoV-2 and NV-CoV-2-R. Both of these drug candidates have demonstrated pan-coronavirus, broad-spectrum effectiveness. This broad-spectrum effectiveness implies that SARS-CoV-2 variants that are continuously generated in the field are quite unlikely to escape either of these two drug candidates.

In contrast, we note that all of the existing antibodies and cocktails with emergency use approvals, including Evusheld, have lost effectiveness against the current SARS-CoV-2 Omicron variants. Paxlovid has been found to be effective only in adults over 65 years of age with co-morbidities, and its composition further limits its usefulness. Molnupiravir is a known mutagen and its use is not recommended or severely restricted by international health authorities. Remdesivir is the only FDA approved drug for treating COVID-19. It is only approved for hospitalized patients and requires long, daily infusions, and it has shown only marginal improvements, with reduction in hospital stay of a few days. Its effectiveness is limited by its metabolism. We developed NV-CoV-2-R to successfully improve the PK/PD (pharmacokinetics and pharmacodynamics) of remdesivir, thereby developing a highly active drug that is a potential cure, we believe. Additionally existing vaccines including the newest “bivalent” vaccines are now known to be only marginally effective, although they are still expected to reduce potential COVID-19 hospitalizations and deaths in the current winter wave that is known to entail multiple Omicron variants that have already escaped existing antibodies and vaccines.

The pandemic has changed in character from each distinct wave being of a single dominant variant to nearly continuous disease prevalence with multiple circulating variants at the same time. The variants have become progressively more communicable and contagious in time. Although the observed severity of the disease has decreased due to multiple factors including the built up population immunity from prior exposure to the virus variants and vaccinations, SARS-CoV-2 continues to be an important health threat especially because of the incidence of “long COVID”, the syndrome in which nasal swabs do not indicate virus presence but the patients continues to have various disease manifestations. A large percentage of long COVID cases are now known to have circulating SARS-CoV-2 virus present in small quantities. There is no therapeutic available for treating even these long COVID cases with manifest virus presence.

Thus the world is woefully unprepared for a new SARS-CoV-2 wave and forever-arising new variants, except for the fact that natural immunity and prior vaccine-boosted immunity may afford some protection. The therapeutics and preventative tools available today are generally known to be inadequate, as summarized above. As the populations get “used to” living with the virus, the societal tools of masking, social distancing, and clean hygiene are also falling off due to the encumbrances they pose. The extremely high infectiveness, of the current Omicron variants implies that even these societal tools would have limited effect unlike with the earlier alpha and delta waves of SARS-CoV-2 wherein lockdowns may have averted substantial spread and thus morbidity and mortality.

The need for the broad-spectrum nanoviricide SARS-CoV-2 drug NV-CoV-2 cannot be overstated in the current circumstances and the present status of the pandemic. As new variants emerge, it is now well established that the efficacy of original vaccines continues to drop, and that the resistance to antibodies from these vaccines as well as antibody drugs continues to rise.

Thus there is an urgent need for rapid development of broad-spectrum, pan-coronavirus drugs such as NV-CoV-2 and NV-CoV-2-R, and the Company diligently continues to do the best it can with the limited resources at its disposal to meet this challenge in an expeditious manner. President Biden’s recent statement to end the pandemic emergency declaration on May 11, 2023 does not take away these realities and in cognizance of these, the US FDA has stated that the Emergency Use Approval protocol will continue past this deadline.

NanoViricides is one of a few biopharma companies that has its own cGMP-compliant manufacturing facility. We are manufacturing the clinical supply of drug substances as well as the oral drug products for NV-CoV-2 at our own facility, simplifying and expediting the cGMP-compliant manufacturing operations. We have the capability to produce sufficient drugs for about 1,000 patients in a single batch of production, depending upon dosage. This production capacity is anticipated to be sufficient for Phase I, Phase II and Phase III human clinical trials for our anti-coronavirus

drugs in development, as well as for the anticipated clinical trials of NV-HHV-1 skin cream for the treatment of shingles.

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We believe that our platform technology enables development of drugs that viruses would not escape from. In fact, we have successfully screened our COVID-19 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.

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, and (b) simultaneously block the reproduction of the virus that has already gone inside a cell. Together, this strategy of a two-pronged attack against the virus, both inside the cell and outside the cell, exemplified by NV-CoV-2-R, can be expected to result in a cure for coronaviruses and other viruses that do not become latent.

This total attack on the whole 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 shown that encapsulation of remdesivir in NV-CoV-2 protects remdesivir from bodily metabolism in animal studies. This allows higher concentrations of remdesivir to be reached and simultaneously extends the effectiveness time period in comparison to the standard Veklury(R) (Gilead) formulation. The resulting drug, NV-CoV-2-R has not only significantly improved characteristics for its remdesivir component, but additionally provides the novel re-infection blocking mechanism of NV-CoV-2.

The Company's 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. It appears that the later variants of SARS-CoV-2 may have evolved to bind to the human cellular receptor ACE2 more strongly, in general, based on published datasets. Thus, if these features of the cellular receptor are appropriately copied, the resulting nanoviricide drug would remain effective against current and future variants of the virus.

Our current drug candidates to combat the COVID-19 pandemic are designed to attack not only SARS-CoV-2 and its current and future variants, but also many other coronaviruses, and will be useful even after the pandemic is over, since several coronaviruses are endemic in human populations. SARS-CoV-2 with its variants and substantial penetration into human populations worldwide is on course to become an endemic virus, if it is not endemic already.

Since completing the IND-enabling safety/toxicology studies, the Company has successfully developed orally active formulations of our drug candidates, in an oral syrup form, as well as an oral gummies ("Chewable Gel") form. We believe that for mild to moderate cases, for pediatric, and older patients, the oral syrup and gummies forms would be highly advantageous over tablets, capsules, injections, infusions, or lung inhalations. The injectable formulation is expected to be valuable in the treatment of severe cases. Further, this formulation is designed to be deliverable as an aerosol by a simple hand-held device directly into lungs. Such inhalation, as an aerosol is expected to provide greater benefits to more severe patients by providing high concentration of the drug locally in the lungs where the SARS-CoV-2 viruses cause the most damage. We are working with advice from a clinical research organization and external consultants and collaborators on developing the initial human clinical studies plan and application documents. Simultaneously, we are working on putting the various agreements together as necessary. A clinical trial application for evaluation of oral administration of NV-CoV-2, as well as most of the associated agreements have been completed for one of our initiatives outside the USA. We expect to announce the resulting collaborations once the formal steps are completed.

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

We are developing a broad-spectrum antiviral drug candidate, NV-CoV-2, where the potential for escape of virus variants is minimized by the very design of the drug for the treatment of COVID-19 infected sick persons. In contrast, vaccines are not treatments for sick persons, and must be administered to healthy individuals, and further require several weeks for the recipient's immune system to become capable of protecting against the target virus strain.

Variants have readily developed that are capable of infecting vaccinated persons although it is believed that vaccinated persons have a low risk of death from COVID-19 compared to unvaccinated persons.

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

We have been executing rapidly and efficiently, as well as in a cost-effective and productive manner, towards the goal of advancing the first drug candidate into human clinical trials as soon as possible. We believe that taking our first drug candidate into initial human clinical trials will be a very important milestone in that it would essentially validate our entire platform technology as being capable of producing drug candidates worthy of human clinical trials, and potentially of success in those clinical trials.

### **Recent Developments**

During the three months ended December 31, 2022, we have been compiling and performing medical writings needed for developing an IND application to the US FDA for human clinical trials of NV-CoV-2 in COVID-19 patients. We have also been compiling and performing medical writings that would be needed for international applications for clinical trials under the ICH and regulatory guidelines of certain countries. As a result, a clinical trial application for evaluation of oral administration of NV-CoV-2, as well as most of the associated agreements have been completed for one of our initiatives outside the USA. We expect to announce the resulting collaborations once the formal steps are completed. Additionally, we have scaled up the processes for the cGMP-compliant manufacture of the active ingredient (“drug substance”) NV-387 that goes into NV-CoV-2 drug product formulations to approximately 5 Kg final production scale. We have also performed additional experimental work resulting in substantial improvements in some of the production steps. We have improved or generated the required documentation for many of the activities. We have begun manufacture of clinical supply of the drug substance NV-387 at the 5 Kg production scale. It is expected that the 5Kg scale would be sufficient to treat approximately 1,000 patients, although the actual required dose for efficacy will only be established in clinical trials.

After the active ingredient is made, it must be formulated into actual drug products for use. We have developed three separate drug product formulations of NV-387: (i) NV-CoV-2 Oral Gummies, a fixed-dose form for use in mild to moderate out-patient treatment; (ii) NV-CoV-2 Oral Syrup, the dosing quantity of which can be adjusted, as is needed in the case pediatric patients (based on body weight); and (iii) NV-CoV-2 Solution (Sterile) for Injection, Infusion, and Inhalation. The injection of sterile solution is expected to be used in moderate to severe out-patient scenario, keeping the patient from hospitalization. The infusion of sterile solution is expected to be used in severe hospitalized cases permitting increased dosing. The inhalation directly into lungs of the same sterile solution using a simple nebulizer is expected to be helpful in severe cases with lung damage where the drug can be provided directly into the lungs at the site of viral attack for presumably enhanced effect.

We have scaled up cGMP-compliant manufacture of the NV-CoV-2 drug products at our Shelton, CT facility. We anticipate completion of the current production batch of NV-CoV-2 oral syrup and oral gummies drug products in approximately March 2023. We have performed extensive documentation and characterization at each reaction and processing cycle of manufacture of the API NV-387, as well as the formulation and packaging of NV-CoV-2 oral gummies and NV-CoV-2 oral syrup in house in order to develop processes and documentation suitable for eventual commercial batches.

The formulated drug product must be suitably packaged for transport and distribution. We have developed the filling and packaging system for our NV-CoV-2 Oral Gummies, which is undergoing testing now. In the reported quarter, we successfully designed and had externally fabricated custom filling, packaging, and sealing equipment for the oral syrup and oral gummies formulations at the clinical batch scale. We plan on having the NV-CoV-2 Injectable formulation made and packaged at an external contract manufacturer. We are in discussions with at least one vendor for the

injectables formulation and packaging. We are thus in the process of establishing drug product primary packaging operations at our cGMP-capable facility in Shelton, CT.

Additionally, in the current quarter, we have continued the process of preparing the dossiers for submission to regulatory agencies and related activities, as stated earlier. We have substantially completed writing of the manufacturing and quality control section as well as

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the non-clinical IND-enabling studies section of a clinical trial application. We have substantially completed development of a clinical protocol for safety and preliminary efficacy evaluation of NV-CoV-2 in human clinical trials. It is expected that the clinical trial protocol we have developed may be modified by the Clinical Trial Provider contract research organization (CRO). We are in the process of engaging a CRO for US IND filing and clinical trials at present. The CRO will need to complete the writing of the clinical protocol section of the IND. Thereafter we can submit the IND to the US FDA. We also have efforts going on for conducting clinical trials of NV-CoV-2 in other regulatory jurisdictions.

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

### **Financial Status**

As of December 31, 2022, the Company had approximately \$11.4 million in cash and cash equivalents and \$8.4 million of property and equipment, net of accumulated depreciation. Our current liabilities are approximately \$0.5 million. Stockholder’s equity was approximately \$19.9 million at December 31, 2022.

During the six-month period ended December 31, 2022, the Company used approximately \$2.4 million in cash toward operating activities. The available cash is sufficient for more than twelve months of operations at the current rate of expenditures from the date of filing of this Quarterly Report on Form 10-Q. As our COVID-19 and shingles drug programs mature into human clinical trials, our expenditures are anticipated to increase due to the costs of the clinical trials. We estimate that the Company has sufficient funds in hand for initial human clinical trials of NV-CoV-2 at this time. The Company estimates that it will need additional funding to continue further development of its drug candidates through later stages of human clinical trials if it does not form a collaborative licensing or partnership agreement with a party that would provide such funding such as Big Pharma.

We do not anticipate any major capital costs going forward in the near future. The Company believes that it has several important milestones that it will be achieving in the current year. Management believes that as it achieves these milestones, the Company’s ability to raise additional funds in the public markets would be enhanced.

### **NanoViricides’ Drug Programs in Brief**

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

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

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

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

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

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

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

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

We believe we have developed sufficient pre-clinical data that will be needed prior to a Phase 2 human clinical trial and have sufficient cash as of December 31, 2022 to fund Phase 1 clinical trials for our lead Coronavirus drug, NV-Cov-2. Thus we believe our anti-coronavirus drug program is now very close to entering the human clinical trials stage.

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

We intend to take NV-CoV-2, our broad-spectrum anti-coronavirus drug candidate, into human clinical trials as soon as feasible. We intend to seek collaborations to develop the COVID-19 drug further towards emergency use approval and full approval by FDA as well as international regulatory authorities.

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

We have recently initiated two new programs in response to public health threats: (a) nanoviricides to treat Poxvirus infections (the Mpox epidemic previously known as MonkeyPox); and (b) nanoviricides to treat enteroviral infections. Enterovirus EV-D68, causes a pediatric disease called acute flaccid myelitis (AFM) that can lead to paralysis (AFP) in a small number of children. The disease incidence appears to peak every two years and has been increasing in the USA. Poliovirus is also an enterovirus, and recently has been detected primarily in New York area. We are engaging these programs in a limited manner at present, and intend to evaluate effectiveness of our existing array of potential drug candidates against these viruses. As noted above, our primary objective at this point is to utilize our NV-387 drug development to its fullest potential to maximize return on investments (ROI).

Previously, we have developed a clinical drug candidate NV-HHV-1 and formulated it as a skin cream for the treatment of Shingles. We plan on undertaking clinical trials of NV-HHV-1 after NV-CoV-2 clinical trials. We have performed cGMP-like manufacture of

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both the active pharmaceutical ingredient (API NV-HHV-1, the nanoviricide against VZV), and the fully formulated skin cream (the drug product candidate), at our own facilities at ~1kg scale (API) with attendant significant time, project management, and cost savings as opposed to going to an external contract manufacturer. Approximately 10kg of fully formulated drug product was manufactured. We believe this scale is sufficient for the requirements of Phase I and Phase II human clinical trials.

The Company has now demonstrated that it has 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 establishment and execution of cGMP manufacturing is an extremely significant milestone for the Company. Our current multi-kg per batch scale of cGMP manufacturing capacity is expected to be more than sufficient for the anticipated Phase I and Phase II human clinical trials. In addition, we believe that our facility can supply required quantities of the drug for Phase III clinical trials as well. Thus, this in-house cGMP production capability is expected to result in significant cost savings across all our programs.

Manufacturing nanomedicines, especially under cGMP conditions, has been identified as a strong risk, and has led to failure of several nanomedicines programs. NanoViricides co-founder Dr. Anil Diwan and his team have employed considerations for cGMP manufacture of our nanomedicines right from the design, development and optimization of the drug candidates, the polymers and ligands that go into them, as well as the processes employed right from the small research scale to the initial process verification batches. The team has successfully and rapidly translated from the research scale production of several grams drug substance to kg-scale cGMP-compliant manufacture for two different drug candidates, namely NV-HHV-1 and NV-CoV-2 in a very short time span. This includes manufacture of the active ingredient (drug substance), the formulated drug products, and packaged drug products for clinical trials usage.

To date, the Company does not have any commercialized products. The Company continues to add to its existing portfolio of products through our internal discovery and clinical development programs and also seeks to do so through an in-licensing strategy.

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

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

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

Both the safety and effectiveness of any new drug has to be determined experimentally. The safety of a nanoviricide drug is expected to depend upon the safety of the nanomicelle portion as well as the safety of the antiviral ligand. We have observed excellent safety of our injectable SARS-CoV-2 drug candidates, as well as of the Shingles skin cream drug candidate. This leads us to believe that the nanomicelle backbones of these drug candidates that were evaluated in preliminary safety studies should be safe in most if not all routes of administration.

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

We are currently focused on the development of an anti-coronavirus drug with urgency. Further, we are performing pre-clinical investigations to expand the usage of NV-387, the API of NV-CoV-2 in developing antiviral drugs against other viruses to improve return on investment, ROI. Additionally, we are also performing topical drug development against several indications related to infections by herpes family viruses.

## **Our Campus in Shelton, CT**

Our campus at Shelton, CT, is fully operative. With our R&D discovery labs, analytical labs, the bio labs for virology R&D, the process scale-up production facility, and the cGMP-capable manufacturing facility established at our Shelton campus, we are in a

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strong position to move our drug development programs into the clinic rapidly. Staff is being trained to achieve full cGMP compliance to support clinical trial manufacture.

### *Process Scale-Up Production Capability*

The process scale-up area is operational at kilogram to multi-kg scales for different chemical synthesis and processing steps now. It comprises reactors and process vessels on chassis or skids, ranging from 250mL to 75L capacities, as needed. Many of the reactors and vessels have been designed by us for specific tasks related to our unique manufacturing processes. Additionally, we have clinical scale filling and packaging equipment for oral syrup and oral gummies (semi-solids) formulations, that was custom-designed and fabricated in the USA.

### *cGMP Production Capability*

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

In the reported quarter, we have modified an existing room into a cGMP-compliant Oral Drug Product Formulation, Fill, and Packaging room. We are in the process of setting up clinical scale filling and packaging equipment for oral syrup and oral gummies (semi-solids) formulations that were custom-designed and fabricated in the USA.

We plan to produce multiple batches of a drug product. If we are satisfied with such strong reproducibility of our processes, we plan to register the facility as a cGMP manufacturing facility with the FDA.

### *Our BSL-2 Certified Virology Lab*

We have significantly enhanced our internal anti-viral cell culture testing capabilities at our Shelton campus. We have achieved BSL-2 (Biological Safety Level 2) certification from the State of Connecticut for our Virology suite at the new campus. This suite comprises three individual virology workrooms, enabling us to work on several different viruses and strains at the same time. This facility is designed only for cell culture studies on viruses, and no animal studies can be conducted at any of our own facilities.

We have established several different types of assays for screening of candidates against Coronaviruses as well as VZV, HSV-1, HSV-2, among others in this lab. In the reported quarter, we have added assays for screening of candidates against BSL2-Orthopoxviruses and Enteroviruses in our lab. Our BSL2 Virological capability has been instrumental in our rapid development of potential drug candidates for further investigation towards human clinical trials. We believe that having developed the internal capabilities for cell culture testing of our ligands and nanoviricides against a variety of viruses has substantially strengthened and accelerated our drug development programs.

## **NanoViricides Business Strategy in Brief**

NanoViricides, Inc. intends to perform the regulatory filings and own all the regulatory licenses for the drugs it is currently developing. The Company will develop these drugs in part via subcontracts to TheraCour, the exclusive source for these nanomaterials. The Company plans to market these drugs either on its own or in conjunction with marketing partners. The Company also plans 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 to the Company. Such licensing and/or co-development agreements may shape the manufacturing and development options that the Company may pursue. There can be no assurance that the Company will be able to enter into co-development or other licensing agreements.

The Company has kept its 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.



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

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

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

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

As a strategy, we plan to develop the same drug, once initial clinical trials towards a first approval of the drug are completed, for commercial approval for additional indications, such as pediatric applications, special case applications for certain classes of immune-compromised patients, among others, provided that appropriate levels of funding become available. We believe that adding further indications would significantly expand market penetration and improve return on investment for our drugs.

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

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

### **Patents, Trademarks, Proprietary Rights: Intellectual Property – Recent events**

In September 2021, the Company 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-19 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-19. 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

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least into the year 2043, with additional specific extensions possible in various countries based on regulatory extensions for pharmaceutical products. All ensuing patents will be automatically exclusively licensed to NanoViricides for anti-coronavirus drugs pursuant to the “CoV License Agreement”.

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

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

PCT/US21/39050 - SELF-ASSEMBLING AMPHIPHILIC POLYMERS AS ANTI- COVID-19 AGENTS	Applied: June 25, 2021	Ca. 2043 (estimated)	PCT Application filed.	TheraCour Pharma, Inc. [Exclusive License].
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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].
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**T**The PCT application PCT/US22/35210 was filed with request for priority of PCT/US21/39050.
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The Company believes that the drugs by themselves, Coronavirus antiviral treatment, would be eligible for patent protection. The Company plans on filing patent applications for protecting these drugs when we have definitive results from in-vitro or in-vivo studies that enable further drug development and IND application filing.

### **Trademarks**

The Company has no registered trademarks.

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

As of December 31, 2022, we had cash and cash equivalents of \$11,448,346, prepaid expenses of \$104,545 and net property and equipment of \$8,417,849. Accounts payable and accrued expenses were \$464,592, inclusive of accounts payables to a related party of \$373,424. The accounts payable-related party is net of a two month advance of \$465,000. Stockholders' equity was \$19,870,371 at December 31, 2022. In comparison, as of June 30, 2022, we had \$14,066,359 in cash and cash equivalents, prepaid expenses of \$350,021 and \$8,694,194 of net property and equipment. Our liabilities at June 30, 2022 were \$412,837 including a third party short term loan payable of \$94,788, accounts payable of \$57,960 payable to third parties and accounts payable to TheraCour of \$214,397, net of a two month advance of \$465,000, and accrued expenses of \$45,692.

During the six -month period ended December 31, 2022, we used approximately \$2.4 million in cash toward operating activities. During the six-month period ended December 31, 2021, we used approximately \$2.8 million in cash toward operating activities.

### **Research and Development Costs**

The Company does not maintain separate accounting line items for each project in development. The Company maintains aggregate expense records for all research and development conducted. Because at this time all of the Company's projects share a common core material, the Company allocates 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 on our COVID-19 program drug candidates.

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### **Results of Operations**

**Revenues** The Company is a biopharmaceutical company and did not have any revenue for the six month period ended December 31, 2022.

**Research and Development Expenses** – Research and development expenses for the three months ended December 31, 2022 decreased \$90,598 to \$1,170,710 from \$1,261,308 for the three months ended December 31, 2021. Research and development expenses for the six months ended December 31, 2022 decreased \$1,074,859 to \$2,283,369 from \$3,358,228 for the six months ended December 31, 2021. The decrease in research and development expenses for the three months ended December 31, 2022 is due to a decrease in outside lab expenses. The decrease in the research and development expenses for the six months ended December 31, 2022 is due to a decrease in outside lab expenses, and a milestone payment during the six months ended December 31, 2021 to a related party, TheraCour, upon execution of a COVID -19 License Agreement.

**General and Administration Expenses** – General and administrative expenses for the three months ended December 31, 2022 increased \$4,016 to \$663,284 from \$659,268 for the three months ended December 31, 2021. General and administrative expenses for the six months ended December 31, 2022 decreased \$1,728 to \$1,172,985 from \$1,174,713 for the six months ended December 31, 2021. The increase in general and administrative expenses for the three months ended December 31, 2022 is due to an increase in professional fees. The decrease in general and administrative expense for the six months ended December 31, 2022 is due to an decrease in office expenses.

**Interest Income** – Interest income for the three months ended December 31, 2022 increased \$86,881 to \$88,954 from \$2,073 for the three months ended December 31, 2021. Interest income for the six months ended December 31, 2022 increased \$138,389 to \$141,516 from \$3,127 for the six months ended December 31, 2021. The increase in interest income for the three and six months ended December 31, 2022 is due to an increase in interest rates during the three and six month period ended December 31, 2022.

**Interest Expense** – Interest expense decreased \$2,537 to \$94 for the three months ended December 31, 2022 from \$2,631 for the three months ended December 31, 2021. Interest expense decreased \$3,450 to \$938 for the six months ended December 31, 2022 from \$4,388 for the six months ended December 31, 2021. The decrease in interest expense for the three and six months ended December 31, 2022 is a result of the full payoff of the mortgage loan and complete amortization of the loan origination fee at December 31, 2021.

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

**Net Loss** – For the three months ended December 31, 2022, the Company had a net loss of \$(1,745,134) or \$(0.15) per share compared to a net loss of \$(1,921,134) or \$(0.17) per share for the three months ended December 31, 2021. For the six months ended December 31, 2022, the Company had a net loss of \$(3,315,776) or \$(0.29) per share compared to a net loss of \$(4,534,202) or \$(0.39) per share for the six months ended December 31, 2021. The decrease in the net loss for the three months ended December 31, 2022 is attributable to a decrease in research and development expenses. The decrease in the net loss for the six months ended December 31, 2022 is attributable to a milestone payment of 100,000 shares of the Company’s Series A preferred stock, with a fair value of approximately \$935,000, issued in September 2021, to TheraCour upon execution of an exclusive license agreement for the sale of drugs to treat COVID-19 infections using TheraCour’s technology and a decrease in outside lab expenses.

### **Liquidity and Capital Reserves**

The Company had cash and cash equivalents of \$11,448,346, and prepaid expenses of \$104,545 as of December 31, 2022 and accounts payable and accrued expenses were \$464,592, inclusive of accounts payable of \$373,424 to a related party as of the same date. The accounts payable – related party is net of a two month advance of \$465,000. Since inception, the Company has expended substantial resources on research and development. Consequently, we have sustained substantial losses. The Company has an accumulated deficit of \$125,807,952 at December 31, 2022. 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. On July 31, 2020, the Company entered into an At The Market (“ATM”) Sales Agreement with B. Riley Securities, Inc. and Kingswood Capital (now E.F.Hutton)(collectively the “Sales Agents) pursuant to

which the Company may offer and sell, from time to time, through or to the Sales Agents, shares of common stock having an aggregate offering price of up to \$50 million. To date the Company has sold 814,242 shares for approximately \$6.4 million under the

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ATM Sales Agreement none of which were sold during the six months ended December 31, 2022. Further, the Company believes that it has several important milestones that should occur in the ensuing year such as entering a drug into the Company's first clinical trials. Management believes that assuming it achieves these milestones, the Company would likely experience improvement in the liquidity of the Company's stock, and would eventually improve the Company's ability to raise funds on the public markets at terms that may be more favorable to the terms we are offered at present.

The Company believes that cash on hand as of December 31, 2022 will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuance of these condensed financial statements. However, 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 which reaches a level sufficient to provide self-sustaining cash flows. There is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company. The Company believes that the management plan, the Company's existing resources and access to the capital markets will permit the Company to fund planned operations and expenditures. However, the Company cannot provide assurance that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates.

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

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

Management also intends to pursue non-diluting funding sources such as government grants and contracts as well as licensing agreements with other pharmaceutical companies. There can be no assurance that the Company will be able to obtain such additional capital resources or that such financing will be on terms that are favorable to the Company.

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

We have not entered into any off-balance sheet arrangements during the six months ended December 31, 2022.

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

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

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

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (the "SEC"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well

designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of

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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, 2022, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2022 due to a material weakness in internal control over financial reporting described in Item 9A of our Form 10-K for the fiscal year ended June 30, 2022. The material weakness in internal control over financial reporting resulted from the lack of timely and effective review of the Company's period-end closing process and adequate personnel and resources. This material weakness remains unremediated as of December 31, 2022. Management has effected an assessment of its internal control over financial reporting and has taken steps to address this material weakness as described under the remediation plan.

### *Changes in Internal Control Over Financial Reporting*

Other than what was described above, there were no material changes in our system of internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) during the quarter ended December 31, 2022 that has materially affected, or is likely to materially affect, our internal control over financial reporting. However, as noted below, we have begun to implement changes in our internal control over financial reporting to address the material weakness described above.

### **Remediation Plan**

The Company has established a financial reporting controls committee comprised of members of senior management and a member of the Audit Committee of the Board of Directors. The committee has established a formal iterative review process which will provide oversight to the Company's efforts for ensuring appropriate and timely internal control over financial reporting including, but not limited to, remediation of the aforesaid material weakness and identifying and testing for potential internal control weakness in the financial reporting process to assure reliability and accuracy.

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

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

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

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

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

On September 14, 2022 the Company's Board of Directors approved the employment extension of Dr. Anil Diwan, President and Chairman of the Board. On October 6, 2022, the Company and Dr. Anil Diwan executed an extension of his employment agreement for a period of one year from July 1, 2022 through June 30, 2023 under the same general terms and conditions. The Company granted Dr. Anil Diwan an award of 10,204 shares of the Company's Series A preferred stock. The shares shall be vested in quarterly installments of 2,551 shares on September 30, 2022, December 31, 2022, March 31, 2023 and June 30, 2023 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of \$10,930 and \$21,860 for the three and six months ended December 31, 2022, respectively. The balance of \$21,861 will be recognized as the remaining 5,102 shares vest and service is rendered for the year ended June 30, 2023.

For the three and six months ended December 31, 2022, 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 \$2,125 and \$5,059, respectively for the three and six months ended December 31, 2022 related to these issuances.

The Scientific Advisory Board was granted in August 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$3.40 per share expiring in August 2026 and in November 2022 fully vested warrants to purchase 286 shares of common stock with an exercise price of \$2.09 per share expiring in November 2026. The fair value of the warrants was \$223 for the three months ended December 31, 2022 and \$703 for the six months ended December 31, 2022 and was recorded as consulting expense.

For the three and six months ended December 31, 2022, the Company's Board of Directors authorized the issuance of 17,366 and 30,076, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded expense of \$27,000 and \$54,000, respectively, for the three and six months ended December 31, 2022, 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, 2022, the Company's Board of Directors authorized the issuance of 7,173 and 12,327, 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, 2022, which is reflective of the fair value of the common stock on the dates of issuance.

All of the securities referred to above were issued without registration under the Securities Act of 1933, as amended (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. All of the foregoing securities as well the Common Stock issuable upon conversion or exercise of such securities, have not been registered under the Securities Act or any other applicable securities laws and are deemed restricted securities, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.



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**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

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**ITEM 6. EXHIBITS**

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

**SIGNATURES**

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

**NANOVIRICIDES, INC.**

Dated: February 14, 2023

/s/ Anil R. Diwan

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

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

Dated: February 14, 2023

/s/ Meeta Vyas

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

Title: Chief Financial Officer  
(Principal Financial Officer)