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

FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended December 31, 2020

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

Yes ☐ No ☒

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

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:

Common Stock	NNVC	NYSE-American

As of February 15, 2021, there were approximately 10,677,000 shares of common stock of the registrant issued and outstanding.

NanoViricides, Inc.
FORM 10-Q
INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NanoViricides, Inc.
Balance Sheets

	December 31, 2020 (Unaudited)	June 30, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 18,393,072	$ 13,708,594
Prepaid expenses	94,298	277,063
Total current assets	18,487,370	13,985,657
PROPERTY AND EQUIPMENT		
Property and equipment	14,138,467	14,100,815
Accumulated depreciation	(4,900,593)	(4,556,384)
Property and equipment, net	9,237,874	9,544,431
TRADEMARK AND PATENTS		
Trademark and patents	458,954	458,954
Accumulated amortization	(104,701)	(100,566)
Trademark and patents, net	354,253	358,388
OTHER ASSETS		
Deferred financing costs	-	12,190
Security deposits	3,515	3,515
Service agreements	2,338	10,158
Other assets	5,853	25,863
Total assets	$ 28,085,350	$ 23,914,339
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Mortgage note payable – related party	$ -	$ 1,081,987
Accounts payable	185,142	380,727
Accounts payable – related party	128,904	561,580
Loan payable	-	62,843
Accrued expenses	25,262	69,240
Total current liabilities	339,308	2,156,377
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, $0.001 par value, 10,000,000 shares designated, 369,376 and 368,602 shares issued and outstanding, at December 31, 2020 and June 30, 2020, respectively	369	369
Common stock, $0.001 par value; 150,000,000 shares authorized, 10,677,448 and 9,083,414 shares issued and outstanding at December 31, 2020 and June 30, 2020, respectively	10,677	9,083
Additional paid-in capital	137,939,407	127,311,634
Accumulated deficit	(110,204,411)	(105,563,124)

Total stockholders' equity	27,746,042	21,757,962
Total liabilities and stockholders' equity	$ 28,085,350	$ 23,914,339

See accompanying notes to the financial statements

Nanoviricides, Inc.
Statements of Operations
(Unaudited)

	For the Three Months Ended December 31,		For the Six Months Ended December 31,	
	2020	2019	2020	2019
OPERATING EXPENSES				
Research and development	$ 1,493,200	$ 1,012,085	$ 3,066,271	$ 2,494,490
General and administrative	798,722	622,347	1,496,034	1,127,819
Total operating expenses	2,291,922	1,634,432	4,562,305	3,622,309
LOSS FROM OPERATIONS	(2,291,922)	(1,634,432)	(4,562,305)	(3,622,309)
OTHER INCOME (EXPENSE)				
Interest income	1,187	784	4,246	6,001
Interest expense	(37,293)	(4,131)	(81,202)	(4,131)
Loss on disposal of property and equipment	(2,026)	-	(2,026)	-
Loss on issuance of Series A preferred stock for accounts payable – related party	-	(142,669)	-	(142,669)
Change in fair value of derivative liability	-	(147,078)	-	274,449
Other (expense) income	(38,132)	(293,094)	(78,982)	133,650
LOSS BEFORE INCOME TAX PROVISION	(2,330,054)	(1,927,526)	(4,641,287)	(3,488,659)
INCOME TAX PROVISION	-	-	-	-
NET LOSS	$ (2,330,054)	$ (1,927,526)	$ (4,641,287)	$ (3,488,659)
Net loss per common share- basic and diluted	$ (0.22)	$ (0.50)	$ (0.44)	$ (0.91)
Weighted average common shares outstanding- basic and diluted	10,666,056	3,853,858	10,576,828	3,849,437

See accompanying notes to the financial statements

NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the period from July 1, 2020 through December 31, 2020
(Unaudited)

	Series A Preferred Stock: Par $0.001		Common Stock: Par $0.001				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 2020	368,602	$ 369	9,083,414	$ 9,083	$127,311,634	$(105,563,124)	$ 21,757,962
Series A Preferred Stock issued for employee stock compensation	387	-	-	-	53,098	-	53,098
Common stock issued for consulting and legal services rendered	-	-	5,135	5	26,995	-	27,000
Net proceeds from issuance of common stock in connection with equity financing	-	-	1,575,342	1,576	10,440,640	-	10,442,216
Warrants issued to Scientific Advisory Board	-	-	-	-	1,986	-	1,986
Common shares issued for Directors fees	-	-	2,040	2	11,248	-	11,250
Net loss	-	-	-	-	-	(2,311,233)	(2,311,233)
Balance, September 30, 2020	368,989	$ 369	10,665,931	$ 10,666	$137,845,601	$(107,874,357)	$ 29,982,279
Series A Preferred Stock issued for employee stock compensation	387	-	-	-	50,602	-	50,602
Common stock issued for consulting and legal services rendered	-	-	7,411	7	26,993	-	27,000
Warrants issued to Scientific Advisory Board	-	-	-	-	1,215	-	1,215
Common shares issued for Directors fees	-	-	4,106	4	14,996	-	15,000
Net loss	-	-	-	-	-	(2,330,054)	(2,330,054)
Balance, December 31, 2020	369,376	$ 369	10,677,448	$ 10,677	$137,939,407	$(110,204,411)	$ 27,746,042

See accompanying notes to the financial statements

NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the period from July 1, 2019 through December 31, 2019
(Unaudited)

	Series A Preferred Stock: Par $0.001		Common Stock: Par $0.001				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 2019	255,714	$ 256	3,844,921	$ 3,845	$102,712,845	$ (92,116,586)	$ 10,600,360
Series A Preferred Stock issued for employee stock compensation	387	-	-	-	51,398	-	51,398
Common stock issued for consulting and legal services rendered	-	-	6,201	6	26,994	-	27,000
Warrants issued to Scientific Advisory Board	-	-	-	-	908	-	908
Common shares issued for Directors fees	-	-	2,553	3	11,247	-	11,250
Net loss	-	-	-	-	-	(1,561,133)	(1,561,133)
Balance, September 30, 2019	256,101	$ 256	3,853,675	$ 3,854	$102,803,392	$ (93,677,719)	$ 9,129,783
Series A Preferred Stock issued for employee stock compensation	387	-	-	-	49,394	-	49,394
Common stock issued for consulting and legal services rendered	-	-	11,932	12	26,988	-	27,000
Series A Preferred Stock issued for accounts payable-related party	100,000	100	-	-	392,569	-	392,669
Series A Preferred Stock issued for loan origination fee	10,000	10	-	-	39,291	-	39,301
Warrants issued to Scientific Advisory Board	-	-	-	-	533	-	533
Common shares issued for Directors fees	-	-	4,965	5	11,245	-	11,250
Net loss	-	-	-	-	-	(1,927,526)	(1,927,526)
Balance, December 31, 2019	366,488	$ 366	3,870,572	$ 3,871	$103,323,412	$ (95,605,245)	$ 7,722,404

See accompanying notes to the financial statements

Nanoviricides, Inc.
Statements of Cash Flows
(Unaudited)

	For the Six Months ended	
	December 31, 2020	December 31, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,641,287)	$ (3,488,659)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	103,700	100,792
Loss on issuance of preferred shares for accounts payable- related party	-	142,669
Common shares issued as compensation and for services	80,250	76,500
Warrants granted to Scientific Advisory Board	3,201	1,441
Depreciation	348,096	345,674
Amortization of loan origination fees	18,013	1,638
Amortization	4,135	4,135
Change in fair value of derivative liabilities	-	(274,449)
Loss on disposal of property and equipment	2,026	-
Write-off of deferred financing costs	12,190	-
Changes in operating assets and liabilities:		
Prepaid expenses	182,765	12,382
Other assets	7,820	7,820
Accounts payable	(195,585)	362,464
Accounts payable - related party	(432,676)	163,587
Accrued expenses	(43,978)	(16,239)
NET CASH USED IN OPERATING ACTIVITIES	(4,551,330)	(2,560,245)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(43,565)	(4,139)
NET CASH USED IN FINANCING ACTIVITIES	(43,565)	(4,139)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants	10,442,216	-
Proceeds from note payable -related party	-	1,100,000
Payment of note payable – related party	(1,100,000)	-
Deferred financing costs	-	(383,175)
Payment of loan payable	(62,843)	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	9,279,373	716,825
NET CHANGE IN CASH AND CASH EQUIVALENTS	4,684,478	(1,847,559)
Cash and cash equivalents at beginning of period	13,708,594	2,555,207
Cash and cash equivalents at end of period	$ 18,393,072	$ 707,648
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	$ 655	$ -
Non-cash Financing and Investing Activities:		
Series A preferred stock issued for accounts payable-related party	$ -	$ 250,000
Series A preferred stock issued for loan origination fee	$ -	$ 39,301

See accompanying notes to the financial statements

NANOVIRICIDES, INC.
December 31, 2020 AND 2019
NOTES TO THE 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 is also unique in the bio-pharma field in that it possesses its own state of the art facilities for the design, synthesis, analysis and characterization of the nanomedicines that we develop, as well as for production scale-up, and c-GMP-like production in quantities needed for human clinical trials, where our design, development, and production work is performed. The biological studies such as the effectiveness, safety, bio-distribution and Pharmacokinetics/Pharmacodynamics on our drug candidates are performed by external collaborators and contract organizations.

The Company has several drugs in various stages of early development. COVID-19 has become our lead drug program due to the necessity of responding to the pandemic. The Company began development of a drug to treat COVID-19 patients just as the cases of the novel disease were being reported from China. Our drug candidates for COVID-19 successfully entered core safety pharmacology studies required prior to any human clinical trials around October/November, 2020. These studies have now been completed; we have received draft reports from the external CRO, and are awaiting the final reports that will be required for an IND. The Company is currently working on a pre-IND application to the US FDA to seek guidance for an IND. The Company is also involved with tasks needed for setting up and executing human clinical trials for our COVID-19 drug candidates assuming that the IND is approved by the US FDA.

The Company plans on re-engaging our other lead antiviral program against herpes viruses, i.e. the HerpeCide™ program, as soon as it becomes feasible to conduct the corresponding antiviral human clinical studies. In the HerpeCide program alone, we have drug candidates against at least five indications at different stages of development. Of these, the Company is advancing the shingles drug candidate towards human clinical trials. The IND-enabling Safety/Toxicology studies required for doing so have been completed and we were in the process of preparing an IND application for this drug candidate when the SRAS-CoV-2 virus struck, whereupon we pivoted our efforts to respond to the threat of what has now become the COVID-19 pandemic. In addition, our drug candidates against HSV-1 "cold sores" and HSV-2 "genital herpes" are in advanced studies and are expected to follow the shingles drug candidate into human clinical trials. Shingles in adults and chicken pox in children is caused by the same virus, namely VZV (Varicella-zoster virus, aka HHV-3 or human herpesvirus-3). There are estimated to be approximately 120,000-150,000 annual chickenpox cases in the USA in the post-vaccination-era, i.e. since childhood vaccination with the live attenuated varicella virus Oka strain has become standard. In addition, we have drugs in development against all influenzas in our FluCide™ program, as well as drug candidates against HIV/AIDS, Dengue, Ebola/Marburg, and other viruses.

Our drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. ("TheraCour"), to which we have broad, exclusive licenses. The first license agreement we executed with TheraCour on September 1, 2005 ("Exclusive License Agreement"), gave us an exclusive, worldwide license 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), Influenza and Asian Bird Flu Virus. On February 15, 2010, the Company executed an Additional License Agreement with TheraCour. Pursuant to the Additional License Agreement, the Company was granted exclusive licenses for technologies, developed by TheraCour, for the development of drug candidates for the treatment of Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes. In addition, on November 1, 2019, the Company entered into a world-wide, exclusive, sub-licensable, license ("VZV License Agreement") to use, promote, offer for sale, import, export, sell and distribute drugs that treat VZV 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. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement. The Company was not required to make any upfront payments to TheraCour and agreed to the following milestone payments to TheraCour; the issuance of 75,000 shares of the Company's Series A Convertible Preferred Stock upon the grant of an IND Application; $1,500,000 in cash upon completion of Phase I Clinical Trials; $2,500,000 in cash upon completion of Phase II clinical trials; and $5,000,000 in cash upon completion of Phase III

clinical trials. The Company has requested TheraCour for a license in the field of coronaviruses. A Memorandum of Understanding ("MOU") towards licensing this field has been agreed to and executed on June 8, 2020. The MOU provides a limited license to the Company for the entire application of human coronavirus infections (the "COVID License Agreement"), while the full license is being perfected. In furtherance of the COVID License Agreement, the Company has appointed a third party consulting firm for independent evaluation of this market space. The terms of the COVID License Agreement, except as otherwise specified in the MOU, is expected to be generally consistent with the terms of the VZV License Agreement dated November 1, 2019, and shall include consistent milestone payments, royalties and sublicense and income derived from grants and contracts.

Note 2 - Liquidity

The Company's 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 financial statements, the Company has an accumulated deficit at December 31, 2020 of approximately $110.2 million and a net loss of approximately $4.6 million and net cash used in operating activities of approximately $4.6 million for the six months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of December 31, 2020, the Company had available cash and cash equivalents of approximately $18.4 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 8, 2020 the Company entered into an underwriting agreement (the "Underwriting Agreement") with Kingswood Capital Markets, a Division of Benchmark Investments, Inc. ("Kingswood"). The offering was consummated on July 10, 2020, whereby the Company sold 1,369,863 shares of common stock and a fully exercised Underwriters' over-allotment option of 205,479 additional shares at the public offering price of $7.30 per share. No warrants were issued in this offering. The net proceeds to the Company from the offering was approximately $10.4 million after deducting underwriting discounts and commissions and other estimated offering expenses.

On July 31, 2020, the Company entered into an At Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc. and Kingswood (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"). Sales pursuant to the Sales Agreement 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. The Company will pay a commission rate of up to 3.5% of the gross sales price per share sold and agreed to reimburse the Sales Agents for certain specified expenses, including the fees and disbursements of its legal counsel in an amount not to exceed $50,000 and have agreed to reimburse the Sales Agents an amount not to exceed $2,500 per quarter during the term of the Sales Agreement for legal fees to be incurred by the Sales Agents. The Company has also agreed pursuant to the Sales Agreement to provide each Sales Agent with customary indemnification and contribution rights. The Company has not performed any ATM Offerings as of this report.

The Company believes that it has several important milestones that it will be achieving 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.

The Company has not experienced a direct financial adverse impact of the effects of the Coronavirus (COVID-19) pandemic. However, the pandemic required the Company to reorganize its priorities, because of the impact on the ability to conduct antiviral drug trials for our then lead program for Shingles drug treatment. While clinical trials were in general adversely affected, the ability to enroll patients into the shingles antiviral drug clinical trial with the desired inclusion criteria became limited due to the widespread coronavirus infection. The shingles clinical trial design and conduct would also become more complex. The emergence of widespread health emergencies due to COVID-19 have led to regional quarantines, shutdowns, shortages, disruptions of supply chains, and economic instability. The impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted at this time. Though the Company has not experienced a direct financial impact, if the financial markets and/or the overall economy are impacted for an extended period, the Company's ability to raise funds, in the future, may be materially adversely affected.

Management believes that the Company's existing resources will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuance of these financial statements. 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 financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

Note 3 - Summary of Significant Accounting Policies

Basis of Presentation – Interim Financial Information

The accompanying unaudited interim 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 financial statements. The unaudited interim 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 financial statements and the information included under the heading "Management's Discussion and Analysis or Plan of Operation" should be read in conjunction with our Company's audited financial statements and related notes included in our Company's Form 10-K for the fiscal year ended June 30, 2020 filed with the SEC on October 13, 2020.

For a summary of significant accounting policies, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2020 filed on October 13, 2020.

Net Loss per Common Share

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

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

	Potentially Outstanding Dilutive Common Shares	
	For the Six Months Ended December 31, 2020	For the Six Months Ended December 31, 2019
Options	5,000	5,000
Warrants	21,646	370,012
Total potentially outstanding dilutive common shares	26,646	375,012

The Company has 369,376 shares of Series A preferred stock outstanding as of December 31, 2020. Only in the event of a "change of control" of the Company, 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, 2020, the number of potentially dilutive shares of the Company's common stock into which these Series A preferred shares can be converted into is 1,292,816 and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

Note 4 - Related Party Transactions

Related Parties

Related parties with whom the Company had transactions are:

Related Parties	Relationship
Dr. Anil R. Diwan	Chairman, President, CEO, significant stockholder and Director
TheraCour Pharma, Inc. ("TheraCour")	An entity owned and controlled by Dr. Anil Diwan

	For the three months ended		For the six months ended	
	December 31, 2020	December 31, 2019	December 31, 2020	December 31, 2019
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	$ -	$ -	$ 2,560	$ 4,139

	As of	
	December 31, 2020	June 30, 2020
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, we 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) we will pay $2,000 or actual costs each month, whichever is higher for other general and administrative expenses incurred by TheraCour on our behalf, (3) to make royalty payments of 15% (calculated as a percentage of net sales of the licensed drugs) to TheraCour and; (4) to pay an advance payment equal to twice the amount of the previous months invoice to be applied as a prepayment towards expenses. On October 2, 2018, the Company agreed to enter into an agreement with TheraCour for a waiver of two months worth of prepaid balance in advance of anticipated invoicing, due under prior agreements until the filing of an IND and the application of the then current advance as a credit against current open invoices. Additionally, TheraCour agreed to defer $25,000 per month of development fees, beginning with July 2018 through December 31, 2019. Accounts payable due TheraCour at December 31, 2020 was $619,904 which was offset by a two month advance (see above) of $491,000. There was no advance at June 30, 2020.	$ 128,904	$ 561,580

	For the three months ended		For the six months ended	
	December 31, 2020	December 31, 2019	December 31, 2020	December 31, 2019
Research and Development Costs Paid to Related Party				
Development fees and other costs charged by TheraCour pursuant to the license agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at December 31, 2020 and June 30, 2020	$ 606,742	$ 543,108	$ 1,255,066	$ 1,119,315

Mortgage Note Payable - Related Party

On December 16, 2019, the Company entered into an Open End Mortgage Note (the "Note") with Dr. Anil Diwan, the Company's founder, Chairman, President and CEO, to loan the Company up to $2,000,000 in two tranches of $1,000,000 (the "Loan"). The Note was paid off on December 31, 2020. The Note bore interest at the rate of 12% per annum and was secured by a mortgage granted against the Company's headquarters. Dr. Anil Diwan received 10,000 shares of the Company's Series A preferred stock as a loan origination fee which was amortized over the one year term of the loan using the effective interest method. The fair value of the 10,000 shares of the Company's Series A preferred stock when issued on December 16, 2019 was $39,301. The Series A preferred stock fair value is based on the greater of the i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the Holder would lose the voting rights upon conversion. For the assumptions used in calculating the fair value of the preferred shares, the conversion of the shares is triggered by a change of control. Amortization expense on the loan origination fee for the three and six months ended December 31, 2020 was $8,188 and $18,013, respectively, and $1,638 for both the three and six months ended December 31, 2019. The Company had drawn down $1.1 million of this loan. Interest was payable only on the amount drawn down. The lender had escrowed $132,000 of interest payable pursuant to the Loan. For the three and six months ended December 31, 2020, the Company incurred interest expense of $29,040 and $62,773, respectively, and $2,493 for both the three and six months ended December 31, 2019, which reduced the interest escrow balance included in prepaid expenses.

Note 5 - Property and Equipment

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

	December 31, 2020	June 30, 2020
GMP Facility	$ 8,020,470	$ 8,020,471
Land	260,000	260,000
Office Equipment	57,781	57,781
Furniture and Fixtures	5,607	5,607
Lab Equipment	5,794,608	5,756,956
Total Property and Equipment	14,138,466	14,100,815
Less Accumulated Depreciation	(4,900,592)	(4,556,384)
Property and Equipment, Net	$ 9,237,874	$ 9,544,431

Depreciation expense for the three months ended December 31, 2020 and 2019 were $172,934 and $172,863, respectively, and for the six months ended December 31, 2020 and 2019 were $348,096 and $345,764, respectively.

Note 6 - Trademark and Patents

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

	December 31, 2020	June 30, 2020
Trademarks and Patents	$ 458,954	$ 458,954
Less Accumulated Amortization	(104,701)	(100,566)
Trademarks and Patents, Net	$ 354,253	$ 358,388

Amortization expense amounted to $2,068 and $2,068 for the three months ended December 31, 2020 and 2019, respectively, and for the six months ended December 31, 2020 and 2019 were $4,135 and $4,135, respectively.

Note 7 - Accrued expenses

Accrued expenses consisted of the following:

	December 31, 2020	June 30, 2020
Severance payment	$ 3,000	$ 21,000
Accrued payroll	22,262	38,240
Consultant	-	10,000
Accrued Expenses	$ 25,262	$ 69,240

Note 8 – Loan Payable

The Company financed its Directors and Officers liability insurance policies through BankDirect. The original loan balance, as of January 1, 2020, was $155,173 payable at the rate of $15,874 per month through October 2020 including interest at an annual interest rate of 5%. At December 31, 2020 and June 30, 2020 the loan balances were $0 and $62,843, respectively. For the three and six

months ended December 31, 2020, the Company incurred interest expense of $66 ad $655, respectively.

Note 9 - Equity Transactions

On July 11, 2018 the Board of Directors approved an extension of the employment agreement with Dr. Anil Diwan, the Company's President. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 26,250 shares of the Company's Series A preferred stock to Dr. Anil Diwan. The shares shall be vested in one-third increments on June 30, 2019, June 30, 2020 and June 30, 2021 and are subject to forfeiture. The Company recognized non-cash compensation expense related to the issuance of the Series A preferred stock of $45,654 and $91,308 for the three and six months ended December 31, 2020. The balance of $91,308 will be recognized as the remaining 8,750 shares vest and service is rendered for the year ended June 30, 2021.

On July 8, 2020 the Company entered into an Underwriting Agreement with Kingswood. Pursuant to the terms and conditions of the Underwriting Agreement, the Company agreed to issue and sell 1,369,863 shares of our common stock, par value $0.001 per share (the "Underwritten Shares"), at a price to the public of $7.30 per share. Pursuant to the Underwriting Agreement, the Company also granted the underwriter an option to purchase up to an additional 205,479 shares of common stock (together with the Underwritten Shares, the "Shares") within 45 days after the date of the Underwriting Agreement to cover over-allotments, if any. The shares were issued pursuant to a prospectus supplement dated July 8, 2020 which was filed with the Securities and Exchange Commission on July 9, 2020 in connection with a takedown from the Company's shelf registration statement on Form S-3, as amended (File No. 333-237370), which became effective on April 2, 2020 and the base prospectus dated April 2, 2020 contained in that registration statement. The offering was consummated on July 10, 2020, whereby the Company sold 1,369,863 shares of common stock and a fully exercised Underwriters' overallotment of 205,479 additional shares at the public offering price of $7.30 per share. The net proceeds to the Company from the offering was approximately $10.4 million after placement agent fees and other estimated offering expenses.

The Company accounted for the proceeds of the Offering at July 10 2020 as follows:

Gross proceeds	$11,499,997
Less: offering costs and expenses	(1,057,781)
Net proceeds from issuance of common stock	$10,442,216

For the three and six months ended December 31, 2020, the Company's Board of Directors authorized the issuance of 387 and 774, respectively fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of $4,948 and $12,392, respectively for the three and six months ended December 31, 2020 related to these issuances.

The fair value of the Series A Preferred stock was the following for the dates indicated:

Date	Shares	Value
7/31/2020	129	$ 3,155
8/31/2020	129	2,391
9/30/2020	129	1,898
10/31/2020	129	1,749
11/30/2020	129	1,596
12/31/2020	129	1,603
	774	$ 12,392

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 Series A preferred stock fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a change of control. The common stock price for the six months ended December 31, 2020 was in the range $2.87 to $9.97.

During the six months ended December 31, 2020, the Scientific Advisory Board was granted in August 2020 fully vested warrants to purchase 572 shares of common stock with an exercise price of $6.86 per share expiring in August 2024 and in November 2020 fully vested warrants to purchase 572 shares of common stock with an exercise price of $4.19 per share expiring in November 2024. The fair value of the warrants was $1,215 for the three months ended December 31, 2020 and $3,201 for the six months ended December 31, 2020 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 weighted-average assumptions:

Expected life (year)	4
Expected volatility	91.4-91.5%

Expected annual rate of quarterly dividends	0.00%
Risk-free rate(s)	.24-.32%

For the three and six months ended December 31, 2020, the Company's Board of Directors authorized the issuance of 7,411 and 12,546, 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, 2020, which was the fair value on the dates of issuance.

For the three and six months ended December 31, 2020, the Company's Board of Directors authorized the issuance of 4,106 and 6,146, respectively, fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of $15,000 and $26,250 for the three and six months ended December 31, 2020, which was the fair value on the dates of issuance.

Note 10- Stock Warrants and Options

Stock Warrants

Stock Warrants	Number of Shares	Weighted Average Exercise Price per share ($)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($)
Outstanding and exercisable at June 30, 2020	22,218	$ 30.82	2.28	$ 4,533
Granted	1,144	5.53	-	-
Expired	1,716	37.90	-	-
Outstanding and exercisable at December 31, 2020	21,646	$ 28.92	2.04	$ 137

Of the above warrants, 1,141 expire in fiscal year ending June 30, 2021; 2,287 expire in fiscal year ending June 30, 2022, 14,787 expire in fiscal year ending June 30, 2023, 2,287 warrants expire in the fiscal year ending June 30, 2024 and 1,144 warrants expire in the fiscal year ending June 30, 2025.

Stock Options

Stock Options	Number of Shares	Weighted Average Exercise Price per share ($)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value ($)
Outstanding and exercisable at June 30, 2020	5,000	$ 10.00	1.16	$ -
Granted	-	-	-	-
Outstanding and exercisable at December 31, 2020	5,000	$ 10.00	.67	-

The options expire on August 31, 2021.

Note 11 - Commitments and Contingencies

Legal Proceedings

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.

Employment Agreements

The Company and Dr. Anil Diwan, President, CEO and Chairman of the Board of Directors, entered into an extension of employment agreement effective July 1, 2018 for a term of three years. Dr. Anil Diwan will be paid an annual base salary of $400,000. Additionally, Dr. Anil Diwan was awarded a grant of 26,250 shares of the Company's Series A preferred stock. 8,750 shares vest equally on June 30, 2019, 2020 and 2021. Any unvested shares are subject to forfeiture.

On March 3, 2010, the Company entered into an employment agreement with Dr. Jayant Tatake to serve as Vice President of Research and Development. The employment agreement provides for a term of four years with a base salary of $150,000. In addition, the Company issued 1,340 shares of Series A preferred stock and 1,786 shares of common stock upon entering into the agreement, and will issue an additional 1,340 shares of Series A preferred stock and 1,786 shares of common stock on each anniversary date of the agreement. The shares of Series A preferred stock were issued in recognition of Dr. Tatake's work towards the achievement of several patents by the Company. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

On March 3, 2010, the Company entered into an employment agreement with Dr. Randall Barton to serve as Chief Scientific Officer. The employment agreement provided for a term of four years with a base salary of $150,000. In addition, the Company issued 1,786 shares of common stock upon entering into the agreement, and will issue an additional 1,786 shares of common stock on each anniversary date of the agreement. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

On May 30, 2013, the Company entered into an employment agreement with Meeta Vyas, wife of our President, CEO and Chairman of the Board, to serve as its Chief Financial Officer. The employment agreement provided for a term of three years with a base salary of $9,000 per month and 129 shares of Series A preferred stock, also on a monthly basis. On January 1, 2015, her cash compensation was increased to $10,800 per month. The agreement is renewable on an annual basis. The Compensation Committee of the Board of Directors has extended the current provisions of the employment agreement pending its review of current industry compensation arrangements and employment agreements.

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 the VZV Licensing 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. Upon commercialization, NanoViricides will pay 15% of net sales to TheraCour, as defined in the agreement. The Company was not required to make any upfront payments to TheraCour and agreed to the following milestone payments to TheraCour; the issuance of 75,000 shares of the Company's Series A preferred stock upon the grant of an IND Application; $1,500,000 in cash upon completion of Phase I Clinical Trials; $2,500,000 in cash upon completion of Phase II clinical trials; and $5,000,000 in cash upon completion of Phase III clinical trials. On June 8, 2020, the Company executed a Memorandum of Understanding ("MOU") with TheraCour that provides a limited license to the Company for the entire application of human coronavirus infections, while the full license is being perfected. The Company has appointed a third party consulting firm for independent evaluation of this market space. Dr. Anil Diwan is recused from these discussions due to a conflict of interest. The terms of the COVID License Agreement, except as otherwise specified in the MOU, is expected to be generally consistent with the VZV License Agreement dated November 1, 2019, and shall include consistent milestone payments, royalties and sublicense and income derived from grants and contracts.

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 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, 2020. 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.

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

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

Since our founding in 2005, we have developed drug candidates against a number of different viruses including coronaviruses, influenza viruses, HIV, herpes viruses (HSV-1, HSV-2, and VZV), and dengue viruses among others. Many of these candidates have been successfully tested in cell culture and animal studies.

We are currently focused on advancing our drug candidates for treatment of patients with COVID-19 infection towards human clinical trials, in response to the current pandemic. We are working on a pre-IND application for COVID-19 treatment at present. 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.

Our clinical drug candidate for shingles, namely NV-HHV-101, a skin cream for the treatment of shingles rash, has completed IND-enabling pre-clinical studies and we were in the process of writing the Investigational New Drug ("IND") application for this drug when the COVID-19 pandemic struck. As we have focused our efforts on the coronavirus program due to the difficulties of conducting human clinical trials for shingles during the pandemic we plan on re-engaging this program and filing an IND once the adverse effects of the coronavirus pandemic on designing and conducting shingles clinical trials is minimized.

We began development of a nanoviricide drug to treat SARS-CoV-2, the virus that causes COVID-19 spectrum of diseases and which became a historic worldwide pandemic, around January 2020, when the news of cases in China broke out. Since then, we have been working diligently on designing, testing, and advancing drug candidates against SARS-CoV-2 (see below). We have recently completed safety pharmacology studies required for filing an IND application with the US FDA of our COVID-19 drug candidate. We are preparing to submit a pre-IND application to the US FDA for this drug candidate to obtain further guidance and plan on submitting an IND application thereafter.

NanoViricides is one of a few biopharma companies that operates its own cGMP-compliant manufacturing facility. The Company intends to produce its drugs for clinical trials in this facility. The Company has the capability to produce sufficient drugs for about 1,000-5,000 patients in a single batch of production, depending upon the drug and the dosage. This production capacity is anticipated to be sufficient for first-in-human use in the current SARS-CoV-2 pandemic for our anti-coronavirus drug in development, as well as for the anticipated clinical trials of NV-HHV-101 skin cream for the treatment of shingles. (see below).

The Company's drug development business model was formed in May 2005 with a license to the patents and intellectual property held by TheraCour Pharma, Inc. ("TheraCour") that enabled creation of drugs engineered specifically to combat viral diseases in humans. This exclusive license from TheraCour serves as a foundation for our intellectual property. TheraCour is a privately owned company, controlled by Dr. Anil Diwan, PhD, principal developer of the polymeric-micelle based nanomedicines technologies. TheraCour licenses its intellectual property from AllExcel, Inc., ("Allexcel") a company that is owned and controlled by Dr. Anil Diwan. The Company has a worldwide exclusive license to this technology for several drugs with specific targeting mechanisms for the treatment of a number of human viral diseases including HSV-1, HSV-2, and VZV. The Company signed a Memorandum of Understanding ("MoU") with respect to anti-viral treatments for coronavirus derived human infections (the "Field") with TheraCour in June 2020. The MoU specifically provides a limited, exclusive license to the Company for all research and development in the Field for further research and development purposes towards human clinical trials.

The Nanoviricide Platform Technology in Brief

NanoViricides is pioneering a unique platform for developing anti-viral drugs based on the "bind-encapsulate-destroy" principles. Viruses would not be able to escape a properly designed nanoviricide® drug by mutations because in doing so they would lose the ability to bind their cognate cellular receptor(s) and thus fail to infect productively, becoming incompetent.

The Company develops its class of drugs, that we call nanoviricides®, using a platform technology. This approach enables rapid development of new drugs against a number of different viruses. A nanoviricide is a "biomimetic" - it is designed to "look like" the cell surface to the virus. The nanoviricide® technology enables direct attacks at multiple points on a virus particle. It is believed that such attacks would lead to the virus particle becoming ineffective at infecting cells. Antibodies in contrast attack a virus particle at only a maximum of two attachment points per antibody.

In addition, the nanoviricide technology also simultaneously enables attacking the rapid intracellular reproduction of the virus by incorporating one or more active pharmaceutical ingredients (APIs) within the core of the nanoviricide. The nanoviricide® technology is the only technology in the world, to the best of our knowledge, that is capable of both (a) attacking extracellular virus, thereby breaking the reinfection cycle, and simultaneously (b) disrupting intracellular production of the virus, thereby enabling complete control of a virus infection.

The Company's technology relies on copying the human cell-surface receptor to which the virus binds, and further designing and making small chemicals that are called "ligands" that will bind to the virus in the same fashion as the cognate receptor. We use molecular modeling techniques for these tasks. These ligands are then chemically attached to a nanomicelle, to create a nanoviricide.

It is anticipated that when a virus comes in contact with the nanoviricide, not only would it land on the nanoviricide surface, binding to the copious number of ligands presented there, but it would also get entrapped because the nanomicelle polymer would turn around and fuse with the virus lipid envelope, harnessing a well-known biophysical phenomenon called "lipid-lipid mixing". In a sense, a nanoviricide drug acts against viruses like a "venus-fly-trap" flower does against insects. Unlike antibodies that tag the virus and require the human immune system to take over and complete the task of dismantling the virus, a nanoviricide is a nanomachine that is designed to not only bind to the virus but also complete the task of rendering the virus particle ineffective.

Recent Developments

We began development of a nanoviricide drug to treat SARS-CoV-2, the virus that causes COVID-19 spectrum of diseases, and has become a historic worldwide pandemic, around January 2020, when the news of cases in China broke out. Since then, we have been working diligently on designing, testing, and advancing drug candidates against SARS-CoV-2.

On September 15, 2020, we reported in a press release that we have nominated a clinical candidate for COVID-19, with additional back-up candidates that we continue to work on advancing further. We have previously reported that our developmental drug candidates have shown effectiveness against multiple coronaviruses in cell culture studies, and have shown strong effectiveness in animal studies against a human coronavirus that uses the same human receptor (ACE2) as SARS-CoV-2, namely h-CoV-NL63. There are reports that common colds coronavirus infection has led to protection from SARS-CoV-2 infection. This protection is most likely associated with infection by hCoV-NL63, because this is the only common cold virus that uses the same human receptor as SARS-CoV-2. Thus we believe our results are significant as they have demonstrated a broad-spectrum anti-coronavirus effectiveness, and, additionally, strong effectiveness in animal model that indicates that our drug candidates should be effective against SARS-CoV-2. Studies involving SARS-CoV-2 require BSL3/BSL4 facilities. Performing studies in BSL3/4 facilities is inherently slow, and requires dependence on high containment laboratory schedules and access. We, therefore, developed animal models and cell culture studies that can be conducted in BSL2 facilities. This enabled our rapid drug development.

The broad-spectrum anti-coronavirus activity of our drug candidates is important because it provides scientific rationale that as a virus mutates, it would not escape the drug. In addition, the drugs we develop should work against seasonal or commonly circulating coronaviruses as well as potentially pandemic and 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.

On November 11, 2020, we announced that we have engaged Calvert Labs to perform core safety pharmacology studies that are generally required for filing an Investigational New Drug (IND) application with the US FDA prior to being able to begin human clinical studies.

On or about February 8, 2021, subsequent to the reporting period, we reported in a press release that our broad-spectrum anti-coronavirus drug candidate for the treatment of COVID-19 infections was found to be well tolerated in safety pharmacology studies required for progressing to human clinical trials.

We reported that our anti-coronavirus drug candidate NV-CoV-2 was found to be safe in the GLP safety pharmacology studies performed by an external contract research organization (CRO) in both rat and non-human primate (NHP) models. Additionally, multiple injections of NV-CoV-2 were also well tolerated in an extensive non-GLP study in rats that was performed by AR Biosystems, Inc., Florida.

Based on the safety of NV-CoV-2 in these studies, the Company believes that projected dosages would be safe 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, if needed, to achieve control over the coronavirus infection from SARS-CoV-2 or its variants.

In a GLP neuro-pulmonary safety pharmacology study in rats, the following conclusion was drawn: The intravenous administration of NV-CoV-2 at doses of 25, 50 and 100 mg/kg did not affect respiratory function in rats.

In a GLP cardiovascular function study in the NHP cynomolgus monkeys, the following conclusion was drawn: Intravenous infusion of NV-CoV-2 at 25, 37.5, and 50 mg/kg did not have any toxicologic effects on cardiac rhythm or ECG morphology in cynomolgus monkeys in this study. No significant effects on blood pressure and heart rate were observed after the intravenous infusion of NV-CoV-2.

These results were consistent with a more extensive, multiple injection non-GLP safety and tolerability study in Sprague-Dawley male and female rats. In this non-GLP study, NV-CoV-2 was injected intravenously (via tail vein) on each of days 0, 1, 2, 3, 4, and 5. Two different doses were used: 320mg/kg BW per injection, and 160 mg/kg BW per injection. Clinical observations, body weight, urine, blood chemistry, post-mortem findings, and organ histology were studied. In all parameters, NV-CoV-2 was well tolerated at both dosages throughout the study.

We have received draft reports from all of these studies. We anticipate receiving final audited reports on the GLP studies shortly. We are now preparing to submit a pre-IND application to the US FDA with safety tolerability and effectiveness data to obtain guidance regarding human clinical trials. Additionally, we are actively seeking opportunities to engage appropriate sites for human clinical trials. Further, we are engaged in the preparation of clinical trial protocols and other activities that would be necessary for submitting an IND application to the US FDA.

The need for the broad-spectrum, pan-coronavirus nanoviricide drug treatment cannot be overstated for combating the COVID-19 pandemic given the current circumstances and the present status of the pandemic. New virus variants continue to develop in the field. The variants that have advantages in terms of transmissibility, infectivity, and escape from drugs and vaccines will continue to evolve and spread, replacing prior variants. This is already well documented.

Several vaccines have been found to be substantially less effective in protecting against infection by the South African variant, N501Y-V.2 (also called lineage B.1.351) than the earlier variants. A mutation present in B.1.351 as well as Brazilian variant P.1 that is thought to be possibly linked to evasion from antibody drugs and vaccines, E484K, has also been reported in UK in a further differentiated mutant of the variant of concern lineage B.1.1.7. The available monoclonal antibody drugs and convalescent plasma antibodies have been reported to be less effective against several variants.

By the very nature of how they work, vaccines and antibodies tend to be highly specific to the target virus variant, and do not afford strong protection against differentiated variants that are evolutionary distant from the target variant. This scientific fact is now well demonstrated for the COVID-19 pandemic.

It is therefore clear that an effective broad-spectrum anti-coronavirus drug will be needed before the world can return to normal activity.

Previously we had advanced NV-CoV-1 and had continued to work further with additional drug candidates. One of these drug candidates, namely, NV-CoV-2 was found to have several advantages over NV-CoV-1 in terms of manufacturability and dose formulation. Therefore, the Company has advanced NV-CoV-2 into GLP safety/pharmacology studies.

We are developing a broad-spectrum antiviral drug 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 which still may not protect against new virus variants circulating by that time.

In addition to NV-CoV-2, we are also developing another anti-coronavirus drug candidate, NV-CoV-2-R. This drug candidate is comprised of holding remdesivir inside our polymeric drug candidate NV-CoV-2 by a process known as encapsulation. Thus NV-CoV-2-R is potentially capable of (1) direct attack on extracellular virus, to break the "re-infection cycle" by virtue of NV-CoV-2, and (2) attack on intracellular reproduction of the virus to break the "replication cycle" as has been validated for remdesivir. If both of these cycles are broken, in theory, it is expected to result in a cure of the virus infection, or at least a substantially strong control of the virus infection. Remdesivir is a challenging drug, because it is rapidly converted by blood and cellular enzymes into a significantly less potent form. It is also almost insoluble in aqueous media. These issues have been cited as possible reasons for different data from clinical trials. In randomized controlled clinical trials, Gilead reported that remdesivir was effective in reducing the hospital stay of COVID-19 patients significantly. However, in analysis of field usage of remdesivir and other clinical trials, WHO reported that remdesivir was not as effective as was thought based on the clinical trials that led to first its emergency use approval (EUA) followed by complete approval (Approval) by the US FDA. Encapsulation of remdesivir in NV-CoV-2 is expected to solve these problems. Encapsulation inside NV-CoV-2 is expected to protect remdesivir from the rapid bodily metabolism, thereby raising the effective drug concentration in the body, and it is also expected to make effective drug available over a longer period of time than the Gilead formulation of remdesivir.

It is important to develop NV-CoV-2 by itself as a drug because the inherent toxicity of remdesivir which can be inferred from its molecular structure may limit its usage in certain patient populations.

We were able to achieve the important milestone of completing the creation of NV-CoV-2-R from NV-CoV-2 and remdesivir in a matter of just a few months. This rapid development was possible only because of the strong advantages of our nanoviricide platform technology.

We are performing the development of NV-CoV-2 and NV-CoV-2-R independently. Remdesivir is sponsored by Gilead. Significant amounts of US government funding has been used in its development, from NIH as well as from BARDA.

We have initiated production of a large batch of NV-CoV-2 and of NV-CoV-2-R under cGMP-compliant conditions for human clinical trials. NanoViricides is one of a few biopharma companies with the strong advantage that it has its own cGMP-capable manufacturing facility. This has made possible rapid translation from synthesis for non-clinical studies to large scale clinical batch production in a very short timeframe. Our cGMP-capable facility is capable of producing approximately 4kg of the COVID-19 drug candidate per batch. We anticipate that this would be sufficient for human clinical trials, and possibly for initial introduction under Compassionate Use, Emergency Use Authorization or similar regulatory approval.

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 and set-up activities, as well as saving several millions of dollars of external costs, while ensuring requisite quality assurance, as compared to using a contract manufacturing organization ("CMO") 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.

Thus, our anti-coronavirus drug program is moving rapidly towards an IND filing to enable human clinical trials.

Financial Status

As of December 31, 2020, we had approximately $18.4 million in cash and cash equivalents and $9.2 million of property and equipment, net of accumulated depreciation. Our current liabilities are approximately $0.3 million. On December 31, 2020, the Company repaid the short term mortgage loan of $1.1 million secured by our facility that we had obtained in December 2019 from Dr. Anil Diwan, our founder President, Chairman and CEO. Stockholder's equity was approximately $27.7 at December 31, 2020.

During the six-month period ended December 31, 2020, we used approximately $4.6 million in cash toward operating activities. The available cash is sufficient for more than twelve months of operations at the current rate of expenditures. 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 we have sufficient funds in hand for initial human clinical trials for at least one of our drug candidates at this time.

We do not anticipate any major capital costs going forward in the near future.

NanoViricides is one of a few bio-pharma companies that possess its own facilities to support all of its drug development activities from discovery, optimization, pre-clinical large scale production, to clinical cGMP production of its drug candidates. The Company has its own lab and cGMP-capable flexible custom manufacturing facility where any of our drug candidates can be produced in multi-kilogram quantities to support corresponding IND-enabling tox package studies, initial human clinical trials, and possibly, initial revenue-generating commercialization batches.

NanoViricides' Drug Programs in Brief

We intend to take one of 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 US FDA as well as international regulatory authorities.

Thereafter, we intend to focus on NV-HHV-101, and develop this drug through initial human clinical trials. We anticipate that, as the NV-HHV-101 drug (skin cream) for Shingles indication goes into human clinical testing, we would develop clinical candidates for topical treatment of HSV-1 "cold sores" and HSV-2 "genital ulcers". Additional indications for these drug candidates or their derivatives as needed for different routes of administration and other considerations are expected to expand our drug pipeline in the near future. As these programs mature, the Company intends to re-engage its FluCide™ and HIVCide™ programs.

The market size for HerpeCide programs is in several tens of billions of dollars because neither cures nor very effective treatments are available. Approved treatments have limited effectiveness, demonstrating a significant unmet medical need. The market size for Influenza drugs is estimated to be in tens of billions of dollars.

Based on data in a Jain PharmaBiotech report prepared for the Company in March 2014, we believe the overall market size for the anti-viral market was $40 billion in 2018 and may be $65.5 billion in 2023, excluding the market size for COVID-19 pandemic responsive drugs and vaccines.

Thus, the Company's technology has substantial capabilities and applications, and the potential to attack as-yet-unsolved problems caused by viral infection, and thus lead to a great health benefit to individuals and societies. We are seeking to add to our pipeline of drug candidates through our internal discovery pre-clinical development programs and through an in-licensing strategy. The Company has a bright future with an expanding pipeline as it furthers the research programs driving towards cures beyond our current objectives of effective treatments.

The Novel Coronavirus Disease ("COVID-19") Pandemic, caused by the new SARS-CoV-2 virus

On January 30, 2020, the Company confirmed in a press release that it had already undertaken an effort to develop a treatment for the novel SARS-CoV-2, a/k/a 2019-nCoV, coronavirus outbreak that appears to have started around November-December 2019 in Wuhan, China. The new SARS-CoV-2 virus is known to be closely related to the SARS-CoV of 2002-2003 epidemic. In fact it has been shown to use the same cell surface receptor as SARS-CoV, namely ACE2. The Company determined, based on molecular modeling screening that it had in its chemicals library ligands that could bind to SARS-CoV S1 spike protein at the same position where the S1 binds to the human receptor ACE2. It is a reasonable expectation that these relatively broad-spectrum ligands would also be able to bind the S1 spike protein of the SARS-CoV-2 coronavirus in the same fashion. Since then, the Company has generated several nanoviricides based on these ligands and has tested them in its own BSL2 virology lab facility against known available human pathogen coronaviruses, including those that use ACE2 as the cellular receptor, with success.

The Company is developing a therapy or drug to combat the SARS-CoV-2 virus itself, for the treatment of infected patients, and not a drug that is designed for reducing clinical symptoms. The drug we are developing is not a vaccine, and does not have to be given to everyone, but will need to be given only to patients, if we can develop it successfully. Currently, two antiviral drugs are in clinical studies or have been approved in emergency protocols for the treatment of COVID-19 patients. Remdesivir has been approved for use in COVID-19 in the US, and favipravir was approved in the USSR for COVID-19 treatment. Both of these drugs affect replication of the virus inside cells, and both have shown limited clinical effectiveness. Additionally, dexamethasone, a corticosteroid, is used as supportive treatment in late stages to minimize the immune attack onto lung cells that leads to lung failure.

A drug, such as a nanoviricide that blocks the virus from binding to cells in the first place may be sufficiently effective by itself in treating COVID-19 patients to be a viable treatment option. Further, a nanoviricide can be combined with other antiviral drugs that inhibit intracellular replication of the virus with the potential for a greater effect than either drug, towards curing the viral infection. The ability of any drug to cure the viral infection can only be established in human clinical trials.

Viruses are known to escape antibody drugs, small chemical drugs, and vaccines due to genomic changes such as mutations or recombinations. In contrast, the NanoViricides platform technology enables development of a drug that a virus is unlikely to escape by mutation. This is because we develop biomimetics that are designed to interfere with the virus binding to its cognate cellular receptor, and are further capable of disabling the virus from binding to cells. It is well known that in spite of genomic changes, the virus binds to the same cellular receptor in a conserved manner. Thus, the nanoviricides technology provides a mechanism that the viruses would not be able to escape due to genomic changes, provided that the virus-binding ligands are designed to mimic the conserved binding site on the cellular receptor.

The Company has the capacity to produce several thousand doses of the potential drug at its cGMP-capable multi-purpose manufacturing facility in Shelton, CT, depending upon the treatment course. If our COVID-19 drug program produces positive results, then the Company anticipates obtaining assistance from US government and international agencies for further testing and potential exploratory clinical use to combat the epidemic. The Company does not at present have any active collaborations with US or international agencies for this purpose. Even if the Company can develop a potential drug candidate, significant support and participation from US and international agencies may be required to make it available to patients, including taking the candidate through exploratory clinical trials. The outbreak was declared a global emergency by the WHO on the same date as our announcement that we were working on therapeutics development against SARS-CoV-2, January 30, 2020, and has since turned into a global pandemic with devastating consequences around the world.

The Company has expertise in developing broad-spectrum antivirals based on mimicking human cellular receptors. For example, NV-HHV-101, the Company's lead drug candidate, which was developed using virus-binding ligands mimicking the binding of HVEM with HSV viral glycoprotein has been shown to be effective against not only HSV-1 and HSV-2, but also was found to be highly effective against VZV, which is a distantly related non-simplex herpesvirus. The Company's business model is based on licensing technology from TheraCour which has licensed intellectual property from Allexcel for specific application verticals of specific viruses, as established at the Company's foundation in 2005.

Several coronaviruses have become endemic human pathogens, such as hCoV- 229E, NL63, OC43, and HKU1. These continually circulate in the human population and cause respiratory infections in adults and children world-wide. In contrast, SARS-CoV has caused only one well-known epidemic, with a mortality rate of about 9%, and MERS-CoV has caused repeated outbreaks, with mortality rates approaching 35%, but with a limited number of cases. A broad-spectrum anti-coronavirus drug, such as a broad-spectrum nanoviricide that the Company is currently developing, could be potentially useful for treating most if not all of the different coronavirus infections that occur every year, and not just for coronavirus epidemics.

The Company has tested its drug candidates for anti-viral effectiveness against two distinctly different, unrelated coronaviruses that cause human disease, namely HCoV-NL63, and HCoV-229E. The assays evaluated the reduction caused by the drug candidate in cell death upon viral infection, formally known as cytopathic effects (CPE) assays.

Human coronavirus NL63 (HCoV-NL63) uses the same ACE2 receptor as the SARS-CoV-2 that causes COVID-19. Both in terms of its clinical pathology, and its receptor usage, it is known to be very similar to SARS-CoV-2, except much milder. Therefore the Company believes HCoV-NL63 is a good surrogate model for therapeutics development against SARS-CoV-2. HCoV-NL63 can be studied in a BSL2 lab whereas SARS-CoV-2 currently requires a BSL3 or BSL4 facility. Human coronavirus 229E causes seasonal common colds, and uses a different but somewhat related receptor called APN (Aminopeptidase-N), a membrane protein on human cells.

The tested nanoviricides drug candidates were several-fold more effective than favipravir in both HCoV-229E infection assay as well as the HCoV-NL63 infection assay in cell culture studies.

Importantly, nanoviricides are designed to act by a novel mechanism of action, trapping the virus particle like the “Venus-fly-trap” flower does for insects. Antibodies, in contrast, only label the virus for other components of the immune system to take care of. It is well known that the immune system is not functioning properly at least in severe COVID-19 patients.

The Company has developed an animal model for coronavirus infection using hCoV-NL63 as a surrogate for SARS-CoV-2, the virus that causes COVID-19 disease. HCoV-NL63 is a circulating human coronavirus that causes a disease that is similar to SARS-CoV-2, but much milder. Both viruses utilize the same cell receptor, namely ACE2, to gain entry into the cell. Because it causes a mild disease, hCoV-NL63 can be used in BSL2 environments, and the Company believes it is a useful surrogate for development of therapeutics against SARS-CoV-2 infection.

On May 19, 2020, the Company announced that strong effectiveness against infection by an ACE2-utilizing coronavirus in an animal model has been observed for the drug candidates it is developing against SARS-CoV-2 to treat COVID-19 spectrum of diseases.

In this lethal direct-lung-infection model, animals in all groups developed lung disease that later led to multi-organ failures, a clinical pathology resembling that of the SARS-CoV-2. In these earlier studies for screening initial drug candidates, reduction in loss of body weight at day 7 was used as the primary indicator of drug effectiveness. Rats were infected directly into lungs with lethal amounts of hCoV-NL63 virus particles and then different groups were treated separately with five different nanoviricides drug candidates, remdesivir as a positive control, and the vehicle as a negative control. The treatment was intravenous by tail-vein injection once daily for five days, except it was twice daily in the case of remdesivir.

Animals treated with five different nanoviricides showed significantly reduced body weight loss. The body weight loss was only 3.9% for the best nanoviricide candidate, ranging to 11.2% for the potentially least effective one, as compared to 20% in the vehicle-treated control group, in female animals (n=5 in each group). Male animals treated with the same nanoviricides also showed significantly reduced body weight loss. The body weight loss in male animals was 8.0% for the best nanoviricide candidate and ranged up to 10.9% for the potentially least effective one, as compared to 25% in the vehicle-treated control group (n=5 in each group). In comparison, remdesivir treatment led to a body weight loss of 15.2% in females and 18.6% in males in this study (see below). Smaller numbers mean less loss in body weight compared to starting body weight in the group, and indicate greater drug effectiveness.

The strong effectiveness of nanoviricide drug candidates in this model is consistent with the effectiveness observed in cell culture studies against infection of both HCoV-NL63, which was used in this study, and HCoV-229E, another circulating coronavirus that uses a distinctly different receptor, namely APN.

Thus this study corroborated the cell-culture effectiveness reported by the Company and provided confidence to the Company that these nanoviricides drug candidates may be expected to result in a clinical candidate to be pursued in human clinical trials.

The Company believes the fact that these nanoviricides anti-coronavirus drug candidates are highly effective against two distinctly different coronaviruses that use different cellular receptors is very significant. Specifically, it provides a rational basis to scientists indicating that even if the SARS-CoV-2 coronavirus mutates, the nanoviricides can be expected to continue to remain effective. Antibodies and vaccines in general cannot be expected to remain effective if the virus undergoes genomic changes.

Importantly, nanoviricides are designed to act by a novel mechanism of action, trapping the virus particle like the “Venus-fly-trap” flower does for insects. Antibodies, in contrast, only label the virus for other components of the immune system to take care of. It is well known that the immune system is not functioning properly at least in severe COVID-19 patients.

The Company believes that these nanoviricides drug candidates are potentially superior to favipravir, based on cell culture studies and may be superior to remdesivir based on the results of the animal study, however, a definite conclusion to that effect cannot be drawn. Oral favipravir and infusion of remdesivir are two anti-viral drugs in clinical trials for the treatment of COVID-19. On October 22, 2020, US FDA approved Veklury (remdesivir), the first drug approved to treat COVID-19, for use in adults and pediatric patients 12 years of age and older and weighing at least 40 kg (about 88 pounds) requiring hospitalization.

Thus, the Company believes that the nanoviricides drug candidates it has developed are expected to warrant human clinical studies.

The striking difference in weight loss between the two sexes in this animal model was remarkable. It has been widely reported that men are more likely to suffer severe infection and fatalities from SARS-CoV-2 than women in the current COVID-19 pandemic. This feature was replicated in our animal model study indicating that biological sex differences are the driver of the differences in the severity of infection by the coronaviruses that utilize the ACE2 receptor.

NanoViricides believes that it is possible for the Company to develop receptor-mimetic virus-binding ligands that have broad-spectrum effectiveness against multiple coronaviruses that use different receptors, because of certain features common to these receptors and the interactions of coronaviruses with them. The various receptors used by different coronaviruses appear to fall in the broad family of membrane-associated serine proteases. As a family, they share several structural features. Their substrate specificities are dictated by specific amino acid residues and their positions. However, the coronaviruses do not appear to insert into the specific substrate sites on their receptors as can be broadly deduced from limited, available knowledge of these interactions.

HCoV-NL63 is known to cause severe lower respiratory tract infections in young children leading to hospitalization. The symptoms are generally less severe than SARS-CoV-2 but are similar. In most cases, HCoV-NL63 causes relatively mild disease, often associated with croup, bronchiolitis, and lower respiratory tract disease in children, and is considered to cause some of the common colds in adults. Thus, the clinical manifestation of hCoV-NL63 infection in pediatric patients is similar to that of SARS-CoV-2, although much less severe. SARS-CoV-2 causes clinically similar milder forms of disease in most patients, but moderate to severe disease requiring hospitalizations in about 15-20% of infected persons. These similarities imply that HCoV-NL63 should be a reasonable model virus for antiviral cell culture and animal studies in BSL2 environment in the course of antiviral drug development for SARS-CoV-2.

Developing a Potential Cure for Coronaviruses Including SARS-CoV-2

Subsequent to the initial cell culture and animal studies that gave us confidence that we were on the right track, we undertook further optimization and development of drug candidates towards the studies required for filing an IND application with the US FDA to enable human clinical trials. We developed NV-CoV-1, NV-CoV-2 and additional drug candidates in the process. We proceeded further with NV-CoV-2 because of certain advantages in manufacturing and formulation of this drug candidate over NV-CoV-1. We have since completed safety pharmacology studies of NV-CoV-2 that are required for an IND. In addition, we also developed a next generation nanoviricide NV-CoV-2-R by encapsulating remdesivir, a known drug with ability to block virus replication, inside NV-CoV-2.

Nanoviricide platform technology is capable of simultaneously (a) attacking extracellular virus and thus blocking the reinfection cycle, and (b) encapsulating an active pharmaceutical ingredient (API) that can block the intracellular virus replication cycle. If both of these cycles can be blocked effectively and simultaneously, it is likely that the resulting drug would be a cure for the SARS-CoV-2 infection. Such a drug would control the viral load in the patient and this would very likely enable the patient's immune system to not go into overdrive, and thus allow the patient to recover.

We are therefore currently advancing an anti-coronavirus drug candidate that encapsulates remdesivir. Although remdesivir is highly effective in blocking intracellular virus replication cycle in cell culture studies, its clinical effect is limited by its rapid metabolism in the bloodstream. There is scientific rationale from numerous nanomedicines developments that encapsulation of a drug can limit such metabolism. If our nanoviricide can successfully limit the metabolism of remdesivir, then the remdesivir effectiveness could be increased. In addition, the effect of the nanoviricide itself in blocking infection of new cells by the virus particles would lead to further therapeutic effect. We believe that these effects, taken together, could create a cure against SARS-CoV-2 as well as other coronaviruses.

We are currently performing these developments on our own. We do not have a collaboration with Gilead Sciences, Inc., the sponsor of remdesivir (trade name Veklury). Substantial U.S. government support has gone into the development of remdesivir, including resources as well as financial support from U.S. government agencies such as NIH and BARDA. We are minimizing our drug development risk by additionally developing and encapsulating other nucleoside-like inhibitors of intracellular virus replication.

We believe that we have been able to accelerate the anti-coronavirus drug development program, and have realized significant time- and cost-savings by scaling up and manufacturing our anti-coronavirus drug candidates in our own cGMP-capable facilities.

The Company believes that, based on feedback from industry research analysts, the major milestone of the IND filing of its first drug, which we believe will happen in the very near future, is expected to serve as a major value inflection point, as has generally been seen in the biopharma sector.

Thus the Company has been executing rapidly and efficiently, as well as in a cost-effective and productive manner, towards its 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.

NV-HHV-101 – The Company's Lead Candidate in the HerpeCide™ Program, with First Indication as a Skin Cream for the Treatment of Shingles Rash

NV-HHV-101 has consistently shown strong effectiveness as well as safety in human skin-based model of VZV infection. In cell culture studies, it was as much as five times more effective than acyclovir, the current standard of care. Our anti-VZV drug candidates have also shown strong effectiveness in studies involving VZV infection of human skin patches ex vivo. These studies were conducted by Professor Jennifer Moffat at the SUNY Upstate Medical Center in Syracuse, NY, an internationally recognized expert on varicella-zoster virus (VZV) infection, pathogenesis, and anti-viral agent discovery. Some of the earlier work was presented by the Moffat Lab at the 31st International Conference on Antiviral Research held June 11 - June 15, 2018 in Porto, Portugal.

There is a significant unmet medical need for the topical treatment of shingles rash. An effective therapy for shingles has been estimated to have a market size into several billions of dollars, if it reduces PHN incidence. An effective therapy against shingles rash reduction alone is estimated to have a market size of several hundred million dollars to low billion dollars. These market size estimates have taken into account the potential impact of the new Shingrix® GSK vaccine and the impact of the existing Zostavax® vaccine.

The Company is also developing drugs against HSV-1 "cold sores" and HSV-2 "genital ulcers", both based on the NV-HHV-101 drug candidate, although final clinical candidates are in pre-clinical optimization stage for both of these indications as of now.

Existing drugs given orally or systemically may not reach required concentrations at the site of shingles outbreak, limiting effectiveness. In addition, unlike HSV-1 and HSV-2, VZV does not have an effective TK enzyme that is required for producing active drug forms from the acyclovir class of drugs (such as Valtrex®), requiring frequent administration of very large doses to treat shingles. Additionally, a dermal topical cream formulation of Cidofovir is employed in very severe cases of shingles. Cidofovir is highly toxic, particularly towards kidneys. A safer, effective, drug is thus an unmet medical need for the treatment of VZV.

Zostavax and other attenuated VZV (Oka strain) vaccines for chickenpox are available, but not widely adopted. These vaccines may lead to a less severe form of shingles in adulthood or at a later age, compared to the "wild type" chickenpox virus ("rebound shingles"). A new vaccine, Shingrix® has been introduced by GSK recently, based on subunits or protein fragments of the virus, which cannot lead to rebound shingles, but suffers from a very severe side effects profile, and has limited availability at present.

While shingles presents with a debilitating "pins-and-needles" pain associated with the characteristic rash that is self-limiting within 2-3 weeks in most patients, in a substantial percentage of patients, it presents as a severe, debilitating disease that leads to complications including hospitalization(s) and in some cases may result in extended treatments including subsequent surgeries.

Limiting initial viral load is expected to minimize the occurrence of such complications, and is also expected to reduce the incidence of post-herpetic-neuralgia ("PHN"). PHN is defined as dermatomal nerve pain that persists for more than 90 days after an outbreak of herpes zoster affecting the same dermatome. Thus, we anticipate that NV-HHV-101 would have significant impact in reducing PHN incidence rates. We anticipate extending the NV-HHV-101 indication to include PHN after obtaining marketing approval for the first indication, namely effect on shingles rash.

Of note, the cGMP-like manufacture of both the active pharmaceutical ingredient (API, the nanoviricide against VZV), and the fully formulated skin cream (the drug product candidate), was accomplished at our own facilities at ~1kg scale (API), saving us millions of dollars and at least one year's worth of time, as opposed to going to an external contract manufacturer. Approximately 10kg of fully formulated drug product has already been manufactured. We believe this scale is sufficient for the requirements of Phase I human clinical trials.

The Company has now demonstrated that it has unique expertise in the industry of performing cGMP manufacture of 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 rapid success of translating the research scale production of several grams drug substance in early CY-2018 to kg-scale cGMP manufacture in early CY-2019 was a result of the tremendous subject matter expertise of the team. External contract manufacturing organizations would likely have required at least three years to scale up these complex products, based on certain discussions we have had.

The Company has previously found that dermally applied nanoviricide drug candidates in the HerpeCide program led to full survival of lethally infected animals in a severe infection with the highly pathogenic, neurotropic strain of HSV-1, namely H129c. Thus the nanoviricide drug candidates applied topically appear to demonstrate strong efficacy. Topical application has the advantage of being able to deliver very high drug concentrations locally to completely eradicate the virus. In contrast, the local concentrations and therefore effectiveness of orally delivered medications is limited by the toxicity and bioavailability of the oral drug, as is known for the existing antiviral therapies for HSV-1, HSV-2, and VZV. Therefore, treating the HSV-1 cold sores, HSV-2 genital ulcers, or VZV chicken pox lesions or shingles rash using dermal topical creams is expected to be highly beneficial.

NV-HHV-101 is a broad-spectrum nanomedicine designed to attack herpesviruses that use the HVEM ("herpesvirus entry mediator") receptor on human cells. This drug candidate is composed of a flexible polymeric micelle "backbone" to which a number of small chemical ligands are chemically attached. The ligands in this case are designed to mimic the binding site of the herpesviruses on HVEM, based on molecular modeling. NV-HHV-101 is expected to bind to VZV (or HSV-1 or HSV-2) virus particle via a number of binding sites (i.e. the ligands), thereby encapsulating the virus particle and destroying its ability to infect human cells. This "Bind, Encapsulate, Destroy" nanoviricide® strategy is distinctly different from the mechanism of action of existing antiviral drugs against VZV, HSV-1, and HSV-2.

The anti-VZV drug development program moved rapidly towards clinical candidate declaration stage because of several factors, namely (a) that it was simply the existing HSV-1 drug program in which the existing candidates were re-tested for effectiveness against VZV, (b) that we have had a highly successful collaboration with Dr. Moffat Lab at SUNY Syracuse with rapid turnaround times, and (c) the drug candidates were found to be highly effective against VZV in these studies.

While the Company has been focused on cGMP production, scale-up, and establishment of required characterization and analytical tools, we have brought down our cash expenditure rate significantly by reducing our workforce and by stopping work on all other programs except the HerpeCide program and the Covid–19 program.

Our HerpeCide™ Product Pipeline

We have focused our efforts exclusively on the anti-Coronavirus drug program at present. Until January 2020, we had focused our efforts almost exclusively on the HerpeCide™ program.

We currently have at least 10 different drug development programs, attesting to the strength of our platform technology. We are currently working on the Coronavirus program at the highest priority of an emergency program. In addition, we have been working on 3 of the HerpeCide program indications (namely VZV Shingles, HSV-1 Cold Sores, and HSV-2 genital Ulcers) in parallel, as explained below (priority level 1). The Herpes Keratitis program and v-ARN program (see below) are at a lower priority level. In addition, we continue to work on the FluCide™ program at the lower priority 3. HIVCide™ program is at priority level 4. We will continue to seek funding for further development in the remaining programs, namely Dengue and Ebola/Marburg antivirals.

The potential broad-spectrum nature of our anti-HSV drug candidates is enabling several anti-Herpes indications under our HerpeCide™ program. Of these, the (i) Topical Treatment for Shingles (VZV) is currently moving most rapidly towards clinical stage. We believe that the other anti-Herpes drug candidates, would follow this lead drug to the clinical stage, namely, (ii) skin cream for the treatment of orolabial herpes (“cold sores”) and recurrent herpes labialis (RHL) mostly caused by HSV-1, and (iii) skin cream for the treatment of genital herpes caused by HSV-2.

In addition, a fourth indication, (iv) ocular eye drops treatment for external eye herpes keratitis (HK), caused by HSV-1 or HSV-2, is expected to follow into further drug development. Further, we have announced that we have begun preclinical drug development work on a fifth indication under the HerpeCide program, namely (v) viral Acute Retinal Necrosis (v-ARN), intravitreal injection.

The market size for an effective anti-shingles drug is currently estimated to be in the range of several billions of dollars, even after a new shingles vaccine, Shingrix® (GlaxoSmithKline) has been approved, based on a report performed for the Company by Dr. Myers of BioEnsemble, LLC, pharma industry consultants, commissioned by the Company. The current vaccine for prevention of chicken pox in children, i.e. the varicella vaccine, is based on the live attenuated virus derived from the Oka strain. Un-vaccinated children usually develop chicken pox at some point in their childhood, and the wild-type virus then remains latent in their bodies, in nerve ganglia. Similarly, Varicella vaccinated children may develop mild syndrome when vaccinated and the weakened Oka strain remains latent in their bodies, All of these children can develop shingles later in life. It is generally believed that the intensity of such disease would be much less severe with the weakened vaccine strain than with the natural or wild type strain. Nevertheless, the severity of the symptoms and overall effects depend upon the immune status of the individual. Pre-vaccination era, (i.e. before varicella vaccination was widely adopted in the USA), there were 3-4 million cases of chicken pox per year (matching the birth rate). Post-vaccination era, this rate has dropped to about 120,000-150,000 cases in the USA. However, in several developing and underdeveloped countries, the rates of chicken pox remain high due to limited access to the vaccine or limited adoption of the vaccine. As stated earlier, nearly every person may be expected to get shingles at some point in their lives, with varying severity. A preventive vaccine for adults, namely Zostavax® is available, based on the attenuated Oka strain. Its effectiveness is variously estimated at around 60-70%. Its coverage remains low, as most people do not get this vaccine. Shingrix is a subunit vaccine, that is, it does not contain intact living virus particles but only certain proteins derived from the virus. As such, it is expected to not have the issue of “breakthrough disease” which occurs when the live latent virus from the vaccine itself causes disease.

More specifically, the report estimated that the anti-shingles drug candidate could reach peak annual sales of as much as $2 billion, depending upon the effectiveness determined in clinical trials, at an assumed 50% market penetration, if it is effective in reducing incidence of post-herpetic neuralgia (PHN). Based on current pre-clinical data, we believe that there is a very strong probability that the shingles treatment would significantly minimize the shingles pain, accelerate healing, and minimize nerve damage, thereby minimizing the occurrence and severity of post-herpetic neuralgia (PHN). Our pre-clinical drug design efforts have been aimed at developing a treatment for shingles that would have pain reduction effects as well as healing effects on skin.

Initially, we plan on performing clinical trials based on VZV related biomarkers and clinical pathology, which we believe would be sufficient for a first indication for approval of the drug for treatment of shingles by the US FDA. Sales of an effective drug against shingles with this limited indication are projected to reach several hundreds of millions of dollars. We plan on performing observations regarding PHN in these clinical trials so that an informed PHN clinical trial may be performed later to extend the drug indication.

We have developed strong chemical manufacturing process controls that enable us to produce the backbone polymers with highly restricted and reproducible molecular size range. In fact, we have achieved highly reproducible and scalable processes that have yielded the same polymer molecular sizes across production scales from 10g to 500g. In other words, we are now able to control the length of the backbone polymer to within one monomer unit, irrespective of production scale, at least up to about 1 kg scale.

We believe that this is a remarkable and possibly unmatched achievement in the field of nanomedicines. We have scaled up the production of the polymer backbone “nanomicelle” to multiple-kilogram scales, and do not anticipate any manufacturing constraints at present. We have also achieved kilogram-scale manufacture of the ligand in NV-HHV-101, and have further scaled up production of the nanoviricide NV-HHV-101, which is chemical conjugate of the ligand to the nanoviricide, in a well defined manner to kilogram scale. Additionally we have scaled up formulation of the resulting drug substance into the skin cream to multi-kilogram scales. The production of the drug substance and the drug product is achieved in a cGMP compatible fashion at our own facility.

Our polymer backbone itself is designed based on the route of administration. In the case of the shingles drug candidate, as well as for HSV-1 cold sores, and for HSV-2 genital ulcers, the route is dermal topical application.

The ligands currently in use for the nanoviricide drug candidates against VZV shingles were actually developed using computer models of HSV binding to its cellular receptor, and not against VZV itself. Our program shifted to advance a VZV candidate as our first indication due to various considerations that led to the prioritization of the different drug indications. The Company identified certain advantages that would enable earlier entry into clinical trials for the shingles candidates. The shingles drug development program has been moving rapidly primarily because of the quick turnaround time and high responsiveness of the Dr. Moffat Lab at SUNY Syracuse, our critical collaborator for human skin effectiveness studies of our drug candidates.

One of the advantages of the shingles program is that the pre-clinical drug development is performed directly in a human skin model, bypassing any animal model, providing significant confidence that a human clinical studies outcome would parallel the preclinical study outcome. VZV does not infect animals other than humans.

Thus, we have made significant and substantial progress in the reporting quarter towards the goal of filing our first IND application, and we continue to build on this progress.

In addition to VZV, we are also developing dermal topical drugs against HSV-1 cold sores and HSV-2 genital ulcers. Dr. Brandt’s Lab at CORL, the University of Wisconsin, Madison, WI, is validating animal models for the study and evaluation of relative efficacies of different treatments for HSV-1 infection in mice as well as for HSV-2 infection in mice. The goal of these developments is to develop animal models that would be able to discriminate an experimental drug that is more effective than the current standard of care drugs, from the standard of care. At present the existing animal models show maximal effectiveness with the standard of care and therefore cannot discriminate a drug that might be superior. If their animal models are successful in differentiating effectiveness of different drug candidates, then we will be able to evaluate our drug candidates for the treatment of HSV-1 cold sores as well as for the treatment of HSV-2 genital ulcers, in addition to the VZV testing being performed.

Acute Retinal Necrosis is characterized by severe ocular inflammation, retinal necrosis, and a high incidence of retinal detachment (RD) leading to visual loss and blindness. This disease is caused by members of the herpesvirus family, including, herpes simplex virus-2 (HSV-2), varicella zoster virus (VZV), and herpes simplex virus (HSV-1). An estimated 50,000 new and recurrent cases of ocular herpes per year are reported in the United States alone, and in a small proportion of the patients, the disease escalates to v-ARN. We anticipate that ocular herpes or v-ARN may qualify for an orphan disease indication.

We have recently reported that we have extended the contracts with both the Moffat Lab, UMC, SUNY Syracuse, as well as the Brandt Lab, CORL, UW, Madison to continue to perform more advanced studies in preparation of an IND for shingles topical treatment and for v-ARN intravitreal treatment, respectively.

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 USFDA 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.

Herpes simplex viral infections cause keratitis of the eye, and severe cases of infection may sometimes necessitate corneal transplants. Oral and genital herpes is also a well-known disease, with no cure and existing treatments that are not very effective. Shingles, caused by VZV, a herpesvirus, does not have an effective treatment at present, although some drugs are approved for use in shingles. Adenoviral Epidemic Kerato-Conjunctivitis (EKC) is a severe pink eye disease that may lead to blurry vision in certain patients after recovery. The epidemic and pandemic potential as well as the constantly changing nature of influenza viruses is well known. The HIV/AIDS worldwide epidemic and the "curse of slow death" nature of HIV viral infection are also well known. Dengue viral infection is also known as "breakbone fever". What is worse, is that when a patient is infected with a dengue virus a second time, if the virus is a different serotype, then it can cause a severe dengue disease, or dengue hemorrhagic syndrome, with very high morbidity and a high rate of fatality. This is because, the patient's immune system mounts an attack, but the antibodies that it generates, directed at the previous infecting virus, are not effective against the new infection, and instead the new infecting virus uses them to hitch a ride into host cells that it infects more severely. This phenomenon is called "Antibody-Dependent Enhancement" or "ADE" for short.

Our current development has focused on API suitable for formulating into a skin ointment for the treatment of VZV shingles, HSV-1 cold sores, or HSV-2 genital ulcers. As these drug candidates advance further, we plan on performing fully integrated drug development for developing eye drops for treatment of external eye infections such as herpes keratitis (a disease of the external eye). Thereafter we plan on undertaking the development of suitable materials for intravitreous or sub-retinal injections for the treatment of certain viral diseases involving the retina.

In the United States alone, approximately 1 million cases of shingles (i.e. zoster) occur annually. The risk of zoster increases with age, and with decreased immune system function, such as occurs in diabetics. Zoster is characterized by pain and rash. Discrete cutaneous lesions occur in groups on the skin. The Company believes that this presentation enables topical therapy for control of the viral outbreak.

One in four patients develop zoster-related pain that lasts more than 30 days. If it persists more than 3 months, it is called post-herpetic neuralgia (PHN), and may persist for years. It is thought that zoster-associated pain and PHN is a result of chronic ganglionitis, i.e. continued low-grade production of the virus in the infected ganglia and related immune response. The Company believes that effective control of the virus production would minimize or eliminate PHN, a debilitating morbidity of zoster.

Zoster occurs mostly in the abdominal region. However, in 20% of cases, it occurs in the head area, with reactivation involving trigeminal distribution. These cases of zoster can lead to serious complications including hemorrhagic stroke (VZV vasculopathy),

VZV encephalitis, ophthalmic complications, and may result in fatalities.

Currently available anti-herpes drugs have had limited impact on zoster. Thus, an effective drug with a good safety profile could have a dramatic impact on zoster as well as possibly PHN.

External eye infections with HSV-1 have been reported to be the leading cause of infectious blindness in the developed world, with recurrent episodes of viral reactivation leading to progressive scarring and opacity of the cornea. HSV epithelial keratitis afflicts the epithelium of the cornea. In some cases, the disease progresses to HSV stromal keratitis, which is a serious condition. HSV stromal keratitis involves the stroma, the layer of tissue in the cornea, which is deeper in the eye than the epithelium. Its pathology disease involves the HSV infection of stromal cells, and also involves the inflammatory response to this infection. It can lead to permanent scarring of the cornea resulting in diminished vision. More serious cases require corneal replacement surgery. About 75% of corneal replacements are known to fail in a 20-year time frame, due to graft versus host disease (i.e. rejection of the foreign implant by the body), requiring a new procedure, or resulting in blindness.

Herpes keratitis incidence rates in the USA alone are reported to be in the range of 65,000 to 150,000 patients per year. Of these, approximately 10,000 per year may be estimated as requiring corneal transplants. The estimates of incidence rates vary widely based on source, and are also assumed to be underreported. A corneal transplant costs approximately $15,000 to $25,000 for the surgery, with additional costs for follow on drugs and treatments.

This scenario exists in spite of available drugs, namely the acyclovir class of drugs, trifluridine, and others, that are used for treatment of herpes keratitis. The failure of these drugs is primarily due to limited safety resulting in insufficient drug availability at the site of infection.

In addition, the Company is developing broad-spectrum eye drop formulations that are expected to be effective against a majority of the viral infections of the external eye. Most of these viral infections are from adenoviruses or from herpesviruses. The Company has shown excellent efficacy of its drug candidates against EKC (adenoviral epidemic kerato-conjunctivitis) in an animal model. Further, our anti-HSV drug candidates have shown excellent efficacy in cell culture studies, as well as in a lethal skin infection animal model.

Thus, an effective drug with a good safety profile could have a dramatic impact on ocular viral infections. Merit-based compensation for the herpes keratitis treatment would enable strong financial incentive and could result in potential revenues in the several hundreds of millions range, depending upon the effectiveness of the drug. The Company believes that it has sufficient production capacity at its current site to supply the US requirement of the drug for treatment of (ocular) herpes keratitis upon drug licensure.

Topical treatment of herpesvirus infections is important because of the disfiguring nature of herpesvirus breakouts, the associated local pain, and the fact that the virus grows in these breakouts to expand its domain within the human host further. Topical treatment can deliver much higher local levels of drugs than a systemic treatment can, and thus can be more effective and safer at the same time. Systemic drug treatment results in side effects because of the high systemic drug concentrations that need to be achieved and the large drug quantities that must be administered. Since the virus remains mostly localized in the area of the rash and connected nerve apparatus, using high concentrations of drugs delivered in small quantities topically would allow maximizing the effectiveness while minimizing the side effects.

Herpesviruses become latent in neuronal cells or in ganglia, and cause periodic localized breakouts that appear as skin rashes and lesions. Systemic drug treatment results in side effects because of the high systemic drug concentrations that need to be achieved and the large drug quantities that must be administered. Since the virus remains mostly localized in the area of the rash and connected nerve apparatus, using high concentrations of drugs delivered in small quantities topically would allow maximizing the effectiveness while minimizing the side effects, leading to minimizing viral production at the site. Such effective local control of the virus titer is expected to lead to reduction in recurrence of herpesvirus “cold sores” or genital ulcers, and reduction in shingles related PHN.

The potential broad-spectrum nature of our anti-HSV drug candidates is expected to enable several antiviral indications. Thus, HSV-1 primarily affects skin and mucous membranes causing “cold sores”. HSV-2 primarily affects skin and mucous membranes leading to genital herpes. HSV-1 infection of the eye causes herpes keratitis that can lead to blindness in some cases. In addition, human herpesvirus-3 (HHV-3), a.k.a. varicella-zoster virus (VZV), causes chickenpox in children and when reactivated in adults, causes shingles. Shingles breakouts are amenable to topical treatment, as are the HSV cold sores, genital lesions, and herpes keratitis of the eye. Most of these indications do not have satisfactory treatments at present, if any. Further, the treatment of herpesvirus infections caused by acyclovir- and famciclovir- resistant mutants is currently an unmet medical need. Drugs with mechanisms of action other than DNA-polymerase inhibitors (such as acyclovir) are needed for effective treatment.

The childhood chickenpox vaccine (varicella vaccine) has reduced the cases of chickenpox, but this is a live attenuated virus vaccine that persists in the body. All adults who have had chickenpox in childhood continue to harbor the chickenpox virus, and are expected to develop shingles at some time, with the risk of shingles increasing with age or weakening of the immune system surveillance. In addition to the shingles breakout itself, post-herpetic neuralgia (pain) (PHN) is a significant morbidity of shingles, and to a lesser extent, of oral and genital herpes. PHN is initially caused probably by the inflammation and immune response related to the local virus expansion, but persists well after the virus has subsided, the blisters have scabbed off, and the skin has recovered, due to the nerve damage that results from the local large viral load during infection. Current PHN treatments are symptomatic, affecting the pain signaling circuit (such as novocaine, pramoxine, capsaicin, etc.), and do not produce lasting control. An effective therapy that results in strong local control of the virus production during the breakout itself is expected to minimize the resulting immune responses and nerve damage, and thereby minimize or possibly eliminate PHN.

The Company thus believes that it can develop its broad-spectrum anti-herpes drug candidate towards at least five topical indications, namely, (a) shingles, (b) oral herpes ("cold sores"), (c) genital herpes, (d) herpes keratitis (external eye infection), and (e) ocular herpes including v-ARN (internal eye infection). As the HerpeCide™ program progresses, it is likely that additional herpesvirus related pathologies may become amenable to treatment with our herpesvirus drug candidates.

Our nanoviricides in the HerpeCide™ program at present are designed as topical treatment for the breakout of shingles or herpes sores. Our animal studies results are very significant considering that topical acyclovir in the form of a cream as well as an ointment, are approved for the treatment of cold sores. We believe our strong anti-herpes nanoviricide® drug candidates are capable of reaching approval as a drug for topical use against herpes cold sores, based on these datasets. Further drug development is necessary towards the goal of drug approval.

Currently, valacyclovir (Valtrex®) is approved as an oral drug for the treatment of severe shingles, but it has limited effectiveness. Another oral drug known as "FV-100" was studied in clinical trials for the treatment of shingles by Bristol-Myers Squibb, and later by Contravir. FV-100 works only against VZV and does not work against other herpesviruses. A Phase 3 study with PHN as end-point was completed in November 2017. Further development appears to have been stopped for FV-100.

There is also a new preventive vaccine for shingles, "Shingrix". Given the number of cases of severe shingles, we believe that there is an unmet medical need for developing a topical skin cream for the treatment of shingles, even with a successful introduction of this vaccine. The Shingrix vaccine has been recently also been shown to produce adverse effects such as painful injection site reactions and pain in a significant number of patients. Local application of a nanoviricide drug should enable delivery of stronger, local doses of medicine, with a stronger patient benefit, than oral systemic dosing allows.

Existing therapies against HSV include acyclovir and drugs chemically related to it. These drugs must be taken orally or by injection. Available topical treatments, including formulations containing acyclovir or chemically related anti-HSV drugs, are not very effective. Currently, there is no cure for herpes infection. Brincidofovir (CMX001) is being developed by Chimerix. It failed in a Phase 3 clinical trial for hCMV in organ transplants, and its Phase1/2 clinical trial for HSV in neonates was withdrawn recently. Cidofovir is a known highly effective but also toxic, broad-spectrum nucleoside analog drug that was modified with a lipidic chain structure to create brincidofovir. Pritelivir, by AiCuris, is a DNA Helicase/Primase inhibitor (HSV-1 and HSV-2) that has successfully completed certain Phase 2 clinical trials, and its indication in immune-compromised patients has received a fast track status from the US FDA. Letermovir (Merck/AiCuris), a terminase complex inhibitor, is effective only against hCMV and has entered a Phase 3 clinical study in kidney transplant patients.

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 anti-influenza drug candidates. 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.

We believe that when effective topical treatments against VZV shingles, HSV-1 cold sores and HSV-2 genital ulcers are introduced, their market sizes are likely to expand substantially, as has been demonstrated in the case of HIV as well as Hepatitis C.

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. We are also performing topical drug development against several indications related to infections by herpes family viruses.

Management Discussion - Current Drug Development Strategy

During the reported quarter, we have focused on development of a drug against SARS-CoV-2, that causes the COVID-19 spectrum of diseases. We have prioritized our resources with the goal of filing our first IND in the shortest possible timeframe.

The Company believes that its anti-coronavirus drug program could result in a cure for SARS-CoV-2, based on attacking both viral replication and the viral reinfection cycles. We are developing a next generation nanoviricide in this program that is capable of attacking the virus particle and also is designed to encapsulate and deliver another drug to block the intracellular virus replication.

The Company believes that its anti-herpes drug candidates for the treatment of cold sores and for genital lesions should lead to effective control of the cold sores rapidly, and may also lead to a long lag time before a new recurrence episode occurs. This is because it is believed that recurrence rates increase by virtue of further infection of new nerve endings from the site of the herpesvirus outbreak, which result in additional nerve cells harboring the virus. If this in situ re-infection is limited, which we believe is the primary mechanism of nanoviricide drugs, then it is expected that the number of HSV harboring reservoir cells should decrease, and recurrence rate should go down.

The Company believes that it will be able to expand its anti-herpes portfolio in the future to include many other herpes viruses such as cytomegalovirus (CMV), HHV-6A, HHV-6B, KSHV, and Epstein-Barr virus (EBV, cause of mononucleosis). This would lead to a very large number of therapeutic indications beyond the four or five indications we are currently targeting.

The Company thus continues to expand its portfolio of opportunities, while also making progress towards the clinical trials stage.

Previously, in the FluCide™ program, the Company has demonstrated extremely high effectiveness in animal models against two unrelated influenza viruses, namely H1N1 and H3N2. In the HIVCide™ program, in the standard SCID-hy Thy/Liv mouse model of HIV infection, the Company's drug candidates were found to maintain viral load to the same level as an approved triple combination drug therapy, beyond 40 days after the nanoviricide treatment was discontinued, even though the combo therapy was continued daily. The Company intends to reactivate these programs upon appropriate collaborations or funding. The Company has also demonstrated preliminary successes in developing drug candidates against Dengue viruses, and Ebola virus, among others.

The Company intends to re-engage its anti-influenza drug candidates upon sufficient financing or upon achieving grants or collaborations for the same. We are developing Injectable FluCide™ for hospitalized patients with severe influenza as our first, broad-spectrum anti-influenza drug candidate. We have demonstrated the very first effective orally available nanomedicine, namely oral FluCide™ for outpatients with influenza. The development of Oral FluCide is expected to follow behind Injectable FluCide. Development of an anti-Influenza drug candidate has been estimated to be an extremely expensive process with a long drug development timeframe. This is because of the large number of virus types and subtypes that change rapidly within and over seasons. The Company at present does not have the resources to engage into a full-fledged anti-Influenza drug development program. Additionally, Xofluza®, a new drug with a novel mechanism of action (an endonuclease inhibitor) was very recently approved in the USA (Roche/Genentech). While it reduced viral load significantly in clinical trials, it did not have a significant effect on the time course of the clinical pathology of influenza infection in the clinical trials that led to its approval. Xofluza is approved for uncomplicated influenza. Information on its usage and effectiveness in the field in the current influenza seasonal cycle in the USA is not yet available. All of the current influenza drugs, including Xofluza have resulted in mutated influenza viruses that are drug-resistant.

Thus, an effective therapy for patients hospitalized with severe influenza continues to be an unmet need. In addition, a single injection treatment of non-hospitalized patients would be a viable drug if it provides superior benefits to existing therapies.

Due to our limited resources, we have now assigned lower development priorities to our other drug candidates in our pipeline such as DengueCide™ (a broad spectrum nanoviricide designed to attack all types of dengue viruses and expected to be effective in the Severe Dengue Disease syndromes including Dengue Hemorrhagic Fever (DHS) and Dengue Shock Syndrome (DSS)) and HIVCide™ (a potential "Functional Cure" for HIV/AIDS).

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.

Our Campus in Shelton, CT

Our campus at Shelton, CT, is fully operative. With our R&D discovery labs, Analytical Labs, the Bio labs for virology R&D, the Process Scale-Up production facility, and the cGMP-capable manufacturing facility established at our Shelton campus, we are in a strong position than ever 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 1L to 50L capacities, as needed. Many of the reactors and vessels have been designed by us for specific tasks related to our unique manufacturing processes.

cGMP Production Capability

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

We plan to produce multiple batches of a drug product and satisfy that said drug product is within our own defined specifications. If we are satisfied with such strong reproducibility of our processes, we plan to register the facility as a cGMP manufacturing facility with the US FDA.

At present, we plan on moving operations to our cGMP-capable manufacturing suite as the operational steps are developed to the level needed for moving them into this facility. This requires the development of draft-level Standard Operating Procedures, training, and drill-through of operations. We will also need to establish a Quality Assurance and Quality Control Department. Our current staff is busy developing our pre-clinical HerpeCide programs. Given our limited financing, we have not been able to attract the necessary talent for replacing the lost staff and for building out additional resources for QA/QC. We are working with available staff, training them further in cGMP requirements and operations, as well as in QA/QC. This inherently leads to serialization of efforts, and can lead to extending the timeline. We have been working diligently to meet our goals in the shortest timeframe possible given these constraints.

We operate in a completely novel area of medicines, which is broadly described as polymeric-micelle based drug conjugates and complex nanomedicines. Our technologies are also completely novel, and unmatched in the industry. As such, we anticipate a longer training period for new employees than in normal small chemical or biological drugs. We continue to seek talented scientists and engineers with specialized training. However, it is difficult to attract such talent for a small, pre- revenue pharma company such as ours.

We employ the same team that developed the small-scale synthesis chemistry for translation of those chemical syntheses into clinical-scale processes, and also to perform the related chemical engineering, quality control, quality assurance, and regulatory tasks along the way. Because of the small size of our scientific staff, this results in significant serialization of efforts. However, the personnel cost, as well as the time and expense cost of transfer of knowledge and training of a separate dedicated team is avoided because the same expert scientists who have developed the chemistries are also involved in scaling them up into process scale. To enable such extensive multi-tasking, we have a continuous training program in place, with both formal and informal components. We believe that this approach helps us keep drug development costs as low as possible.

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 and HSV-2 in our lab. This 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. We believe that this internal screening enables speedy evaluation of a much larger number of candidates than external collaborations allow. This has significantly improved our ability of finding highly effective ligands and performing structure-activity-relationship studies of the same in a short time period.

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 other 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.

Collaborations, Agreements and Contracts

Our strategy is to minimize capital expenditures. We therefore rely on third party collaborations for the testing of our drug candidates. We continue to engage with our previous collaborators. We also seek to engage with additional collaborators, as necessitated for the progress of our programs.

We have engaged Calvert Labs for core safety/pharmacology studies of our anti-coronavirus drug candidates.

We have signed a collaboration agreement with the Professor Moffat Lab at SUNY Upstate Medical Center, Syracuse, NY, for evaluating safety and effectiveness studies of drug candidates in cell culture and in animal models for shingles VZV infections.

We have signed a collaboration agreement with the CORL at the University of Wisconsin, Madison, WI, for HSV-1 and HSV-2, with focus on small animal models for ocular disease.

We have engaged Biologics Consulting Group, Inc., to help us with the US FDA regulatory submissions. We are also engaged with Australian Biologics Pty, Ltd to help us with clinical trials and regulatory approvals in Australia. We believe that cGMP-like manufactured product is acceptable for entering human clinical trials in Australia.

We have contracted NorthEast BioLab, Hamden CT, to conduct the bio-analytical studies and facilitate the toxicokinetic analyses of NV-HHV-101. These studies and analyses are part of the required general safety and toxicology studies that will go into an IND Application to the US FDA. NorthEast BioLab has already performed the bio-analytical assay development and validation and is in the process of determining the concentrations of NV-HHV-101 in blood samples from the general safety and toxicology studies that are required for IND.

We also engaged MB Research Labs, Spinnerstown, PA, to conduct the studies to assess the dermal sensitization and ocular irritation potential of the drug candidate. These initial studies involve two separate types of studies: 1) assess the direct potential of the drug candidate to induce skin sensitization after repeated treatment of the skin (contact dermal sensitization); and 2) assess the potential of the drug candidate to cause ocular irritation following potential exposure. The ocular irritation test (EpiOcular^{TM} Eye Irritation Test, EIT) is a non-animal test in compliance with multi-national regulatory guidelines. Additional IND-enabling studies are in progress. Upon completion of all of these required studies, the Company anticipates filing an IND with the US FDA to advance NV-HHV-101 into human clinical trials for topical dermal treatment of the shingles rash as the initial indication.

We anticipate completing master services agreements, after performing our due diligence, with additional parties in furtherance of our anti-viral drug development programs.

We have continued to achieve significant milestones in our drug development activities. Our lead program, NV-HHV-101 skin cream for the treatment of shingles rash, is in advanced pre-clinical stage, as we await final reports from external collaborators to produce and file the IND application with the US FDA. All of our remaining drug development programs are presently at pre-clinical or advanced pre-clinical stage.

Patents, Trademarks, Proprietary Rights: Intellectual Property

The nanomedicine technologies licensed from TheraCour, which licenses its intellectual property from AllExcel, serve as the foundation for our intellectual property. NanoViricides holds a worldwide exclusive perpetual license to this technology for several drugs with specific targeting mechanisms in perpetuity for the treatment of the following human viral diseases: Human Immunodeficiency Virus (HIV/AIDS), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rabies, Herpes Simplex Virus (HSV-1 and HSV-2), Influenza and Asian Bird Flu Virus. The Company has entered into an Additional License Agreement with TheraCour granting NanoViricides the exclusive licenses in perpetuity for technologies developed by TheraCour for the additional virus types: Dengue viruses, Japanese Encephalitis virus, West Nile Virus, Viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes, and Ebola/Marburg viruses.

In addition, on November 1, 2019, NanoViricides entered into a world-wide, exclusive, sub-licensable, license to use, promote, offer for sale, import, export, sell and distribute drugs that treat VZV 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. The Company was not required to make any upfront payments to TheraCour and agreed to the following milestone payments to TheraCour; the issuance of 75,000 shares of the Company's Series A Convertible Preferred Stock upon the grant of an IND Application; $1,500,000 in cash upon completion of Phase I Clinical Trials; $2,500,000 in cash upon completion of Phase II clinical trials; and $5,000,000 in cash upon completion of Phase III clinical trials.

In June 2020, the Company signed a Memorandum of Understanding with TheraCour for the field of human coronavirus treatments. The Company has obtained a limited license for the development of nanoviricides drug candidates against coronaviruses while a final license agreement for this field is in progress. The Company has initiated an independent review of the field in order to form terms of the final license agreement, which are expected to be similar to those for the VZV license agreement.

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. In addition, unless there is an event of default, in which case the license would revert to TheraCour, the licenses are held in perpetuity by NanoViricides for worldwide use. The licenses are also exclusively provided to NanoViricides for the licensed products so NanoViricides is the only party that can further sublicense the resulting drugs to another party, if it so desires. The licenses can revert only in the case of a default by NanoViricides. The terms of default are such that, effectively, TheraCour would be able to take the licenses back only in the event that NanoViricides files bankruptcy or otherwise declares insolvency and the inability to conduct its business, in the case of the VZV license a failure to make a milestone payment within 90 days or a failure to use its commercially reasonable efforts to obtain FDA approval for 24 consecutive months.

A fundamental Patent Cooperation Treaty ("PCT") patent application, on which the nanoviricides® technology is based, has resulted in additional issued patents in Europe and Korea. As with issuances in other countries including the United States, these patents have been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The corresponding original "pi-polymer" international application, namely, PCT/US06/01820, was filed under the Patent Cooperation Treaty (PCT) system in 2006. Several other patents have already been granted previously in this patent family in various countries and regions, including Australia, ARIPO, Canada, China, Hong Kong, Indonesia, Israel, Japan, Mexico, New Zealand, OAPI, Philippines, Singapore, Vietnam, South Africa, and the USA. Prosecution in several other countries continues. In May 2012, the US Patent (No. 8,173,764) was granted for "Solubilization and Targeted Delivery of Drugs with Self-Assembling Amphiphilic Polymers." The US patent term is expected to last through October 1, 2028, including anticipated extensions in compensation for time spent in clinical trials. This US Patent has been allowed with a very broad range of claims to a large number of families of chemical structure compositions, pharmaceutical compositions, methods of making the same, and uses of the same. The disclosed structures enable self-assembling, biomimetic nanomedicines. Estimated expiry dates for these patents range nominally from 2027 to 2029 with various extensions accounting for delays in clinical trials. Additional issuances are expected in Europe, and in several other countries around the world.

In addition to this basic PCT application that covers the "pi-polymer" structure itself, another PCT application, PCT/US2007/001607, that discloses making antiviral agents from the TheraCour family of polymers and such structures is in various stages of prosecution in several countries, and has already issued in at least seven countries and regions. The counterparts of the international PCT application have issued as a granted patent in Australia, Japan, China, ARIPO, Mexico, New Zealand, OAPI, Pakistan, and, South Africa to date. Additional issuances are expected in Europe, USA, and in several other countries around the world. This patent application covers antivirals based on the TheraCour polymeric micelle technologies, their broad structures and compositions of matter, pharmaceutical compositions, methods of making the same, and their uses. The nominal expiry dates are expected to range from 2027 to 2029.

More than 61 patents have been issued globally on the basis of the two international PCT patent families that cover the fundamental aspects of our platform technology. Additional patent grants are expected to continue as the applications progress through prosecution processes. All of the resulting patents have substantially broad claims.

The patents are issued to the inventors Dr. Anil R. Diwan, PhD, Jayant G. Tatake, PhD, and Ann L. Onton, all of whom are among the founders of NanoViricides, Inc. The patents have been assigned to AllExcel, Inc., the Company at which the groundbreaking work was performed. AllExcel, Inc. has contractually transferred this intellectual property to TheraCour.

Patents and other proprietary rights are essential for our operations. If we have a properly designed and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and intend to file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

The Company believes that the drugs by themselves, Coronavirus antiviral treatment, Shingles antiviral topical treatment, HerpeCide for Cold Sores, HerpeCide for genital ulcers, antiviral nanoviricide eye drops, Injectable FluCide, Oral FluCide, DengueCide, HIVCide, RabiCide, and others, 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.

The issued patents have nominal expiry dates in 2026 to 2029. The dates can be further extended in several countries and regions for the additional allowances due to the regulatory burden of drug development process, or other local considerations, such as licensing to a local majority held company. Many countries allow up to five years extension for regulatory delays.

The estimated expiry date for HerpeCide patents, if and when issued, would be no earlier than 2040. No patent applications have been filed for the actual drug candidates that we intend to develop as drugs as of now. We intend to file the patent application for FluCide and HerpeCide compounds on or about when the drug candidates are entering human clinical trials, depending upon prevailing considerations regarding the confidentiality of the information.

We may obtain patents for our compounds many years before we obtain marketing approval for them. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions, based on delays experienced in marketing products due to regulatory requirements. There is no assurance we would be able to obtain such extensions. The Company controls the research and work TheraCour performs on its behalf and no costs may be incurred without the prior authorization or approval of the Company.

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or reexamination proceedings regarding the enforcement or validity of our licensor, TheraCour's existing patents or any future patents, could invalidate TheraCour's patents or substantially reduce their protection. In addition, the pending patent applications and patent applications filed by TheraCour, may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing the same compounds and products that we have developed or are developing. In addition, certain countries do not permit enforcement of our patents, and manufacturers are able to sell generic versions of our products in those countries.

We also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. In particular, a great deal of our material manufacturing expertise, which is a key component of our core material technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by the individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by our competitors.

Trademarks

On April 20, 2010, the United States Patent and Trademark Office granted trademark registration number 3,777,001 to the Company for the standard character mark "nanoviricides" (the "Mark") for International Class 5, pharmaceutical preparation for the treatment of viral diseases.

Analysis of Financial Condition, and Result of Operations

As of December 31, 2020, we had cash and cash equivalents of $18,393,072, prepaid expenses of $94,298 and net property and equipment of $9,237,874. Accounts payable and accrued expenses were $339,308, inclusive of account payables to a related party of $619,904, of which $200,000 is deferred until the filing of an IND. The accounts payable–related party was offset by a two month advance of $491,000. At December 31, 2020 we repaid a loan payable to a related party, Dr. Anil Diwan, of $1,100,000. Stockholders equity was $27,746,042 at December 31, 2020.

In comparison, as of June 30, 2020, we had $13,708,594 in cash and cash equivalents, prepaid expenses of $277,063 and $9,544,431 of property and equipment. Our liabilities were $2,156,377 including a short term mortgage loan of $1,081,987 payable to Dr. Anil Diwan, accounts payable of $380,727 and accounts payable to TheraCour of $561,580 of which $200,000 of such accounts payable is deferred until the filing of an IND. Stockholders' equity was $21,757,962 at June 30, 2020.

During the six-month period ended December 31, 2020, we used approximately $4,551,000 in cash toward operating activities. During the six-month period ended December 31, 2019 we used approximately $2,560,000 in cash toward operating activities.

We do not anticipate any major capital costs going forward in the near future.

The Company believes that its existing resources will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuance of these financial statements. However, the Company will need to raise additional capital to fund its long term operations and research and development plans 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 to fund continuing operations. Management believes that as a result of the July 10, 2020 underwritten offering the Company has sufficient funds in hand for initial human clinical trials of its first drug candidate for the treatment of SARS-CoV-2 infection. Management believes we will have to raise additional capital to fund and perform additional projected work, including further required clinical trials of the first drug candidate towards approval, as well as engaging in further IND-enabling development and subsequent anticipated IND filings of human clinical trials of additional HerpeCide program drug candidates.

The Company does not currently have any revenue. All of the Company's products are in the development stage and require successful development through regulatory processes before commercialization. We have generated funding through the issuances of debt and private placement of common stock and also the sale of our registered securities. The Company does not currently have any short or long-term debt. We have not generated any revenues and we may not be able to generate revenues in the near future. We may not be successful in developing our drugs and start selling our products when planned, or we may not become profitable in the future. We have incurred net losses in each fiscal period since inception of our operations.

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 this quarter, we have focused primarily on our COVID-19 program drug candidates.

The Company has signed several cooperative research and development agreements with different agencies and institutions. The Company expects to enter into additional cooperative agreements with other governmental and non-governmental, academic, or commercial, agencies, institutions, and companies. There can be no assurance that a final agreement may be achieved and that the Company will execute any of these agreements. However, should any of these agreements materialize, the Company will need to implement a system to track these costs by project and account for these projects as customer-sponsored activities and show these project costs separately.

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 or have planned to develop sufficient data on our first drug candidate, for the treatment of SARS-CoV-2 infection, to support an IND filing, towards the goal of obtaining FDA approval for testing the drug in human 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.

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. In addition, we also plan to develop the same drug for commercial approval for additional indications for the same drug, 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.

Results of Operations

The Company is a biopharmaceutical company and did not have any revenue for the three and six month periods ended December 31, 2020.

Revenues – The Company is currently a non-revenue producing entity.

Research and Development Expenses – Research and development expenses for the three months ended December 31, 2020 increased $481,115 to $1,493,200 from $1,012,085 for the three months ended December 31, 2019. Research and development expenses for the six months ended December 31, 2020 increased $571,781 to $3,066,271 from $2,494,490 for the six months ended December 31, 2019. The increase in the cost of research and development expenses for the three and six months ended December 31, 2020 is due to increases in outside lab fees, laboratory supplies and materials and laboratory repairs and maintenance.

General and Administration Expenses – General and administrative expenses for the three months ended December 31, 2020 increased $176,375 to $798,722 from $622,347 for the three months ended December 31, 2019. General and administrative expenses for the six months ended December 31, 2020 increased $368,215 to $1,496,034 from $1,127,819 for the six months ended December 31, 2019. The increase in general and administrative expenses during the three and six months ended December 31, 2020 compared to the prior period resulted primarily from increases in professional fees and in operating expenses in general.

Interest Income – Interest income for the three months ended December 31, 2020 increased $403 to $1,187 from $784 for the three months ended December 31, 2019. Interest income for the six months ended December 31, 2020 decreased $1,755 to $4,246 from $6,001 for the six months ended December 31, 2019. The increase in interest income for the three months ended December 31, 2020 is

due to an increase in cash and cash equivalents. The decrease in interest income for the six months ended December 31, 2020 is due to a decrease in interest rates, offset, in part, by increases in cash and cash equivalents.

Interest Expense – Interest expense increased $33,162 to $37,293 for the three months ended December 31, 2020 from $4,131 for the three months ended December 31, 2019. Interest expense increased $77,071 to $81,202 for the six months ended December 31, 2020 from $4,131 for the six months ended December 31, 2019. The increase is a result of the interest paid on an Open End Mortgage Note, amortization of the mortgage loan origination fee, and interest paid on a short term loan payable.

Loss on disposal of property and equipment- For the three and six months ended December 31, 2020 the Company recognized a loss of $2,026 from disposal of nonfunctioning equipment.

Loss on issuance of Series A preferred stock for accounts payable – related party –For the six months ended at December 31, 2019, the Company recognized a loss of $142,669 arising from the difference in fair value of the exchange of 100,000 shares of Series A preferred stock with a fair value of $392,669 for $250,000 of previously deferred development fees owed to Theracour.

Change in fair value of derivative – Change in fair value of derivative for the three months ended December 31, 2020 decreased $147,078 to $0 from $147,708 expense for the three months ended December 31, 2019. Change in fair value of derivative for the six months ended December 31, 2020 decreased $274,449 to $0 from $274,449 income for the six months ended December 31, 2019. The decrease resulted from the elimination of derivative liabilities with the exercise of the Company's outstanding warrants in January 2020.

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

Net Loss – For the three months ended December 31, 2020, the Company had a net loss of $(2,330,054) or $ (0.22) per share compared to a net loss of $(1,927,526) or ($0.50) per share for the three months ended December 31, 2019. For the six months ended December 31, 2020, the Company had a net loss of $(4,641,287) or $ (0.44) per share compared to a net loss of $(3,488,659) or ($0.91) per share for the three months ended December 31, 2019. The increase in the net loss for the three months ended December 31, 2020 is attributable mainly to an increase in operating expenses for the three months ended December 31, 2020. The increase in the net loss for the six months ended December 31, 2020 is attributable mainly to a decrease in the income from the change in fair value of derivative liabilities of $274,449 and an increase in operating expenses.

Liquidity and Capital Reserves

The Company had cash and cash equivalents of $18,393,072, and prepaid expenses of $94,298 as of December 31, 2020 and accounts payable and accrued expenses were $339,308, inclusive of account payables of $128,904 to a related party. On December 16, 2019, the Company entered into an Open End Mortgage Note with Dr. Anil Diwan, the Company's founder, Chairman and President, to loan the Company up to $2,000,000. On December 31, 2020, the Company repaid this note in full. 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 $110,204,411 at December 31, 2020. 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 Market Issuance Sales Agreement with B. Riley Securities, Inc. and Kingswood (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 having an aggregate offering price of up to $50 million. The Company believes that its existing resources will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuance of these financial statements.

In addition, the Company believes that it has several important milestones that it anticipates achieving in the ensuing year. 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 has not experienced a direct financial adverse impact of the effects of the Coronavirus (COVID-19) pandemic. However, the pandemic required the Company to reorganize its priorities, because of the impact on the ability to conduct antiviral drug trials for our then lead program for shingles drug treatment. While clinical trials were in general adversely affected, the ability to enroll patients into the shingles antiviral drug clinical trial with the desired inclusion criteria became limited due to the widespread coronavirus infection. The shingles clinical trial design and conduct would also become more complex. The emergence of widespread health emergencies due to COVID-19 have led to regional quarantines, shutdowns, shortages, disruptions of supply chains, and economic instability. The impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted at this time. Though the Company has not experienced a direct financial impact, if the financial markets and/or the overall economy are impacted for an extended period, the Company's ability to raise funds, in the future, may be materially adversely affected.

The Company believes that its existing resources will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuance of these 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 nine months ended December 30, 2020.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

ITEM 4. CONTROLS AND PROCEDURES

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

As of December 31, 2020, 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, 2020 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, 2020. This material weakness remains unremediated as of December 31, 2020.

Changes in Internal Control Over Financial Reporting

Other than what was described below, 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, 2020 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 will provide oversight to the Company's efforts for ensuring appropriate internal control over financial reporting including, but not limited to, remediation of the aforesaid material weakness and identifying and testing for potential internal control 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.

For the three and six months ended December 31, 2020, the Company's Board of Directors authorized the issuance of 387 and 774, respectively, fully vested shares of its Series A preferred stock for employee compensation, The Company recorded an expense of $4,948 and $12,392, respectively, for the three and six months ended December 31, 2020 related to the issuances.

During the six months ended December 31, 2020, the Scientific Advisory Board was granted in August 2020 fully vested warrants to purchase 572 shares of common stock with an exercise price of $6.86 per share expiring in August 2024 and in November 2020 fully vested warrants to purchase 572 shares of common stock with an exercise price of $4.19 per share expiring in November 2024. The fair value of the warrants were $1,215 for the three months ended December 31, 2020 and $3,201 for the six months ended December 31, 2020 and was recorded as a consulting expense.

For the three and six months ended December 31, 2020, the Company's Board of Directors authorized the issuance of 7,411 and 12,546, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of $27,000 and $54,000, respectively, for the three and six months ended December 31, 2020 which was the fair value on the date of issuance.

For the three and six months ended December 31, 2020, the Company's Board of Directors authorized the issuance of 4,106 and 6,146, respectively, fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of $15,000 and $26,250, respectively, for the three and six months ended December 31, 2020 which was the fair value on the date 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.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
31.1	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Executive Officer
31.2	Rule 13(a)-14(a)/15(d)-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101.INS	XBRL Instance Document

101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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.

/s/ Anil R. Diwan

Dated: February 16, 2021

Name: Anil R. Diwan
Title: President, Chairman of the Board
(Principal Executive Officer)

/s/ Meeta Vyas

Dated: February 16, 2021

Name: Meeta Vyas
Title: Chief Financial Officer
(Principal Financial Officer)