

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 March 31, 2020

Commission File Number: 001-36081

NANOVIRICIDES, INC.

(Exact name of Company as specified in its charter)

NEVADA

(State or other jurisdiction)
of incorporation or organization)

76-0674577

(IRS Employer Identification No.)

1 Controls Drive

Shelton, Connecticut 06484

(Address of principal executive offices and zip code)

(203) 937-6137

(Company's telephone number, including area code)

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

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

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

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

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

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

Yes No

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

Title of each class:

Trading Symbol(s)

Name of each exchange on which registered:

Common Stock

NNVC

NYSE-American

As of June 22, 2020, there were approximately 9,073,000 shares of common stock of the registrant issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NanoViricides, Inc. Balance Sheets

	<u>March 31,</u> <u>2020</u>	<u>June 30,</u> <u>2019</u>
	<u>(Unaudited)</u>	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 6,105,530	\$ 2,555,207
Prepaid expenses	331,772	270,214
Total current assets	<u>6,437,302</u>	<u>2,825,421</u>
PROPERTY AND EQUIPMENT		
Property and equipment	14,096,316	14,092,177
Accumulated depreciation	(4,383,466)	(3,864,930)
Property and equipment, net	<u>9,712,850</u>	<u>10,227,247</u>
TRADEMARK AND PATENTS		
Trademark and patents	458,954	458,954
Accumulated amortization	(98,500)	(92,296)
Trademark and patents, net	<u>360,454</u>	<u>366,658</u>
OTHER ASSETS		
Security deposits	3,515	3,515
Service agreements	13,984	25,672
Other assets	17,499	29,187
Total assets	<u>\$ 16,528,105</u>	<u>\$ 13,448,513</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Mortgage note payable – related party	\$ 1,072,162	\$ -
Accounts payable	410,174	309,893
Accounts payable – related party	578,155	823,783
Loan payable	109,295	-
Derivative liability – warrants	-	1,645,606
Accrued expenses	43,558	68,871
Total current liabilities	<u>2,213,344</u>	<u>2,848,153</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Series A Convertible Preferred stock, \$0.001 par value, 10,000,000 shares designated, 368,215 and 255,714 shares issued and outstanding, at March 31, 2020 and June 30, 2019, respectively	368	256
Common stock, \$0.001 par value; 150,000,000 shares authorized, 7,673,357 and 3,844,921 shares issued and outstanding at March 31, 2020 and June 30, 2019, respectively	7,673	3,845
Additional paid-in capital	117,995,269	102,712,845
Accumulated deficit	(103,688,549)	(92,116,586)
Total stockholders' equity	<u>14,314,761</u>	<u>10,600,360</u>

Total liabilities and stockholders' equity

\$ 16,528,105 \$ 13,448,513

See accompanying notes to the financial statements

Nanoviricides, Inc.
Statements of Operations
(Unaudited)

	For the Three Months Ended March 31,		For the Nine Months Ended March 31,	
	2020	2019	2020	2019
OPERATING EXPENSES				
Research and development	\$ 1,134,132	\$ 1,310,326	\$ 3,628,622	\$ 4,335,105
General and administrative	1,408,231	772,561	2,536,050	2,156,078
Total operating expenses	<u>2,542,363</u>	<u>2,082,887</u>	<u>6,164,672</u>	<u>6,491,183</u>
LOSS FROM OPERATIONS	(2,542,363)	(2,082,887)	(6,164,672)	(6,491,183)
OTHER INCOME (EXPENSE):				
Interest income	9,264	8,915	15,265	46,664
Interest expense	(44,937)	-	(49,068)	-
Gain on warrant settlement	614,494	-	614,494	-
Loss on issuance of Series A preferred stock for accounts payable – related party	-	-	(142,669)	-
Change in fair value of derivative liability	<u>(6,119,762)</u>	<u>(65,858)</u>	<u>(5,845,313)</u>	<u>232,234</u>
Other (expense) income	<u>(5,540,941)</u>	<u>(56,943)</u>	<u>(5,407,291)</u>	<u>278,898</u>
LOSS BEFORE INCOME TAX PROVISION	(8,083,304)	(2,139,830)	(11,571,963)	(6,212,285)
INCOME TAX PROVISION	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
NET LOSS	<u>\$ (8,083,304)</u>	<u>\$ (2,139,830)</u>	<u>\$ (11,571,963)</u>	<u>\$ (6,212,285)</u>
Net loss per common share- basic and diluted	<u>\$ (1.24)</u>	<u>\$ (0.59)</u>	<u>\$ (2.45)</u>	<u>\$ (1.77)</u>
Weighted average common shares outstanding- basic and diluted	<u>6,518,077</u>	<u>3,597,796</u>	<u>4,732,514</u>	<u>3,508,113</u>

See accompanying notes to the financial statements

NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the period from July 1, 2019 through March 31, 2020
(Unaudited)

	Series A Preferred Stock: Par \$0.001		Common Stock: Par \$0.001		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 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
Series A Preferred Stock issued for employee stock compensation	1,727	2	-	-	73,465	-	73,467
Net proceeds from issuance of common stock in connection with equity financing	-	-	2,875,000	2,875	7,454,700	-	7,457,575
Common stock issued for consulting and legal services rendered	-	-	56,854	56	173,194	-	173,250
Common stock issued for employee compensation	-	-	3,572	4	29,247	-	29,251
Common stock issued for accounts payable	-	-	8,467	9	51,991	-	52,000
Common stock issued in exchange							

for warrants	-	-	677,224	677	5,721,866		5,722,543
Common stock issued upon cashless exercise of warrants	-	-	180,087	180	1,153,701	-	1,153,881
Warrants issued to Scientific Advisory Board	-	-	-	-	2,444	-	2,444
Common shares issued for Directors fees	-	-	1,581	1	11,249	-	11,250
Net loss	-	-	-	-	-	(8,083,304)	(8,083,304)
Balance, March 31, 2020	<u>368,215</u>	<u>\$ 368</u>	<u>7,673,357</u>	<u>\$ 7,673</u>	<u>\$ 117,995,269</u>	<u>\$(103,688,549)</u>	<u>\$ 14,314,761</u>

See accompanying notes to the financial statements

NanoViricides, Inc.
Statement of Changes in Stockholders' Equity
For the period from July 1, 2018 through March 31, 2019
(Unaudited)

	<u>Series A Preferred Stock: Par \$0.001</u>		<u>Common Stock: Par \$0.001</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Amount</u>	<u>Number of Shares</u>	<u>Amount</u>			
Balance, June 30, 2018	226,570	\$ 227	3,458,587	\$ 3,459	\$ 101,352,724	\$ (83,692,146)	\$ 17,664,264
Series A Preferred Stock issued for employee stock compensation	26,636	27	-	-	55,000	-	55,027
Common stock issued for consulting and legal services rendered	-	-	9,576	10	79,450	-	79,460
Stock options issued for compensation	-	-	-	-	11,920	-	11,920
Warrants issued to Scientific Advisory Board	-	-	-	-	1,543	-	1,543
Common shares issued for Directors fees	-	-	966	1	7,499	-	7,500
Net loss	-	-	-	-	-	(1,841,463)	(1,841,463)
Balance, September 30, 2018	253,206	\$ 254	3,469,129	\$ 3,470	\$ 101,508,136	\$ (85,533,609)	\$ 15,978,251
Series A Preferred Stock issued for employee stock compensation	386	-	-	-	53,621	-	53,621
Common stock issued for consulting and legal services rendered	-	-	4,198	4	26,996	-	27,000
Warrants issued to Scientific Advisory Board	-	-	-	-	1,429	-	1,429
Common shares issued for Directors fees	-	-	1,743	2	11,248	-	11,250
Net loss	-	-	-	-	-	(2,230,992)	(2,230,992)
Balance, December 31, 2018	253,592	\$ 254	3,457,070	\$ 3,476	\$ 101,601,430	\$ (87,764,601)	\$ 13,840,559
Series A Preferred Stock issued for employee stock compensation	1,726	2	-	-	77,086	-	77,088
Net proceeds from issuance of common stock in connection with equity financing	-	-	347,223	347	822,394	-	822,741
Common stock issued for employee compensation	-	-	3,572	4	28,568	-	28,572
Common stock issued for consulting and legal services	-	-	9,187	9	75,491	-	75,500
Warrants issued to Scientific Advisory Board	-	-	-	-	1,543	-	1,543
Common shares issued for Directors fees	-	-	1,707	2	11,248	-	11,250
Net loss	-	-	-	-	-	(2,139,830)	(2,139,830)
Balance, March 31, 2019	<u>255,318</u>	<u>\$ 256</u>	<u>3,818,759</u>	<u>\$ 3,838</u>	<u>\$ 102,617,760</u>	<u>\$ (89,904,431)</u>	<u>\$ 12,717,423</u>

See accompanying notes to the financial statements

Nanoviricides, Inc.
Statements of Cash Flows
(Unaudited)

	For the Nine Months ended	
	March 31, 2020	March 31, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (11,571,963)	\$ (6,212,285)
Adjustments to reconcile net loss to net cash used in operating activities		
Preferred shares issued as compensation	174,259	185,736
Loss on issuance of preferred shares for accounts payable- related party	142,669	-
Common shares issued as compensation and for services	290,250	240,532
Warrants granted to Scientific Advisory Board	3,885	4,515
Options granted as compensation	-	11,920
Depreciation	518,536	515,286
Amortization	6,204	6,204
Amortization of loan origination fees	11,463	-
Change in fair value of derivative liabilities	5,845,313	(232,234)
Gain on warrant settlement	(614,494)	-
Changes in operating assets and liabilities:		
Prepaid expenses	(61,558)	(152,981)
Other assets	11,688	2,145
Accounts payable	152,281	23,363
Accounts payable - related party	4,372	622,595
Accrued expenses	(25,313)	(145,583)
NET CASH USED IN OPERATING ACTIVITIES	(5,112,408)	(5,130,787)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(4,139)	(64,139)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from note payable -related party	1,100,000	-
Net proceeds from issuance of common stock and warrants	7,457,575	2,350,000
Proceeds from loan payable	155,173	-
Payment of loan payable	(45,878)	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	8,666,870	2,350,000
NET CHANGE IN CASH AND CASH EQUIVALENTS	3,550,323	(2,844,926)
Cash and cash equivalents at beginning of period	2,555,207	7,081,771
Cash and cash equivalents at end of period	<u>\$ 6,105,530</u>	<u>\$ 4,236,845</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:		
Interest paid	\$ -	\$ -
Non-cash Financing and Investing Activities:		
Cashless exercise of warrants reclassified from warrant liability to common stock	\$ 1,153,881	
Series A preferred stock issued for accounts payable-related party	\$ 250,000	-
Series A preferred stock issued for loan origination fee	\$ 39,301	-
Common stock issued to settle accounts payable	\$ 52,000	-
Stock warrants classified as a liability issued in connection with registered direct offering	\$ -	\$ 1,527,259

See accompanying notes to the financial statements

NANOVIRICIDES, INC.
March 31, 2020 AND 2019
NOTES TO THE FINANCIAL STATEMENTS
(Unaudited)

Note 1 - Organization, Nature of Business and Reverse Stock Split

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.

We are a company with several drugs in various stages of early development. In our lead antiviral program against herpes viruses, i.e. 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 began as of the end of December 2018 at the contract research organization (“CRO”) Bioanalytical Systems, Inc. (“BASI”), in Indiana. Those studies as well as several additional IND-enabling studies have been completed successfully. The Company is now in the process of writing the IND application itself, including protocols for human clinical studies, with the help of its several regulatory consultants. The Company is in the process of identifying and selecting appropriate partners and collaborators for the intended Phase1/2a human clinical studies for this drug candidate. 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.

As the pandemic COVID-19 caused by the SARS-CoV-2 coronavirus was breaking out, the Company bootstrapped a rapid drug development program to develop drug candidates for the treatment of SARS-CoV-2 infection. With the advantages of our prior work on coronaviruses, and having a library of chemical ligands, many of them already synthesized in our lab, we were able to advance this program very quickly into cell culture studies against coronaviruses. We reported these studies were successful in a May 12, 2020 press release, subsequent to the reporting period. We believe that this program is likely to advance rapidly towards human clinical trials due to the global COVID-19 pandemic emergency situation.

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, 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. We hold exclusive licenses for developing drugs against several different viruses from TheraCour, including HSV-1 and HSV-2. NanoViricides has requested TheraCour for a license on the field of coronaviruses. A Memorandum of Understanding towards licensing this field is being negotiated by the Board. 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.

Reverse Stock Split

On September 24, 2019 (the “Effective Date”), the Company effected a reverse stock split of its outstanding shares of common stock and shares of preferred stock at a ratio of one-for-twenty (the “Reverse Stock Split”).

The Reverse Stock Split, which was approved by the Company’s Board of Directors under authority granted under the laws of the State of Nevada, was consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Nevada on September 23, 2019 (the “Certificate of Amendment”). Unless the context otherwise requires, all references in these financial statements to shares of the Company’s common stock and series A preferred stock, including prices per share of its common stock and Series A preferred stock, reflect the Reverse Stock Split. Fractional shares were not issued, and the final number of shares were rounded up to the next whole share.

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 March 31, 2020 of approximately \$104.0 million and a net loss of approximately \$11.6 million and net cash used in operating activities of approximately \$5.1 million for the nine months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of March 31, 2020, the Company had available cash and cash equivalents of approximately \$6.1 million.

Management adjusted its planned expenditures, activities, and programs, in accordance with budgetary constraints and in accordance with its expectations of obtaining additional financing.

The Company has made several adjustments to its past expenditures in the ensuing annual budget, eliminating several expenses including a reduction in workforce and consultants to the extent feasible without affecting its program of drug development. In addition, the Company has focused its efforts primarily on a single lead program to minimize cost outlays, namely, taking the shingles drug candidate against VZV into human clinical trials. Management’s budget indicates that these changes have freed up sufficient funds to allow for the ensuing costs of the external advanced IND-enabling studies of this drug candidate. Management has engaged in an additional drug development program for COVID-19 with limited additional costs in the current development stage, and anticipates that costs of advanced drug development for COVID-19 are likely to be supported by non-dilutive government funding or equity-based funding. Management has advanced several options for financing the net working capital deficit as well as to obtain additional funds that will be needed for future human clinical trials.

On December 16, 2019 the Company entered into an Open End Mortgage with Anil Diwan, the Company’s founder, Chairman and President, to loan the Company up to \$2,000,000. As of March 31, 2020 the Company has drawn down \$1.1 million on this note.

On December 17, 2019, the Company entered into a Deferred Expense Exchange Agreement with TheraCour, whereby TheraCour agreed to exchange a portion of the previously deferred development fees in the amount of \$250,000 into 100,000 Series A preferred shares.

On November 7, 2019, the Company engaged Aegis Capital Corp for an underwritten offering pursuant to a Form S-1 filing. On January 21, 2020, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Aegis Capital Corp. Pursuant to the terms and conditions of the Underwriting Agreement, we agreed to issue and sell 2,500,000 shares of our common stock, par value \$0.001 per share for \$3.00 per share. We also granted the underwriter an option to purchase up to an additional 375,000 shares of our common stock (together with the Underwritten Shares, the “Shares”) within 45 days after the date of the Underwriting Agreement to cover over-allotments. The offering was consummated on January 25, 2020. The Company sold the Underwritten Shares and the underwriter exercised its option to purchase an additional 375,000 shares of common stock at the public offering price of \$3.00 per share. The net proceeds to the Company after underwriter's commission, agreed upon customary fees and expenses, and the Company's legal and accounting expenses related to the Offering were approximately \$7.5 million. See Note 7.

On May 21, 2020, the Company entered into a Securities Purchase Agreement with certain institutional investors for a registered direct offering (the “Offering”) of 1,400,000 shares of the Company’s common stock, par value \$0.001 per share at the purchase price of \$7.30 per share. Maxim Group LLC and Kingswood Capital Markets, a division of Benchmark Investments, Inc. acted as placement agents (collectively, the “Placement Agents”) in connection with the Offering pursuant to a placement agent agreement dated as of May 21, 2020 by and among the Company and the Placement Agents (the “Placement Agent Agreement”). The Offering closed on May 22, 2020. The net proceeds to the Company from the offering is approximately \$9.3 million after placement agent fees and other estimated offering expenses payable by the Company. See Note 12.

In addition, the Company believes that it has several important milestones that it anticipates achieving in the ensuing year. Management believes that assuming that 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. The Company is relying on the Order of the Securities and Exchange Commission of March 25, 2020 (Release No. 34-88465) (the “Order”), to request an extension for filing of the Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2020, as a result of the circumstances set forth in Note 12- Subsequent events. The said Order allows for the delay of certain filings required under the Securities and Exchange Act of 1934, as amended.

However the emergence of widespread health emergencies due to COVID-19 may lead 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 and the proceeds of the registered direct offering of May 22, 2020 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.

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, 2019 filed with the SEC on August 23, 2019.

For a summary of significant accounting policies, see the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2019 filed on August 23, 2019.

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 Nine Months Ended March 31, 2020	For the Nine Months Ended March 31, 2019
Options and Warrants	27,505	402,855
Total potentially outstanding dilutive common shares	27,505	402,855

The Company has also issued 368,215 shares of Series A preferred stock to investors and others as of March 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 March 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 1,288,753 and is not included in diluted earnings per share since the shares are contingently convertible only upon a change of control.

Recently Issued Accounting Pronouncements

In July 2017, the FASB issued Accounting Standards Update (“ASU”) No. 2017-11. “Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features, II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception (“ASU 2017-11”) ASU 2017-11 revises the guidance for instruments with down round features in Subtopic 815-40, Derivatives and Hedging – Contracts in Entity’s Own Equity, which is considered in determining whether an equity-linked financial instrument qualifies for a scope exception from derivative accounting. An entity still is required to determine whether instruments would be classified in equity under the guidance in Subtopic 815-40 in determining whether they qualify for that scope exception. If they do qualify, freestanding instruments with down round features are no longer classified as liabilities. ASU 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018, and early adoption is permitted, including adoption in an interim period. ASU 2017-11 provides that upon adoption, an entity may apply this standard retrospectively to outstanding financial instruments with a down round feature by means of a cumulative-effect adjustment to the opening balance of accumulated deficit in the fiscal year and interim period adoption. The Company has adopted ASU 2017-11 retrospectively as of January 1, 2019. The adoption of this ASU did not have any impact on its financial statements.

In June 2018, the FASB issued ASU 2018-07, “Compensation – Stock Compensation (Topic 718) (“ASU 2018-07”): Improvements to Nonemployee Share Based Payment Accounting,” which simplifies the accounting for non-employee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. Upon transition, non-employee awards are required to be measured at fair value as of the adoption date. The Company had adopted ASU 2018-07 as of July 1, 2019. The adoption of this ASU did not have a significant impact on its financial statements.

Note 4 - Related Party Transactions

Related Parties

Related parties with whom the Company had transactions are:

Related Parties	Relationship
Anil R. Diwan	Chairman, President, acting CEO, significant stockholder and Director
TheraCour Pharma, Inc.	An entity owned and controlled by a significant stockholder

	As of	
	March 31, 2020	June 30, 2019
<u>Account Payable – Related Party</u>		

Pursuant to an Exclusive License Agreement we entered into with TheraCour, the Company was granted exclusive licenses in perpetuity for technologies developed by TheraCour for the virus types: HIV, HCV, Herpes, Asian (bird) flu, Influenza and rabies. In consideration for obtaining this exclusive license, we agreed: (1) that TheraCour can charge its costs (direct and indirect) plus no more than 30% of 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; (4) to pay an advance payment equal to twice the amount of the previous month's invoice to be applied as a prepayment towards expenses. On October 2, 2018, the Company entered into an agreement with TheraCour for a waiver of the two months worth of prepaid balance advance of anticipated invoicing until the filing of an IND and the application of the 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. On December 17, 2019, the Company entered into a Deferred Expense Exchange Agreement with TheraCour, whereby the Company and TheraCour agreed to the exchange of 100,000 shares of Series A preferred stock with a fair value of \$392,669 for \$250,000 previously deferred development fees owed to TheraCour, and recognized a loss on the exchange of \$142,669.

Accounts payable due TheraCour on the reporting date was \$ 578,155 \$ 823,783

	For the three months ended		For the nine months ended	
	March 31, 2020	March 31, 2019	March 31, 2020	March 31, 2019
<u>Property and Equipment</u>				

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

\$ - \$ 6,603 \$ 4,139 \$ 14,011

	For the three months ended		For the nine months ended	
	March 31, 2020	March 31, 2019	March 31, 2020	March 31, 2019
<i>Research and Development Costs Paid to Related Party</i>				
Development fees and other costs charged by TheraCour pursuant to exclusive License Agreements between TheraCour and the Company for the development of the Company's drug pipeline. No royalties are due TheraCour from the Company at March 31, 2020 and June 30, 2019	\$ 601,016	\$ 574,853	\$ 1,720,331	\$ 2,320,726

Mortgage Note Payable - Related Party

On December 16, 2019, the Company entered into an Open End Mortgage Note (the "Note") with Anil Diwan, the Company's founder, Chairman and President, to loan the Company up to \$2,000,000 in two tranches of \$1,000,000 (the "Loan"). The Note bears interest at the rate of 12% per annum and is secured by a mortgage granted against the Company's headquarters. The unpaid principal balance is due and payable on December 15, 2020. The lender received 10,000 shares of the Company's Series A preferred stock as a loan origination fee which is to be amortized over the one year term of the loan using 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. See note 7 for inputs used in calculation of fair value. Amortization expense on the loan origination fee for the three and nine months ended March 31, 2020 was \$9,825 and \$11,463, respectively. As of March 31, 2020, the Company has drawn down \$1.1 million of this loan and may, at its option, draw down the remainder of the loan. Interest is payable only on the amount drawn down. The lender has escrowed \$132,000 of interest payable pursuant to the Loan. The balance at March 31, 2020 of the prepaid interest escrowed by the lender is \$ 96,140 and is included in Prepaid expenses. For the three and nine months ended March 31, 2020, the Company incurred interest expense of \$33,367 and \$35,860, respectively, which reduced the interest escrow balance included in prepaid expenses. On April 30, 2020, the Company and Dr. Diwan mutually agreed to extend the maturity date of the note at the Company's option, to May 15, 2021, with the rest of the terms remaining the same.

At March 31, 2020, mortgage note payable – related party consisted of:

Mortgage note payable	\$ 1,100,000
Less: unamortized loan origination fee	(27,838)
	<u>\$ 1,072,162</u>

Note 5 - Property and Equipment

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

	March 31, 2020	June 30, 2019
GMP Facility	\$ 8,020,471	\$ 8,020,471
Land	260,000	260,000
Office Equipment	57,781	57,781
Furniture and Fixtures	5,607	5,607
Lab Equipment	<u>5,752,457</u>	<u>5,748,318</u>

Total Property and Equipment	14,096,316	14,092,177
Less Accumulated Depreciation	(4,383,466)	(3,864,930)
Property and Equipment, Net	<u>\$ 9,712,850</u>	<u>\$ 10,227,247</u>

Depreciation expense for the three months ended March 31, 2020 and 2019 were \$172,862 and \$172,151, respectively, and for the nine months ended March 31, 2020 and 2019 were \$518,536 and \$515,286, respectively.

Note 6 - Trademark and Patents

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

	March 31, 2020	June 30, 2019
Trademarks and Patents	\$ 458,954	\$ 458,954
Less Accumulated Amortization	(98,500)	(92,296)
Trademarks and Patents, Net	<u>\$ 360,454</u>	<u>\$ 366,658</u>

Amortization expense amounted to \$2,069 and \$2,068 for each of the three-month periods ended March 31, 2020 and 2019 and \$6,204 and \$6,204 for the nine months ended March 31, 2020 and 2019, respectively.

Note 7- 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 \$47,260 and \$141,780, respectively, for the three and nine months ended March 31, 2020. The balance of \$229,870 will be recognized as the shares vest and service is rendered.

On January 21, 2020, the Company entered into an Underwriting Agreement with Aegis Capital Corp. Pursuant to the terms and conditions of the Underwriting Agreement, we agreed to issue and sell 2,500,000 shares of our common stock, par value \$0.001 per share, at a price to the public of \$3.00 per share. Pursuant to the Underwriting Agreement, we also granted the underwriter an option to purchase up to an additional 375,000 shares of our common stock within 45 days after the date of the Underwriting Agreement to cover over-allotments, if any. The Final Prospectus for the offering was filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(1) of the Securities Act of 1933, as amended, on January 23, 2020.

The offering was consummated on January 25, 2020. The Company sold the Underwritten Shares and the underwriter exercised its option to purchase an additional 375,000 shares of common stock at the public offering price of \$3.00 per share. The net proceeds to the Company after underwriter's commission and agreed upon customary fees and expenses, and deducting the Company's legal and accounting expenses related to the Offering was \$7,457,575.

The Company accounted for the proceeds of the Offering at January 25, 2020 as follows:

Gross proceeds	\$ 8,625,000
Less: offering costs	(1,167,425)
Net proceeds from issuance of common stock	<u>\$ 7,457,575</u>

On January 24, 2020, the Company entered into a Binding Term Sheet which was incorporated on January 27, 2020 in a Settlement Agreement and Mutual Release (the "Settlement Agreement") with the investor parties (collectively, the "Investors") to that certain Securities Purchase Agreement dated as of February 27, 2019 (the "Securities Purchase Agreement") to settle an action commenced by the Investors to, among other things, enjoin the Company's previously disclosed underwritten public offering (the "Action")

On January 27, 2020, the Company entered into an Exchange Agreement with each of the Investors pursuant to the Settlement Agreement. Pursuant to the terms and conditions of the Exchange Agreement, the Investors agreed to terminate certain restrictive covenants in the Securities Purchase Agreement, including a bar on all offerings of securities below the exercise price of the Warrants to purchase common stock issued February 19, 2019 (the "Old Warrants"), and the Company agreed to exchange 347,222 of the Investors' Old Warrants for an aggregate of (i) 677,224 shares of common stock and (ii) new warrants, to purchase 347,222 shares of common stock at an exercise price of \$3.00 per share and expire on August 24, 2024 (the "New Warrants"). The common stock issued had a fair value of \$5,722,543 using the closing price of \$8.45 on January 24, 2020 resulting in an increase to common stock of \$677 and additional paid in capital of \$5,721,866 and the New Warrants had a fair market value of \$2,066,425 which was recorded as a derivative liability. The aggregate fair value of the common stock and New Warrants issued as part of the Exchange Agreement was \$7,788,968. The Old Warrants were remeasured to a fair value of \$8,403,468 on January 24, 2020 immediately prior to the exchange. As a result of the Exchange Agreement, a gain on warrant settlement was recognized in the amount of \$614,494 calculated as the difference between the fair value of the Old Warrants immediately prior to the exchange and the aggregate fair value of the common stock and New Warrants issued in the exchange. On March 16, 2020 the shareholders of NanoViricides authorized an increase in the number of authorized common stock to 150,000,000 shares and the New Warrants were issued and exercisable. These warrants contained a full-ratchet anti-dilution feature but also contained other adjustment features which required that the warrants be classified as a derivative liability.

The 347,222 New Warrants were exercised on March 23, 2020 and March 25, 2020 pursuant to a cashless exercise provision resulting in the issuance of 180,087 shares of common stock. The fair value of the warrants were reset to fair value as of March 23, 2020 and March 25, 2020, and, upon exercise of the warrants, the derivative liability was reclassified to equity of \$1,153,881.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 0 and 10,000 fully vested shares, respectively, of its Series A preferred stock for a loan origination fee to a related party with a fair value of \$39,301.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 0 and 100,000 fully vested shares, respectively, of its Series A preferred stock with a fair value of \$0 and \$392,669 in exchange for \$250,000 of previously deferred development fees to a related party and recognized a loss on the exchange of \$142,669.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 1,727 and 2,501, respectively, fully vested shares of its Series A preferred stock for employee compensation. The Company recorded an expense of \$26,207 and \$32,479, respectively, for the three and nine months ended March 31, 2020 related to these issuances, which was the fair value on the dates of the issuance.

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

Date	Shares	Value
7/31/2019	129	\$ 1,472
8/31/2019	129	1,345
9/30/2019	129	1,321
10/31/2019	129	628
11/30/2019	129	677
12/16/2019	10,000	39,301
12/17/2019	100,000	392,669
12/31/2019	129	829
01/31/2020	129	592
02/29/2020	129	2,610
03/01/2020	1,340	20,990
03/31/2020	129	2,015
	<u>112,501</u>	<u>\$ 464,449</u>

There is currently no market for the shares of Series A Convertible 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 Convertible Preferred Stock granted to various employees and others on the date of grant. The Series A Convertible 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 valuations of the Series A Convertible Preferred Stock at each issuance used the following inputs:

- a. The common stock price was in the range \$2.03 to \$10.82
- b. The calculated weighted average number of shares of common stock in the period;
- c. A 26.63% premium over the common shares for the voting preferences;
- d. The calculated weighted average number of total voting shares and the monthly shares representing voting rights of 14.9% to 18.3% of the total;
- e. Prior to January 1, 2020, the conversion value is based on an assumption for calculation purposes only of a Change of Control in 4 years from October 31, 2016 and a remaining restricted term of 1.08 to .92 years. From January 1, 2020 the conversion value is based on the assumption for calculation purposes only, of a Change of Control in five years from 12/31/2019 for the issuances and a remaining restricted term of 5.00 to 4.84 years;
- f. 29.30% to 48.66% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 80.41% to 82.23% volatility, 1.73% to 1.69% risk free rate) applied to the converted common shares.

During the nine months ended March 31, 2020, the SAB was granted fully vested warrants in August 2019 to purchase 572 shares of common stock with an exercise price of \$5.88 per share expiring in August 2023 and in November 2019, 572 fully vested warrants to purchase shares of common stock with an exercise price of \$2.63 per share expiring in November 2023 and in February 2020, 572 fully vested warrants to purchase shares of common stock with an exercise price of \$8.68 per share expiring in February 2024. The fair value of the warrants was \$2,444 for the three months ended March 31, 2020 and \$3,885 for the nine months ended March 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	47.99-87.10%
Expected annual rate of quarterly dividends	0.00%
Risk-free rate(s)	1.41-1.63%

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 3,572 of fully vested shares of its common stock for employee compensation. The Company recognized compensation expense of \$29,251 for the three and nine months ended March 31, 2020, which was the fair value on the dates of issuance.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 1,581 and 9,099, respectively, fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of \$11,250 and \$33,750 for the three and nine months, respectively, which was the fair value on the dates of issuance.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 56,854 and 74,987, respectively fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$173,250 and \$227,250 for the three and nine months ended March 31, 2020, respectively, which was the fair value on the dates of issuance.

For both the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 25,667 fully vested shares of its common stock with a restrictive legend to satisfy open accounts payable of \$77,000 for consulting services. The number of shares issued to settle the accounts payable was calculated using the market price of the common stock on the settlement date.

On January 9, 2020 the Company's Board of Directors authorized the settlement with a vendor to redeem and cancel 17,200 shares of

its common stock with a restrictive legend, which were initially issued in payment of accounts payable of \$25,000. The shares were cancelled and reported as reductions of common stock issued in exchange for accounts payable reported in the Statement of Changes in Shareholder Equity as a decrease of \$25,000. The redemption and cancellation had no effect on the results of operations for the three and nine months ended March 31, 2020.

Note 8 - 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, 2019	398,156	\$ 18.20	4.69	\$ -
Granted	348,938	3.01		
Exercised	347,222	3.00		
Expired or cancelled	377,367	8.82	-	-
Outstanding and exercisable at March 31, 2020	<u>22,505</u>	<u>\$ 31.54</u>	<u>2.40</u>	<u>\$ -</u>

Of the above warrants 857 expire in fiscal year ending June 30, 2020, 2,858 expire in fiscal year ending June 30, 2021, 2,287 expire in the fiscal year ending June 30, 2022, 14,787 warrants expire in the fiscal year ending June 30, 2023 and 1,716 warrants expire in the fiscal year ending June 30, 2024.

Stock Options

Stock Options	Number of Shares	Weighted Average Exercise Price per share (\$)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (\$)
Outstanding at June 30, 2019	5,000	\$ 10.00	2.17	\$ -
Granted	-	-	-	-
Forfeited	-	-	-	-
Outstanding at March 31, 2020	5,000	10.00	1.42	-

The options expire on August 31, 2021

Note 9 – 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 March 31, 2020 the loan balance was 109,295. For the three and nine months ended March 31, 2020 the Company incurred interest expense of \$1,745.

Note 10 - Fair Value Measurement

Fair value measurements

At March 31, 2020 and June 30, 2019 the estimated fair values of the liabilities measured on a recurring basis are as follows:

	Fair Value Measurements at March 31, 2020:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability - warrants	\$ -	\$ -	\$ -

	Fair Value Measurements at June 30, 2019:		
	(Level 1)	(Level 2)	(Level 3)
Derivative liability - warrants	\$ -	\$ -	\$ 1,645,606

In a concurrent private placement on February 27, 2019, the purchasers received warrants (the “Old Warrants”) to purchase up to 347,222 shares of common stock. The Old Warrants had an exercise price of \$12.20 per share, shall be exercisable on the six month anniversary of issuance and were to expire five (5) years thereafter. The Old Warrants are exercisable for cash or, solely in the absence of an effective registration statement or prospectus, by cashless exercise.

The Company accounts for stock purchase warrants as either equity instruments or derivative liabilities depending on the specific terms of the warrant agreements. Under applicable accounting guidance contained in ASU 2017-11, adopted by the Company on January 1, 2019, stock warrants are to be accounted for as equity if the warrants contain full-ratchet anti-dilution provisions. The Old Warrants issued on February 27, 2019, contained a full-ratchet anti-dilution feature but also contained other adjustment features which required that the Old Warrants be classified as a derivative liability.

The Company used a lattice model to calculate the fair value of the derivative warrants based on a probability weighted discounted

cash flow model. This model is based on future projections of the various potential outcomes. The features that were analyzed and incorporated into the model included the exercise and full reset provisions.

The Old Warrants were valued as of June 30, 2019 with the following assumptions:

- The 5 year warrants issued on February 27, 2019 (expire February 27, 2024) included with an exercise price of \$12.20 (subject to adjustments – full ratchet reset and fundamental transactions).
- The stock price would fluctuate with the Company projected volatility.

- The holder would exercise the warrant as they become exercisable (effective registration at issuance) at target prices of the higher of 2 times the projected reset exercise price or 2 times the stock price.
- The holder would exercise the warrant at maturity if the stock price was above the project reset prices.
- The next capital raise is projected to occur during 2020 (annually 12 months from issuance) at prices approximating 100% of market triggering a reset event and exercise price adjustment.
- The fundamental transaction projected with 0% probability increasing 1% per quarter to a maximum of 10% and settlement based on the Black Scholes value.
- The stock price would fluctuate with an annual volatility. The projected volatility curve was based on historical volatilities of the Company for the valuation period.

1 Year	
3/31/20	-
6/30/19	76.1%

The Company remeasured the fair value of the derivative Old Warrants at January 24, 2020 to \$8,403,468 with the following assumptions:

- Valuation based on 347,222 warrants with an exercise price of \$12.20
- Lattice model based on market stock price of \$8.45
- The Holder would exercise the warrant at maturity if the stock price was above the projected exercise price.
- An imminent reset event to \$3.00 was projected based on the Company's offering.
- Future capital raises are projected to occur starting 1/31/21, and annually thereafter, at prices approximating 100% of market, which may trigger a reset event adjusting the exercise and the number of warrants.
- The fundamental transaction was projected to occur 10% of the time, tested on an annual basis, with settlement equal to the Black Scholes value.
- The stock price would fluctuate with an annual volatility. The projected volatility curve was based on historical volatility of the Company for the valuation date. The projected annual volatility for the valuation date was 106.5%.

The fair value of the New Warrants was \$2,066,425 upon issuance at January 24, 2020 using the following assumptions:

- Valuation based on 347,222 warrants with an exercise price of \$3.00
- Lattice model simulation based on market stock price of \$8.45
- The Holder would exercise the warrant at maturity if the stock price was above the projected exercise price.
- Future capital raises are projected to occur starting 1/31/21, and annually thereafter, at prices approximating 100% of market, which may trigger a reset event adjusting the exercise and the number of warrants.
- The fundamental transaction was projected to occur 10% of the time, tested on an annual basis, with settlement equal to the Black Scholes value.
- The stock price would fluctuate with an annual volatility. The projected volatility curve was based on historical volatility of the Company for the valuation date. The projected annual volatility for the valuation date was 106.5%.

The 347,222 New Warrants were exercised on March 23, 2020 and March 25, 2020 pursuant to a cashless exercise provision resulting in the issuance of 180,087 shares of common stock. The Company remeasured the fair value of the new warrants just prior to their exercise.

The Company remeasured the fair value of the derivative New Warrants exercised at March 23, 2020 to \$941,701 with the following assumptions:

- Valuation based on 266,614 warrants exercised with an exercise price of \$3.00
- Lattice model based on market stock price of \$6.11
- The Holder would exercise the warrant at maturity if the stock price was above the projected exercise price.
- Future capital raises are projected to occur starting 4/30/21, and annually thereafter, at prices approximating 100% of market, which may trigger a reset event adjusting the exercise and the number of warrants.
- The fundamental transaction was projected to occur 10% of the time, tested on an annual basis, with settlement equal to the Black Scholes value.
- The stock price would fluctuate with an annual volatility. The projected volatility curve was based on historical volatility of the Company for the valuation date. The projected annual volatility for the valuation date was 122.6%.

The Company remeasured the fair value of the derivative New Warrants at March 25, 2020 to \$212,175 with the following assumptions:

- Valuation based on 80,608 warrants exercised with an exercise price of \$3.00
- Lattice model based on market stock price of \$4.80
- The Holder would exercise the warrant at maturity if the stock price was above the projected exercise price.
- Future capital raises are projected to occur starting 4/30/21, and annually thereafter, at prices approximating 100% of market, which may trigger a reset event adjusting the exercise and the number of warrants.
- The fundamental transaction was projected to occur 10% of the time, tested on an annual basis, with settlement equal to the Black Scholes value.
- The stock price would fluctuate with an annual volatility. The projected volatility curve was based on historical volatility of the Company for the valuation date. The projected annual volatility for the valuation date was 123.0%.

The following tables present the activity for liabilities measured at estimated fair value using unobservable inputs for the nine months ended March 31, 2020:

Fair Value Measurement

	Fair Value Measurement Using Significant Unobservable Inputs
	Derivative Liability- Warrant
Beginning balance at July 1, 2019	\$ 1,645,606
Additions during the year- New warrants	2,066,425
Change in fair value	5,845,313
Transfer out of Level 3	(9,557,344)
Balance at March 31, 2020	<u>\$ -</u>

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. Diwan, President 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. Diwan will be paid an annual base salary of \$400,000. Additionally, Dr. 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.

The Company and Dr. Irach Taraporewala, the Company's Chief Executive Officer, entered into an employment agreement effective September 1, 2018, for a term of three years. Dr. Taraporewala would be paid an annual base salary of \$360,000. Additionally, Dr. Taraporewala was awarded a grant of 15,000 options to purchase shares of the Company's common stock. 5,000 options vested on September 1, 2018 and the remainder of the options would vest over the two-year vesting period and are subject to forfeiture. On January 24, 2019, Dr. Taraporewala resigned as the Chief Executive Officer of the Company for personal reasons. Also on that date, the Company and Dr. Taraporewala agreed that Dr. Taraporewala would become a consultant for the Company for a period of two years. In connection with his resignation and new consulting services, the Company and Dr. Taraporewala entered into a Confidential Separation and Consulting Agreement and General Release (the "Agreement") pursuant to which the Company will pay Dr. Taraporewala monthly consulting payments of \$3,000 from February 1, 2019, the effective date of the Agreement, through January 31, 2021. The Agreement includes a general release of claims against the Company, obligations of confidentiality, non-disclosure, non-disparagement and other customary provisions found in similar agreements. The remaining 10,000 options not vested upon resignation have been forfeited.

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 issued 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 issued 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 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 a Licensing Agreement (the "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. 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.

Note 12 – Subsequent events

On May 14, 2020 the Company filed a Current Report on Form 8-K to indicate it is relying on the COVID-19 Order of the Securities and Exchange Commission dated March 25, 2020 (Release No. 34-88465) (the "Order"), which allows for the delay of certain filings required under the Securities and Exchange Act of 1934, as amended.

The Company is relying on the Order in connection with the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2020, as a result of the circumstances set forth below. The Company expects to file its Quarterly Report on Form 10-Q no later

than 45 days after the due date of filing of May 15, 2020.

The Company has been working diligently on development of therapeutics for the treatment of COVID-19, in addition to its current primary business activity of development of therapeutics against shingles. While the Company's employees and immediate families did not have any known incidences of COVID-19 infection, several of the Company's key employees have been on self-isolation from time to time, due to potential unintended exposure to likely COVID-19 cases. While such personnel continue to work remotely on matters such as documentation and paper research, the primary work of the Company is focused in the laboratory and such personnel are then unavailable to conduct such work. These absences have created a number of shortages of essential personnel needed to perform various operations for the Company including the preparation of the Company's financial statements and management report. Additionally, the Company's accounting staff has been unavailable from time to time due to self-isolation and other local travel and shelter-in-place restrictions.

Effective May 15, 2020, the Board of Directors of NanoViricides, Inc. appointed Todd Rokita as a new member of the Board to serve until the next annual meeting of stockholders of the Company and until his successor is duly elected and qualifies. At the same time, Mr. Rokita was also appointed to the Board's Nomination Committee and Compensation Committee.

On May 21, 2020, the Company entered into a Securities Purchase Agreement with certain institutional investors for an offering of 1,400,000 shares (the "Shares") of the Company's common stock, par value \$0.001 per share at the purchase price of \$7.30 per share. The Shares were issued pursuant to a prospectus supplement dated May 21, 2020 which was filed with the Securities and Exchange Commission on May 22, 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.

Maxim Group LLC and Kingswood Capital Markets, a division of Benchmark Investments, Inc. acted as placement agents in connection with the Offering pursuant to a placement agent agreement dated as of May 21, 2020 by and among the Company and the Placement Agents. The Offering closed on May 22, 2020. The net proceeds to the Company from the offering are approximately \$9.3 million after placement agent fees and other estimated offering expenses payable by the Company.

Effective May 29, 2020, Mark Day resigned as a Member of the Board of Directors of NanoViricides, Inc. as well as a Member of its Audit, Nominating and Compensation Committees. Mr. Day did not indicate that his decision to resign was a result of any disagreement with the Company on any matter relating to the Company's operations, policies or practices.

On June 8, 2020, the Company announced that it has 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 is in the process of appointing 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, shall, except as otherwise specified in the MOU, be generally consistent with the VZV License Agreement dated October 28, 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, 2019. 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.

Recent Developments

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.

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. This has enabled rapid translation of our first drug candidate 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.

The Company's Drug Programs in Brief

Since founding in 2005, the Company has developed drug candidates against a number of different viruses including influenza, HIV, and dengue among others.

In December 2014, the Company purchased at cost the nanomedicines research and cGMP production facility that was designed and built by Dr. Diwan, its co-founder, who had used his personal funds and his privately raised financing. With this purchase, the Company became a unique company in the industry with its own cGMP manufacturing capability, and end-to-end discovery-to-drug-product drug development capability that is rare in the biopharma industry.

Since then, the Company has focused on drug programs that it believes it can execute on with the limited financing that it believes it can bring in to support the projects. Thus the Company decided to focus on the HerpeCide™ program. In particular, the Company decided to develop dermal topical treatments (skin creams) for HSV-1 and HSV-2. When the Company's internal research showed that, surprisingly, the same drug candidates were effective against VZV (the Varicella-Zoster virus) in cell culture, the Company extended the HerpeCide program to include VZV studies. VZV is the cause of shingles and chickenpox. Further, the Company has also demonstrated that some of these drug candidates were effective in viral-ARN ("Acute Retinal Necrosis") in an animal model. Thus the Company has three immediate drug programs, namely dermal topical treatments for HSV-1, HSV-2 and VZV, and two additional drug programs, namely eye drops for treatment of Herpes Keratitis (an infection of the external eye), and intra-vitreal injection for the treatment of vARN, in the HerpeCide program alone.

The Company is in the process of writing and completing its first IND ("Investigational New Drug") application to the US FDA. This application covers the indication of the Company's drug, namely, NV-HHV-101 skin cream for the treatment of shingles rash, caused by VZV (varicella-zoster virus). The IND-enabling and required pre-clinical studies have been completed, and reports of almost all of the analyses of the samples resulting from these studies are being circulated between parties involved for completion. The Company cannot project an exact date for filing an IND because of its dependence on a number of external collaborators and consultants, and the effects of recent COVID-19 restrictions.

The Company anticipates 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 the pipeline wider 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. 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.

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. The Company has a bright future with expanding a pipeline, as we further the research programs driving towards cures beyond our current objectives of effective treatments.

We have declared a clinical drug candidate, namely, NV-HHV-101, with its first indication as the dermal topical treatment of shingles rash (as a skin cream), and we have had a positive pre-IND application response from the US FDA for our drug development plan. The Company has completed the IND-enabling required safety/toxicology studies for this drug candidate, and we now have most of the final reports from the various external collaborators in our hands. We are currently compiling the IND application, with the help of several industry expert regulatory consultants familiar with the US FDA as well as international regulations. We are also in discussions for clinical sites and for finalizing clinical programs with various consultants and vendors. Once these reports are compiled, a final clinical program is defined, and the IND application content is agreed upon by our regulatory consultants, we anticipate completing the IND application for submission to the US FDA.

Financing

On December 16, 2019, the Company entered into an Open End Mortgage Note with Anil Diwan, the Company's founder, Chairman and President, to loan the Company up to \$2,000,000. The Company has drawn down approximately \$1.1 million on this note as of March 31, 2020. The Company is not required to draw down the remaining \$0.9 million of the note. Subsequently, on February 11, 2020, the Company and Dr. Diwan have mutually agreed to extend the maturity date of the note, at the Company's option, to March 15, 2021, with the rest of the terms remaining the same.

On December 17, 2019, the Company entered into a Deferred Expense Exchange Agreement with TheraCour Pharma, Inc. ("TheraCour"), whereby TheraCour agreed to exchange a portion of the previously deferred development fees owed to TheraCour in the amount of \$250,000 into 100,000 Series A preferred shares with a fair value of \$392,669. The Company recognized a loss on the exchange of \$142,669.

The terms of the loan from Dr. Diwan, and the terms of the agreement for the satisfaction of certain current liabilities with TheraCour, were accepted by the independent members of the Company's Board of Directors, with Dr. Diwan recused from any discussions. Together, these two transactions have effectively provided a total of \$1.35 million of cash infusion into the Company and made available an additional \$0.9 million, significantly improving the Company's cash position and liquidity.

On January 25, 2020, the Company announced that it had completed an underwritten public offering (the "Offering") with gross proceeds of \$8.625 million before deducting underwriting discounts and other estimated offering expenses. The Offering included 2,500,000 shares of the Company's common stock and 375,000 additional shares from the exercise of the underwriter's option to purchase to cover over-allotments at the public offering price of \$3.00 per share.

Subsequent to the reporting period, on May 21, 2020, the Company completed a registered direct offering with gross proceeds of \$10.2 million from the sale of 1.4 million shares of common stock, and no warrants, at a price of \$7.30 per share (the "Offering"). The net proceeds were approximately \$9.3 million, after deducting placement agent fees and other costs.

The Company ended the quarter with approximately \$6.1 million of cash and cash equivalents in hand, and approximately \$1.1 million of current liabilities in the normal course of business (excluding the December 16, 2019 mortgage note with draw-down of approximately \$1.1 million). In addition, the Company has property and equipment assets worth \$9.7 million after depreciation, subject to a mortgage of approximately \$1.1 million. The property and equipment assets correspond to the Company's facility in Shelton with chemistry R&D and production scale-up labs, c-GMP manufacturing suites, a state of the art nanomedicines characterization lab, and a BSL2 Virology lab.

With the additional May 20, 2020 raise, the Company believes its existing resources will be sufficient to fund its planned operations and expenditures for at least the next twelve months from the issuances of these financial statements.

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 aka 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 our 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 limited approval for use in COVID-19 in the US, and favipravir was recently 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.

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 Pharma Inc. ("TheraCour") which is licensed intellectual property from Allexcel, Inc. ("Allexcel") for specific application verticals of specific viruses, as established at its foundation in 2005.

Subsequent to the reporting period, on June 8, 2020, the Company announced that it has executed a Memorandum of Understanding with TheraCour ("MoU") for a license for the research and development of anti-viral treatments for coronavirus derived human infections (the "Field") on substantially similar terms as the November 1, 2019 License Agreement between the Company and TheraCour. The MoU also provides a limited license to the Company for the entire application of human coronavirus infections, while the full license is being perfected or August 31, 2020. The Company is in the process of appointing 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.

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 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.

Subsequent to the reporting period, on May 12, 2020, the Company announced that it has developed drug candidates that have demonstrated very high anti-viral effectiveness in cell culture studies against multiple coronaviruses.

Two of the tested nanoviricides drug candidates were highly effective in cell culture assays against multiple coronaviruses that infect humans. In particular, they were several-times more effective than favipravir (aka T-705), against the tested viruses. Favipravir is a broad-spectrum nucleoside-like analog drug that is in clinical testing against SARS-CoV-2, originally developed by Fujifilm.

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.

Subsequent to the reporting period, 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.

The Company is developing 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.

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. 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 nanoviricidic 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 nanoviricidic drugs showed significantly reduced body weight loss. The body weight loss was only 3.9% for the best nanoviricidic drug 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 nanoviricidic drugs also showed significantly reduced body weight loss. The body weight loss in male animals was 8.0% for the best nanoviricidic drug 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 nanoviricidic 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 provides confidence to the Company that these nanoviricidic 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 nanoviricidic 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 nanoviricidic drugs 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, nanoviricidic drugs 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 nanoviricidic drug candidates are potentially superior to favipiravir, 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 favipiravir and infusion of remdesivir are two anti-viral drugs in clinical trials for the treatment of COVID-19. Thus, the Company believes that the nanoviricidic drug candidates it has developed are expected to warrant human clinical studies.

Prior to filing for human clinical trials, NanoViricidic plans on conducting studies to further determine the effectiveness against SARS-CoV-2, perform drug development studies for safety/toxicology, and request a pre-IND Meeting with the US FDA for regulatory guidance.

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.

NanoViricides in the News

Dr. Anil Diwan, the Company's President and Chairman of the Board was interviewed on Fox Business News ("FBN"), on the Kennedy Show, at approximately 9:15 pm on January 23, 2020. The Company has licensed a copy of the video excerpt from FBN and it is available on the Company's website (www.nanoviricides.com) under the heading "NanoViricides In the News", by clicking on "Dr. Anil Diwan on Fox Business - 01/23/2020 - By - Kennedy".

The Company issued a press release on February 4, 2020 detailing the interview, in which Dr. Diwan explained certain potential applications of the nanoviricide technology that can enable preparedness against novel viral outbreaks, in that, it allows for quick screening and picking an effective nanoviricide from a library-on-a-chip.

On January 28, 2020, Dr. Diwan was interviewed on the Stuart Varney Show on FBN. The Company has licensed a copy of the video excerpt from FBN and it is available on the Company's website (www.nanoviricides.com), home page, under the heading "Dr. Anil Diwan on Fox Business - 01/28/2020".

On April 6, 2020, the Company announced that U.S. Senator Richard Blumenthal visited the Company's facility in Shelton, Connecticut, on Tuesday, March 31, 2020. The Honorable Senator Blumenthal visited the Company to receive an update regarding the COVID-19 drug development program and to tour the cGMP-capable manufacturing facility. The Senator, his staff, and members of the press participated in a tour of the Company's lab and manufacturing facility, and held a press conference after the tour.

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 near future, is expected to serve as a major value inflection point, as has generally been seen in the biopharma sector.

The Company's top priority remains working on its first IND application for NV-HHV-101. The Company intends to solicit interest and financing from government agencies in order to accelerate its work on the coronaviruses and novel pathogens.

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.

The Company is pleased to note that it has been executing on all milestones towards the IND filing for its first clinical candidate along a reasonable projected timeline, and is doing so with highly conservative expenditures. These continuing developments are substantially dependent on external collaborations as well as on continuing to achieve successful results.

On January 9, 2020 the Company announced that its lead drug candidate, NV-HHV-101, was found to be safe in terms of potential genotoxicity in the suite of tests that were performed by an independent laboratory. The drug did not induce mutations in bacteria and did not cause chromosomal damage in human cells.

In the Ames test, NV-HHV-101 was negative for the ability to induce mutations in genes of several strains of *Salmonella typhimurium* and of *Escherichia coli*, both in the presence and absence of an exogenous metabolic activation system. The Ames test is used to assess the direct ability of a drug to cause mutations in DNA or genes, using bacterial cells. Similarly, in the standard “Micronucleus” test NV-HHV-101 was negative at all doses tested for the induction of chromosomal damage in the human TK6 cell line, both in the presence and absence of the exogenous metabolic activation system. The Micronucleus test is used to assess the potential of a drug candidate to cause chromosomal damage in human cells.

These tests, taken together, are conducted to identify potential carcinogens. These tests are conducted in the presence and absence of metabolic activation system. This is because metabolism of a drug can cause the formation of potential carcinogens. A high, but not complete, correlation has been found between carcinogenicity in animals and mutagenicity in the Ames test or chromosomal damage in the micronucleus test. NV-HHV-101 was found to have no DNA, gene, or chromosome damaging activity in these tests. The US FDA and other international regulatory authorities require these genetic toxicological studies to support the Investigational New Drug (IND) Applications for entering human clinical trials.

The Company had tested the drug candidate in a human skin-based model of VZV infection, albeit *ex vivo* (i.e. using human skin patches cultured in petri dishes, not in human beings), for effectiveness as well as for safety. This testing was performed by Professor Jennifer Moffat at the Upstate Medical Center, SUNY, Syracuse, NY. Professor Moffat is an expert in VZV, shingles, and chickenpox.

Given that the testing in human skin patches was successful, the risk in human clinical trials is expected to be relatively minimal, as compared to drugs that are developed using animal models of disease.

The Company had gone to great lengths to develop analytical techniques and perform characterization of the manufactured drug in order to de-risk the manufacturing quality and to provide well characterized, cGMP manufactured materials for the anticipated clinical programs. Nanomedicines such as the Company’s nanoviricides are complex materials that, as a class, have been challenging to characterize, and that the Company is learning from past failures in this class of drugs. The Company has therefore spent a substantial amount of time in developing analytical techniques and critical quality attributes in order to be able to manufacture consistent quality of drug from batch to batch.

Previously on August 5, 2019, the Company reported that its first drug candidate, NV-HHV-101, has been found to be safe and well tolerated in the clinical observation portion of the GLP Safety/Toxicology study of NV-HHV-101 as a dermal treatment, and thus is on track with required preclinical GLP Safety and Toxicology studies moving towards human clinical trials.

The in-life stage of the first part of the GLP studies is complete, allowing assessment of clinical observations. The Company is waiting on the full histology studies to assess the effects of this drug candidate on all primary organs. The study was conducted by BASi, Evansville, IN, a Contract Research Organization that specializes in IND-enabling safety/toxicology studies.

The first of these GLP studies, a GLP safety and tolerability study following dermal treatment, was conducted using minipigs, who received twice daily skin treatment for 28 days, at different dosage levels. The animals were evaluated daily for general signs of toxicity including body weight, detailed clinical physical observations as well as the specific evaluation of the skin treatment areas. Topical treatment of the skin at all doses was well tolerated in all animals and all measured parameters remained within normal range in the study.

The Company has previously found that NV-HHV-101 was safe and well tolerated in non-GLP safety/toxicology studies. The GLP studies are an expanded version of the non-GLP studies, with extended treatment, larger number of subjects, and stringent operational requirements as specified by the current Good Laboratory Practices guidelines for such studies.

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 is currently performing additional analytical tests development, documentation development, as well as process systems development to set up manufacture as per the requirements of cGMP manufacture for Phase I human clinical trials, in our own facilities. Simultaneously, we are scaling up manufacture to ~2kg of API per batch, which would be sufficient for production of anywhere from 40~ 200kg of the final skin cream (assuming 5%~1% API).

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.

Manufacture of 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. 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.

NanoViricides' platform technology and programs are based on the TheraCour® nanomedicine technology of TheraCour, which TheraCour licenses from AllExcel. NanoViricides holds licenses for developing drugs against several different viruses from TheraCour, including HSV-1 and HSV-2.

On November 1, 2019, the Company executed an agreement with TheraCour and obtained 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.

NanoViricides did not pay any upfront licensing fee under the Agreement. The Company will be required to pay a first milestone payment to TheraCour upon the grant of approval of an Investigational New Drug application ("IND"), of 75,000 shares of the Company's Series A preferred stock. A second milestone payment will be due upon completion of Phase I human clinical trials in the cash amount of \$1.5 million. A third milestone payment will be payable to TheraCour upon completion of Phase II human clinical trials in the cash amount of \$2.5 million, and a fourth milestone payment will be due upon completion of Phase III human clinical trials in the cash amount of \$5 million. However, NanoViricides shall have no obligation to continue clinical trials beyond Phase I.

Upon commercialization, NanoViricides will pay royalties of 15% of net sales to TheraCour, as defined in the Agreement. The Agreement contemplates that the parties will enter into a separate Manufacturing and Supply Agreement for the commercial manufacture and supply of the drug products if and when NanoViricides intends to engage into commercialization of the drugs. The Agreement provides that the Manufacturing and Supply agreement would be on customary and reasonable terms, on a cost-plus basis, using a market rate based on then-current industry standards, and include customary backup manufacturing rights.

To assist in the analysis of the terms of the Agreement, NanoViricides commissioned research reports on VZV drug market sizes for the VZV field from two different, independent, consulting agencies, namely, Nanotech Plus, LLC, and BioEnsemble LLC. Additionally, the Company obtained business analysis and valuation reports for potential licensing terms for a VZV shingles drug from BioEnsemble LLC, using multiple different market scenarios, that accounted for the introduction of the Shingrix® GSK vaccine for VZV. Dr. Carolyn Myers, Principal of Bioensemble LLC, has over 25 years of experience in licensing and negotiations, drug development and commercialization from Startups, small-, mid- and large- Pharma, having acted in very senior business development roles from both sides of the equation. NanoViricides was represented by McCarter & English, LLP while TheraCour was represented by DuaneMorris LLP.

The anti-VZV drug development program has 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.

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.

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, to approximately \$1.7 Million per quarter by reducing our workforce and by stopping work on all other programs except the HerpeCide program and the Covid-19 program.

The Company is in discussions regarding freeing up its fixed capital for use as working capital by obtaining a mortgage, from an institutional lender, secured by our cGMP manufacturing and R&D lab facility in Shelton, CT. The Company is also pursuing additional equity-based transactions. Based on our current discussions, we believe that we will be successful in obtaining the required financing to be able to continue our programs. However, there can be no assurance that any of these commitments or discussions will result in actual financing at this time or that such financing would be on terms that are favorable to the Company. If the Company cannot raise the additional financing, our business plan will need to be significantly restructured.

Background - The Nanoviricide® Platform Technology

NanoViricides, Inc. is a globally leading company in the application of nanomedicine technologies to the complex issues of viral diseases. 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.

Our anti-viral therapeutics, that we call “nanoviricides®” are designed to appear to the virus like the native host cell surface to which it binds. Since these binding sites for a given virus do not change despite mutations and other changes in the virus, we believe that our drugs will be broad-spectrum, i.e. effective against most if not all strains, types, or subtypes, of a given virus, provided the virus-binding portion of the nanoviricide is engineered appropriately. Viruses would not be able to escape the nanoviricide by viral mutations since they continue to bind to the same cellular receptor and thus would be captured by the nanoviricide. Virus escape by mutations is a major problem in the treatment of viral diseases using conventional drugs.

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. To accomplish this, we have developed a polymeric micelle structure composed of PEG and fatty acids that is designed to create a surface like the cell membrane, with the fatty acids going inside of the micelle. On this surface, we chemically attach, at regular intervals, virus-binding ligands. The virus is believed to be attracted to the nanomicelle by these ligands, and thereby binds to the nanoviricide using the same glycoproteins that it uses for binding to a host cell. Upon such binding, a “lipid mixing” interaction between the lipid envelope of the virus and the nanomicelle is thought to take place, leading to the virus attempting to enter the nanomicelle. We believe many different kinds of viruses are likely to get destroyed in this process.

We engineer the ligands to “mimic” the same site on the cell surface protein to which the virus binds. These sites do not change no matter how much a given virus mutates. Thus, we believe that if a virus so mutates that it is not attacked by our nanoviricide, then it also would not bind to the human host cell receptor effectively and therefore would be substantially reduced in its pathogenicity. Our success at developing broad-spectrum nanoviricides depends upon how successfully we can design decoys of the cell surface receptor as ligands, among other factors.

NanoViricides, Inc. is one of a few bio-pharma companies that has all the capabilities needed from research and development to marketable drug manufacture in the small quantities needed for human clinical trials. At our campus at 1 Controls Drive, Shelton, CT, we possess state of the art nanomedicines characterization facilities that we believe enable us to perform pre-IND nanomedicine analysis and characterization studies of any of our various drug candidates in house. In addition, we believe we now have the ability to scale up production of any of our drug candidates, and implement state of the art in-process controls as well as post-process analysis controls in order to establish robust c-GMP-capable production methodologies. We also have a Biological Safety Level 2 (BSL2) certified virological cell culture lab at this campus. We are able to perform initial cell culture based screening of large numbers of drug candidates for effectiveness and safety against certain of the viruses that we have targeted for drug development. This capability boosts our drug development capabilities significantly. Other than this limited initial screening, all of the biological testing and characterization of our drug candidates continues to be performed by external academic or institutional collaborators and contract research organizations (CRO). In particular, all of the animal studies are performed by our collaborators and CROs.

Our Product Pipeline

We have focused our efforts almost exclusively on the HerpeCide™ program, given our budgets and current financial condition.

We currently have at least 9 different drug development programs, attesting to the strength of our platform technology. Of these, 5 of the indications are under the HerpeCide™ program. We are currently working on 3 of these indications (VZV, HSV-1 and HSV-2) in parallel, as explained below (priority level 1). The HK 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 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 intravitreal 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 topical drug development against several indications related to infections by herpes family viruses. The Company recognized, after consultations with its FDA regulatory advisors, namely Biologics Consulting Group (of Alexandria, VA), and several other experts in the field, that the development of these topical drug candidates towards human clinical trials is likely to be considerably faster than the development of our anti-influenza systemic (injectable) drug candidate.

Management Discussion - Current Drug Development Strategy

During the reported quarter, we have engaged in development of a drug against SARS-CoV-2, that causes the COVID-19 spectrum of diseases. In addition, we have continued to focus our drug development work plans towards regulatory development primarily on our lead anti-shingles and anti-Herpes-virus programs. In particular, we have focused on a work plan towards our clinical development candidate for the topical skin ointment for the treatment of shingles rash, namely, NV-HHV-101. Because of the broad-spectrum nature of our anti-herpes drug candidates, we have also simultaneously continued further development of our drug candidates for four additional indications in the HerpeCide™ project, namely, cold sores, genital ulcers, and external ocular viral infections. We have prioritized our resources with the goal of filing our first IND in the shortest possible timeframe.

The Company has continued the development of anti-HSV-1 and anti-HSV-2 drug candidates, and has tested the same against VZV in cell cultures, in addition to against HSV-1 and HSV-2. Since the candidates showed preliminary efficacy against VZV as well, the Company added shingles as an additional indication to pursue under the HerpeCide™ program.

Our earlier animal studies for efficacy testing of HSV-1 drug candidates in a mouse dermal model of the infection were performed by Professor Ken Rosenthal's Lab at NEOUCOM/NEOMED. Professor Rosenthal has retired and his lab has closed.

We therefore engaged Dr. Brandt's Lab at CORL, University of Wisconsin, Madison, WI, to further develop their animal models of dermal HSV-1 and HSV-2 infections in mice and to make them suitable for screening of drugs for relative efficacy. They are working on validating their HSV-1 mouse model for discriminative efficacy of different existing drugs. Once they can establish that the model distinguishes different effective drugs, we will be able to use the model for testing our HerpeCide drug candidates against HSV-1, and optimizing the same only if necessary. Following HSV-1 model development, we have commissioned Dr. Brandt's Lab to perform similar studies for their HSV-2 genital infection mouse model as well. Dr. Brandt's Lab also developed the mouse model of viral Acute Retinal Necrosis (v-ARN) caused by HSV-1 that we have tested some of our drug candidates in as reported elsewhere.

Based on our discussions with our regulatory advisors and consultants that indicated that the shingles drug candidate would be likely to reach the human clinical evaluation phase earliest compared to the other drug candidates we have focused on the treatment of the shingles rash using our skin cream formulation of NV HHV-101 as the lead drug candidate. Other drug candidates in the HerpeCide project are expected to follow into clinical stage rapidly thereafter. This is primarily because of the topical treatment nature of the drug candidates we have chosen to develop in these indications.

Animal model studies of lethal herpesvirus infection using the highly pathogenic and neurotropic HSV-1 H129 strain in two different sites resulted in 85% to 100% survival in animals treated with certain anti-HSV nanoviricide drug candidates, while control animals uniformly died. We reported on these studies in April 2015, from Professor Emeritus Ken Rosenthal's lab at NEOMED, and in August 2015, from TransPharm Preclinical Solutions, LLC, Jackson, MI (TransPharm), a CRO. Previously, we have improved the anti-HSV drug candidates in cell culture studies and were able to achieve significant effectiveness before engaging into animal studies. We re-designed the anti-HSV drug candidates so that the solutions would not run off the skin when applied. With this redesign, our drug candidates demonstrated complete survival of HSV-1 H129 lethally infected animals.

The Company thus has achieved animal studies efficacy proof of concept for HSV-1 skin topical treatment. The Company believes that the broad-spectrum nature of these drug candidates should allow effectiveness against related herpesvirus types such as HSV-2 as well as the more distantly related HHV-3 aka VZV or chickenpox/shingles virus.

The Company has established additional collaborations towards IND-enabling development of drug candidates against the four indications listed earlier. We now have collaboration agreements with the CORL at the University of Wisconsin, the Campbell Lab at the University of Pittsburgh, and, the Moffat Lab at SUNY Upstate Medical Center, for the evaluation of our nanoviricides® drug candidates in models of ocular herpesvirus and adenovirus infections as well as VZV infections in *in vitro* and *ex vivo* models. The Company also now has the ability to perform initial screening of our drug candidates in our BSL2 certified Virology Lab in Shelton, CT, against several viruses that include various strains and subtypes of HSV-1, HSV-2, VZV, and Influenza.

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 herpesviruses 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.

Because of 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 new 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 brought in Brian Friedrich, Ph.D. as the Company's Virologist. Dr. Friedrich has previously performed drug screening of hundreds of candidates against several viruses including alphaviruses, bunyaviruses, and filoviruses (namely, Ebola and Marburg, which are BSL-4), to discover potential therapeutics, while he was at United States Army Medical Research Institute of Infectious Diseases (USAMRIID). Brian has also worked extensively on Flaviviruses, specifically West Nile Virus, while at University of Texas Medical Branch (UTMB). He has also worked on HIV as part of his PhD thesis. Dengue viruses as well as the Zika virus belong to the Flavivirus family.

Dr. Friedrich has established several different types of assays for screening of candidates against VZV, HSV-1 and HSV-2 in our lab, and is establishing assays for Influenza viruses and HIV. Most recently, he has also established assays for drug development against human coronavirus infections, towards development of a drug lead for the current SARS-CoV-2 virus that has caused the COVID-19 worldwide pandemic. 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 Pharma, Inc., 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 expenditure. 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 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 (EpiOcularTM 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 Pharma, Inc. (“TheraCour”), which licenses its intellectual property from AllExcel, Inc. (“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 Varicella Zoster Virus (“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.

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 Anil R. Diwan, PhD, Jayant G. Tatake, PhD, and Ann L. Onton, all of who 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 Pharma, Inc.

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, 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 2038. 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 Pharma Inc.'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. The Mark was registered on the Principal Register and is protected in all its letter forms, including corresponding plural and singular forms, various forms of capitalization, and fonts and designs.

Analysis of Financial Condition, and Result of Operations

As of March 31, 2020, we had cash and cash equivalents of \$6,105,530, prepaid expenses of \$331,772 and net property and equipment of \$9,712,850. Accounts payable, loan payable, and accrued expenses were \$1,141,182, inclusive of account payables of \$578,155 to a related party. At March 31, 2020 we reported a loan payable to a related party of \$1,072,162 payable to Dr. Anil Diwan.

In comparison, as of June 30, 2019, we had cash and cash equivalents of \$2,555,207, prepaid expenses of \$270,214 and net property and equipment of \$10,227,247. Accounts payable and accrued expenses were \$1,202,547, inclusive of account payables of \$823,783 to a related party. Stockholders' equity was \$10,600,360 at June 30, 2019.

During the nine-month period ended March 31, 2020 we used approximately \$5,110,000 in cash toward operating activities. During the Nine-month period ended March 31, 2019 we used approximately \$5,130,000 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 January 24, 2020 underwritten offering and the May 21, 2020 registered direct offering it has sufficient funds in hand for initial human clinical trials of its first drug candidate, NV-HHV-101. 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. Except for the debt facility provided by Dr. Diwan and trade payables, 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 HerpeCide 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 sufficient data on our first drug candidate, NV-HHV-101, to support an IND filing, and are now preparing the IND application, towards the goal of obtaining FDA approval for testing the drugs in human patients. The FDA may require additional studies to be done before approving the IND. Assuming that the FDA allows us to conduct human clinical studies as we intend to propose, we believe that this coming year's work plan will lead us to obtain certain information about the safety and efficacy of one of the drugs under development in human clinical studies. If our studies are not successful, we will have to develop additional drug candidates and perform further studies. If our studies are successful, then we expect to be able to undertake further Phase II and Phase III human clinical studies, additional studies in animal models to obtain any necessary data regarding the pharmacokinetic and pharmacodynamic profiles of our drug candidates towards drug approval or licensure from regulatory agencies. 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 nine month periods ended March 31, 2020 and 2019.

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

Research and Development Expenses – Research and development expenses for the three months ended March 31, 2020 decreased \$176,194 to \$1,134,132 from \$1,310,326 for the three months ended March 31, 2019, and for the nine months ended March 31, 2020 decreased \$706,483 to \$3,628,622 from \$4,335,105 for the nine months ended March 31, 2019. The decrease in the cost of research and development for the three and nine months ended March 31, 2020 is due to decreases in outside laboratory fees to collaborators, laboratory staffing and lab supplies and materials.

General and Administration Expenses – General and administrative expenses for the three months ended March 31, 2020 increased \$635,670 to \$1,408,231 from \$772,561 for the three months ended March 31, 2019, and for the nine months ended March 31, 2020 increased \$379,972 to \$2,536,050 from \$2,156,078 for the nine months ended March 31, 2019. The increase in expenses during the three and nine month periods ended March 31, 2020 compared to the prior periods resulted primarily from increases in professional fees, and an increase in operating expenses in general offset by decreases in officers compensation arising from the resignation of the Company's former Chief Executive Officer and travel costs.

Interest Income – Interest income for the three months ended March 31, 2020 increased \$349 to \$9,264 from \$ 8,915 for the three months ended March 31, 2019 and decreased \$31,399 to \$15,265 for the nine months ended March 31, 2020 from \$46,664 for the nine months ended March 31, 2019. The increase for the three month period ended March 31, 2020 is due to an increase in cash and cash equivalents due to the January 24, 2020 underwritten offering. The decrease for the nine month period ended March 31, 2020 was due to lower cash and cash equivalents for the majority of the nine month period ended March 31, 2020 as well as lower interest rates.

Interest Expense – Interest expense increased \$44,937 and \$49,068 for the three and nine months ended March 31, 2020 respectively from \$-0- for the three and nine months ended March 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 issuance of Series A preferred stock for accounts payable – related party – Loss of \$142,669 for the nine months ended March 31, 2020 represents the difference on 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 March 31, 2020 increased \$6,053,904 to \$(6,119,762) from \$(65,858) for the three months ended March 31, 2019. Change in fair value of derivative for the nine months ended March 31, 2020 increased \$6,077,547 to \$(5,845,313) from \$232,234 for the nine months ended March 31, 2019.

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

Net Loss – For the three months ended March 31, 2020, the Company had a net loss of \$(8,083,304), or \$ (1.24) per share on a fully diluted basis compared to a net loss of \$(2,139,830) or (\$0.59) per share on a fully diluted basis for the three months ended March 31, 2019. For the nine months ended March 31, 2020, the Company had a net loss of \$(11,571,963), or \$ (2.45) per share on a fully diluted basis compared to a net loss of \$(6,212,285) or \$(1.77) per share on a fully diluted basis for the nine months ended March 31, 2019. The increase in the reported loss for the three and nine month periods ended March 31, 2020 is attributable mainly to an increase in the change in fair value of derivative liabilities of \$6,053,904 and \$6,077,547, respectively and an increase in general and administrative expenses offset by decrease in research and development expenses and a gain on warrant settlement.

Liquidity and Capital Reserves

The Company had cash and cash equivalents of \$6,105,530, and prepaid expenses of \$331,772 as of March 31, 2020 and accounts payable, loan payable, and accrued expenses were \$1,141,182, inclusive of account payables of \$578,155 to a related party. On December 16, 2019, the Company entered into an Open End Mortgage Note with Anil Diwan, the Company's founder, Chairman and President, to loan the Company up to \$2,000,000. As of March 31, 2020, the Company had drawn down \$1.1 million on this note. 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 \$103,688,549 at March 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. The Company is able to draw down \$0.9 million from its current debt facility and as a result of the underwritten offering consummated on January 25, 2020 and the registered direct offering on May 21, 2020 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). However the emergence of widespread health emergencies due to COVID-19 may lead 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 and the proceeds of the registered direct offering of May 22, 2020 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 reprioritize 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 March 31, 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 March 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 March 31, 2020 due to material weaknesses in internal control over financial reporting described in Item 9A of our 10-K for the fiscal year ended June 30, 2019. These material weaknesses remain unremediated as of March 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 reporting period ended March 31, 2020 that has materially affected, or is reasonably 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 weaknesses described above.

We are remediating the material weaknesses by, among other things, implementing a process of enhanced review of all financial transactions including engagement of outside specialists to evaluate our financial transactions as they arise. The actions that we are taking are subject to ongoing senior management review and Audit Committee oversight.

The Company has engaged outside tax counsel to assist in the preparation of the Company's tax provisions and Company personnel in preparing the Company's income tax provision footnote.

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 nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 0 and 10,000 fully vested shares, respectively of its Series A preferred stock for a loan origination fee with a fair value of \$39,301.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 0 and 100,000 fully vested shares of its Series A preferred stock, respectively, with a fair value of \$0 and \$392,669 in exchange for \$250,000 of previously deferred development fees and recognized a loss on the exchange of \$142,669.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 3,572 fully vested shares of its common stock for employee compensation. The Company recorded an expense of \$29,251 for the three and nine months ended March 31, 2020, which was the fair value on the dates of issuance

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 1,727 and 2,501, respectively, fully vested shares of its Series A preferred stock for employee compensation. The Company recorded expense of \$26,207 and \$32,479, respectively, for the three and nine months ended March 31, 2020 related to these issuances, which was the fair value on the dates of issuance.

During the nine months ended March 31, 2020, the SAB was granted in August 2019 fully vested warrants to purchase 572 shares of common stock with an exercise price of \$5.88 per share expiring in August 2023. in November 2019 572 fully vested warrants to purchase shares of common stock with an exercise price of \$2.63 per share expiring in November 2023 and in February 2020 fully vested warrants to purchase 572 shares of common stock with an exercise price of \$8.68 per share expiring in February 2024. The fair value of the warrants was \$2,444 for the three months ended March 31, 2020 and \$3,885 for the nine months ended March 31, 2020 and was recorded as consulting expense.

For the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 56,854 and 74,987, respectively fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$173,250 and \$227,250 for the three and nine months ended March 31, 2020, respectively, which was the fair value on the dates of issuance.

For the three and six months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 1,581 and 9,099, respectively, fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of \$11,250 and \$33,750 for the three and nine months, respectively, which was the fair value on the dates of issuance.

For both the three and nine months ended March 31, 2020, the Company's Board of Directors authorized the issuance of 25,667 fully vested shares of its common stock with a restrictive legend to satisfy open accounts payable for consulting services. The common stock issued had a fair value of \$77,000, which was the fair value on the date of issuance.

On January 9, 2020 the Company's Board of Directors authorized the settlement with a vendor to redeem and cancel 17,200 shares of its common stock with a restrictive legend, which were initially issued in payment of accounts payable, for a payment of \$25,000. The shares were cancelled and reported as reductions of common stock issued in exchange for accounts payable reported in the Statement of Changes in Shareholder Equity as a decrease of \$25,000..The redemption and cancellation had no effect on the results of operations for the three and nine months ended March 31, 2020.

All of the unregistered securities set forth above were issued by the Company pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, or the provisions of Rule 504 of Regulation D promulgated under the Securities Act. All such shares issued contained a restrictive legend and the holders confirmed that they were acquiring the shares for investment and without intent to distribute the shares. All of the purchasers were experienced in making speculative investments, understood the risks associated with investments, and could afford a loss of the entire investment. Except as set forth above, the Company did not utilize an underwriter or a placement agent for any of these offerings of its securities.

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.

Dated: June 22, 2020

/s/ Anil R. Diwan

Name: Anil R. Diwan

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

Dated: June 22, 2020

/s/ Meeta Vyas

Name: Meeta Vyas

Title: Chief Financial Officer
(Principal Financial Officer)