



(203) 937-6137

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

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

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company   
Emerging growth company

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

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

Yes  No

As of February 14, 2019, there were approximately 69,501,000 shares of common stock of the registrant issued and outstanding.



NanoViricides, Inc.

FORM 10-Q

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NanoViricides, Inc.

## Balance Sheets

|  | December 31,<br>2018<br>(Unaudited) | June 30,<br>2018 |
|--|-------------------------------------|------------------|
| <b>ASSETS</b>  |                                     |                  |
| <b>CURRENT ASSETS:</b>   |                                     |                  |
| Cash and cash equivalents  | \$3,903,672                         | \$7,081,771      |
| Prepaid expenses   | 168,948                             | 240,257          |
| Total current assets   | 4,072,620                           | 7,322,028        |
| <b>PROPERTY AND EQUIPMENT</b>  |                                     |                  |
| Property and equipment   | 14,075,919                          | 14,018,383       |
| Accumulated depreciation   | (3,520,425 )                        | (3,177,290 )     |
| Property and equipment, net  | 10,555,494                          | 10,841,093       |
| <b>TRADEMARK AND PATENTS</b>   |                                     |                  |
| Trademark and patents  | 458,954                             | 458,954          |
| Accumulated amortization   | (88,161 )                           | (84,025 )        |
| Trademark and patents, net   | 370,793                             | 374,929          |
| <b>OTHER ASSETS</b>  |                                     |                  |
| Security deposits  | 3,515                               | 3,515            |
| Service agreements   | 1,797                               | 4,647            |
| Other assets   | 5,312                               | 8,162            |
| Total assets   | \$ 15,004,219                       | \$ 18,546,212    |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                                     |                  |
| <b>CURRENT LIABILITIES:</b>  |                                     |                  |
| Accounts payable   | \$223,781                           | \$223,339        |
| Accounts payable – related party   | 800,830                             | 107,468          |
| Derivative liability - warrants  | -                                   | 298,092          |
| Accrued expenses   | 139,049                             | 253,049          |
| Total current liabilities  | 1,163,660                           | 881,948          |
| <b>COMMITMENTS AND CONTINGENCIES</b>   |                                     |                  |
| <b>STOCKHOLDERS' EQUITY:</b>   |                                     |                  |
| Series A Convertible Preferred stock, \$0.001 par value, 8,500,000 shares designated, 5,071,826 and 4,531,394 shares issued and outstanding, at December 31, 2018 and June 30, 2018, respectively. | 5,072                               | 4,531            |
| Common stock, \$0.001 par value; 150,000,000 shares authorized, 69,501,354 and 69,171,740 shares issued and outstanding at December 31, 2018 and June 30, 2018, respectively                       | 69,502                              | 69,172           |

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|  |               |               |
|--|---------------|---------------|
| Additional paid-in capital                 | 101,530,586   | 101,282,707   |
| Accumulated deficit                        | (87,764,601 ) | (83,692,146 ) |
| Total stockholders' equity                 | 13,840,559    | 17,664,264    |
| Total liabilities and stockholders' equity | \$ 15,004,219 | \$ 18,546,212 |

*See accompanying notes to the financial statements*

Nanoviricides, Inc.

## Statements of Operations

(Unaudited)

|   | For the Three Months<br>Ended<br>December 31, |                       | For the Six Months Ended<br>December 31, |                       |
|---|---|-----------------------|--|-----------------------|
|   | 2018  | 2017                  | 2018                                     | 2017                  |
| <b>OPERATING EXPENSES</b>                                     |   |                       |  |                       |
| Research and development                                      | \$ 1,657,838                                  | \$ 1,639,643          | \$ 3,024,779                             | \$ 3,091,549          |
| General and administrative                                    | 711,360                                       | 754,138               | 1,383,517                                | 1,532,678             |
| Total operating expenses                                      | 2,369,198                                     | 2,393,781             | 4,408,296                                | 4,624,227             |
| <b>LOSS FROM OPERATIONS</b>                                   | (2,369,198 )                                  | (2,393,781 )          | (4,408,296 )                             | (4,624,227 )          |
| <b>OTHER INCOME (EXPENSE):</b>                                |   |                       |  |                       |
| Interest income   | 15,665  | 24,970                | 37,749                                   | 49,362                |
| Interest expense on convertible debenture                     | -   | (60,275 )             | -  | (185,274 )            |
| Loss on extinguishment of debt                                | -   | (1,348,247 )          | -  | (1,348,247 )          |
| Discount on convertible debenture                             | -   | (119,863 )            | -  | (359,214 )            |
| Change in fair value of derivative                            | 122,541                                       | 1,100,302             | 298,092                                  | 1,665,151             |
| Other income (expense)  | 138,206                                       | (403,113 )            | 335,841                                  | (178,222 )            |
| <b>LOSS BEFORE INCOME TAX PROVISION</b>                       | (2,230,992 )                                  | (2,796,894 )          | (4,072,455 )                             | (4,802,449 )          |
| <b>INCOME TAX PROVISION</b>                                   | -   | -                     | -  | -                     |
| <b>NET LOSS</b>   | <b>\$(2,230,992 )</b>                         | <b>\$(2,796,894 )</b> | <b>\$(4,072,455 )</b>                    | <b>\$(4,802,449 )</b> |
| Net loss per common share- basic and diluted                  | \$(0.03 )                                     | \$(0.04 )             | \$(0.06 )                                | \$(0.08 )             |
| Weighted average common shares outstanding- basic and diluted | 69,383,850                                    | 63,335,601            | 69,284,908                               | 63,321,342            |

See accompanying notes to the financial statements





NanoViricides, Inc.

## Statement of Changes in Stockholders' Equity

For the period from July 1, 2018 through December 31, 2018

(Unaudited)

|  | Series A Preferred<br>Stock: Par \$0.001 |          | Common Stock:<br>Par \$0.001 |           | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit | Total<br>Stockholders'<br>Equity |
|--|--|----------|------------------------------|-----------|----------------------------------|------------------------|----------------------------------|
|  | Number<br>of<br>Shares                   | Amount   | Number of<br>Shares          | Amount    |                                  |                        |                                  |
| Balance, June 30, 2018   | 4,531,394                                | \$ 4,531 | 69,171,740                   | \$ 69,172 | \$ 101,282,707                   | \$(83,692,146)         | \$ 17,664,264                    |
| Series A Preferred<br>Stock issued for<br>employee stock<br>compensation | 532,716                                  | 533      | -                            | -         | 54,494                           | -                      | 55,027                           |
| Common stock issued<br>for consulting and legal<br>services rendered     | -  | -        | 191,510                      | 192       | 79,268                           | -                      | 79,460                           |
| Stock options issued for<br>compensation                                 | -  | -        | -                            | -         | 11,920                           | -                      | 11,920                           |
| Warrants issued to<br>Scientific Advisory<br>Board                       | -  | -        | -                            | -         | 1,543                            | -                      | 1,543                            |
| Common shares issued<br>for Directors fees                               | -  | -        | 19,310                       | 19        | 7,481                            | -                      | 7,500                            |
| Net loss   | -  | -        | -                            | -         | -                                | (1,841,463 )           | (1,841,463 )                     |
| Balance, September 30,<br>2018   | 5,064,110                                | 5,064    | 69,382,560                   | 69,383    | 101,437,413                      | (85,533,609)           | 15,978,251                       |
| Series A Preferred<br>Stock issued for<br>employee stock<br>compensation | 7,716                                    | 8        | -                            | -         | 53,613                           | -                      | 53,621                           |

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|  |           |          |            |           |                |                |               |
|--|-----------|----------|------------|-----------|----------------|----------------|---------------|
| Common stock issued for consulting and legal services rendered | -         | -        | 83,943     | 84        | 26,916         | -              | 27,000        |
| Warrants issued to Scientific Advisory Board                   | -         | -        | -          | -         | 1,429          | -              | 1,429         |
| Common shares issued for Directors fees                        | -         | -        | 34,851     | 35        | 11,215         | -              | 11,250        |
| Net loss   | -         | -        | -          | -         | -              | (2,230,992 )   | (2,230,992 )  |
| Balance, December 31, 2018                                     | 5,071,826 | \$ 5,072 | 69,501,354 | \$ 69,502 | \$ 101,530,586 | \$(87,764,601) | \$ 13,840,559 |

See accompanying notes to the financial statements

NanoViricides, Inc.

## Statement of Changes in Stockholders' Equity

For the period from July 1, 2017 through December 31, 2017

(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, 2017  | 4,348,744                             | \$ 4,349 | 63,306,774                | \$ 63,305 | \$ 95,382,979              | \$(75,128,691)      | \$ 20,321,942              |
| Series A Preferred Stock issued for employee stock compensation | 7,716                                 | 7        | -                         | -         | 25,220                     | -                   | 25,227                     |
| Common stock issued for consulting and legal services rendered  | -                                     | -        | 20,062                    | 20        | 26,980                     | -                   | 27,000                     |
| Warrants issued to Scientific Advisory Board                    | -                                     | -        | -                         | -         | 5,773                      | -                   | 5,773                      |
| Common shares issued for Directors fees                         | -                                     | -        | 8,358                     | 8         | 11,242                     | -                   | 11,250                     |
| Net loss  | -                                     | -        | -                         | -         | -                          | (2,005,555 )        | (2,005,555 )               |
| Balance, September 30, 2017                                     | 4,356,460                             | 4,356    | 63,335,194                | 63,333    | 95                         | (77,134,246)        | 18,519,209                 |
| Series A Preferred Stock issued for employee stock compensation | 7,716                                 | 8        | -                         | -         | 153,400                    | -                   | 153,408                    |
| Common stock issued for consulting and legal services rendered  | -                                     | -        | 26,468                    | 27        | 26,973                     | -                   | 27,000                     |
|   | -                                     | -        | -                         | -         | 4,401                      | -                   | 4,401                      |

Warrants issued to  
Scientific Advisory  
Board

|  |           |         |            |          |              |                |              |
|--|-----------|---------|------------|----------|--------------|----------------|--------------|
| Common shares issued<br>for Directors fees | -         | -       | 11,019     | 11       | 11,239       | -              | 11,250       |
| Net loss                                   | -         | -       | -          | -        | -            | (2,796,894 )   | (2,796,894 ) |
| Balance, December 31,<br>2017              | 4,364,176 | \$4,364 | 63,372,681 | \$63,371 | \$95,781,779 | \$(79,931,140) | \$15,918,374 |

See accompanying notes to the financial statements

Nanoviricides, Inc.

## Statements of Cash Flows

(Unaudited)

|  | For the Six Months ended |                    |
|--|--------------------------|--------------------|
|  | December                 | December           |
|  | 31,                      | 31,                |
|  | 2018                     | 2017               |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                               |                          |                    |
| Net loss   | \$(4,072,455)            | \$(4,802,449)      |
| Adjustments to reconcile net loss to net cash used in operating activities |                          |                    |
| Preferred shares issued as compensation                                    | 108,648                  | 312,207            |
| Common shares issued as compensation and for services                      | 125,210                  | 76,500             |
| Warrants granted to Scientific Advisory Board                              | 2,972                    | 10,174             |
| Stock-based compensation expense   | 11,920                   | -                  |
| Common shares to be issued for debenture interest                          | -                        | 60,274             |
| Depreciation   | 343,135                  | 332,921            |
| Amortization   | 4,136                    | 4,135              |
| Change in fair value of derivative liability                               | (298,092)                | (1,665,151)        |
| Amortization of debt discount on convertible debenture                     | -                        | 359,214            |
| Loss on extinguishment of convertible debenture                            | -                        | 1,348,247          |
| Changes in operating assets and liabilities:                               |                          |                    |
| Prepaid expenses   | 71,309                   | (49,366)           |
| Other assets   | 2,850                    | 28,514             |
| Accounts payable   | 442                      | (59,966)           |
| Accounts payable - related party   | 693,362                  | 1,134,141          |
| Accrued expenses   | (114,000)                | (8,249)            |
| Deferred interest payable  | -                        | (41,667)           |
| <b>NET CASH USED IN OPERATING ACTIVITIES</b>                               | <b>(3,120,563)</b>       | <b>(2,960,521)</b> |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                               |                          |                    |
| Purchase of property and equipment   | (57,536)                 | (92,540)           |
| <b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>                             | <b>(3,178,099)</b>       | <b>(3,053,061)</b> |
| Cash and cash equivalents at beginning of period                           | 7,081,771                | 15,099,461         |
| Cash and cash equivalents at end of period                                 | \$3,903,672              | \$12,046,400       |
| <b>SUPPLEMENTAL DISCLOSURE OF CASH FLOWS INFORMATION:</b>                  |                          |                    |
| Interest paid  | \$-                      | \$166,667          |

Non-cash Financing and Investing Activities:

|   |     |             |
|---|-----|-------------|
| Obligation to issue shares for Series C debenture payment | \$- | \$5,739,337 |
| Obligation to issue shares for deferred interest          | \$- | \$125,000   |

*See accompanying notes to the financial statements*

**NANOIRICIDES, INC.**

**December 31, 2018 AND 2017**

**NOTES TO THE FINANCIAL STATEMENTS**

**(Unaudited)**

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

NanoViricides, Inc. (the Company”) is a nano-biopharmaceutical research and development company specializing in the discovery, development, and commercialization of drugs to combat viral infections using its unique and novel nanomedicines technology. NanoViricides is also unique in the bio-pharma field in that it possesses its own state of the art facilities for the design, synthesis, analysis and characterization of the nanomedicines that we develop, as well as for production scale-up, and c-GMP-like production in quantities needed for human clinical trials, where our design, development, and production work is performed. The biological studies such as the effectiveness, safety, bio-distribution and Pharmacokinetics/Pharmacodynamics on our drug candidates are performed by external collaborators and contract organizations.

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 have begun as of the end of December, 2018 at the contract research organization (“CRO”) BASi, Indiana. Typically these studies may last six to nine months. If successful, the Company intends to file an IND after receiving a formal report on these studies from BASi. In addition, our drug candidates against HSV-1 “cold sores” and HSV-2 “genital herpes” are in advanced studies and are expected to follow the shingles drug candidate into human clinical trials. Shingles in adults and chicken pox in children is caused by the same virus, namely VZV (Varicella-zoster virus, aka HHV-3 or human herpesvirus-3). There are estimated to be approximately 120,000-150,000 annual chickenpox cases in the USA in the post-vaccination-era, i.e. since childhood vaccination with the live attenuated varicella virus Oka strain has become standard. In addition, we have drugs in development against all influenzas in our FluCide™ program, as well as drug candidates against HIV/AIDS, Dengue, Ebola/Marburg, and other viruses.

Our drugs are based on several patents, patent applications, provisional patent applications, and other proprietary intellectual property held by TheraCour Pharma, Inc. (“TheraCour”), to which we have broad, exclusive licenses in perpetuity. 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, in perpetuity, for technologies, developed by TheraCour, for the development of drug candidates for the treatment of Dengue viruses, Ebola/Marburg viruses, Japanese Encephalitis, viruses causing viral Conjunctivitis (a disease of the eye) and Ocular Herpes. In addition, the Company is negotiating a license for VZV (shingles, chicken pox virus), and the remaining human herpesviruses from TheraCour. For this purpose, the Company has conducted a valuation for the shingles and PHN indications. The Company expects to arrive at an agreement on terms of the license very soon. To date, TheraCour has not withheld any licenses for antiviral nanomedicines that NanoViricides has asked for, and we anticipate that the licenses to the remaining herpes viruses including VZV will be executed once the due diligence process is completed.

## **Note 2 - 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, 2018 filed with the SEC on October 13, 2018.

For a summary of significant accounting policies, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2018 filed on October 13, 2018.

Reclassifications and Prior Year Adjustments

Certain prior year amounts have been reclassified for consistency with current year presentation. These reclassifications had no effect on the reported results of operations. The Company reclassified \$253,508 and \$550,186 of expenses for the three and six months ended December 31, 2017 respectively, related to the Company's laboratory facilities from general and administrative expenses into research and development expenses for consistency with current year presentation. The reclassifications had no impact on the reported results of operations and net loss reported for the three and six months ended December 31, 2017.

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, convertible preferred stock, and convertible debenture.

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

|   | <b>Potentially Outstanding Dilutive Common Shares</b>         |   |
|---|---|---|
|   | <b>For the<br/>Six Months<br/>Ended<br/>December 31, 2018</b> | <b>For the<br/>Six Months<br/>Ended<br/>December 31, 2017</b> |
| <b>Options and Warrants</b>                                 | 4,423,471   | 6,696,724   |
| <b>Total potentially outstanding dilutive common shares</b> | 4,423,471   | 6,696,724   |

The Company has also issued 5,071,826 shares of Series A Preferred Stock to investors and others as of December 31, 2018. 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 convertible Preferred Stock is not convertible into common stock, and does not carry any dividend rights or any other financial effects. At December 31, 2018, the number of potentially dilutive shares of the Company’s common stock into which these Series A Preferred shares can be converted into is 17,751,391, and is not included in diluted earnings per share since the shares are contingently convertible only upon a Change of Control.

The following table represents the basic and diluted per share calculations for loss from continuing operations;

|   | <b>For the three months ended</b> |                  | <b>For the six months ended</b> |                  |
|---|-----------------------------------|------------------|---------------------------------|------------------|
|   | <b>December 31, 2018</b>          | <b>2017</b>      | <b>December 31, 2018</b>        | <b>2017</b>      |
| <b>Calculation of basic and diluted loss per share of common stock:</b> |                                   |                  |                                 |                  |
| Net loss attributable to common stockholders                            | \$(2,230,992 )                    | \$(2,796,894 )   | \$(4,072,455 )                  | \$(4,802,449 )   |
| Denominator for basic weighted average shares of common stock           | 69,383,850                        | 63,335,601       | 69,284,908                      | 63,321,342       |
| <b>Basic and diluted loss per share of common stock</b>                 | <b>\$(0.03 )</b>                  | <b>\$(0.04 )</b> | <b>\$(0.06 )</b>                | <b>\$(0.08 )</b> |

The Series C debenture was redeemed for Common Stock effective November 13, 2017. See Note 7. The Series C debenture was excluded from the loss per share calculation for the three and six month period ended December 31, 2017 because the impact is antidilutive

Recently Issued Accounting Pronouncements

In August 2018, the SEC issued the final rule on Disclosures About Changes in Stockholder's Equity For filings on Form 10-Q, which extends to interim periods the annual requirement in SEC Regulation S-X, Rule 3-04.2 to disclose (1) changes in stockholders' equity and (2) the amount of dividends per share for each class of shares (as opposed to common stock only, as previously required). Pursuant to the final rule, registrants must now analyze changes in stockholders' equity, in the form of reconciliation, for "the current and comparative year-to-date [interim] periods, with subtotals for each interim period," i.e., a reconciliation covering each period for which an income statement is presented. Rule 3-04 permits the disclosure of changes in stockholders' equity (including dividend-per-share amounts) to be made either in a separate financial statement or in the notes to the financial statements. The final rule is effective for all filings made on or after November 5, 2018. The staff of the SEC has indicated it would not object if the filer's first presentation of the changes in shareholders' equity is included in its form 10-Q for the quarter that begins after the effective date of the amendments. The Company conformed to this rule in its Form 10-Q for the quarter ending December 31, 2018.

In June 2018, the FASB issued ASU 2018-07, 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. The standard will be effective for the Company in the first quarter of fiscal year 2020, although early adoption is permitted (but no sooner than the adoption of Topic 606). The Company does not expect that the adoption of this ASU will have a significant impact on its financial statements.

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 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 retaining earnings in the fiscal year and interim period adoption. The Company is currently in the process of assessing the impact of this ASU on its financial statements.

**Note 3 - Liquidity and Going Concern**

The Company's financial statements have been prepared assuming that it will continue as a going concern, which contemplates continuity of operations, realization of assets and liquidation of liabilities in the normal course of business. As reflected in the financial statements, the Company has an accumulated deficit at December 31, 2018 of approximately \$87.8 million and a net loss of approximately \$4.1 million and net cash used in operating activities of approximately \$3.1 million for the six months then ended. In addition, the Company has not generated any revenues and no revenues are anticipated in the foreseeable future. Since May 2005, the Company has been engaged exclusively in research and development activities focused on developing targeted antiviral drugs. The Company has not yet commenced any product commercialization. Such losses are expected to continue for the foreseeable future and until such time, if ever, as the Company is able to attain sales levels sufficient to support its operations. There can be no assurance that the Company will achieve or maintain profitability in the future. As of December 31, 2018, the Company had available cash and cash equivalents of approximately \$3.9 million. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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 considered several options for obtaining additional funds that will be needed for future human clinical trials and to obtain the additional license from TheraCour for VZV and the remaining human herpes viruses. The Company is also evaluating the possibility of obtaining a mortgage on its fully owned cGMP-capable laboratory facility in Shelton, CT, in order to free up a portion of the fixed capital for usage as liquid working capital.

In addition, the Company believes that it has several important milestones that it will be achieving in the ensuing year. Management believes that as it achieves these milestones, the Company would experience substantial improvement in the liquidity of the Company's stock, and would significantly improve the Company's ability to raise funds on the public markets at terms that may be substantially superior to the terms we are offered at present.

Management is actively exploring additional required funding through debt or equity financing pursuant to its plan. 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 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. The accompanying unaudited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

#### **Note 4 - Related Party Transactions**

##### Related Parties

Related parties with whom the Company had transactions are:

| <b>Related Parties</b> | <b>Relationship</b>   |
|------------------------|---|
| Anil R. Diwan          | Chairman, President, significant stockholder and Director   |
| TheraCour Pharma, Inc. | An entity owned and controlled by a significant stockholder |
| Milton Boniuk, MD      | Significant stockholder                                     |

|          |          |
|----------|----------|
| As of    |          |
| December | June 30, |
| 31,      | 2018     |
| 2018     |          |

Account Payable – Related Party

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 Pharma, Inc. 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 has agreed to defer \$25,000 per month of development fees for six months, beginning with July 2018. Accounts payable due TheraCour on the reporting date was

|           |           |
|-----------|-----------|
| \$800,830 | \$107,468 |
|-----------|-----------|

|  | For the three months ended |                   | For the six months ended |                   |
|--|----------------------------|-------------------|--------------------------|-------------------|
|  | December 31, 2018          | December 31, 2017 | <b>December 31, 2018</b> | December 31, 2017 |

## Property and Equipment

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

|  |          |      |          |      |
|--|----------|------|----------|------|
|  | \$ 7,408 | \$ - | \$ 7,408 | \$ - |
|--|----------|------|----------|------|

|  | For the three months ended |                   | For the six months ended |                   |
|--|----------------------------|-------------------|--------------------------|-------------------|
|  | December 31, 2018          | December 31, 2017 | <b>December 31, 2018</b> | December 31, 2017 |

## Research and Development Costs Paid to Related Parties

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 December 31, 2018 and June 30, 2018

|  |            |            |              |              |
|--|------------|------------|--------------|--------------|
|  | \$ 899,184 | \$ 923,588 | \$ 1,745,872 | \$ 1,770,861 |
|--|------------|------------|--------------|--------------|

Debenture Interest Payable to a Director

Coupon interest expense on the \$5,000,000 Series C Debenture paid to Dr. Milton Boniuk for the three and six months ended December 31, 2017 was \$60,274 and \$185,274, respectively. The Series C debenture was redeemed for Common Stock effective November 13, 2017. See Note 7.



**Note 5 - Property and Equipment**

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

|                               | December 31,<br>2018 | June 30,<br>2018 |
|-------------------------------|----------------------|------------------|
| GMP Facility                  | \$ 8,020,471         | \$8,011,230      |
| Land                          | 260,000              | 260,000          |
| Office Equipment              | 57,781               | 57,781           |
| Furniture and Fixtures        | 5,607                | 5,607            |
| Lab Equipment                 | 5,732,060            | 5,683,765        |
| Total Property and Equipment  | 14,075,919           | 14,018,383       |
| Less Accumulated Depreciation | (3,520,425 )         | (3,177,290 )     |
| Property and Equipment, Net   | \$ 10,555,494        | \$ 10,841,093    |

Depreciation expense for the three months ended December 31, 2018 and 2017 were \$171,815 and \$166,732, respectively, and for the six months ended December 31, 2018 and 2017 were \$343,135 and \$332,921, respectively.

**Note 6 - Trademark and Patents**

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

|                               | December 31,<br>2018 | June 30,<br>2018 |
|-------------------------------|----------------------|------------------|
| Trademarks and Patents        | \$ 458,954           | \$458,954        |
| Less Accumulated Amortization | (88,161 )            | (84,025 )        |
| Trademarks and Patents, Net   | \$ 370,793           | \$374,929        |

Amortization expense amounted to \$2,067 for each of the three month periods ended December 31, 2018 and 2017, and \$4,136 and \$4,135 for the six months ended December 31, 2018 and 2017 respectively.

**Note 7 - Convertible Debenture and Derivatives**

**Debenture - Series C**

The Company's Series C Convertible Debenture, in the amount of \$5,000,000, was redeemed on November 13, 2017.

For the three-month period ended December 31, 2017, the Holder of the Company's Series C Convertible Debenture elected to receive \$60,274 (through November 13, 2017) of their coupon interest payment and \$125,000 of deferred interest payment in shares of the Company's common stock. For the six-month period ended December 31, 2017, the Holder elected to receive \$60,274 (through November 13, 2017) of its coupon interest payment and \$125,000 of deferred interest payment in common stock of the Company and \$125,000 of its coupon interest payment and \$41,667 of its deferred interest payment in cash.

The Company's Series C Debenture in the amount of \$5,000,000 was due to mature on June 30, 2018. On November 13, 2017, the Company entered into a Debenture Redemption Agreement (the "Agreement") with the Holder, to redeem (the "Redemption") its \$5,000,000 Series C Convertible Debenture (the "Debenture") for an aggregate of 5,500,000 shares of the Company's \$0.001 par value Common Stock ("Purchase Price") comprising 5,000,000 shares for the principal of the Debenture and 500,000 shares for unpaid coupon interest from October 1, 2017 through June 30, 2018. The unpaid interest included \$60,274 of accrued interest through November 13, 2017, \$314,726 in coupon interest through June 30, 2018 and \$125,000 of unpaid deferred interest. The price per share was equal to the closing price of the Company's stock on Friday, November 10, 2017 of one (\$1.00) dollar per share. The Holder waived all early redemption penalty payments provided for in the Debenture for consideration of 150,000 shares of the Company's \$0.001 par value Series A Convertible Preferred Stock. The Company did not incur placement agent fees in redemption of the Series C Convertible Debenture. The Company recognized a non-cash loss on extinguishment of debt of \$1,348,247 on the extinguishment of the aforesaid principal attributable to the Series C Debenture into the Company's common and preferred stock. The loss on extinguishment arises from, the obligation to issue 150,000 shares of the Company's Series A Preferred shares with a fair value of \$364,337, as of November 13, 2017, obligation to issue 314,726 shares of the Company's \$0.001 par value Common Stock with a fair value of \$314,726 as of November 13, 2017, in consideration of Debenture coupon interest from the redemption date through June 30, 2018, and unamortized discount of \$684,633 as of the redemption date, offset by the derivative liability of (\$15,449) as of the redemption date.

Pursuant to the redemption agreement for the Company's Series C Debenture, the Company issued 5,500,000 shares of its registered Common Stock from its shelf registration and the 150,000 shares of its Series A Preferred Stock upon receiving consent to issue the shares pursuant to New York Stock Exchange ("NYSE") regulations. The Company submitted a request for authorization to issue the Common Stock and Series A Preferred Shares to the NYSE, which was authorized on March 18, 2018 and the shares were issued on March 21, 2018.

On July 2, 2014, in conjunction with the issuance of the Company's Series C Convertible Debenture, the Company issued 187,000 shares of its Series A Convertible Preferred Stock (the "Series A") to Dr. Milton Boniuk, pursuant to the terms of the Debenture. Proceeds received in a financing transaction are allocated to the instruments issued prior to evaluating hybrid contracts for bifurcation of embedded derivatives. Since the Series A Convertible Preferred Stock is classified as equity, the proceeds allocated to the Preferred Stock are recorded at relative fair value. The fair value of the Series A was \$1,645,606 at issuance and the relative fair value was calculated as \$1,152,297. The remaining amount of the proceeds was allocated to the Debenture and a debt discount of \$1,152,297 was recorded to offset the amount of the proceeds allocated to the Series A. Then, the embedded derivative was bifurcated at its fair value of \$1,879,428 with the remaining balance allocated to the host instrument (Debenture). The total debt discount was amortized over the actual term of the Debenture using the effective interest method.

The Company recognized amortization of this discount as an additional interest charge to "Discount on convertible debenture" in the amount of \$-0- and \$119,863 for the three month periods ended December 31, 2018 and 2017, respectively, and \$-0- and \$359,214 for the six month periods ended December 31, 2018 and 2017, respectively.

**Note 8 – Accrued expenses**

Accrued expenses consisted of the following:

|                                   | <b>December<br/>31,<br/>2018</b> | <b>June 30,<br/>2018</b> |
|-----------------------------------|----------------------------------|--------------------------|
| Severance payment- Eugene Seymour | \$ 33,333                        | \$ 233,333               |
| Accrued payroll                   | 49,716                           | 19,716                   |
| Professional services             | 25,000                           | -                        |
| Other accruals                    | 31,000                           | -                        |
| Accrued expenses                  | \$ 139,049                       | \$ 253,049               |

**Note 9 - Equity Transactions**

On July 11, 2018 the Board of Directors approved an extension of the employment agreement with Dr. Anil Diwan, the Company's President. Pursuant to the terms of the employment agreement, the Company's Board of Directors authorized the issuance of 525,000 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 \$94,520, respectively, for the three and six months ended December 31, 2018. The balance of \$466,170 will be recognized as the shares vest and service is rendered.

For the three and six months ended December 31, 2018, the Company's Board of Directors authorized the issuance of 7,716 and 15,432, respectively, fully vested shares of its Series A Convertible Preferred stock for employee compensation. The Company recorded expense of \$6,361 and \$14,128, respectively, for the three and six months ended December 31, 2018 related to these issuances.

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

| Date       | Shares  | Value     |
|------------|---------|-----------|
| 7/11/2018  | 525,000 | \$560,690 |
| 7/31/2018  | 2,572   | 2,795     |
| 8/31/2018  | 2,572   | 2,374     |
| 9/30/2018  | 2,572   | 2,598     |
| 10/31/2018 | 2,572   | 2,233     |
| 11/30/2018 | 2,572   | 1,883     |
| 12/31/2018 | 2,572   | 2,245     |
|            | 540,432 | \$574,818 |

There is currently no market for the shares of Series A Preferred Stock and they can only be converted into shares of common stock upon a Change of Control of the Company as more fully described in the Certificate of Designation. The Company, therefore, estimated the fair value of the Series A Preferred stock granted to various employees and others on the date of grant. The Series A Preferred stock fair value is based on the greater of i) the converted value to common at a ratio of 1:3.5; or ii) the value of the voting rights since the Holder would lose the voting rights upon conversion. The conversion of the shares is triggered by a Change of Control. The valuations of the Series A Preferred stock at each issuance used the following inputs:

- a. The common stock price was in the range \$.31 to \$.58;
- 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 19.22% to 19.28% of the total;

e. 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 2.34 to 1.84 years;

f. 29.42% to 32.24% restricted stock discount (based on a restricted stock analysis and call-put analysis curve: 55.76% to 71.74% volatility, 2.09% to 2.70% risk free rate) applied to the converted common.

On July 19, 2018, the Company entered into an Employment Agreement with Dr. Irach Taraporewala as Chief Executive Officer of the Company beginning on September 1, 2018. Dr. Taraporewala was granted options to purchase up to 300,000 shares of the Company's common stock, par value \$0.001 per share at an exercise price equal to 20% above the closing bid price of \$0.41 of the common stock on September 1, 2018 ("Effective Date"). The options shall vest in three, equal, annual installments commencing on the Effective Date. The grant date fair value of the options was \$35,761 of which \$11,920 was recognized and recorded as compensation expense for the three and six months ended December 31, 2018. See Note 13 - Subsequent Events.

The Company estimated the fair value of the options granted to Dr. Taraporewala on the date of grant using a lattice simulation model that values the options based upon a stock price modeled such that it follows a geometric Brownian motion with constant drift and volatility.

For the three months ended December 31, 2018, the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 11,432 shares of common stock with an exercise price of \$.41 per share expiring in November 2022. For the six months ended December 31, 2018, the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 11,432 shares of common stock with an exercise price of \$.41 per share expiring in August 2022 and 11,432 fully vested warrants to purchase shares of common stock with an exercise price of \$.41 per share expiring in November 2022. The fair value of the warrants was \$1,429 for the three months and \$2,972 for the six months ended December 31, 2018 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                         | 49.76-55.12% |   |
| Expected annual rate of quarterly dividends | 0.00         | % |
| Risk-free rate(s)                           | 2.71-2.93    | % |

For the three and six months ended December 31, 2018, the Company's Board of Directors authorized the issuance of 83,943 and 275,453, respectively fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$27,000 and \$106,460 for the three and six months ended December 31, 2018, respectively, which was the fair value on the dates of issuance.

For the three and six months ended December 31, 2018, the Company's Board of Directors authorized the issuance of 34,851 and 54,161, respectively, fully vested shares of its common stock with a restrictive legend for Director Services. The Company recorded an expense of \$11,250 and \$18,750 for the three and six months, respectively, which was the fair value on the dates of issuance.

## Note 10 - Stock Warrants and Options

### Stock Warrants

Stock Warrants

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|  | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price<br>per share<br>(\$) | Weighted<br>Average<br>Remaining<br>Contractual Term<br>(years) | Aggregate<br>Intrinsic Value<br>(\$) |
|--|---------------------|---|---|--------------------------------------|
| Outstanding and exercisable at June 30, 2018     | 6,969,588           | \$ 4.80   | .53   | \$ -                                 |
| Granted  | 22,864              | .41   |   |                                      |
| Expired  | 2,868,981           | 5.25  | -   |                                      |
| Outstanding and exercisable at December 31, 2018 | 4,123,471           | \$ 4.48   | .63   | \$ -                                 |

Of the above warrants, 3,127,668 expire in fiscal year ending June 30, 2019; 620,051 expire in fiscal year ending June 30, 2020, 57,160 expire in fiscal year ending June 30, 2021, 45,728 expire in the fiscal year ending June 30, 2022 and 272,864 warrants expire in the fiscal year ending June 30, 2023.



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, 2018     | -                | \$ -   | -   | \$ -                           |
| Granted                          | 300,000          | .50  | -   | -                              |
| Outstanding at December 31, 2018 | 300,000          | .50  | 2.67  | -                              |

Of the above options, 100,000 are vested and exercisable as of December 31, 2018, 100,000 become vested and exercisable on September 1, 2019 and 100,000 become vested and exercisable on September 1, 2020. The options expire on August 31, 2021. The options will not become vested and exercisable until the option is vested pursuant to the vesting schedule set forth above, provided that Dr. Taraporewala continues to be employed by, or provide service to, the Company. If Dr. Taraporewala's continuous service terminates for any reason other than cause, any such option exercisable as of the date of termination may be exercised at any time by the participant prior to the expiration date. If Dr. Taraporewala's continuous service should be terminated for "Cause" (as defined in the option), then any outstanding option, vested or unvested, shall terminate immediately and shall no longer be exercisable. See Note 13 – Subsequent Events.

The Company estimated the fair value of the options granted to Dr. Taraporewala on the date of grant using a lattice model that values the options based upon a stock price modeled such that it follows a geometric Brownian motion with constant drift and volatility:

|   |        |
|---|--------|
| Expected life (year)                        | 3      |
| Expected volatility                         | 55.09% |
| Expected annual rate of quarterly dividends | 0.00 % |
| Risk-free rate(s)                           | 2.71 % |
| Expected forfeiture (attrition) rate (%)    | 5.00%  |

Expected volatility is based on historical volatility of the Company's common stock and the expected life of options. The Company estimates forfeitures at the time of valuation and reduces expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ or are expected to differ, from the previous estimate.

**Note 11 - Fair Value Measurement****Fair value measurements**

At December 31, 2018 and June 30, 2018 the estimated fair values of the liabilities measured on a recurring basis are as follows:

Fair Value Measurements at  
December 31, 2018:  
(Level 1) (Level 2) (Level 3)

Derivative liability - warrants \$ - \$ - \$ -

Fair Value Measurements at  
June 30, 2018:  
(Level 1) (Level 2) (Level 3)

Derivative liability - warrants \$ - \$ - \$ 298,092

In conjunction with the Company's registered direct offerings of Units, consisting of the Company's common stock and warrants, on September 12, 2013 and January 24, 2014, the Company issued an aggregate of 5,425,363 warrants, of which 2,479,935 and 5,290,006, are outstanding at December 31, 2018 and June 30, 2018, respectively. Additionally, the Company issued 135,216 warrants to the placement agents of which 76,306 and 135,216, are also outstanding at December 31, 2018 and June 30, 2018, respectively, for a total number of 2,556,241 and 5,425,222 warrants outstanding and issued as of December 31, 2018 and June 30, 2018, respectively, pursuant to the aforesaid registered direct offerings.

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, stock warrants must be accounted for as derivative financial instruments if the warrants contain full-ratchet anti-dilution provisions, which preclude the warrants from being considered indexed to its own stock. The warrants described above contained a full-ratchet anti-dilution feature and are thus 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 features.

The Warrants were valued as of December 31, 2018 and June 30, 2018 with the following assumptions:

The 5-year warrants issued on 9/12/13 and 1/24/14 included Investor and Placement Agent Warrants with an exercise price of \$5.25 and \$6.05 (subject to adjustments-full ratchet reset).

-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 exercise/reset price or **2 times** the stock price.

The next capital raise would fluctuate with an annual volatility. The projected volatility curve was based on historical volatilities of the Company for the valuation periods. The projected annual volatility for the valuation dates are:

| <b>1 Year</b> |     |
|---------------|-----|
| 12/31/18      | 76% |
| 6/30/18       | 56% |

The primary factors driving the economic value of options are stock price; stock volatility; reset events and exercise behavior. Projections of these variables over the remaining term of the warrant are either derived or based on industry averages. Based on the above, a probability was assigned to each scenario for each future period, and the appropriate derivative value was determined for each scenario. The option value was then probability weighted and discounted to the present.

The following tables present the activity for liabilities measured at estimated fair value using unobservable inputs for the three months ended December 31, 2018:

**Fair Value Measurement**

|                                   | <b>Fair Value Measurement<br/>Using Significant<br/>Unobservable Inputs<br/>Derivative</b> |         |
|-----------------------------------|--|---------|
|                                   | <b>Liability-</b>  |         |
|                                   | <b>Warrant</b>   |         |
| Beginning balance at July 1, 2018 | \$   | 298,092 |
| Additions during the year         | -  |         |
| Change in fair value              | (298,092   | )       |
| Transfer in and out of Level 3    | -  |         |
| Balance at December 31, 2018      | \$   | -       |

**Note 12 - 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's will be paid an annual base salary of \$400,000. Additionally, Dr. Diwan was awarded a grant of 525,000 shares of the Company's Series A Preferred Stock. 175,000 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 will be paid an annual base salary of \$360,000. Additionally, Dr. Taraporewala was awarded a grant of 300,000 options to purchase shares of the Company's Common Stock. 100,000 options vested on September 1, 2018 and the remainder of the options will vest

over the two-year vesting period and are subject to forfeiture.

On March 3, 2010, the Company entered into an employment agreement with Dr. Jayant Tatake to serve as Vice President of Research and Development. The employment agreement provides for a term of four years with a base salary of \$150,000. In addition, the Company issued 26,786 shares of Series A Preferred Stock and 35,715 shares of common stock upon entering into the agreement, and issued an additional 26,786 shares of Series A Preferred Stock and 35,715 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. See Note 13 – Subsequent Events.

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 35,715 shares of common stock upon entering into the agreement, and issued an additional 35,715 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 2,572 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 agreement with TheraCour (See Note 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. The Company is currently negotiating for a license for VZV from the Licensor, TheraCour. For this purpose, the Company has conducted a valuation for the shingles and PHN indications. TheraCour has not withheld any licenses for antiviral nanomedicines sought by the Company and we anticipate that the licenses for VZV will be executed once the due diligence process is completed.

### **Note 13 - Subsequent Events**

Management performed an evaluation of the Company's activity through the date these financials were issued to determine if they must be reported. The Company determined that there were certain reportable subsequent events to be disclosed as follows:

On January 24, 2019, Irach Taraporewala resigned as the Chief Executive Officer of NanoViricides, Inc. (the "Company") for personal reasons. Also on that date, the Company and Mr. Taraporewala agreed that Mr. 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 Mr. Taraporewala entered into a Confidential Separation and Consulting Agreement and General Release (the "Agreement") pursuant to which the Company will pay Mr. Taraporewala monthly consulting payments of Three Thousand Dollars (\$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 Registrant, obligations of confidentiality, non-disclosure, non-disparagement and other customary provisions found in similar agreements. Dr. Taraporewala was granted options to purchase up to 300,000 shares of the Company's common stock, on September 1, 2018. Pursuant to the option grant, 100,000 options vested on September 1, 2018. The remaining 200,000 options were not vested and have been forfeited.

## **PART I**

### **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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, and 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, 2018. 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 of these 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**

The Company reported on February, 4, 2019, subsequent to the reporting period, that it has formally commenced the IND-Enabling Non-GLP and GLP Safety/Toxicology studies for its first drug candidate in the HerpeCide™ Program. These studies are being conducted by BASi, Indiana, a Contract research Organization (“CRO”). This marks a major milestone for the Company.

The drug candidate selected for advancing towards human clinical studies is designated as NV-HHV-101. The Company is presently advancing this selected drug candidate as a treatment for shingles rash. Shingles and chickenpox are caused by the same virus, namely Varicella Zoster Virus (“VZV”). The NV-HHV-101 or a closely related drug candidate is expected to be advanced as a clinical drug candidate against HSV-1 “cold sores” and against HSV-2 “genital ulcers” as these programs mature. All of these current candidates are being developed as skin creams for dermal topical applications. The Company has previously found that dermally applied nanoviricide drug candidates 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 is expected to be highly beneficial.

Of these drugs in development, treatments for HSV-1 and HSV-2 are already licensed by the Company from TheraCour Pharma, Inc. (“TheraCour”).

Subsequent to the reporting period, Irach Taraporewala, PhD, resigned as CEO effective February 1, 2019 for personal reasons. As a result, Anil R. Diwan, PhD, President and Chairman, was elevated by the Board to the position of Executive Chairman. The Company has retained Dr. Taraporewala as a consultant to help with drug development into the regulatory stage for a period of two years.

We are pleased to report that Mr. James Sapirstein has joined the Board of Directors of the Company as of November 1, 2018, as an independent director. He has also become a member of the Audit Committee, the Compensation Committee, and the Nomination Committee of the Board.

Mr. Sapirstein has over 35 years of experience in the pharmaceutical industry. He has held various roles in small as well as big pharmaceutical companies, including as CEO for multiple small companies. He has also served and is currently serving as a director of multiple pharmaceutical companies and of pharmaceutical industry associations. He has been part of almost two dozen drug product launches and specifically either led or has been a key member of several HIV product launches into different new classes of therapeutics at the time.

Mr. Sapirstein began his career in 1984 with big pharmaceutical companies, joining Eli Lilly in Sales; moving on to Hoffmann-LaRoche in 1987 where he served for almost a decade as part of its commercial teams in the USA and abroad, rising to become a Product Director; and thereafter at Bristol Myers Squibb (BMS) as the Director of International Marketing in the Infectious Diseases group in 1996. While at BMS, he worked on several important HIV/AIDS projects including Secure the Future.

Mr. Sapirstein's entry into the world of smaller pharma companies began with Gilead Sciences, Inc. (GILD) in 2000 where he led the Global Marketing team in its launch of Viread (tenofovir). Later, in 2002, he accepted the position of Executive Vice President, Metabolic and Endocrinology, for Serono Laboratories, acquired by Merck GMBH in 2006. Thereafter in 2006, he became the founding CEO of Tobira Therapeutics, then a private company. In 2012, Mr. Sapirstein became the CEO of Alliqua Biomedical at Alliqua, Inc. Thereafter, he served as CEO of Contravir Pharmaceuticals (CTRV) from March 2014 until October 2018. Mr. Sapirstein has raised over \$120 Million dollars in venture capital and public capital markets financing in his various engagements as CEO. He was named as a Finalist for Ernst & Young Entrepreneur of the Year award in 2015 as well as in 2016. Mr. Sapirstein received an MBA from Fairleigh Dickinson University in 1997, and a BS (Pharmacy) from Rutgers University in 1984.

Mr. Sapirstein currently holds Board positions on Enochian Biosciences (ENOB), RespireRx Pharmaceuticals (RSPI) and the privately held company Leading Biosciences. He is a Director and was Chairman, until February 2019, of the Board for BioNJ, an association of biopharma industries in New Jersey. In addition, he is a Board Director for BIO, the leading Biopharma Industries Organization promoting public policy and networking in the healthcare space, where he sits on both the Health Section and Emerging Companies Section Governing Boards.

The Annual Shareholders' Meeting of the Company was held on November 30th, 2018 at the Sheraton Stamford Hotel, Stamford, CT. All of the proposals presented for voting were approved by a majority of votes, except for Dr. Taraporewala's appointment as a Director. Mr. Sapirstein's appointment as an Independent Director of the Board was ratified by majority shareholder vote.

As a result of Mr. Sapirstein's appointment as a Director, the Company has regained full compliance with the listing requirements of NYSE-American for having a majority of independent directors and three independent members on its Audit Committee. The Company received notification from the Exchange that it is in full compliance with the listing requirements on November 19, 2018.

Additionally, management has continued and significantly accelerated its efforts at investor outreach and communications.

Dr. Irach B. Taraporewala, then Chief Executive Officer of the Company, presented a corporate overview and discussed the Company's progress in taking its first drug candidate into human clinical trials at the Biotech ShowCase Meeting held in San Francisco, in parallel to the JP Morgan Life Sciences Conference, on January 7, 2019. Previous to that, he presented the Company overview at the MicroCap Investment Conference, held on October 1-2, 2018 at the Essex House Hotel in New York City.

The Company has engaged Zacks Investment Research for the purpose of developing and disseminating investment research analysis reports on the Company. Zack Small Company Research (SCR) has published their first Analyst Report on NanoViricides on November 13, 2018

<https://scr.zacks.com/News/Press-Releases/Press-Release-Details/2018/NNVC-NanoViricides-Developing-Antiviral-Medicati>

Previously, the Company has reported that we have engaged The Money Channel NYC for the purpose of investor and brokerage outreach. Subsequent to the reporting period, the Company has elected to continue this engagement.

The formal IND-enabling Safety/Toxicology studies of the Company's first drug candidate to move into regulatory stage began at the end of December 2018. The first part of these studies, namely non-GLP Safety/Tolerability and Toxicity using Dermal Exposure in Mini-Pigs, was completed recently. Following initial observations on this mini-pigs study, the next non-GLP studies for Systemic Exposure using sub-cutaneous administration in Rats began in the second week of January 2019. Another study of Systemic Exposure using sub-cutaneous administration in Dogs began recently. The Company expects to report on these various studies as soon as the data become available to us and is reviewed by our scientists. The Company previously performed a Safety/Tolerability study in rats on two closely related development candidates (see below under "Our Product Pipeline"). These studies showed that the tested drug candidates were safe and well tolerated. No signs of toxicity were seen in gross or microscopic examination of tissues. The Company believes that the selected clinical candidate should have a similar safety profile. Therefore, the Company is negotiating the earliest possible date for entering the next phase, namely, the GLP Safety/Toxicology studies with BASi.

The start of these IND-enabling studies marks a major milestone for the Company and an important step in establishing our nanoviricide® platform technology and validity of our approach.

### ***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.

We are currently scaling up the production of our lead candidates to make the large batch required for the ensuing IND-enabling GLP Safety/Toxicology studies. The required amount for these studies was estimated to be a few kg of the API as a rough estimate. We believe we will achieve this scale of production during the currently ongoing production cycle.

A preliminary safety and toxicology evaluation (Safety and Tolerability study) of the Company’s optimized nanoviricides® drug candidates in the HerpeCide™ program was performed at AR Biosystems, Beverly, MA in Dec 2017-March 2018. This preliminary safety/toxicology study in the rat animal model is an important step in the drug development pathway. It was conducted in order to provide information for designing the IND enabling non-GLP and GLP safety/toxicology (“Tox Package”) studies. It was designed to (i) evaluate the direct effects of topical delivery of the drug candidates on the skin, (ii) assess if the drugs attain detectable levels in the blood, and also (iii) evaluate whether there are any effects on the blood and primary organs, in uninfected animals. Dermal topical treatment of rats with formulated drug candidates was evaluated in this study as a primary objective, since skin is the primary breakout site of HSV-1, HSV-2, and VZV infections.

As a result of the success of its drug lead optimization process, the Company selected two clinical development candidates for further evaluation in this initial safety/toxicology study.

No clinically observable adverse safety and toxicology effects were seen in this study of the Company's optimized topical dermal drug candidates. There were no adverse effects on the skin at the treatment sites. Equally importantly, the results of the non-GLP safety and toxicology study showed that there were no overall observable systemic effects either. There were no observable direct effects on the primary organ function whether the drug was administered to the skin or administered systemically. This includes liver and kidney function. This is important as the liver and kidneys are major organs involved in drug toxicity.

These results are consistent with the positive findings in a model of VZV (the shingles virus) infection of human skin in which no safety or toxicology concerns have been observed, further demonstrating the safety of these drug candidates.

Moreover, these drug candidates have shown strong effectiveness in the human skin organ culture model of VZV infection studies as well, as previously reported. Further, these candidates have demonstrated strong anti-viral activities against HSV-1, HSV-2, and VZV in cell culture studies using multiple cell lines.

These studies established that our optimized drug candidates were worthy of further development in the regulatory pathway for approval. Since then, we engaged in production scale-up and chemistry, manufacture and control studies ("CMC" studies) at our Shelton facility. This c-GMP capable facility has been designed to be able to manufacture any of our nanoviricides drug candidates from scratch in research quantities to multi-kilogram production quantities that would be needed for the regulatory Tox Package studies as well as for human clinical trials.

The success of our drug candidates in this preliminary rat safety/toxicology study cleared the path for taking these candidates into formal GLP safety/toxicology studies that are required for filing an IND. We believe that, additionally, the results of this preliminary rat safety/toxicology study give us confidence that the dermal topical treatments we are developing for the treatment of HSV-1 cold sores, and HSV-2 genital ulcers should also exhibit similar strong safety characteristics.

The Company's drug candidates in the HerpeCide™ program are being developed for direct topical application on the affected areas to control the infections. Direct topical application enables delivery of the highest possible concentrations of the active substance directly at the site of infection. This allows for maximal clinical effectiveness, while at the same time minimizing side effects that are seen with systemic therapy (such as oral drugs or injectables).

We have already begun to scale up production of these tested candidates to the larger amounts as estimated to be required for the ensuing Tox Package studies. We have estimated the amount of the candidate that will be needed to be supplied for such a study, based on discussions with BASi, Inc., IN, the service provider, and Biologics Consulting Group, VA, our regulatory consultants. We have increased the scale of production to meet this required quantity and have the ability to produce multi-kilogram quantities of materials. We are also working on detailed optimization of the manufacture and characterization of the materials at different synthetic steps as will be needed for the Chemistry, Manufacture, and Controls (CMC) section of an IND application.

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 recent report 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. However, Shingrix has significantly greater severe side-effects than Zostavax in more than 10-15% of the persons taking it. This may keep its adoption rate much lower than expected by the manufacturer GSK. Currently, Shingrix is unavailable in most markets because the manufacturer has apparently not scaled up production more than one year since its introduction. Thus it appears that a significant market would continue to exist for an anti-shingles drug, at least for several years.

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.

Typically, the synthesis of small chemicals, such as the ligands we use to direct the nanoviricide against a specific type of virus, is substantially easier to scale up than the synthesis of polymers. We have been able to scale up production of the two different ligands under potential clinical development consideration for VZV shingles treatment already. We anticipate being able to scale up to multi-kg levels, as necessary.

The process of chemically covalently connecting the ligands to the polymer backbone, to produce the nanoviricides, is now being optimized for scalability.

Our polymer backbone itself is designed based on the route of application. 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.

We have finished the development of final clinical formulation of our drug candidate, i.e. the “drug product” in just about six weeks. After synthesizing the active chemical component, additional substances called “excipients” are added to it to provide specific desired characteristics. The resulting substance is called the drug product. Typically most pharmaceutical companies require several months to a few years to achieve successful drug product formulation, depending upon the characteristics of the API. Our internal expertise in formulations and the fact that the nano micelle is designed based on the route of administration helped us achieve this objective in such a short time.

Thus, we are on course to be able to manufacture the required quantities of materials for the Tox Package studies.

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.

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. The Company is currently negotiating for a license for VZV, Shingles Virus, from the Company’s licensor, TheraCour Pharma, Inc. (“TheraCour”).

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.

We are currently scheduling the time-slots for the Tox Package studies with BASi, IN, our CRO for this task. The non-GLP portion of the IND-enabling Safety/Toxicology studies has already been completed at BASi, We anticipate receiving reports on these studies in six to eight weeks from study completion.

Additional studies as required regarding effectiveness of our drug candidate in human skin organ culture (“ex vivo”) model are continuing at Professor Moffat’s lab in the Upstate Medical Center, SUNY, Syracuse, NY.

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.

NanoViricides, Inc. reported in July 2017, that its anti-shingles nanoviricides® drug candidates achieved dramatic reduction in infection of human skin by the varicella-zoster virus (VZV), the shingles virus. These findings corroborate the previously reported findings of inhibition of VZV infection of human cells in culture. VZV is restricted to human tissue and only infects and replicates in human tissue.

Over the time course of VZV infection, the nanoviricides® drug candidates showed marked inhibition of VZV infection, replication and spread in human skin cultured *ex vivo*. The data suggest that select nanoviricides® drug candidates may have direct virucidal activity based on their antiviral effects within the first 24 hours after viral infection.

The antiviral effect of certain nanoviricide drug candidates was substantially greater than the effect of the standard positive control of cidofovir added into media. Even more remarkably, the effect of these nanoviricides drug candidates was equivalent to a topical formulation of 1% cidofovir applied directly onto the skin patch. A topical skin cream containing 2% cidofovir is clinically used in very severe cases of shingles. However, the cytotoxicity of cidofovir is known to cause ulceration of the skin to which it is applied, followed by natural wound healing.

Histopathology studies have demonstrated a lack of VZV-associated lesions in nanoviricide-treated skin patches. This work was presented as a poster presentation by the Moffat group at the 31st International Conference on Antiviral Research held June 11 - June 15, 2018 in Porto, Portugal, (<https://www.isar-icar.com/page/31icar>).

Since VZV causes skin lesions as a result of direct attack of the re-awakened virus released from nerve endings onto the human skin cells, this *ex vivo* human skin patch model involving VZV infection of cultured human skin *ex vivo* is considered to be a close representation of natural course of shingles.

The Company has previously reported that these same nanoviricides® compounds displayed potent inhibition of VZV infection of a human retinal epithelial pigment cell line in an *in vitro* cell culture virus infection model with no evidence of toxicity to the cells. These *ex vivo* and *in vitro* studies are a critical step in the selection of final clinical drug development candidates for safety and toxicology studies with the goal of an IND submission to the FDA for the topical treatment of shingles in humans.

These human skin studies were performed in the laboratory of Dr. Jennifer Moffat at SUNY Upstate Medical University in Syracuse, NY. The Company previously reported the collaboration with Dr. Moffat, an internationally recognized expert on varicella-zoster virus. She has extensive experience in varicella-zoster virus (VZV) infection, pathogenesis, and anti-viral agent discovery. The National Institutes of Health has a contract with Dr. Moffat's lab for evaluating anti-viral compounds against VZV, although the Company chose to set up a direct collaboration with Dr. Moffat rather than going through the NIH program.

Dr. Vivien Boniuk, then Consultant in Ophthalmology at the Company, presented the successful results of certain anti-herpes nanoviricide treatments for v-ARN at the 2017 Annual meeting of the Ocular Microbiology and Immunology Group (OMIG) of the American Academy of Ophthalmology held in New Orleans, LA, on November 10, 2017. In this study, HSV-2 infection was given to mice as a single injection to cause v-ARN. The mice that received either of two nanoviricides drug candidates simultaneously with the virus in this single injection, showed significant improvements using a number of parameters. In contrast, mice that received foscarnet injection simultaneously with the virus did not show any improvements. Of note, foscarnet is a current standard of treatment, although the treatment is long in duration and arduous, being multiple intravitreal injections. In addition, another group of HSV-2 infected animals received acyclovir by intraperitoneal injection (50mg/kg), twice daily for 7 days, as a positive control. Acyclovir and its derivatives are also used currently for treating v-ARN, although the clinical efficacy is limited and generally requires long durations of treatment. Vehicle treated and untreated negative controls also were employed. These studies were performed in the lab of Dr. Curtis Brandt at CORL, University of Wisconsin, Madison, WI.

Both nanoviricides tested showed remarkable efficacy using multiple parameters. In particular, nanoviricide-A treated group showed viral load going down to undetectable levels by day 7 itself (approximately 4 logs viral load reduction

from baseline), whereas acyclovir group showed no reduction in viral load from baseline at day 7, but approximately 2 logs reduction at day 9, indicating a much lower efficacy.

Both nanoviricides A and B resulted in 100% maintenance of body mass by day 9, indicating complete control of infection. However, the acyclovir group showed a loss of at least 10% body mass, close to the nearly 15% loss in the negative controls, indicating that it was either much less effective than the nanoviricides A and B or was somewhat toxic to the animals.

The mean disease score for the vitreous infiltrate (fluid inside the eye) was zero (best) for 9 days with nanoviricide A treatment, and was about 0.5 for acyclovir treated group, whereas it was about 4 (worst) in untreated and vehicle groups, indicating that nanoviricide A was more effective than the acyclovir treatment in this model.

In both nanoviricide A and nanoviricide B groups, the retina was protected fully from viral damage, which is very significant. In contrast, the acyclovir treated group showed retinal damage approximately similar to the vehicle treated group, in spite of reduced viral load in the acyclovir group, indicating that acyclovir may have been toxic. These results were also confirmed by histological staining of retinal sections.

Taken together, both nanoviricide A and nanoviricide B had substantial effectiveness in protecting the retina, in spite of the high infectious dose of HSV-2 employed in this model. Significantly, they were both substantially more effective than foscarnet (single injection) or acyclovir (bid 7days) in this particular study. If these results are reproducible, then the Company would be able to identify a clinical candidate for v-ARN as well.

Of note, both nanoviricides tested against v-ARN are closely chemically related to those that have shown significant efficacy against varicella zoster virus (VZV) in the human skin patch model in Professor Moffat's lab at the Upstate Medical Center, SUNY, Syracuse, NY. We have previously shown that closely chemically related nanoviricides were also effective against HSV-1 in animal models as well as in cell culture models. This is important because about 50% of v-ARN cases are caused by VZV, about 40+% caused by HSV-2, with HSV-1 and CMV accounting for a small percentage of cases. VZV does not infect mice, and therefore the HSV-2 v-ARN model should be indicative model for our drug development. Thus the broad-spectrum activity of our nanoviricides against multiple different herpesvirus types has been instrumental in rapid expansion of our HerpeCide program.

Additional successful studies on v-ARN are expected to add a fifth indication to the Company's growing portfolio of anti-herpes drug indications, further expanding the potential market. The Company intends to maximize shareholder value from its broad-spectrum anti-herpes nanoviricides asset by aggressively expanding its portfolio of herpesvirus indications.

v-ARN is a disease of the retina of the eye caused by various herpes viruses that leads to severe loss of vision and blindness. The infecting agent in this study was herpes simplex virus-2 (HSV-2), the type of herpes virus that also causes genital herpes.

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.

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.

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.

In addition, we have continued work on our other drug candidates albeit at a very low priority. These include (vi) Injectable FluCide™ for hospitalized patients with severe influenza, (vii) Oral FluCide™ for out-patients, (viii) 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 (ix) HIVCide™ for HIV/AIDS. In addition, the Company has research programs, enabled by the robust nanoviricides platform technology, to develop drugs against Rabies virus, Ebola and Marburg viruses, and other viruses.

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.

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 Phase 1/2 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.

The current market size for drugs for the treatment of various herpes infections is well over \$4 billion. Similarly, the current market size for the treatment of influenza infections is in excess of \$4 billion, and that for HIV treatments is in excess of \$40 billion. The total market sizes for the drug development programs we have in progress are estimated at around \$100 billion.

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.

We believe we are now one of the very few small pharmaceutical drug innovators that possess their own cGMP or cGMP-capable manufacturing facility (see below). With our new campus and pilot-scale c-GMP-capable manufacturing facility, we are now in a position to advance our drug candidates into clinical trials, produce the pre-clinical tox package batches, and the clinical drug substance batches.

### **Management Discussion - Current Drug Development Strategy**

During the reported quarter we have continued to focus our drug development work plans primarily on our lead anti-shingles and anti-Herpes-virus programs. In particular, we have focused on a work plan towards clinical development candidate for the topical skin ointment for the treatment of shingles outbreak. 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, external ocular viral infections, and viral acute retinal necrosis. We have also continued to work on our anti-influenza drug development programs under the FluCide™ project at a slow pace. The FluCide program is expected to be quite expensive for development, based on our pre-IND discussions with the US FDA. We have therefore prioritized our resources with the goal of filing our first IND in the shortest possible timeframe.

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.

NanoViricides currently has existing licenses from TheraCour Pharma, Inc., (TheraCour), our development partner and where the intellectual property has originated, for HSV-1 and HSV-2, but not for the remaining herpesviruses. NanoViricides has disclosed our intention to obtain licenses for VZV as well as other remaining unlicensed herpesvirus indications from TheraCour Pharma. As is the standard process with such agreements, and the process that we have followed in the past, the Company needs to obtain a valuation of the assets under consideration. We retained Dr. Carolyn Myers of BioEnsemble LLC, an expert in in-licensing, out-licensing, valuations, and M&A in pharmaceutical industry to help with the valuations and related matters. Dr. Myers presented her initial report to our Board of Directors on December 9, 2017. Thereafter, we asked that further modeling and analysis be performed incorporating additional assumptions that reflect the current situation more closely than in the model that was presented, such as the subsequent approval of Shingrix vaccine in early 2018. Dr. Myers has recently presented us with a revised valuation report on the VZV as of October 2018. Additional consultations with Dr. Myers on various aspects of the licenses sought are ongoing. TheraCour has in the past not denied any licenses for any virus programs that we initiated.

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 have 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 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.

Recent developments and our discussions with our regulatory advisors and consultants indicate that the shingles drug candidate may be likely to reach the human clinical evaluation phase earliest compared to the other drug candidates. 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. The FluCide drug candidates are now expected to enter human clinical stage later than the HerpeCide drug candidates.

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 has previously reported the successes of its nanoviricides drug candidates in pre-clinical studies of dermal herpes virus infections in mouse models. The studies in Dr. Brandt's laboratory, namely CORL, at the University of Wisconsin will be critical in optimizing our anti-herpes drug candidates against ocular herpes virus infections. The goal of these studies will be to identify a drug development candidate as a treatment for ocular keratitis in humans caused by herpes simplex virus infections. We anticipate undertaking these studies as we are testing our HerpeCide drug candidates developed as skin ointment/cream against all three of dermal HSV-1, genital HSV-2, and VZV models. The treatment of ocular keratitis requires an eye drops formulation. We have tested certain of our polymer backbones in eye drop formulation application successfully previously. However, we are at present constrained by resource availability and the workload of moving our first drug candidate into IND stage.

The Company has continued to test several drug candidates with different formulation consistencies in multiple studies in order to select a clinical development candidate for the topical treatment of shingles. Following identification of the clinical development candidate, the Company will engage into scaled up production of said drug candidate at our Scale-Up Lab at our Shelton, CT campus. The Scale-up Lab has been in operation since June 2015, and we have scaled most production operations to 200g scale previously, and some steps to kilogram level scales recently; levels sufficient to provide clinical trial material supplies.

The Company has initiated manufacture of the shingles drug candidates as it is scaling up the production processes to meet the quantity requirements for the IND-enabling safety/toxicology studies. We will also continue to perform additional pre-clinical studies in parallel to the Tox Package studies. These studies include formulation optimization studies, dose-response efficacy studies, efficacy studies with different viral strains, and PK/PD studies (pharmacokinetics and pharmacodynamics studies) in standard animal models.

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.

The Company continues to work on its anti-influenza drug candidates in parallel to its HerpeCide program. 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. These programs are being conducted at a much lower priority, with the highest priority being given to the various indications in the HerpeCide programs. 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.

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 now 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 scales of about 200g to 1kg per step for different chemical synthesis and processing steps. It comprises reactors and process vessels on chassis or skids, ranging from 1L to 50L capacities, as needed. Many of the reactors or 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 at least three consecutive 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 the necessary additional resources such as QA/QC.

If we are able to attract and hire quality candidates that we severely need, we anticipate that it will take at least six months to one year for each such person to be fully productive as an integrated part of our team. In the past, we have been very fortunate that newly hired personnel were immediately productive in tasks delineated to them, and they were productively integrated within a short time frame of several months into independent but integrated parts of our team. However, this is not always the case.

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. 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.

*Manufacturing Requirements of Some of Our Drug Candidates*

The HerpeCide program drug product batch requirements are estimated to be fairly modest because of the topical nature of treatment. In consultation with BASi and BCG, we have currently estimated a batch size of approximately 1~2 kg will be sufficient for the full Tox Package (i.e. safety and toxicology) studies of the dermal topical shingles drug candidate. We are estimating that a ~500g batch will be more than sufficient for initial Phase-I human clinical studies as well. Our current estimate for a Phase IIa human clinical efficacy study is also in the range of a ~500g batch requirement. We already have the facilities for producing up to 1kg per batch or more. Many of our synthesis steps have already been scaled up to ~1kg scales. Thus we believe that we have sufficient production capability for the amounts of the HerpeCide drugs that would be needed for tox package as well as clinical studies.

As we move our drug candidates into clinical studies, we plan to perform further scale-up studies to get to about 1kg per batch production scale. In the current facility, we may be able to manufacture about 10kg to 20kg of cGMP product annually. Depending upon the drug's potency and indication, this production size may fetch modest revenues of around \$50 million to \$500 million, depending upon the cost metrics, enabling profitable market entry. Such initial commercialization would allow the Company to turn itself into a stand-alone pharmaceutical company, by enabling capital formation for larger scale manufacturing facilities and fueling further growth.

### **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 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. All of our drug development programs are presently at pre-clinical or advanced pre-clinical stage. We believe we are advancing these programs at a faster pace than industry peers. We continue to test several drug candidates under each program even though we may achieve extremely strong results with some of the candidates

### **Patents, Trademarks, Proprietary Rights: Intellectual Property**

The nanomedicine technologies licensed from TheraCour Pharma, Inc. (“TheraCour”) 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.

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, 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.

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.

NanoViricides has entered into a Memorandum of Understanding with TheraCour, whereby TheraCour will initiate discovery and development for drug candidates for a new virus or indication upon request. If the resulting drug candidates are worthy of further drug development, NanoViricides may determine that it should enter into a licensing

agreement with TheraCour. In such a case, NanoViricides would obtain an independent asset valuation for the asset(s) to be licensed from a party experienced in such valuations. NanoViricides and TheraCour would thereafter negotiate the terms of compensation for the new license agreement. However, there can be no assurance that an agreement for licenses for new viruses will be entered into on terms that are favorable to NanoViricides. We believe this process has been generally beneficial for NanoViricides, since this process saves NanoViricides from the cost of acquiring and paying for licenses that it may not want to pursue further. At present, TheraCour has licensed to NanoViricides HSV-1 and HSV-2, but has not licensed the VZV area, nor has it licensed any of the remaining herpesviruses. Licensing of these assets is currently in process as described earlier. However there can be no assurance that the Company will be able to enter into an agreement with TheraCour for such license or that the agreement will be on terms that are favorable to the Company.

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, may 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.

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 before entering human clinical trials. The estimated expiry date for the FluCide and HerpeCide patents, if and when issued, would be no earlier than 2038.

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 December 31, 2018, we had cash and cash equivalents of \$3,903,672, prepaid expenses of \$168,948, and net property and equipment of \$10,555,494. Accounts payable and accrued expenses were \$1,163,660. Stockholders' equity was \$13,840,559 at December 31, 2018.

In comparison, as of June 30, 2018, we had cash and cash equivalents of \$7,081,771, and \$240,257 in prepaid expenses, and net property and equipment stood at \$10,841,093. Accounts payable and accrued expenses were \$583,856 and current derivative liabilities-warrants were \$298,092. Stockholders' equity was \$17,664,264 at June 30, 2018.

During the six-month period ended December 31, 2018 we used approximately \$3,100,000 in cash toward operating activities. During the six-month period ended December 31, 2017 we used approximately \$2,961,000 in cash toward operating activities.

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

The Company believes that our spending continues to be in line with our estimates. Management is actively exploring additional required funding through debt or equity financing pursuant to its plan. 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 it will have to raise additional capital to fund and perform additional projected work, which is beyond normal pre-clinical development operations, leading towards an Investigational New Drug Application (IND) filing with the U.S. Food and Drug Administration (FDA), to continue.

The Company does not currently have any revenue. All of the Company's products are in the development stage and require successful development through regulatory processes before commercialization. We have generated funding through the issuances of debt and private placement of common stock and also the sale of our registered securities. The Company does not currently have any 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, while continuing limited work on our FluCide program

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 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 animal models. 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 studies in animal models to obtain necessary data regarding the pharmaco-kinetic and pharmaco-dynamic profiles of our drug candidates, provided that appropriate levels of funding become available. We

believe this data will enable us to file an Investigational New Drug Application, towards the goal of obtaining FDA approval for testing the drugs in human patients.

## **Results of Operations**

The Company is a biopharmaceutical company and did not have any revenue for the three and six month periods ended December 31, 2018 and 2017.

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

*Research and Development Expenses* – Research and development expenses for the three months ended December 31, 2018 increased \$18,195 to \$1,657,838 from \$1,639,643 for the three months ended December 31, 2017, and for the six months ended December 31, 2018 decreased \$66,770 to \$3,024,779 from \$3,091,549 for the six months ended December 31, 2017. The increase in the cost of research and development for the three months ended December 31, 2018 is largely attributable to the increase in outside laboratory fees to collaborators, lab supplies and materials during the three month period ended December 31, 2018. The Company began laboratory studies with its collaborators in the quarter ended December 31, 2018. The decrease in research and development expenses for the six months ended December 31, 2018 results from a decrease in laboratory payroll, and related expenses, and patent fees offset by an increase in lab supplies and chemical expenses.

**General and Administration Expenses** – General and administrative expenses for the three months ended December 31, 2018 decreased \$42,778 to \$711,360 from \$754,138 for the three months ended December 31, 2017 and for the six months ended December 31, 2018 decreased \$149,161 to \$1,383,517 from \$1,532,678 for the six months ended December 31, 2017. The decrease over the three month period ended December 31, 2018 compared to the prior period resulted primarily from decreases in officers compensation arising from the resignation of Dr. Seymour on January 27, 2018, travel expense and operating expenses in general. The decreased expenses were offset by increases in professional fees and insurance expenses. The decrease over the six month period ended December 31, 2018 compared to the prior period resulted primarily from decreases in officers compensation arising from the resignation of Dr. Seymour, travel expense, office salary, office expenses and operating expenses in general. The decreased expenses were offset by increases in professional fees and insurance expenses.

**Interest Income**– Interest income decreased \$9,305 to \$15,665 for the three months ended December 31, 2018 from \$24,970 for the three months ended December 31, 2017. Interest income decreased \$11,613 to \$37,749 for the six months ended December 31, 2018 from \$49,362 for the six months ended December 31, 2017. Interest income included interest on cash equivalent deposits in interest-bearing accounts at market rates. The decrease is due to a decrease in the account balances.

**Interest Expense on Convertible Debenture** – Interest expense decreased \$60,275 to \$-0- for the three months ended December 31, 2018, from \$60,275 for the three months ended December 31, 2017. Interest expense decreased \$185,274 to \$-0- for the six months ended December 31, 2018 from \$185,274 for the six months ended December 31, 2017. The decreases are a result of the redemption of the Company's Series C Debenture on November 13, 2017.

**Other Expenses** – Discount on convertible debenture for the three months ended December 31, 2018 decreased \$119,863 to \$-0- from \$119,863 for the three months ended December 31, 2017. Discount on convertible debenture for the six months ended December 31, 2018 decreased \$359,214 to \$-0- from \$359,214 for the six months ended December 31, 2017. The decreases in amortization are a result of the redemption of the Company's Series C Debenture on November 13, 2017. The Company recorded an extinguishment loss of (\$1,348,247) on the redemption of the Series C Debenture on November 13, 2017 for the three and six months ended December 31, 2017.

**Change in fair value of derivative**– Change in fair value of derivative for the three months ended December 31, 2018 decreased \$977,761 to \$122,541 from \$1,100,302 for the three months ended December 31, 2017. Change in fair value of derivative for the six months ended December 31, 2018 decreased \$1,367,059 to \$298,092 from \$1,665,151 for the six months ended December 31, 2017.

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

**Net Loss** - For the three months ended December 31, 2018, the Company had a net loss of (\$2,230,992), or \$ (\$0.03) per share on a fully diluted basis compared to a net loss of (\$2,796,894) or (\$0.04) per share on a fully diluted basis for the three months ended December 31, 2017. The decrease in the reported loss for the three-month period ended December 31, 2018 is attributable mainly to a decrease in operating expenses of approximately \$25,000, and a decrease of expenses related to the Company's convertible debenture which was redeemed on November 13, 2017. These decreased expenses were offset by a decrease in the gain on the change in fair value of derivative for the three months ended December 31, 2018 of \$977,761. Additionally the cost of compensation paid in Company securities was reduced. For the six months ended December 31, 2018, the Company had a net loss of (\$4,072,455), or \$ (\$0.06) per share on a fully diluted basis compared to a net loss of (\$4,802,449) or (\$0.08) per share on a fully diluted basis for the six months ended December 31, 2017. The decrease in the reported loss for the six-month period ended December 31, 2018 is attributable mainly to a decrease in operating expenses of approximately \$216,000, and a decrease of expenses related to the Company's convertible debenture which were redeemed on November 13, 2017. These decreased expenses were offset by a decrease in the gain on the change in fair value of derivative for the six months ended December 31, 2018 of \$1,367,059. Additionally the cost of compensation paid in Company securities was reduced. The Company recorded a loss of (\$1,348,247) on the redemption of the Series C Debenture for the three and six months ended December 31, 2017. No loss on the redemption was recognized for the three and six months ended December 31, 2018.

### *Liquidity and Capital Reserves*

The Company had cash and cash equivalents of \$3,903,672 as of December 31, 2018 and current liabilities of \$1,163,660, inclusive of account payables of \$800,830 to a related party, TheraCour Pharma, Inc.

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 approximately \$87,765,000 at December 31, 2018.

Management is actively exploring additional required funding through debt or equity financing pursuant to its plan. 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 the Company's existing resources and access to the capital markets will permit the Company to fund planned operations and expenditures. However, management believes that the current available funds are insufficient for the Company's projected work, which is beyond normal pre-clinical development operations, leading toward an Investigational New Drug Application (IND) filing with the U.S. Food and Drug Administration (FDA), to continue. The Company, therefore, has engaged investment banks to advise it as to raising further funding as the Company progresses towards human clinical trials. The Company believes that it can adjust its business plan according to its available resources. Further, the Company believes that it will be able to raise additional funding at an opportune time as it progresses towards human clinical trials. 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. Further, the Company cannot provide assurances that it will continue as a going concern or be able to raise additional funding in a timely manner, and if it can, that it will be on terms favorable for the Company's current shareholders. The accompanying unaudited financial statements do not include any adjustments that may result from the outcome of such unidentified uncertainties.

While the Company continues to incur significant operating losses with significant capital requirements, the Company has been able to finance its business through sale of its securities. The Company has in the past adjusted its priorities and goals in line with the cash on hand and capital availability. The Company believes it can adjust its priorities of drug development and its plan of operations as necessary, if it is unable to raise additional funds.

We anticipate undertaking additional expenditures towards the goal of filing at least one Investigational New Drug application (IND) with the US FDA or another regulatory agency. We anticipate that we will need to raise additional funds to support these activities as well as the human clinical trials that would follow. Further development of other drug candidates in our drug pipeline will depend upon the availability of appropriate levels of additional funding. The Company believes it will continue to be able to successfully raise financing as needed. If we are unable to obtain

additional financing, our business plan will be significantly delayed.

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

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

Management intends to use capital and debt financing, as required, to fund the Company’s operations. 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 three and six months ended December 31, 2018.

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

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

#### ITEM 4. CONTROLS AND PROCEDURES

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

As of December 31, 2018, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(f) under the Securities Exchange Act of 1934). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that the Company’s disclosure controls and procedures were not effective as of December 31, 2018, due to material weaknesses in internal control described in Part II, Item 9A of our 10-K for the fiscal year ended June 30, 2018. These material weaknesses remain unremediated as of December 31, 2018.

##### *Management’s Report on Internal Control Over Financial Reporting*

##### *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 December 31, 2018 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.



*Remediation Plan*

We are remediating the material weaknesses by, among other things, implementing a process of enhanced review of all financial transactions. The actions that we are taking are subject to ongoing senior management review and Audit Committee oversight.

Effective September 1, 2018, the Company has appointed Dr. Irach Taraporewala as Chief Executive Officer, an experienced pharmaceutical industry executive, to provide additional management review of financial reporting and the period-end closing processes identified. Subsequent to the reporting period, as of February 1, 2019, Dr. Taraporewala has resigned for personal reasons. As such, the period-end closing reviews will be conducted by Mr. Stan Glick, Chairman of the Audit Committee of our Board of Directors.

The Company will provide additional training and development classes for management, accounting and finance staff regarding current changes in accounting for income taxes and deferred income taxes, pursuant to ASC 740, to enhance their current skills and understanding of the components of deferred taxation and accounting for income taxes.

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

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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

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

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

On 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 525,000 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.

For the three and six months ended December 31, 2018, the Company's Board of Directors authorized the issuance of 7,716 and 15,432, respectively, fully vested shares of its Series A Convertible Preferred stock for employee compensation.

For the three months ended December 31, 2018, the Scientific Advisory Board (SAB) was granted fully vested warrants to purchase 11,432 shares of common stock with an exercise price of \$.41 per share expiring in November 2022. For the six months ended December 31, 2018, the SAB was granted fully vested warrants to purchase 11,432 shares of common stock with an exercise price of \$.41 per share expiring in August 2022 and 11,432 fully vested warrants to purchase shares of common stock with an exercise price of \$.41 per share expiring in November 2022.

For the three and six months ended December 31, 2018, the Company's Board of Directors authorized the issuance of 83,943 and 275,453, respectively, fully vested shares of its common stock with a restrictive legend for consulting services. The Company recorded an expense of \$27,000 and \$106,460 for the three and six months ended December 31, 2018, respectively, which was the fair value on the dates of issuance.

For the three and six months ended December 31, 2018, the Company's Board of Directors authorized the issuance of 34,851 and 54,161, respectively, fully vested shares of its common stock with a restrictive legend for Director Services.

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

None.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **ITEM 5. OTHER INFORMATION**

### **- Subsequent Events**

Management performed an evaluation of the Company's activity through the date these financials were issued to determine if they must be reported. The Company determined that there were certain reportable subsequent events to be disclosed as follows:

On January 24, 2019, Irach Taraporewala resigned as the Chief Executive Officer of NanoViricides, Inc. (the "Company") for personal reasons. Also on that date, the Company and Mr. Taraporewala agreed that Mr. 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 Mr. Taraporewala entered into a Confidential Separation and Consulting Agreement and General Release (the "Agreement") pursuant to which the Company will pay Mr. Taraporewala monthly consulting payments of three thousand dollars (\$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 Registrant, obligations of confidentiality, non-disclosure, non-disparagement and other customary provisions found in similar agreements.

**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.

**NANOIRICIDES, INC.**

/s/ Anil R. Diwan

Dated: February 14, 2019 Name: Anil R. Diwan  
Title: President, Chairman of the Board  
(Principal Executive Officer)

/s/ Meeta Vyas

Dated: February 14, 2019 Name: Meeta Vyas  
Title: Chief Financial Officer  
(Principal Financial Officer)