

ONCOLYTICS BIOTECH INC

Form 6-K

November 04, 2004

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**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 6-K**

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

For the month of November

Commission File Number 000-31062

**Oncolytics Biotech Inc.**

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*(Translation of registrant's name into English)*

**Suite 210, 1167 Kensington Crescent NW  
Calgary, Alberta, Canada T2N 1X7**

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*(Address of principal executive offices)*

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's home country), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If  Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82 - \_\_\_\_\_

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Oncolytics Biotech Inc.**  
(Registrant)

Date: November 3, 2004

By: /s/ Doug Ball, CFO

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Doug Ball, CFO  
Chief Financial Officer

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210, 1167 Kensington Cr. N.W  
Calgary, Alberta  
Canada T2N 1X7

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**FOR IMMEDIATE RELEASE**

**Oncolytics Biotech Inc. Announces 2004 Third Quarter Results**

**CALGARY, AB, November 4, 2004** Oncolytics Biotech Inc. ( Oncolytics ) (TSX:ONC, NASDAQ:ONCY) today announced its financial results for the three and nine-month periods ending September 30, 2004.

The current clinical program for REOLYSIN<sup>®</sup> includes a Phase I systemic administration trial in the United Kingdom, and a Phase I/II recurrent malignant glioblastoma trial in Canada. Enrolment is continuing as expected in the Phase I systemic administration trial at the Royal Marsden Hospital, and the Company added a second clinical site at St. George's Hospital in London.

The Company also announced a poster presentation at the 16<sup>th</sup> EORTC-NCI-AACR 2004 Symposium entitled "The oncolytic reovirus, REOLYSIN<sup>®</sup>, augments the anticancer effects of cytotoxic agents in vitro against the ras-mutated human colon cancer cell line HCT 116." The data will be helpful in designing future clinical studies.

Oncolytics continues to prepare for the expected expansion of the human clinical program by working with manufacturing suppliers to ensure that supplies of REOLYSIN<sup>®</sup> are available.

The Company continues to implement a step-wise approach to developing REOLYSIN<sup>®</sup> as a potential cancer therapeutic, said Dr. Brad Thompson, President and CEO of Oncolytics.

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This discussion and analysis should be read in conjunction with the unaudited financial statements of Oncolytics Biotech Inc. ( Oncolytics or the Company ) as at and for the three and nine months ended September 30, 2004 and 2003, and should also be read in conjunction with the audited financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations ( MD&A ) contained in Oncolytics' annual report for the year ended December 31, 2003. The financial statements have been prepared in accordance with Canadian generally accepted accounting principles ( GAAP ).

**FORWARD-LOOKING STATEMENTS**

*The following discussion contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company's belief as to the potential of REOLYSIN<sup>®</sup> as a cancer therapeutic, the Company's expectation regarding the adequacy of its existing capital resources, and the Company's expectations as to the success of its research and development programs in 2004 and beyond, future financial position, business strategy and plans for future operations, and statements that are not historical facts, involve known and unknown risks and uncertainties, which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN<sup>®</sup> as a cancer treatment, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN<sup>®</sup>, uncertainties related to the research and development of pharmaceuticals, uncertainties*

*related to competition, changes in technology, the regulatory process and general*

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*changes to the economic environment. Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Forward-looking statements are based on assumptions, projections, estimates and expectations of management at the time such forward looking statements are made, and such assumptions, projections, estimates and/or expectations could change or prove to be incorrect or inaccurate. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements except as required by law.*

## **OVERVIEW**

### **Oncolytics Biotech Inc. is a Development Stage Company**

Since its inception in April of 1998, Oncolytics has been a development stage company and has focused its research and development efforts on the development of REOLYSIN®, its potential cancer therapeutic. The Company has not been profitable since its inception and expects to continue to incur substantial losses from its research and development. The Company does not expect to generate significant revenues until, if and when, its cancer product becomes commercially viable.

### **General Risk Factors**

Prospects for biotechnology companies in the research and development stage should generally be regarded as speculative. It is not possible to predict, based upon studies in animals, or early studies in humans, whether a new therapeutic will ultimately prove to be safe and effective in humans, or whether necessary and sufficient data can be developed through the clinical trial process to support a successful product application and approval.

If a product is approved for sale, product manufacturing at a commercial scale and significant sales to end users at a commercially reasonable price may not be successful. There can be no assurance that the Company will generate adequate funds to continue development, or will ever achieve significant revenues or profitable operations. Many factors (e.g. competition, patent protection, appropriate regulatory approvals) can influence the revenue and product profitability potential.

In developing a product for approval, the Company will rely upon its employees, contractors, consultants and collaborators and other third party relationships, including the ability to obtain appropriate product liability insurance. There can be no assurance that these reliances and relationships will continue as required. In addition to developmental and operational considerations, market prices for securities of biotechnology companies generally are volatile, and may or may not move in a manner consistent with the progress being made by the Company.

### **Highlights**

During the third quarter of 2004, the Company's net loss and cash usage from operating activities was \$3,096,042 and \$1,820,118 respectively compared to \$1,822,703 and \$1,243,976 respectively for the third quarter of 2003. The increase in the Company's net loss reflects the increase in its research and development activity in 2004 compared to 2003. Specifically, manufacturing and related process development expenses increased in the third quarter of 2004 compared to 2003 as the Company continues to increase its production of REOLYSIN® in order to supply its clinical trial program. Clinical trial expenses increased in the third quarter of 2004 compared to 2003 reflecting the ongoing patient enrollment in the Company's systemic (intravenous) delivery clinical trial in the United Kingdom ( U.K. ) and the addition of a second U.K. trial site. Also, the Company's pre-clinical trial and research collaboration expenses increased in support of future clinical trial applications that include other jurisdictions and methods of application and future expansion of its intellectual property base. Finally, the Company entered into an agreement with one of the



non-management founding shareholders that cancelled a portion of its future contingent payment obligations. As a result, the Company's future contingent payment obligations have been reduced by 17.60%.

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The difference between the Company's net loss and cash usage from operating activities reflects non-cash charges associated with amortization, stock based compensation, foreign exchange loss, gains and losses from the sale of investments and the non-cash component of the royalty buy back.

The Company continues to receive cash proceeds from the exercise of warrants from previously closed financings. In the third quarter of 2004, \$673,080 was received from the exercise of warrants and \$3,813 was received from the exercise of stock options. During the nine months ended September 30, 2004, the Company received additional cash proceeds from a private placement of \$6,223,763, from warrants of \$3,973,119 and from stock options of \$744,795 for a total from financing activities of \$10,941,677. The Company exited the third quarter of 2004 with cash and short-term investments of \$23,805,685 compared to \$20,752,735 as at December 31, 2003.

**THIRD QUARTER RESULTS OF OPERATIONS**  
**(for the three months ended September 30, 2004 and 2003)**

Net loss for the three month period ended September 30, 2004 was \$3,096,042 compared to \$1,822,703 for 2003. The increase in the Company's net loss in the third quarter of 2004 was due to increases in the Company's operating activities as follows:

**Research and Development Expenses ( R&D )**

|  | <b>2004</b>      | <b>2003</b> |
|--|------------------|-------------|
|  | <b>\$</b>        | <b>\$</b>   |
|  | <hr/>            | <hr/>       |
| Manufacturing and related process development expenses     | <b>1,152,718</b> | 581,520     |
| Clinical trial expenses                                    | <b>184,347</b>   | 10,258      |
| Pre-clinical trial expenses and research collaborations    | <b>181,397</b>   | 100,351     |
| Cancellation of contingent payment obligation              | <b>400,000</b>   |             |
| Quebec scientific research and development ( SRED ) refund |                  | (222,000)   |
| Other R&D expenses   | <b>313,919</b>   | 253,424     |
|  | <hr/>            | <hr/>       |
| Research and development expenses                          | <b>2,232,381</b> | 723,553     |
|  | <hr/>            | <hr/>       |

For the third quarter of 2004, R&D increased to \$2,232,381 compared to \$723,553 for the third quarter of 2003. The increase in R&D was due to the following:

***Manufacturing & Related Process Development***

The Company's manufacturing and related process development expenses increased to \$1,152,718 compared to \$581,520 for the third quarter of 2003. The increase in the third quarter of 2004 relates to the Company's continued focus on the production of REOLYSIN® in order to supply its R&D activity. As well, additional process development costs were incurred relating to the technology transfer and set up costs associated with the Company's second manufacturer.

***Clinical Trial Programs***

The Company's clinical trial expenses increased to \$184,347 in the third quarter of 2004 compared to \$10,258 for the third quarter of 2003. The increase in the third quarter of 2004 relates to the Company's patient enrolment in and supporting its systemic (intravenous) delivery clinical trial in the United Kingdom and costs associated with establishing a second clinical trial site for the systemic study.

***Pre-Clinical Trial Expenses and Research Collaborations***

During the third quarter of 2004, the Company's pre-clinical trial expenses and research collaborations increased to \$181,397 compared to \$100,351 for the third quarter of 2003. Pre-clinical trial costs include toxicology and equivalency studies that are performed in support of future clinical trial applications. Research collaboration expenses include costs associated with collaborations that are intended to expand the Company's intellectual

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property base and identify potential licensing opportunities arising from the Company's technology base. These types of pre-clinical studies and research collaborations were limited in the third quarter of 2003.

***Cancellation of Contingent Payment Obligation***

On September 23, 2004, the Company reached an agreement that cancelled a portion of its future contingent obligation to one of its non-management founding shareholders for consideration of \$400,000. The consideration paid included cash of \$250,000 and non-cash consideration of 21,459 common shares valued at \$150,000 and was recorded as additional research and development expense. The value of the common shares was based on the September 23, 2004 closing price of \$6.99. As a result, the Company's future contingent payment obligations have been reduced by 17.60% to 11.75% (14.25% prior to the cancellation payment) of payments received associated with a partnership or other arrangement for development. Similarly, if the Company develops the reovirus treatment to the point where it may be marketed at a commercial level, the payment referred to in the foregoing sentence has been amended to a royalty payment of 2.35% (2.85% prior to the cancellation payment) of Net Sales received by the Company for such products.

***Quebec SRED Refund***

The Company recorded a Quebec SRED refund in the third quarter of 2003 of \$222,000 relating to research and development expenses incurred in 2001 in the Canadian province of Quebec. The Company filed its 2002 refund claim of \$33,905 in the fourth quarter of 2003 and its 2003 refund claim of \$23,940 in the second quarter of 2004.

**Operating Expenses**

|   | <b>2004</b>    | <b>2003</b> |
|---|----------------|-------------|
|   | <b>\$</b>      | <b>\$</b>   |
|   | <hr/>          | <hr/>       |
| Salary, insurance and other office expenses | <b>364,717</b> | 349,025     |
| Public company and other operating expenses | <b>200,749</b> | 244,529     |
|   | <hr/>          | <hr/>       |
|   | <b>565,466</b> | 593,554     |
|   | <hr/>          | <hr/>       |

For the third quarter of 2004, the Company's operating expenses decreased to \$565,466 compared to \$593,554 for the third quarter of 2003. The timing of professional fees contributed to the decrease in public company and other operating costs in the third quarter of 2004. The slight overall change reflects the fact that a majority of these costs are contractually fixed in nature and the Company has not had to increase its administrative costs to support the increase in its research and development activity.

**Stock Based Compensation**

| <b>2004</b> | <b>2003</b> |
|-------------|-------------|
| <b>\$</b>   | <b>\$</b>   |
| <hr/>       | <hr/>       |

|                          |               |         |
|--------------------------|---------------|---------|
| Stock based compensation | <b>48,878</b> | 437,554 |
|--------------------------|---------------|---------|

Stock based compensation recorded in the third quarter of 2004 related to previously granted options that vested in this quarter and options granted to consultants. During the third quarter of 2003, the Company recorded stock based compensation of \$437,554 associated with the granting of stock options to its employees, directors, and certain consultants.

**Foreign Exchange Loss**

|                       | <b>2004</b>    | <b>2003</b> |
|-----------------------|----------------|-------------|
|                       | <b>\$</b>      | <b>\$</b>   |
| Foreign exchange loss | <b>239,881</b> | 861         |

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The Company acquires investments in foreign currency to pay for anticipated expenses that are to be incurred in the United States ( U.S. ) and the United Kingdom ( U.K. ). These investments have provided better yields than their counterpart Canadian investments. As a result of recent movements in the U.S. and U.K. exchange rates the Company recorded a non-cash loss of \$239,881 for the three month period ending September 30, 2004.

**YEAR TO DATE RESULTS OF OPERATIONS**  
**(for the nine months ended September 30, 2004 and 2003)**

Net loss for the nine month period ended September 30, 2004 was \$8,964,166 compared to \$6,848,490 for 2003. The increase in the Company's net loss was due to the following:

**Research and Development Expenses ( R&D )**

|  | <b>2004</b>      | <b>2003</b> |
|--|------------------|-------------|
|  | <b>\$</b>        | <b>\$</b>   |
| Manufacturing and related process development expenses     | <b>3,339,895</b> | 1,112,598   |
| Clinical trial expenses                                    | <b>436,542</b>   | 56,703      |
| Pre-clinical trial expenses and research collaborations    | <b>735,461</b>   | 238,316     |
| Cancellation of contingent payment obligation              | <b>400,000</b>   |             |
| Quebec scientific research and development ( SRED ) refund | <b>(23,940)</b>  | (222,000)   |
| Other R&D expenses   | <b>794,754</b>   | 866,292     |
|  | <b>5,682,712</b> | 2,051,909   |

For the nine month period ending September 30, 2004, R&D increased to \$5,682,712 compared to \$2,051,909 for 2003. The increase in R&D was due to the following:

***Manufacturing & Related Process Development***

During the later half of 2003 and throughout 2004 the Company's focus has been on the production of REOLYSIN® in order to supply its existing and planned R&D activity. As well, the Company has taken steps to mitigate the risk of economic dependence associated with having had only one supplier of REOLYSIN®. Consequently, for the nine month period ending September 30, 2004, almost 72% of the Company's manufacturing and related process development expenses incurred related to the production of REOLYSIN® compared to only 51% for the same period in 2003. The Company's manufacturing expenses in 2004 also include technology transfer and set up costs associated with the addition of a second supplier which is expected to be completed by the end of 2004.

The remaining manufacturing and related process development costs incurred in 2004 and 2003 relate to process development. During the first nine months of 2003 the Company was completing the development of its manufacturing process and also developing its viral and cell banks. Consequently, 49% of the Company's manufacturing and related process development expenses incurred in 2003 related to these activities compared to only 28% in 2004.

For the remainder of 2004 and into 2005, the Company expects that it will continue to produce REOLYSIN® and that a majority of these costs will relate directly to manufacturing. As well, future manufacturing costs may be impacted by the need to supply additional clinical trials to be run by the Company as well as by the U.S. National Cancer Institute and to continue to supply future pre-clinical trial studies and research collaborations.

***Clinical Trial Programs***

The Company's clinical trial expenses increased to \$436,542 for the nine month period ending September 30, 2004 compared to \$56,703 in 2003. The increase in clinical trial expenses relates mainly to the costs associated with the Company's systemic (intravenous) delivery clinical trial in the United Kingdom which now includes a second trial site. The Company also continues to incur expenses related to the Canadian malignant glioma clinical trial.

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For the remainder of 2004, the Company expects that clinical trial expenses will continue to be incurred as enrolment continues in the systemic (intravenous) delivery clinical trial for two clinical trial sites. As well, the Company expects that its clinical trial costs may increase as it continues to expand its clinical trial program into other jurisdictions.

***Pre-Clinical Trial and Research Collaboration Expenses***

The Company's pre-clinical trial expenses and research collaboration expenses increased to \$735,461 for the nine month period ending September 30, 2004 compared to \$238,316 in 2003. Pre-clinical costs include toxicology studies and are incurred by the Company in support of expanding its clinical trial program into other jurisdictions and other applications. Research collaborations are intended to expand the Company's intellectual property related to reovirus and other viruses and identify potential licensing opportunities arising from the Company's technology base.

**Operating Expenses**

|   | <b>2004</b>      | <b>2003</b> |
|---|------------------|-------------|
|   | <b>\$</b>        | <b>\$</b>   |
| Salary, insurance and other office expenses | <b>1,087,756</b> | 854,919     |
| Public company and other operating expenses | <b>1,025,127</b> | 966,147     |
|   | <b>2,112,883</b> | 1,821,066   |

For the nine month period ending September 30, 2004, the Company's operating expenses increased to \$2,112,883 compared to \$1,821,066 for the nine month period ending September 30, 2003. Salary, insurance and other office expenses increased to \$1,087,756 for the nine month period ending September 30, 2004 from \$854,919 in 2003 due to the increase in staff levels and insurance premiums that commenced in the second quarter of 2003. Public company and other operating costs increased to \$1,025,127 for the nine month period ending September 30, 2004 from \$966,147 in the first nine months of 2003 reflecting the increased costs associated with the preparation of the Company's annual filings, annual general meeting and shareholder mail outs plus additional expenses incurred in investor relations and business development.

**Stock Based Compensation**

|                          | <b>2004</b>    | <b>2003</b> |
|--------------------------|----------------|-------------|
|                          | <b>\$</b>      | <b>\$</b>   |
| Stock based compensation | <b>788,974</b> | 506,343     |

Stock based compensation recorded during the nine month period ending September 30, 2004 increased to \$788,974 compared to \$506,343 for the nine month period ending September 30, 2003 associated with the granting of stock options to its employees, directors, and certain consultants.



**Foreign Exchange Loss**

|                       | <b>2004</b>    | <b>2003</b> |
|-----------------------|----------------|-------------|
|                       | <b>\$</b>      | <b>\$</b>   |
| Foreign exchange loss | <b>353,964</b> | 9,662       |

The Company acquires investments in foreign currency to pay for anticipated expenses that are to be incurred in the United States ( U.S. ) and the United Kingdom ( U.K. ). These investments have provided better yields than their counterpart Canadian investments. As a result of recent movements in the U.S. and U.K. exchange rates the Company recorded a non-cash loss of \$353,964 for the nine month period ending September 30, 2004.

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|  | <b>2004</b>   | <b>2003</b>      |
|--|---------------|------------------|
|  | <b>\$</b>     | <b>\$</b>        |
| Gain on sale of investment in BCY LifeSciences Inc. ( BCY )        | <b>34,185</b> | <b>—</b>         |
| Loss on sale of investment in Transition Therapeutics Inc. ( TTH ) | <b>—</b>      | <b>2,156,685</b> |

For the nine month period ending September 30, 2004 the Company sold 697,945 common shares of BCY for net cash proceeds of \$133,609. This resulted in a net accounting gain of \$34,185 after a write down of \$12,817. As at September 30, 2004, the Company owned 200,000 common share of BCY with an estimated market value of \$12,000. These remaining shares are held in escrow and will be released over the next two years.

For the nine month period ending September 30, 2003, the Company sold its investment in TTH for net cash proceeds of \$2,552,695 resulting in a recorded loss of \$2,156,685.

**Commitments**

As at September 30, 2004, the Company has committed to payments totaling \$283,000 for activities primarily related to product manufacturing, product development and continued pre-clinical trial related work. The Company anticipates that these committed payments will occur in 2004. All of these committed payments are considered to be part of the Company's normal course of business.

**LIQUIDITY AND CAPITAL RESOURCES****Liquidity**

As at September 30, 2004, the Company had cash of \$23,805,685 (including cash, cash equivalents and short-term investments) and a working capital position of \$22,884,144 compared to \$20,752,735 and \$20,088,868 respectively as at December 31, 2003. During the third quarter of 2004, the Company continued to receive cash proceeds from the exercise of warrants from previously closed financings of \$673,080 for total cash proceeds for the nine month period from the exercise of warrants of \$3,973,119. For the nine month period ending September 30, 2004, the Company has received a net amount of \$10,941,677 which includes the proceeds from warrants, options and a private placement. This increase in the Company's cash position has been offset by cash outflows from operating activities of \$6,951,991 and purchases of intellectual property and other assets of \$775,110.

The Company desires to maintain adequate cash and short-term investment reserves to support its planned activities which include its clinical trial program, production manufacturing, and its intellectual property expansion and protection as well as administrative activities. The Company believes that its existing capital resources are adequate to fund its current plans for research and development activities into 2007 without presuming the further exercise of outstanding warrants and options. In the event that the Company chooses to seek additional capital, the Company will look to fund additional capital requirements through the issue of additional equity as well as potential partnering or licensing opportunities. The Company recognizes the challenges and uncertainty inherent in the capital markets and

the potential difficulties it might face in today's environment. Market prices for securities in biotechnology companies are volatile and the ability to raise funds will be dependent on a number of factors, including the progress of R&D, availability of clinical trial information, and general market conditions.

**Capital Expenditures**

During the nine month period ending September 30, 2004, the Company spent \$766,317 on intellectual property compared to \$892,532 in 2003. The difference relates to variances in filing fees on existing patent applications.

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The following unaudited quarterly information is presented in thousands of dollars except for per share amounts:

|  | 2004                 |                     |                      | 2003                |                |                     | 2002           |                |
|--|----------------------|---------------------|----------------------|---------------------|----------------|---------------------|----------------|----------------|
|  | Sept. <sup>(2)</sup> | June <sup>(2)</sup> | March <sup>(2)</sup> | Dec. <sup>(2)</sup> | Sept.          | June <sup>(2)</sup> | March          | Dec.           |
| <b>Revenue<sup>(1)</sup></b>                 | <b>194</b>           | <b>183</b>          | <b>117</b>           | <b>127</b>          | <b>102</b>     | <b>41</b>           | <b>43</b>      | <b>44</b>      |
| <b>Net loss<sup>(3)</sup></b>                | <b>3,096</b>         | <b>3,192</b>        | <b>2,676</b>         | <b>1,696</b>        | <b>1,823</b>   | <b>3,911</b>        | <b>1,114</b>   | <b>1,542</b>   |
| <b>Loss per common share<sup>(3)</sup></b>   | <b>\$ 0.11</b>       | <b>\$ 0.11</b>      | <b>\$ 0.10</b>       | <b>\$ 0.06</b>      | <b>\$ 0.07</b> | <b>\$ 0.17</b>      | <b>\$ 0.05</b> | <b>\$ 0.07</b> |
| <b>Total assets<sup>(4), (6)</sup></b>       | <b>29,471</b>        | <b>31,221</b>       | <b>25,435</b>        | <b>26,051</b>       | <b>21,532</b>  | <b>18,815</b>       | <b>16,702</b>  | <b>17,968</b>  |
| <b>Total cash<sup>(5), (6)</sup></b>         | <b>23,806</b>        | <b>25,522</b>       | <b>20,298</b>        | <b>20,753</b>       | <b>15,843</b>  | <b>13,486</b>       | <b>6,887</b>   | <b>8,319</b>   |
| <b>Total long-term debt<sup>(7)</sup></b>    | <b>150</b>           | <b>150</b>          | <b>150</b>           | <b>150</b>          | <b>150</b>     | <b>150</b>          | <b>150</b>     | <b>150</b>     |
| <b>Cash dividends declared<sup>(8)</sup></b> | <b>Nil</b>           | <b>Nil</b>          | <b>Nil</b>           | <b>Nil</b>          | <b>Nil</b>     | <b>Nil</b>          | <b>Nil</b>     | <b>Nil</b>     |

(1) Revenue is comprised of interest income.

(2) Included in net loss and net loss per share in March 2004 and December 2003 is a gain on sale of investment of \$47,648 and \$264,453 respectively and in September 2004, June 2004 and 2003 is a loss from sale of investments of \$12,817, \$646 and \$2,156,685 respectively.

(3) Included in net loss and net loss per share for 2002 is a future income tax recovery of \$647,618 (2004 and 2003 nil).

(4) Subsequent to the acquisition of the Company by SYNSORB in April 1999, the Company applied push down accounting. See note 2 to the audited financial statements for 2003.

(5) Included in total cash are cash, cash equivalents and short-term investments.

(6) The Company issued 2,332,730 common shares for cash proceeds of \$10,941,677 in 2004 (2003 5,062,978 common shares for \$16,004,981 and 2002 1,040,000 common shares for \$1,803,877).

(7) The long-term debt recorded in 2004, 2003 and 2002 represents repayable loans from the Alberta Heritage Foundation.

(8) The Company has not declared or paid any dividends since incorporation.

**OTHER MD&A REQUIREMENTS**

The Company has 29,639,335 common shares outstanding at November 2, 2004. If all of the Company's warrants and options were exercised the Company would have 35,296,536 common shares outstanding.

**Table of Contents****Oncolytics Biotech Inc.****BALANCE SHEETS**

As at,

|  | September 30,<br>2004<br>\$<br>(unaudited) | December 31,<br>2003<br>\$<br>(audited)* |
|--|--|--|
| <b>ASSETS</b>  |  |  |
| <b>Current</b>   |  |  |
| Cash and cash equivalents  | 2,500,897                                  | 2,641,127                                |
| Short-term investments   | 21,304,788                                 | 18,111,608                               |
| Accounts receivable  | 48,585                                     | 64,224                                   |
| Prepaid expenses   | 403,625                                    | 156,837                                  |
|  | <hr/>                                      | <hr/>                                    |
|  | 24,257,895                                 | 20,973,796                               |
| <b>Capital assets</b>  | 5,201,313                                  | 4,965,379                                |
| <b>Investments [note 2]</b>  | 12,000                                     | 111,425                                  |
|  | <hr/>                                      | <hr/>                                    |
|  | 29,471,208                                 | 26,050,600                               |
|  | <hr/>                                      | <hr/>                                    |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>                                     |  |  |
| <b>Current</b>   |  |  |
| Accounts payable and accrued liabilities                                       | 1,373,751                                  | 884,928                                  |
|  | <hr/>                                      | <hr/>                                    |
| <b>Alberta Heritage Foundation loan</b>  | 150,000                                    | 150,000                                  |
|  | <hr/>                                      | <hr/>                                    |
| <b>Shareholders equity</b>   |  |  |
| Share capital [note 4]   |  |  |
| Authorized: unlimited  |  |  |
| Issued: 29,562,451 common shares (December 31, 2003) 27,208,262 common shares) | 55,241,253                                 | 44,712,589                               |
| Warrants [note 4]  | 2,195,418                                  | 1,598,250                                |
| Contributed surplus  | 4,469,544                                  | 3,699,425                                |
| Deficit  | (33,958,758)                               | (24,994,592)                             |
|  | <hr/>                                      | <hr/>                                    |
|  | 27,947,457                                 | 25,015,672                               |

|                   |                   |
|-------------------|-------------------|
| <u>29,471,208</u> | <u>26,050,600</u> |
|-------------------|-------------------|

*See accompanying notes*

\* Derived from the December 31, 2003 audited financial statements

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## Oncolytics Biotech Inc.

## STATEMENTS OF LOSS AND DEFICIT

|   | Nine Month<br>Period<br>Ending<br>September<br>30,<br>2004<br>\$<br>(unaudited) | Nine Month<br>Period<br>Ending<br>September<br>30,<br>2003<br>\$<br>(unaudited) | Three Month<br>Period<br>Ending<br>September<br>30,<br>2004<br>\$<br>(unaudited) | Three Month<br>Period<br>Ending<br>September<br>30,<br>2003<br>\$<br>(unaudited) | Cumulative<br>from<br>inception<br>on April 2,<br>1998 to<br>September<br>30,<br>2004<br>\$<br>(unaudited) |
|---|---|---|--|--|--|
| <b>Revenue</b>  |   |   |  |  |  |
| Rights revenue  |   |   |  |  | 310,000  |
| Interest income   | <b>494,816</b>  | 186,608   | <b>194,001</b>   | 102,082  | 2,580,799  |
|   | <b>494,816</b>  | 186,608   | <b>194,001</b>   | 102,082  | 2,890,799  |
| <b>Expenses</b>   |   |   |  |  |  |
| Research and development <i>[note 3]</i>  | <b>5,682,712</b>  | 2,051,909   | <b>2,232,381</b>   | 723,553  | 22,101,242   |
| Operating   | <b>2,112,883</b>  | 1,821,066   | <b>565,466</b>   | 593,554  | 9,315,008  |
| Stock based compensation  | <b>788,974</b>  | 506,343   | <b>48,878</b>  | 437,554  | 1,818,399  |
| Foreign exchange loss   | <b>353,964</b>  | 9,662   | <b>239,881</b>   | 861  | 355,866  |
| Amortization  | <b>554,476</b>  | 488,491   | <b>190,620</b>   | 169,551  | 2,464,566  |
|   | <b>9,493,009</b>  | 4,877,471   | <b>3,277,226</b>   | 1,925,073  | 36,055,081   |
| <b>Loss before the following:<br/>(Gain) loss on sale and write<br/>down of BCY LifeSciences Inc.<br/><i>[note 2]</i></b> | <b>8,998,193</b>  | 4,690,863   | <b>3,083,225</b>   | 1,822,991  | 33,164,282   |
| <b>Loss on sale of Transition<br/>Therapeutics Inc.</b>   | <b>(34,185)</b>   |   | <b>12,817</b>  |  | (298,638)  |
|   |   | 2,156,685   |  |  | 2,156,685  |
| <b>Loss before taxes</b>  | <b>8,964,008</b>  | 6,847,548   | <b>3,096,042</b>   | 1,822,991  | 35,022,329   |
| <b>Capital tax (recovery)</b>   | <b>158</b>  | 942   |  | (288)  | 51,429   |
| <b>Future income tax recovery</b>   |   |   |  |  | (1,115,000)  |
| <b>Net loss for the period</b>  | <b>8,964,166</b>  | 6,848,490   | <b>3,096,042</b>   | 1,822,703  | 33,958,758   |

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|  |                          |                   |                          |                   |                             |
|--|--------------------------|-------------------|--------------------------|-------------------|-----------------------------|
| <b>Deficit, beginning of period</b>      | <b><u>24,994,592</u></b> | <u>16,450,561</u> | <b><u>30,862,716</u></b> | <u>21,476,348</u> | <u>                    </u> |
| <b>Deficit, end of period</b>            | <b><u>33,958,758</u></b> | <u>23,229,051</u> | <b><u>33,958,758</u></b> | <u>23,299,051</u> | <u>33,958,758</u>           |
| <b>Basic and diluted loss per share</b>  | <b><u>0.31</u></b>       | <u>0.29</u>       | <b><u>0.11</u></b>       | <u>0.07</u>       |                             |
| <b>Weighted average number of shares</b> | <b><u>28,552,643</u></b> | <u>23,314,397</u> | <b><u>29,448,859</u></b> | <u>25,120,758</u> |                             |

*See accompanying notes*

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## Oncolytics Biotech Inc.

## STATEMENTS OF CASH FLOWS

|  | Nine Month<br>Period<br>Ending<br>September<br>30,<br>2004<br>\$<br>(unaudited) | Nine Month<br>Period<br>Ending<br>September<br>30,<br>2003<br>\$<br>(unaudited) | Three Month<br>Period<br>Ending<br>September<br>30,<br>2004<br>\$<br>(unaudited) | Three Month<br>Period<br>Ending<br>September<br>30,<br>2003<br>\$<br>(unaudited) | Cumulative<br>from<br>inception<br>on April 2,<br>1998 to<br>September<br>30,<br>2004<br>\$<br>(unaudited) |
|--|---|---|--|--|--|
| <b>OPERATING ACTIVITIES</b>  |   |   |  |  |  |
| Net loss for the period  | <b>(8,964,166)</b>  | (6,848,490)   | <b>(3,096,042)</b>   | (1,822,703)  | (33,958,758)   |
| Deduct non-cash items  |   |   |  |  |  |
| Amortization   | <b>554,476</b>  | 488,491   | <b>190,620</b>   | 169,551  | 2,464,566  |
| Non-cash compensation  | <b>788,974</b>  | 506,343   | <b>48,878</b>  | 437,554  | 1,818,399  |
| Foreign exchange loss  | <b>353,964</b>  | 9,662   | <b>239,881</b>   | 861  | 355,866  |
| Cancellation of contingent<br>payment obligation settled in<br>common shares <i>[note 3]</i> | <b>150,000</b>  |   | <b>150,000</b>   |  | 150,000  |
| (Gain) loss on sale and write<br>down of BCY LifeSciences Inc.                               | <b>(34,185)</b>   |   | <b>12,817</b>  |  | (298,638)  |
| Loss on sale of Transition<br>Therapeutics Inc.  |   | 2,156,685   |  |  | 2,156,685  |
| Future income tax recovery   |   |   |  |  | (1,115,000)  |
| Net changes in non-cash working<br>capital   | <b>198,946</b>  | (707,492)   | <b>633,728</b>   | (29,239)   | 776,244  |
|  | <b>(6,951,991)</b>  | (4,394,801)   | <b>(1,820,118)</b>   | (1,243,976)  | (27,650,636)   |
| <b>INVESTING ACTIVITIES</b>  |   |   |  |  |  |
| Intellectual property  | <b>(766,317)</b>  | (892,532)   | <b>(340,389)</b>   | (297,385)  | (3,431,143)  |
| Other capital assets   | <b>(8,793)</b>  | (46,430)  | <b>(900)</b>   | (4,999)  | (519,765)  |
| Purchase of short-term<br>investments  | <b>(6,602,415)</b>  | (12,029,492)  | <b>(187,231)</b>   | (12,029,492)   | (24,714,023)   |
| Redemption of short-term<br>investments  | <b>3,114,000</b>  |   | <b>1,114,000</b>   |  | 3,114,000  |
| Investment in BCY LifeSciences<br>Inc.   | <b>133,609</b>  |   |  |  | 456,637  |
|  |   | 2,552,695   |  |  | 2,532,343  |

Investment in Transition  
Therapeutics Inc.

|   |                    |                     |                  |                     |                     |
|---|--------------------|---------------------|------------------|---------------------|---------------------|
|   | <u>(4,129,916)</u> | <u>(10,415,759)</u> | <u>585,480</u>   | <u>(12,331,876)</u> | <u>(22,561,951)</u> |
| <b>FINANCING ACTIVITIES</b>   |                    |                     |                  |                     |                     |
| Alberta Heritage Foundation loan  |                    |                     |                  |                     | 150,000             |
| Proceeds from exercise of<br>warrants and stock options                           | <b>4,717,914</b>   | 459,895             | <b>676,893</b>   | 119,920             | 8,178,899           |
| Proceeds from private placements  | <b>6,223,763</b>   | 9,844,700           |                  | 3,783,115           | 22,741,983          |
| Proceeds from public offerings  |                    |                     |                  |                     | 21,642,602          |
|   | <u>10,941,677</u>  | <u>10,304,595</u>   | <u>676,893</u>   | <u>3,903,035</u>    | <u>52,713,484</u>   |
| <b>(Decrease) increase in cash and<br/>cash equivalents during the<br/>period</b> | <b>(140,230)</b>   | <b>(4,505,965)</b>  | <b>(557,745)</b> | <b>(9,672,817)</b>  | <b>2,500,897</b>    |
| <b>Cash and cash equivalents,<br/>beginning of the period</b>                     | <u>2,641,127</u>   | <u>8,319,244</u>    | <u>3,058,642</u> | <u>13,486,096</u>   |                     |
| <b>Cash and cash equivalents, end<br/>of the period</b>                           | <u>2,500,897</u>   | <u>3,813,279</u>    | <u>2,500,897</u> | <u>3,813,279</u>    | <u>2,500,897</u>    |

*See accompanying notes*

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**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

September 30, 2004 and 2003 (*unaudited*)

**1. ACCOUNTING POLICIES**

These unaudited interim financial statements do not include all of the disclosures included in the Company's annual financial statements. Accordingly, these unaudited interim financial statements should be read in conjunction with the Company's most recent annual financial statements. The information for the year ended December 31, 2003 has been derived from the Company's audited financial statements for the year then ended.

The accounting policies used in the preparation of these unaudited interim financial statements conform with those used in the Company's most recent annual financial statements.

**2. INVESTMENTS**

During the three month period ending September 30, 2004, the Company recorded a write down of its investment in BCY LifeSciences Inc. (BCY) of \$12,817 to reflect the investment's market value of \$12,000. The write down was a result of a reduction in the BCY's market value (as estimated based on its publicly traded share price) below the Company's recorded book value that was deemed to be other than temporary.

During the nine month period ending September 30, 2004, the Company sold 697,945 of its BCY shares for net cash proceeds of \$133,609 recording a gain on sale of investment of \$47,002. As at September 30, 2004, the Company's remaining ownership in BCY was 200,000 common shares with a book value (net of write down) of \$12,000.

**3. CONTINGENCY**

On September 23, 2004, the Company reached an agreement that reduced its contingent payments to its founding shareholders through the cancellation of a portion of these contingent payments from one of its non-management founding shareholders. The consideration paid by the Company consisted of \$250,000 cash and 21,459 common shares valued at \$150,000 and has been recorded as research and development expense. The value of the common shares was based on the closing market price on September 23, 2004.

As a result of the above cancellation, if the Company receives royalty payments or other payments as a result of entering into partnerships or other arrangements for the development of the reovirus technology, the Company is obligated to pay to the founding shareholders 11.75% (14.25% prior to the cancellation payment) of the royalty payments and other payments received. Alternatively, if the Company develops the reovirus treatment to the point where it may be marketed at a commercial level, the Company is obliged to pay the founding shareholders 2.35% (2.85% prior to the cancellation payment) of Net Sales received by the Company for such products.

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**Table of Contents****Oncolytics Biotech Inc.****NOTES TO FINANCIAL STATEMENTS**September 30, 2004 and 2003 (*unaudited*)**4. SHARE CAPITAL****Authorized:**

Unlimited number of common shares

| <b>Issued:</b>  | <b>Shares</b> |                      | <b>Warrants</b> |                      |
|---|---------------|----------------------|-----------------|----------------------|
|   | <b>Number</b> | <b>Amount<br/>\$</b> | <b>Number</b>   | <b>Amount<br/>\$</b> |
| Balance, December 31, 2002                                      | 22,145,284    | 30,191,572           | 550,000         | 114,286              |
| Issued for cash pursuant to February 10, 2003 private placement | 140,000       | 265,540              | 77,000          | 16,000               |
| Issued for cash pursuant to June 19, 2003 private placement     | 2,120,000     | 5,912,113            | 1,272,000       | 543,287              |
| Issued for cash pursuant to August 21, 2003 private placement   | 1,363,900     | 3,801,778            | 813,533         | 349,176              |
| Issued for cash pursuant to October 14, 2003 public offering    | 1,200,000     | 5,528,972            | 720,000         | 617,428              |
| Exercise of options   | 64,700        | 149,615              |                 |                      |
| Exercise of warrants  | 174,378       | 593,194              | (174,378)       | (41,927)             |
| Share issue costs   |               | (1,730,195)          |                 |                      |
| Balance, December 31, 2003                                      | 27,208,262    | 44,712,589           | 3,258,155       | 1,598,250            |
| Issued for cash pursuant to April 7, 2004 private placement (i) | 1,077,100     | 5,924,050            | 646,260         | 1,028,631            |
| Issued pursuant to cancellation of contingent payment [note 3]  | 21,459        | 150,000              |                 |                      |
| Exercise of warrants  | 1,058,130     | 4,407,332            | (1,058,130)     | (431,463)            |
| Exercise of options   | 197,500       | 778,951              |                 |                      |
| Share issue costs   |               | (731,669)            |                 |                      |
| Balance, September 30, 2004                                     | 29,562,451    | 55,241,253           | 2,846,285       | 2,195,418            |

**Table of Contents****Oncolytics Biotech Inc.****NOTES TO FINANCIAL STATEMENTS**September 30, 2004 and 2003 (*unaudited*)

- (i) Pursuant to a private placement, the Company sold 1,077,100 units at an average price of \$6.25 per unit for gross cash proceeds of \$6,731,875. The units were comprised of 1,077,100 common shares and 538,550 common share purchase warrants and have ascribed values of \$5.50 and \$1.50 respectively. Each common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$7.75 per share until October 7, 2005. Share issue costs related to the private placement were \$728,918. In addition, the Company issued 107,710 common share purchase warrants to its advisor entitling the holder to acquire one common share of the capital of the Company upon payment of \$7.00 per share until October 7, 2005. The ascribed value of these additional warrants was \$220,806 (\$2.05 per additional warrant) and has been included in the share issue costs above. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.

The following table summarizes the Company's outstanding warrants as at September 30, 2004:

| <b>Exercise Price</b> | <b>Outstanding,<br/>December<br/>31,<br/>2003</b> | <b>Issued<br/>During<br/>the<br/>Period</b> | <b>Exercised<br/>During the<br/>Period</b> | <b>Outstanding,<br/>September<br/>30,<br/>2004</b> | <b>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Life<br/>(years)</b> |
|-----------------------|---|---|--|--|--|
| \$3.00                | 480,755   |   | 480,755                                    |  | 0.00   |
| \$4.00                | 1,243,867   |   | 396,522                                    | 847,345  | 0.22   |
| \$4.00                | 813,533   |   | 44,561                                     | 768,972  | 0.40   |
| \$5.00                | 120,000   |   | 66,042                                     | 53,958   | 0.54   |
| \$6.25                | 600,000   |   | 70,250                                     | 529,750  | 0.54   |
| \$7.00                |   | 107,710                                     |  | 107,710  | 1.00   |
| \$7.75                |   | 538,550                                     |  | 538,550  | 1.00   |
|                       | <b>3,258,155</b>                                  | <b>646,260</b>                              | <b>1,058,130</b>                           | <b>2,846,285</b>                                   | <b>0.49</b>  |

**Stock Option Plan**

The Company has issued stock options to acquire common stock through its stock option plan of which the following are outstanding at:

|  | <b>September 30, 2004</b>   | <b>December 31, 2003</b>    |
|--|-----------------------------|-----------------------------|
|  | <b>Weighted<br/>Average</b> | <b>Weighted<br/>Average</b> |

|                                      | <b>Stock<br/>Options</b> | <b>Share<br/>Price<br/>\$</b> | <b>Stock<br/>Options</b> | <b>Share<br/>Price<br/>\$</b> |
|--------------------------------------|--------------------------|-------------------------------|--------------------------|-------------------------------|
| Outstanding at beginning of period   | <b>2,800,800</b>         | <b>3.81</b>                   | 2,653,500                | 4.40                          |
| Granted during period                | <b>284,500</b>           | <b>7.66</b>                   | 599,000                  | 3.71                          |
| Cancelled during period              |                          |                               | (387,000)                | 7.97                          |
| Exercised during period              | <b>(197,500)</b>         | <b>3.77</b>                   | (64,700)                 | 2.31                          |
|                                      | <b>2,887,800</b>         | <b>4.12</b>                   | 2,800,800                | 3.81                          |
| Options exercisable at end of period | <b>2,783,133</b>         | <b>4.19</b>                   | 2,720,383                | 3.87                          |

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**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

September 30, 2004 and 2003 (*unaudited*)

As the Company is following the fair value based method of accounting for stock option awards, compensation expense related to options granted to employees and consultants was \$721,914 and \$67,060, respectively for the nine month period ending September 30, 2004 (September 30, 2003 \$383,060 and \$123,283, respectively) and \$4,638 and \$64,178 respectively for the three month period ending September 30, 2004 with an offsetting credit to contributed surplus.

**5. COMPARATIVE FIGURES**

Certain comparative figures have been reclassified to conform to the current period's presentation.

**About Oncolytics Biotech Inc.**

Oncolytics is a Calgary-based biotechnology company focused on the development of REOLYSIN<sup>®</sup>, its proprietary formulation of the human reovirus, as a potential cancer therapeutic. Oncolytics' researchers have demonstrated that the reovirus is able to selectively kill cancer cells and, in vitro, kill human cancer cells that are derived from many types of cancer including breast, prostate, pancreatic and brain tumours, and have also demonstrated successful cancer treatment results in a number of animal models. Phase I clinical trial results have indicated that REOLYSIN<sup>®</sup> was well tolerated and that the reovirus demonstrated activity in tumours injected with REOLYSIN<sup>®</sup>.

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