

ONCOLYTICS BIOTECH INC  
Form 40-F  
April 19, 2004

U.S. SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 40-F

REGISTRATION STATEMENT PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: **December 31, 2003**

Commission File Number: **000-31062**

**ONCOLYTICS BIOTECH INC.**

(Exact name of Registrant as specified in its charter)

**Not Applicable**  
(Translation of Registrant's name into English (if applicable))

**Province of Alberta, Canada**  
(Province of other jurisdiction of incorporation or organization)

**Not Applicable**  
(I.R.S. Employer Identification Number (if applicable))

**2834**

(Primary Standard Industrial Classification Code Number (if applicable))

**Suite #210, 1167 Kensington Crescent N.W., Calgary, Alberta, Canada, T2N 1X7**

**(403) 670-7377**

(Address and telephone number of Registrant's principal executive offices)

**DL Services, Inc., 1420 Fifth Avenue, Suite 3400, Seattle, Washington 98101**

**(206) 903-8800**

(Name, address (including zip code) and telephone number (including area code) of agent for service in the United States)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class  
**Common Shares**

Name of each exchange on which registered  
**NASDAQ SmallCap**

Securities registered or to be registered pursuant to Section 12(g) of the Act.

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None  
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None  
(Title of Class)

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For annual reports, indicated by check mark the information filed with this Form:

Annual information form

Audited annual financial statements

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

**As at December 31, 2003, 27,208,262 Common Shares without par value were issued and outstanding.**

Indicate by check mark whether the Registrant by filing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934 (the Exchange Act). If Yes is marked, indicate the filing number assigned to the Registrant in connection with such Rule.

Yes: 82-\_\_\_\_\_

No

Indicate by check mark whether the Registrant (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 Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes

No

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Explanatory Note: Oncolytics Biotech Inc. (the Company or the Registrant) is a Canadian issuer eligible to file its annual report pursuant to Section 13 of the Securities Exchange Act of 1934 (the 1934 Act) on Form 40-F. The Company is a foreign private issuer as defined in Rule 3b-4 under the 1934 Act and in Rule 405 under the Securities Act of 1933. Equity securities of the Company are accordingly exempt from Sections 14(a), 14(b), 14(c), 14(f) and 16 of the 1934 Act pursuant to Rule 3a12-3.

### NOTE REGARDING FORWARD LOOKING STATEMENTS

Certain statements in this document and the documents attached as exhibits hereto constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Oncolytics Biotech Inc. (Oncolytics, or the Company), or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Forward-looking statements are statements that are not historical facts, and include but are not limited to, estimates and their underlying assumptions; statements regarding plans, objectives and expectations with respect to the efficacy of the Company's technologies; the timing and results of clinical studies related to the Company's technologies; future operations, products and services; the impact of regulatory initiatives on the Company's operations; the size of and opportunities related to the markets for the Company's technologies; general industry and macroeconomic growth rates; expectations related to possible joint and/or strategic ventures and statements regarding future performance. Forward-looking statements generally, but not always, are identified by the words expects, anticipates, believes, intends, estimates, project, potential, possible and similar expressions, or that events or conditions will, may, could or should occur.

The forward-looking statements in this Annual Report are subject to various risks and uncertainties, most of which are difficult to predict and generally beyond the control of the Company, including without limitation:

uncertainty as to the Company's ability to achieve the goals and satisfy assumptions of management;  
the uncertainties related to the outcome of clinical studies and the long process related to such studies;  
the need for regulatory approvals to market REOLYSIN® and other products of the Company;

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the Company's need for additional financing which may not be available on acceptable terms or at all; uncertainty as to whether the Company will be able to complete any licensing, partnering or marketing arrangements for its technologies; uncertainty as to the market acceptance of the Company's products and the Company's ability to generate sufficient revenues to make its products and technologies commercially viable; the intense competition in the biotechnology industry and risks related to changing technology that may render the Company's technology obsolete; and other factors identified under the heading "Risk Factors" in the Company's Renewal Annual Information Form, and those that are discussed or identified in the Company's other public filings with the SEC.

The Company's actual results, performance or achievement could differ significantly from those expressed in, or implied by, the Company's forward-looking statements. Accordingly, the Company

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cannot assure that any of the events anticipated by the Company's forward-looking statements will occur, or if they do, what impact they will have on the Company's results of operations and financial condition.

Forward-looking statements are based on the beliefs, opinions and expectations of the Company's management at the time they are made, and the Company does not assume any obligation to update its forward-looking statements if those beliefs, opinions, or expectations, or other circumstances, should change.

For all of the reasons set forth above, investors should not place undue reliance on forward-looking statements.

### CURRENCY

Unless otherwise indicated, all dollar amounts in this report are Canadian dollars. The exchange rate of Canadian dollars into United States dollars, on December 31, 2003, based upon the noon buying rate in New York City for cable transfers payable in Canadian dollars as certified for customs purposes by the Federal Reserve Bank of New York, was U.S.\$1.00 = CDN \$1.3916.

### AUDITED ANNUAL FINANCIAL STATEMENTS AND MANAGEMENT'S DISCUSSION AND ANALYSIS

#### *Audited Annual Financial Statements*

The audited financial statements, including the report of the auditors with respect thereto are included herein by reference. For a reconciliation of important differences between Canadian and United States generally accepted accounting principles, see Note 16 "Reconciliation of Canadian GAAP to US GAAP" of the Notes to Audited Financial Statements included herein by reference.

#### *Management's Discussion and Analysis*

The Company's management discussion and analysis of financial conditions and results of operations ("MD&A") is included herein by reference.

### DISCLOSURE CONTROLS AND PROCEDURES

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision of the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures pursuant to Rule 13a-15 of the United States Securities Exchange Act of 1934 ("Exchange Act"). Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

### CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

During the period covered by this Annual Report on Form 40-F, no changes occurred in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company's management, including the Chief Executive Officer and Chief Financial Officer, does not expect that its disclosure controls and procedures or internal controls over financial reporting will prevent all error and all fraud. A control system can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of 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. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

#### **CODE OF ETHICS FOR CHIEF EXECUTIVE OFFICER, CHIEF FINANCIAL OFFICER AND CONTROLLER**

The Company has adopted a Code of Ethics for Chief Executive Officer, Chief Financial Officer and Controller. This code applies to the Company's President and Chief Executive Officer, the Chief Financial Officer and the Controller. It is available on the Company's web site at [www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com) and in print without charge to any shareholder who requests it in writing. All amendments to the code, and all waivers of the code with respect to any of the officers covered by it, will be posted on the Company's web site and provided in print to any shareholder who requests them.

#### **AUDIT COMMITTEE**

The Company's Board of Directors has a separately-designated standing Audit Committee for the purpose of overseeing the accounting and financial reporting processes of the Company and audits of the Company's annual financial statements. As at the review of the 2003 Annual Report, and as at the date of this Report, the following individuals comprise the entire membership of the Company's Audit Committee, which has been established in accordance with Section 3(a)(58)(A) of the Exchange Act:

Fred Stewart  
Robert Schultz  
Antoine Noujaim

#### *Independence*

The Company has adopted the criteria for director independence and unrelatedness prescribed by the Sarbanes-Oxley Act of 2002, Section 10A(m)(3) of the Exchange Act and Rule 10A-3(b)(1) promulgated thereunder, for members of public company audit committees.

#### *Audit Committee Financial Expert*

Mr. Robert Schultz has been determined by the Company to meet the audit committee financial expert criteria prescribed by the Securities and Exchange Commission and has been designated as an audit committee financial expert for the Audit Committee. Each of the aforementioned directors have also been determined by the Company to be independent within the criteria referred to above under the subheading "Audit Committee Independence".

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#### **PRINCIPAL ACCOUNTANT FEES AND SERVICES INDEPENDENT AUDITORS**

The table setting forth the Company's fees paid to its independent auditor, Ernst & Young LLP, Chartered Accountants for the years ended December 31, 2003 and December 31, 2002 are set forth under the heading "Additional Information - External Auditor Service Fees" of the Company's 2003 Annual Information Form included herein by reference.

**PRE-APPROVAL OF AUDIT AND NON-AUDIT SERVICES PROVIDED BY  
INDEPENDENT AUDITORS**

The Audit Committee pre-approves all audit services to be provided to the Company by its independent auditors. The Audit Committee's policy regarding the pre-approval of non-audit services to be provided to the Company by its independent auditors is that all such services shall be pre-approved by the Audit Committee or by the Chairman of the Audit Committee, who must report all such pre-approvals to the Audit Committee at their next meeting following the granting thereof. Non-audit services that are prohibited to be provided to the Company by its independent auditors may not be pre-approved. In addition, prior to the granting of any pre-approval, the Audit Committee or the Chairman, as the case may be, must be satisfied that the performance of the services in question will not compromise the independence of the independent auditors.

**OFF-BALANCE SHEET ARRANGEMENTS**

As disclosed in the Company's MD&A included herein by reference, under the heading *Liquidity and Capital Resources - Off-Balance Sheet Arrangements*, the Company has not entered into any off-balance sheet arrangements.

**TABLE OF CONTRACTUAL COMMITMENTS**

As disclosed in the Company's MD&A included herein by reference, under the heading *Liquidity and Capital Resources - Capital Expenditures and Commitments*, the Company has set forth its contractual commitments.

**UNDERTAKING AND CONSENT TO SERVICE OF PROCESS**

*Undertaking*

The Company undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the Commission staff, and to furnish promptly, when requested to do so by the Commission staff, information relating to: the securities registered pursuant to Form 40-F; the securities in relation to which the obligation to file an annual report on Form 40-F arises; or transactions in said securities.

*Consent to Service of Process*

The Company filed an Amended Appointment of Agent for Service of Process and Undertaking on Form F-X signed by Oncolytics Biotech Inc. and its agent for service of process on November 10, 2003 with respect to the class of securities in relation to which the obligation to file the Form 40-F arises, which Form F-X is incorporated herein by reference.

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**Signatures**

Pursuant to the requirements of the Exchange Act, the Registrant certifies that it meets all of the requirements for filing on Form 40-F and has duly caused this annual report to be signed on its behalf by the undersigned, thereto duly authorized.

**Registrant**

**Oncolytics Biotech Inc.**

By /s/ Doug Ball

Date: April 19, 2004

**DOCUMENTS FILED AS PART OF THIS REPORT**

1. Renewal Annual Information Form of the Registrant for the year ended December 31, 2003
2. The following audited financial statements of the Registrant, are exhibits to and form a part of this Annual Report:
  - Auditors' Report on Financial Statements
  - Balance Sheets as of December 31, 2003 and 2002;
  - Statements of Loss and Deficit for the years ended December 31, 2003, 2002 and 2001;
  - Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001;
  - Notes to Financial Statements (which include reconciliation with United States generally accepted accounting principles).
3. Management Discussion and Analysis of Financial Conditions and Results of Operations

**EXHIBITS**

- A. Certifications by the Chief Executive Officer of the Company pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- B. Certifications by the Chief Financial Officer of the Company pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- C. Certificate of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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- D. Certificate of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- E. Consent of Ernst & Young LLP, Independent Chartered Accountants.

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## **RENEWAL ANNUAL INFORMATION FORM**

**for the Year Ended December 31, 2003**

**April 19, 2004**

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*This Annual Information Form contains forward-looking statements reflecting the current expectations of Oncolytics Biotech Inc. Investors are cautioned that these forward-looking statements involve risks and uncertainties, including, without limitation, clinical trial study delays, product development delays, the ability to attract and retain business partners, future levels of government funding, competition from pharmaceutical and other biotechnology companies and the ability to provide the capital required for research, product development, operations and marketing. These factors should be carefully considered and readers should not place undue reliance on the Company's forward-looking statements. Actual events may differ materially from current expectations due to risks and uncertainties.*

*In the context of this Annual Information Form, statements of the Company's belief are based primarily upon the Company's results derived to date from its research and development program with animals and early stage human results, upon which the Company believes that it has a reasonable scientific basis to expect the particular results to occur. It is not possible to predict, based upon studies in animals or early stage human results, whether a new therapeutic will be proved to be safe and effective in humans. There can be no assurance that the particular result expected by the Company will occur. See Management's Discussion and Analysis and Risk Factors.*

## CORPORATE STRUCTURE

Oncolytics Biotech Inc. (the Company) was incorporated pursuant to the provisions of the ABCA on April 2, 1998 as 779738 Alberta Ltd. On April 8, 1998, the Company amended its articles and changed its name to Oncolytics Biotech Inc. On July 29, 1999, the Company further amended its articles by removing the private company restrictions and subdividing its issued and outstanding 2,222,222 common shares to create 6,750,000 common shares. The head office and principal place of business of the Company is located at 210, 1167 Kensington Crescent N.W., Calgary, Alberta T2N 1X7. The registered office of the Company is located at 4500 Bankers Hall East, 855 Street S.W., Calgary, Alberta T2P 4K7.

## GENERAL DEVELOPMENT OF THE BUSINESS

### General

The Company focuses on the discovery and development of oncolytic viruses for the treatment of cancers that have not been successfully treated with conventional therapeutics. Recent scientific advances in oncology, virology, and molecular biology have created opportunities for new approaches to the treatment of cancer. The product presently being developed by the Company may represent a novel treatment for Ras mediated cancers which can be used as an alternative to existing cytotoxic or cytostatic therapies, as an adjuvant therapy to conventional chemotherapy, radiation therapy, or surgical resections, or to treat certain cellular proliferative disorders for which no current therapy exists.

The Company's technologies are based primarily on discoveries in the Department of Microbiology and Infectious Diseases at the University of Calgary in the 1990s. The Company was formed in 1998 to explore the natural oncolytic capability of the reovirus, a virus that preferentially replicates in cells with an activated Ras pathway.

The lead product being developed by the Company may represent a novel treatment for certain tumor types and some cellular proliferative disorders. The Company's lead product is a virus that is able to replicate specifically in, and hence kill, certain tumor cells both in tissue culture as well as in a number of animal models. See *Narrative Description of the Business*, *Business of the Company*; *Scientific Background*.

The Company is also assessing the potential opportunities for product candidates resulting from issued patents received for Ras targeted adenovirus and herpes virus.

## Clinical Trials

On October 29, 2003, the Company announced the approval by the Drug Development Group of the Division of Cancer Treatment and Diagnosis, U.S. National Cancer Institute ( NCI ) for multiple clinical trials to evaluate the efficacy of REOLYSIN® in a range of cancers. The NCI approved REOLYSIN® for collaborative development after an analysis of preclinical, GLP toxicology and available clinical data. The Company and NCI plan to collaborate to select cancer indications and suitable development programs for a number of clinical trials. The NCI is an agency of the National Institutes of Health, one of eight agencies that compose the Public Health Service in the U.S. Department of Health and Human Services. The NCI, established under the National Cancer Act of 1937, is the U.S. Federal Government's principal agency for cancer research and training.

On July 3, 2002, the Company commenced its Phase I/II clinical trial for recurrent glioma (brain tumor) for which it had received approval to proceed from Health Canada on April 11, 2002. The Company reported positive interim safety results from this trial on December 23, 2002, indicating that the product appeared to be well tolerated in the first six patients treated. As a result of information from the interim review, the Company and an independent data safety monitoring board submitted recommended changes to the protocol, which were reviewed and approved by Health Canada on May 6, 2003. With approval received from Health Canada, the Company resumed enrollment in the trial.

On April 16, 2002, the Company commenced patient enrollment in its clinical trial for T2 prostate cancer. This trial, which was approved by Health Canada on October 11, 2001, is primarily a technical study designed to allow the Company to measure overall tumour response and examine changes or effects inside the tumour and in surrounding normal tissue, as part of a human clinical trial. On March 31, 2003, the Company reported results of an interim assessment of its T2 prostate cancer trial. These results were presented by Dr. Don Morris, from the Alberta Cancer Board, the principal investigator for the trial. Dr. Morris reported that there was evidence of viral activity in five of six patients and there were no safety concerns, from either a clinical or histopathological perspective, in all six patients reported upon. The preliminary data, in four of the six patients, showed clear histopathological evidence of apoptotic tumour cell death (one measure of viral activity). In a fifth patient, the PSA level dropped by 53% and the prostate gland shrunk by 67% from the period of time prior to treatment to the time of surgical removal. There was no evidence of viral activity in the sixth patient. In all six patients, there was no histopathological evidence of any viral effect on healthy prostate tissue.

On March 21, 2002, the Company announced summary results from its Phase I clinical trial of REOLYSIN®. The study examined the administration of escalating dosages of REOLYSIN® directly into a subcutaneous (underneath the skin) tumour in eighteen terminal cancer patients with progressive (actively growing) cancer that had failed to respond to conventional therapies. The primary outcome of the trial was safety. None of the patients receiving reovirus experienced any serious adverse events related to the reovirus, nor were there any dose limiting toxicities detected in any of the patients. The secondary outcomes measured in the study related to tumour responses. Tumour responses were measured at both the treated lesion as well as remote tumour sites. Viral activity is defined as a transitory or lasting tumour regression of at least 30% measured in two dimensions against the tumour size prior to injection on the first day of treatment. Evidence of viral activity was detected in 11 of 18 patients (61%), with tumour regression ranging from 32% to 100%.

## Animal Studies

On February 14, 2003, the Company announced successful completion of a primate toxicology study testing the safety of intravenous infusion of REOLYSIN® over 28 days. At the maximum daily dose used in the study, each primate received daily from 10 to 100 times the expected maximum single human dose per unit of body weight. The product was well tolerated and no product-related serious adverse events were observed.

On April 18, 2002, the Company reported results from a study conducted by a third party, which examined the use of REOLYSIN® in canines (companion pet dogs) with naturally occurring tumours. The study examined the effect of three injections of REOLYSIN® administered on alternating days directly into a subcutaneous malignant tumour in 17 dogs. Efficacy was assessed by both measurement of tumour response and by histopathological comparison of pre-treatment and post-treatment tumour biopsies (tissue sample comparison). Canines were considered to be

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evaluable for tumour response only if they were available for all follow-ups. None of the animals were screened for Ras activation of their tumours prior to enrolment. In six of the 15 evaluable canines, the injected tumours were classified as stable disease (five) or partial response (one) on day 32 after the first injection of REOLYSIN®. Fifteen of 17 cases were evaluable by histopathology, where tumour necrosis (cell death) is the primary indication of efficacy in cancer therapy. Nine of 15 (60%) post-treatment biopsies from tumour masses showed increased cell death. Two of the treated masses appeared to be completely replaced by non-cancerous cells and fibrous tissue and another four cases had evidence of cell death in at least 75% of the biopsy sample.

On February 8, 2002, the Company announced the successful completion of its eighth formal toxicology study of REOLYSIN®. This study involved daily injections of REOLYSIN® for 28 days in a non-tumor bearing canine model. The total cumulative amount of virus injected per animal at the highest dose was more than one hundred times the highest dose used in the recently completed Phase I human clinical trial on a per unit of body weight basis.

On December 4, 2001, the Company announced results of its first systemic toxicology study of multiple injections of REOLYSIN® in animals. The toxicology study examined the effects of 28 consecutive days of intravenous administration of REOLYSIN® in Sprague-Dawley rats. These studies were conducted in support of future systemic clinical trials. The results of the study demonstrated that there were no significant adverse clinical outcomes as a result of the administration of the reovirus at any of the dose levels tested.

On August 8, 2001, the Company reported on research work done at the University of Calgary, which demonstrated in animals that REOLYSIN® could be successfully delivered systemically for the treatment of cancer. This research explored the degree of involvement of the immune system in potential systemic REOLYSIN® therapy, and those conditions that may benefit from co-therapy with immune suppressants.

On June 19, 2001, the Company reported results of research conducted through the Alberta Cancer Board and the University of Calgary on the use of REOLYSIN® for the treatment of human malignant gliomas (brain cancer) in animal models. Dr. Peter Forsyth and his colleagues demonstrated that nude mice with intracerebral (in the brain) gliomas treated with a single injection of REOLYSIN® administered intratumourally survived significantly longer than untreated animals in the control group. Complete tumour regression was found in 20 of the 23 animals treated with REOLYSIN®.

On February 28, 2001, the Company reported summary results of work done by a research team at the University of Calgary examining the effectiveness of REOLYSIN® for the treatment of metastatic cancer in animal models. These results, along with three additional papers related to the reovirus technology, were presented at the annual meeting of the American Association of Cancer Research held in New

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Orleans on March 26, 2001. The team demonstrated, in an immune competent mouse model, that REOLYSIN® administered intravenously led to a significant reduction in tumour volume, and resulted in a significant enhancement of survival rates in these animals. Experiments conducted as part of this study also demonstrated a potential use for REOLYSIN® as a co-therapy with existing drugs.

On November 10, 2000, the Company reported that Dr. Peter Forsyth and his research group at the Tom Baker Cancer Centre in Calgary, Alberta, Canada presented the results of their work with REOLYSIN® for the treatment of malignant gliomas, a specific type of brain tumor. The results were presented in Chicago at the Society for Neuro-Oncology. Dr. Forsyth and his colleagues were able to demonstrate in an athymic mouse model that REOLYSIN® treatment of intra-cerebral tumours resulted in dramatic extension of life. In one set of investigations, 82% of treated animals were alive at 90 days at which point the experiment was terminated. Animals not receiving REOLYSIN® treatment experienced a median survival of 48 days. Further, no side effects of the therapy were observed in the REOLYSIN® treated animals.

On June 28, 2000, the Company reported that Dr. Ron Moore and his research group at the Cross Cancer Institute in Edmonton, Alberta, Canada presented the results of their work with REOLYSIN® in selectively killing superficial transitional cell carcinoma ( TCC ) of the bladder in animal models. The purpose of the investigation was to compare the efficacy of REOLYSIN® to standard interventions of this disease state. Animal survival, tumor response, and potential side effects were all examined. The results demonstrated better efficacy with fewer adverse outcomes for animals receiving REOLYSIN® as compared to the currently accepted standard treatment. In an animal model of TCC, Dr. Moore s group found

that 70% of the animals had no evidence of tumors after treatment with REOLYSIN®, with no evidence of toxicology as a result of the treatment.

On June 16, 2000, the Company's initial toxicology studies examining the effects of REOLYSIN® in animals was announced. The toxicology studies examined the effects of subcutaneous injections of REOLYSIN® in rats and dogs. These studies were conducted in support of the initial Phase I clinical study. The results of the studies demonstrated that there were no significant adverse clinical outcomes as a result of the administration of REOLYSIN® in rats and dogs at any of the dose levels tested.

### **Manufacturing**

The Company has employed a toll manufacturer, BioReliance Company, for the production of reovirus for animal toxicology studies and all human clinical trials. The product will be produced in compliance with current regulatory requirements and the manufacturer will confirm biosafety testing. See *Risk Factors - Manufacturing*.

On February 6, 2003, the Company announced the successful completion of its program for the development of a commercial process for the manufacturing of REOLYSIN®, and indicated that it had filed selective patent applications with respect to the process.

### **Reovirus for Animal Use**

The Company announced on November 20, 2000, that it had entered into an agreement with U.S. based pharmaceutical firm, Pfizer Inc. ( Pfizer ) which had the potential of leading to the development and marketing of a formulation of the reovirus for animal use. It was anticipated that the agreement would also provide invaluable information towards the Company's primary objective of developing the potential of REOLYSIN® as a product for human use. On January 10, 2002, the Company reported that Pfizer had terminated its agreement with the Company for the development of the reovirus as a potential cancer therapeutic for animals. Based upon a review of the information available to the Company, there was nothing that caused concerns with respect to safety or effectiveness of the reovirus as a potential cancer

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therapy for human use. In addition, the Company eventually received information that has assisted the Company in development of the reovirus as a potential therapeutic. The primary focus of the Company has been and will continue to be the development of REOLYSIN® as a human therapeutic.

### **Financings and Other Distributions**

The Company has completed the following offerings of securities since its initial public offering:

on November 8, 1999, the Company completed its initial public offering of 4,000,000 common shares at a price of \$0.85 per share;

on February 1, 2000, the Company issued 3,000,000 special warrants at \$4.70 per special warrant (all special warrants were exercised on March 9, 2000 into common shares);

on July 17, 2000, the Company issued 244,898 common shares at \$12.25 per share.

on December 11, 2002, the Company issued 1,000,000 units at \$2.00 per unit (each unit consisting of one common share and one-half of one common share purchase warrant with each full share purchase warrant exercisable into one common share at an exercise price of \$3.00 per share until June 11, 2004);

on February 10, 2003, the Company issued 140,000 units at \$2.00 per unit (each unit consisting of one common share and one-half of one common share purchase warrant with each full share purchase warrant exercisable into one common share at an exercise price of \$3.00 per share until August 10, 2004);

on June 19, 2003, the Company issued 2,120,000 units at \$3.00 per unit (each unit consisting of one common share and one-half of one common share purchase warrant with each full share purchase warrant exercisable into one common share at an exercise price of \$4.00 per share until December 19, 2004);

on August 21, 2003, the Company issued 1,363,900 common shares and 681,943 common share purchase warrants (each full common share purchase warrant exercisable into one common share at an exercise price of \$4.00 per share until February 21, 2005) for gross proceeds equal to \$4,091,738; and

on October 14, 2003, the Company issued 1,200,000 units at \$5.00 per unit (each unit consisting of one common share and one-half of one common share purchase warrant with each full share purchase warrant exercisable into one common share at an exercise price of \$6.25 per share until April 14, 2005).

On May 8, 2002, SYNSORB Biotech Inc. (now Hawker Resources Inc. by name change) distributed 4,000,000 common shares in the capital of the Company to its shareholders. These common shares were previously held in escrow; however, upon receipt of approval of the shareholders of the Company, such common shares were distributed to the shareholders of SYNSORB without any trading restrictions. In consideration for the early release from escrow of these common shares, the Company acquired certain securities of BCY LifeSciences Inc. ( BCY ) from SYNSORB.

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### **Shareholdings in Other Issuers**

The Company reduced its shareholdings in BCY in the fourth quarter of 2003, selling 1,496,500 of its BCY shares for net cash proceeds of \$450,151 and reported a gain on the sale of these shares of \$264,453. After these sales in 2003, the Company owned 897,945 common shares (representing, as at December 31, 2003, approximately 2.6% of the 33,937,757 issued and outstanding shares) in the capital of BCY (TSXV: BCY), the right to acquire an additional 200,000 common shares of BCY for no additional consideration upon the attainment of certain milestones by BCY and warrants to purchase up to 694,445 common shares of BCY at an exercise price of \$0.27 per share at any time prior to April 23, 2004. BCY is a pharmaceutical company with license rights to technologies to treat certain diseases of the respiratory tract. Since December 31, 2003, the Company has sold an additional 676,945 shares, and, as at the date hereof, owns 221,000 shares of BCY.

On June 6, 2003, the Company sold its 6,890,000 common shares in the capital of Transition Therapeutics Inc., for net proceeds of \$2,552,695. These shares were acquired by the Company on June 18, 2002 in exchange for the issuance of 1,913,889 common shares in the capital of the Company. The Company recorded a loss on sale with respect to the sale of these shares of \$2,156,685.

### **Publications and Presentations**

On September 23, 2003, the Company announced that Dr. Ramon Alemany, a collaborator to the Company since July 30, 2003, and his colleagues at the Unstitut Catala d Oncologia in Barcelona, Spain, had published a research paper in the September 1, 2003 issue of *Cancer Research*, entitled "Ras-dependent Oncolysis with an adenovirus VAI Mutant." The researchers were able to show that VAI mutant adenoviruses selectively replicated in and killed pancreatic cancer cells with a Ras-activated pathway. The Company currently holds issued U.S. patent number 6,596,268 with claims covering the treatment of Ras-mediated tumors using adenoviruses modified in the VAI domain.

## Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

On March 19, 2003, the Company announced that Dr. Don Morris and his research group with the Alberta Cancer Board and the University of Calgary had published the results of their work with the reovirus for the removal of contaminating cancer cells from autologous (harvested from the patient themselves) blood stem cells in model systems. The results were published in the March 13, 2003 issue of *Blood*.

In addition, two recent publications addressed different elements of research into the use of the reovirus as a potential cancer therapeutic. Hirasawa et al. in the January 15th edition of *Cancer Research* demonstrated the use of the reovirus in treating metastatic disease in animal models using the reovirus delivered systemically. This is the first published examination of the systemic use of the reovirus in immune competent animals. Etoh et al. in the March 9th edition of *Clinical Cancer Research* examined the use of the reovirus to kill pancreatic cancers both in vitro and in animal models.

On March 26, 2002, the Company announced the publication of a research paper entitled "Reovirus Oncolysis of Human Breast Cancer" by Norman et al. (*Human Gene Therapy*, Vol. 13, March 20, 2002). The research examined the use of the reovirus as a treatment for breast cancer in two animal models and various breast cancer cell lines. In the first animal model, a single injection of the reovirus caused a continuous regression of a pre-established tumour, during a 30-day observation period. In the second animal model, independent tumours were established on both flanks of the mice. After the tumours had been established, a single injection of the reovirus into only one tumour resulted in complete regression of both the injected and non-injected tumours over 32 days. The research group also examined the ability of the reovirus to infect and kill breast cancer cell lines. Widespread cell killing was seen in all five established breast cancer cell lines and in one surgical specimen. No cell killing was observed in two cell lines established from normal breast tissue.

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On March 7, 2002, the Company announced that independent research assessing the potential of the reovirus as a potential cancer therapeutic was scheduled to be presented at the American Association for Cancer Research meeting in San Francisco in April.

### Patents

The Company received notification of issuance of two additional patents in the U.S., during 2002, and on March 6, 2002 received notification of its first issued European Patent. In 2003, the Company received notification of issuance of three further patents in the U.S. related to its reovirus technology, and also received notification of issuance of its first U.S. patent covering the treatment of Ras mediated tumors using modified adenoviruses and its first U.S. patent covering the treatment of Ras mediated tumors using modified herpes viruses. As at December 31, 2003, the Company had been granted a total of ten U.S. and one European patents. In addition, the Company has a number of other patents under application, both in the United States, and through filings under the Patent Cooperation Treaty. See *Narrative Description of the Business Patent and Patent Application Summary*.

### Recent Developments

On April 5, 2004, the Company appointed Mark Lievonen to its board of directors. Mr. Lievonen is currently the President of Aventis Pasteur Limited and responsible for the company's operations in Canada. Mr. Lievonen holds a Bachelor's Degree in Business Administration and an MBA from York University and received his Chartered Accountant designation in 1981 while working with Coopers and Lybrand. He is a member of the Board of Directors of BIOTECanada and served as Chair from January 2000 to May of 2003. He was also Chair of the Steering Committee of the BIO 2002 International Biotechnology Exhibition. In 2003, he was appointed as a Director of the Ontario Genomics Institute Board and Cabinet Member of the United Way of Greater Ontario Board, chairing the Health Care Division.

On March 30, 2004, the Company appointed Jim Dinning to its board of directors. Mr. Dinning is currently executive vice-president, TransAlta Corporation. Prior to joining TransAlta in 1997, Mr. Dinning held several key positions during his 11 years as a member of the legislative assembly of Alberta, including his term as provincial treasurer from 1992 to 1997. Today he serves as a director for a number of public, private and not-for-profit entities.

## Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

On March 24, 2004, the Company announced that it entered into a private placement with a European institutional investor. Subject to regulatory approval and upon completion of the transaction, Oncolytics will issue 1,077,100 common shares and 538,550 common share purchase warrants for aggregate gross proceeds of \$6,731,875. Each whole common share purchase warrant will entitle the holder to acquire one common share of Oncolytics upon payment of \$7.75 per share until 18 months following the closing date. An advisor retained by the Company received on closing, a commission of 7% of the gross proceeds and was issued common share purchase warrants entitling the holder to acquire, on or before October 7, 2005 up to 107,710 common share of Oncolytics upon payment of \$7.00 per warrant. The private placement closed on April 8, 2004.

On February 27, 2004, the Company reported that it received approval to commence a Phase I clinical trial to investigate the systemic delivery of REOLYSIN® as a treatment for patients with advanced or metastatic solid tumors from the Medicines and Healthcare products Regulatory Authority in the United Kingdom. The principal investigator for the study is Dr. J. de Bono of the Royal Marsden Hospital in London, England. This clinical trial will be the first to examine the systemic delivery of REOLYSIN®, which is expected to result in delivery of the virus throughout the body to both the primary tumor and metastatic disease sites. The trial is an open-label, dose escalation Phase I study in which REOLYSIN® will be administered intravenously to patients diagnosed with advanced or metastatic solid tumors that are refractory (have not responded) to standard therapy or for which no curative standard therapy exists. The primary objective of the study is to determine the maximum tolerated dose, dose limiting toxicity and safety profile of REOLYSIN®. Secondary objectives include the evaluation of viral replication, immune

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response to the virus and any evidence of antitumor activity. The enrolment in this study is expected to be up to 40 evaluable patients and will depend upon the number of dose levels tested.

On February 27, 2004, the Company provided the final update related to its T2 prostate cancer study. The clinical trial met its histopathological objective of showing that REOLYSIN® selectively infects and kills cancer cells in humans without damaging adjacent healthy tissue. The trial, a technical study designed to provide further information in support of commencing a systemic study, provided data that was helpful in meeting this objective. On March 31, 2003, the Company reported results from an interim assessment of this clinical study. See *General Development of the Business - Clinical Trials*. Additional histopathological analysis has demonstrated immune cell infiltration (B and T cells) into virus infected tumor mass. This infiltration was not noted in adjacent normal tissue. Further histopathological analysis, including microarray (a measure of gene expression) is currently being conducted.

The Company announced on March 9, 2004 that it had been granted U.S. Patent 6,703,232 entitled *Methods of Producing Reovirus*. Claims in this patent cover producing reassorted reoviruses for the treatment of Ras-mediated tumours. This is the eleventh U.S. patent issued to the Company.

### Future Developments

The Company anticipates that many important activities related to its clinical trial program, its product manufacturing and its intellectual property development and protection will occur in 2004 and beyond. The Company presently intends to continue to focus its clinical trial program on the evaluation of the effectiveness of REOLYSIN® as a potential treatment for various cancer indications. This will include continuing its clinical trial program presently underway, utilizing its association with the NCI to broaden its clinical trial program. The Company also intends to commence human clinical trials to determine the safety and effectiveness of systemic delivery of REOLYSIN® as a cancer therapeutic. Various forms of cancer are being assessed and the Company intends to evaluate and select one or more forms of cancer that appear to provide the best opportunity for timely approval.

The Company plans to continue its focus on establishing strategic relationships with potential partners who can provide expertise in marketing and distribution, as well as assistance with research and development.

**Except for historical information, this review contains statements which by their nature are forward-looking and which involve known and unknown risks, delays, uncertainties and other factors not under the Company's control. Any of these factors may cause actual**

results, performance or achievement of the Company to be materially different from the results, performance or expectations implied by these forward-looking statements. These factors include, but are not limited to, results of current or pending clinical trials, actions by the Food and Drug Administration in the United States or the Health Protection Branch in Canada, as well as those factors detailed in the Company's regulatory filings.

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## NARRATIVE DESCRIPTION OF THE BUSINESS

### Business of the Company

The Company's potential product for human use, REOLYSIN®, is developed from the reovirus. This virus has been demonstrated to replicate specifically in tumor cells bearing an activated Ras pathway. Activating mutations of Ras occur in approximately thirty per cent of all human tumors directly, but considering its central role in signal transduction, activation of the Ras pathway may play a role in approximately two-thirds of all tumors.

The functionality of the product is based upon the finding that tumors bearing an activated Ras pathway are deficient in their ability to activate the anti-viral response mediated by the host cellular protein, PKR. Since PKR is responsible for preventing reovirus replication, tumor cells lacking the activity of PKR are susceptible to reovirus infections. As normal cells do not possess Ras activations, these cells are able to thwart reovirus infections by the activity of PKR. In a tumor cell with an activated Ras pathway, reovirus is able to freely replicate and hence kill the host tumor cell. The result of this replication is progeny viruses that are then free to infect surrounding cancer cells. This cycle of infection, replication and cell death is believed to be repeated until there are no longer any tumor cells carrying an activated Ras pathway available.

The following schematic illustrates the molecular basis of how the reovirus kills cancer cells.

### Scientific Background

The Ras protein is a key regulator of cell growth and differentiation. It transmits signals from the cell's surface, via growth factor receptors, to downstream elements, which are in turn relayed to the nucleus. This transmission of signals from the cell surface to the cell's nucleus is collectively referred to as signal transduction. The transmission of these signals results in cell growth, division, and in some instances cellular differentiation. In normal cells, cell growth occurs only in the presence of factors stimulating the cells to grow. Mutations in Ras itself, or any of the elements along the Ras pathway, often lead to activation of the pathway in the absence of the appropriate growth stimuli, leading to the uncontrolled growth of these cells and ultimately to the development of a cancerous state. In fact, approximately 30% of all cancers are known to be due to mutations in Ras itself. The frequency of these Ras mutations, as

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well as their etiology in a given tumor is however, tissue specific. Activating mutations in Ras are found in many types of human malignancies but are highly represented in pancreatic (90%), sporadic colorectal (50%), lung carcinomas (40%), and myeloid leukemia (30%). Because Ras is a regulator of key mitogenic signals, aberrant function of upstream elements such as receptor tyrosine kinases (RTKs) can also result in Ras activation in the absence of mutations in Ras itself. Indeed, over-expression of these RTKs such as HER2/neu/ErbB2 or the epidermal growth factor receptor is common in breast cancer (25-30%), and over-expression of the platelet-derived growth factor receptor (PDGFR) is common in glioblastomas and gliomas, all of which are tumor types in which Ras mutations are relatively rare. Although activating mutations of Ras itself is thought to occur in only about 30% of all tumors it is expected that approximately two-thirds of all tumors have activated Ras signaling pathways as a result of mutations in genes that lie upstream of Ras. With this in mind, Ras becomes a significant therapeutic target in oncology.

All available scientific evidence developed or reviewed by the Company to date supports the premise that the reovirus only actively infects and replicates in cells with an activated Ras pathway. This naturally occurring virus is believed to cause only mild infections of the respiratory and gastrointestinal tract and in general, reovirus infections in humans are asymptomatic and usually sub-clinical. Research has indicated this virus replicates in, and therefore kills, only cancer cells (i.e. cancer cells with an activated Ras pathway), but does not replicate in normal cells. It has been demonstrated that reovirus replication is restricted in normal cells due to the activation of the double stranded RNA-activated protein kinase (PKR). PKR is a crucial element in protecting cells from reovirus infection and is capable of blocking viral protein translation. Activated Ras (or an activated element of the Ras pathway) prevents PKR activation, and thus allows viral replication to ensue only in this subset of cancer cells. To prove that reovirus could be used as a potential cancer therapeutic, a number of animal models were developed. Experiments using this virus to treat mouse tumors, expanded animal models as well as human brain, breast, and prostate tumors implanted in immuno-compromised mice have yielded promising results. In animals where tumor regression was noted, a single injection of reovirus is often enough to cause complete tumor regression. More importantly, it was demonstrated that this treatment is effective in causing tumor regression in immune competent animals. The Company will conduct an expanded animal toxicology program to determine any long-term side effects of REOLYSIN® therapy. Management of the Company believes that the nature of this virus, combined with its selective replication makes it an attractive candidate as a cancer therapy.

The Company believes that this research may have broad utility in the treatment of tumours with an activated Ras pathway as well as a potential use as an adjuvant therapy following surgical tumor resection or as an adjuvant therapy to conventional chemotherapeutic or radiation therapies.

### **The Potential Cancer Product**

Cancer is a group of related diseases characterized by the aberrant or uncontrolled growth of cells and the spread of these cells to other sites in the body. These cancer cells eventually accumulate and form tumors that can disrupt and impinge on normal tissue and organ function. In many instances, cells from these tumors can break away from the original tumor and travel through the body to form new tumors through a process referred to as metastasis.

The Company's cancer product is a potential therapeutic for tumors possessing an activated Ras pathway. In tumor cells with this type of activation, the virus is cytotoxic but may have no effect on the surrounding normal tissue. Activating mutations of Ras are believed to account for approximately 30% of all human tumors directly. It is also possible to activate Ras through mutation of proteins that control its activity rather than through direct mutations of Ras itself. This suggests that approximately two thirds of tumors may respond to this treatment.

## Repayable Grants

Pursuant to the Technology Commercialization Agreement with the Alberta Heritage Foundation, the Company received \$150,000 to offset the REOLYSIN® development costs. Under the Technology Commercialization Agreement, the Company agreed to repay the amount of the grant from gross sales of the Company. The Company agreed to repay the Alberta Heritage Foundation in annual installments in an amount equal to the lesser of: (a) 5% of gross sales; or (b) \$15,000 per annum until the entire grant has been paid in full.

In accordance with the Clinical Trial Agreement with the ACB, the Company has received funding and overhead support from the ACB to offset the REOLYSIN® clinical trial expenditures. Under the Clinical Trial Agreement, the Company agreed to repay the amount of the grant together with a royalty, to a combined maximum amount of \$400,000 plus an overhead repayment of \$100,000, upon sales of product. The Company agreed to repay the ACB in annual installments from the date of commencement of sales in an amount equal to the lesser of: (a) 5% of gross sales of REOLYSIN®; or (b) \$100,000 per annum. See *Management's Discussion and Analysis* .

## Business Strategy

The Company's business strategy is to develop and market REOLYSIN® in an effective and timely manner, and access additional technologies at a time and in a manner that the Company believes best for its development. The Company intends to achieve its business strategy by focusing on these key areas:

- Develop REOLYSIN® by initiating toxicology and manufacturing programs and progress the product through a clinical setting to assess its safety and efficacy in human subjects.

- Establish collaborations with experts to assist the Company with scientific and clinical developments of this new potential pharmaceutical product.

- Implement strategic alliances with selected pharmaceutical and biotechnology companies and selected laboratories, where such alliances may complement and expand the Company's research and development efforts on the product and provide sales and marketing capabilities.

- Utilize the Company's broadening patent base and collaborator network as a mechanism to meet its strategic objectives.

- Develop relationships with companies that could be instrumental in assisting the Company to access other innovative therapeutics.

The Company's business strategy is based on attaining a number of commercial objectives, which, in turn, are supported by a number of product development goals. The development of a new product presently being conducted by the Company is primarily of a research and development nature. In the context of this Annual Information Form, statements of the Company's belief are based primarily upon the Company's results derived to date from its research and development program with animals, and early stage human trials, and upon which the Company believes that it has a reasonable scientific basis to expect the particular results to occur. It is not possible to predict, based upon studies in animals, or early stage human trials, whether a new therapeutic will ultimately prove to be safe and effective in humans. There are no assurances that the particular result expected by the Company will occur. See *Risk Factors* .

At this time the Company does not intend to become a fully integrated pharmaceutical company with substantial in-house research and development, marketing and distribution or manufacturing capabilities.

The Company is pursuing a strategy of establishing relationships with larger companies as strategic partners. The Company intends to partner or joint venture with larger pharmaceutical companies that have existing and relevant marketing capability for its products. It is anticipated that future clinical development of the Company's products outside Canada would generally occur in conjunction with a strategic partner or partners, who would contribute expertise and financial assistance. In exchange for certain product rights and commitments to market the Company's products, the strategic partners would be expected to share in gross proceeds from the sale of the Company's product or products. The proceeds generated from partnering or joint venturing projects are expected to be distributed on the basis of relative risk taken and resources contributed by each party to the partnership or joint venture.

### **Regulatory Requirements**

The development of new pharmaceuticals is strongly influenced by a country's regulatory environment. The drug approval process in Canada is regulated by Health Canada. In the United States, the primary regulatory body is the FDA. Similar processes are conducted in other countries by equivalent regulatory bodies. Regulations in each jurisdiction require the licensing of manufacturing facilities and mandate strict research and product testing standards. Companies must establish the safety and efficacy of their products, comply with Good Manufacturing Practices and submit marketing materials before being allowed to market pharmaceutical products. While the Company plans to pursue or support the pursuit of the approval of its product, success in acquiring regulatory approval for any product is not assured.

In order to market its pharmaceutical product in Canada, the United States, Europe and other jurisdictions, a company must successfully meet the requirements of those jurisdictions. The requirements of the Appropriate Regulatory Authority will generally include the following stages as part of the regulatory process:

***Pre-Pharmacological Studies*** Pre-Pharmacological studies involve extensive testing on laboratory animals to determine if a potential therapeutic product has utility in an *in vivo* disease model and has any adverse toxicology in a disease model.

***Investigational New Drug Application*** An Investigational New Drug ( IND ) Submission, or the equivalent, must be submitted to the appropriate regulatory authority prior to conducting Pharmacological Studies.

***Pharmacological Studies*** (or Phase I Clinical Trials) Pharmacological studies are designed to assess the potential harmful or other side effects that an individual receiving the therapeutic compound may experience. These studies, usually short in duration, are often conducted with healthy volunteers or actual patients and use up to the maximum expected therapeutic dose.

***Therapeutic Studies*** (or Phase II and III Clinical Trials) Therapeutic studies are designed primarily to determine the appropriate manner for administering a drug to produce a preventive action or a significant beneficial effect against a disease process. These studies are conducted using actual patients with the condition that the therapeutic is designed to remedy.

Prior to initiating these studies, the organization sponsoring the program is required to satisfy a number of requirements via the submission of documentation to support the approval for a clinical trial.

***New Drug Submission*** After all three phases of a clinical trial have been completed, the results are submitted with the original IND Submission to the appropriate regulatory authority for marketing approval. Once marketing approval is granted, the product is approved for commercial sales.

### **Market and Competition**

According to estimates for 2002 from the American Cancer Society, 1.28 million Americans are expected to be diagnosed with cancer in the year, and 555,500 Americans are forecast to die of cancer. In the United States cancer accounts for 25% of all deaths, second only to cardiovascular disease. In the United States, the relative lifetime risk of a male developing cancer is 1 in 2, while for women, this risk is 1 in 3.

The costs of this disease state are also significant. In the United States, the National Institute of Health estimates that the overall annual costs for cancer are \$107 billion. Of this figure, \$37 billion can be attributed to direct patient costs.

It has been estimated that approximately 30% of all tumors are a result of activating mutations of Ras itself. Since Ras can be activated by mechanisms other than direct mutations it is believed that the number of tumors with activated Ras (either through direct activating mutation or mutation or over-expression of elements upstream of Ras) is approximately two thirds.

The Company is aware of large pharmaceutical companies developing small molecule programs for the development of therapeutics to treat Ras mediated tumors. In addition, there are numerous companies, both big and small, that are working in the field of cancer therapeutics including some companies developing other oncolytic viruses. See *Risk Factors* .

### **Product Marketing Strategy**

The markets for the cancer product being developed by the Company may be large and could require substantial sales and marketing capability. Before or upon successful completion of the development of a cancer product, the Company intends to enter into one or more strategic partnerships or other collaborative arrangements with a pharmaceutical company or other company with marketing and distribution expertise to address this need. If necessary, the Company will establish arrangements with various partners for different geographical areas or specific applications. The Company's management and consultants have relevant experience with the partnering process.

### **Third Party Advisor, Collaborators and Scientific Advisory Board**

On July 30, 2003, the Company announced a research collaboration with Dr. Ramon Alemany of the Institut Catala d Oncologia, Barcelona, Spain to develop modified adenoviruses that are selective for Ras mediated cancers. The research has the potential to add a new generation of viruses that could be designed to be selective for Ras mediated tumors.

Pursuant to the Research Contract with the Governors of the University of Calgary, the Company paid to the University of Calgary an aggregate sum of \$102,000 over a twelve month period, to perform research for the REOLYSIN® project commencing August 31, 1999. This contract was extended for an additional 12 months, but was not renewed beyond August 2001. Under the contract, the research was under the direction and supervision of Dr. Patrick Lee. Work to be conducted in Dr. Lee's laboratory included dose response studies, studies of alternate routes of administration, and work to further enable patent claims.

During 2001 and 2002, and in connection with the progress from pre-clinical research to the present clinical trial program, the Company broadened its advisor base. In addition to receiving assistance from Dr. Don Morris and Dr. Peter Forsyth, the Principal Investigators responsible for the prostate and brain tumour clinical trials respectively, the Company engaged Dr. George Gill and Dr. Alan Tuchman to apply their expertise in their respective fields of clinical and regulatory affairs and neurology as the Company progresses its clinical trial program for gliomas into the United States. The Company is at various stages

of discussion with other advisors and collaborators, who are expected to provide assistance in addressing clinical trial and regulatory issues as the development program of the Company progresses.

On September 15, 2003, the Company announced the formation of a Scientific Advisory Board to provide the Company with additional scientific and clinical guidance on the development of REOLYSIN®. The advisory board is comprised of Ramon Alemany, Ph.D., Richard Gorlick, M.D., Alan Tuchman, M.D., and Frank Tufaro, Ph.D.

Ramon Alemany, Ph.D., is a recognized expert on the development of antitumoral agents based on the adenovirus. During an eight year period in the United States he held progressively more senior positions in gene therapy laboratories at the MD Anderson Cancer Center, Baxter Healthcare Corporation and the University of Alabama at Birmingham. In 2001, he was appointed Director of the Gene and Viral Therapy Group at the Institut Catala d Oncologia in Barcelona. Dr. Alemany is currently collaborating with the Company to develop modified adenoviruses that are selective for Ras mediated cancers.

Richard Gorlick, M.D., is the Director of the Pediatric Sarcoma Laboratory and an Assistant Attending Pediatrician at Memorial Sloan-Kettering Cancer Center in New York. He is actively involved in the national pediatric cooperative group, the children's Oncology Group, for which he serves as the Chairman of the subcommittee on Bone Tumour Biology. Dr. Gorlick is known for his research work on molecular pharmacology of antifolate resistance and developing new therapeutic approaches for osteosarcoma.

Alan Tuchman, M.D., works in private practice and is Clinical Professor of Neurology at New York Medical College. He is also the Principal of NeuroPhysics Corporation, a healthcare and neuroscience consulting firm. From 1997 to 2001 Dr. Tuchman was the Senior Vice President of Equity Research for Oscar Gruss & Son, where he conducted investment research and helped develop marketing strategies for healthcare companies. He also held senior neurology positions at New York Medical College and Lincoln Medical and Mental Health Center.

Frank Tufaro, Ph.D., has extensive start-up experience with biotech firms and was one of the founders of NeuroVir Inc., a Vancouver-based biotech company, which is now merged with MediGene AG to develop Herpes Simplex virus-based oncolytic vectors for cancer therapy. Under Dr. Tufaro's direction, NeuroVir and then MediGene Inc. were able to initiate and complete the first Phase I/II U.S. clinical trials of two herpes-based oncolytic viruses for the treatment of malignant brain tumours, and the treatment of colorectal cancer metastatic to the liver. He currently serves on scientific advisory boards for several biotech companies.

### **Intellectual Property Policy**

The Company has 11 patents issued in the United States (nine of the 11 related to the reovirus technology), one European patent issuance, and additional applications in process. All potentially valuable intellectual property is identified by the inventory, and classified by the Company in terms of its sensitivity. All sensitive documentation related to the intellectual property is protected and kept in secure areas. All employees execute agreements containing confidentiality clauses, which assign any new intellectual property to the Company. The Company believes that it applies its intellectual property protection policy consistently.

Where appropriate, and consistent with management's objective, patents are pursued as soon as the concepts have been validated through appropriate laboratory work. To that end, patents will continue to be sought on components or concepts that management of the Company perceives to be essential.

The Company believes that one of the best intellectual property control policies is a strong human resources policy to ensure that technical leaders with access to proprietary intellectual property do not



## Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

<u>Title</u>	<u>Ownership</u>	<u>Inventors</u>	<u>Status of Patent</u>	
Patent Number U.S. 6,528,305 Method of Producing Infectious Reovirus	Oncolytics Biotech Inc.	Dr. Bradley G. Thompson Dr. Matthew C. Coffey	Filing date: Issued :	Aug. 2, 2001 March 4, 2003
Patent Number U.S. 6,565,831 Methods of Preventing Reovirus Recognition for the Treatment for Cellular Proliferative Disorders	Oncolytics Biotech Inc.	Dr. Matthew C. Coffey Dr. Bradley G. Thompson	Filing date: Issued:	Aug. 10, 2000 May 20, 2003
Patent Number U.S. 6,576,234 Reovirus for the Treatment of Neoplasia	Oncolytics Biotech Inc.	Dr. Patrick L. Lee Dr. James E. Strong Dr. Matthew C. Coffey	Filing date: Issued:	May 10, 2001 June 6, 2003
Patent Number U.S. 6,596,268 Viruses for the Treatment of Cellular Proliferative Disorders	Oncolytics Biotech Inc.	Dr. Matthew C. Coffey Dr. Bradley G. Thompson	Filing date: Issued:	Nov. 9, 2000 July 22, 2003
Patent Number U.S. 6,649,157 Viruses for the Treatment of Cellular Proliferative Disorders	Oncolytics Biotech Inc.	Dr. Matthew C. Coffey Dr. Bradley G. Thompson	Filing date: Issued:	Sept. 28, 2001 Nov 18, 2003
Patent Number U.S. 6,703,232 Methods of Producing Infectious Reovirus	Oncolytics Biotech Inc.	Dr. Matthew C. Coffey Dr. Bradley G. Thompson	Filing date: Issued:	January 8, 2003 March 9, 2004

### Notes:

- (1) Claims cover the treatment of Ras mediated tumors using modified adenoviruses.
- (2) Claims cover the treatment of Ras mediated tumors using modified herpes viruses.

Other patent applications have been filed by the Company, but have yet to be published or approved.

### Acquisition of all of the Shares of the Company by SYNSORB

In April 1999, the Company, the Vendors and SYNSORB entered into the Share Purchase Agreement whereby SYNSORB acquired all of the then outstanding common shares of the Company for a share and cash exchange valued at \$2,500,000 paid primarily in common shares of SYNSORB, four milestone payments payable to the Vendors valued, in the aggregate, at up to \$4,000,000 and a royalty commitment. Pursuant to an assignment dated July 29, 1999, the obligation to make the milestone and certain royalty payments was assigned from SYNSORB to the Company. The Company thereby agreed to indemnify and save harmless SYNSORB from all actions, suits, demands, claims, costs, losses, expenses, charges and damages brought against SYNSORB in relation to the payment or non-payment of such obligations, however such assignment did not affect or release SYNSORB from its liabilities and responsibilities under the terms of the Share Purchase Agreement. As at the date hereof, the Company has made three milestone payments totaling \$3,000,000. The final milestone payment is \$1.0 million payable within 90 days of the first receipt, in any country, from the Appropriate Regulatory Authority, for marketing approval to sell REOLYSIN® to the public or the approval of a new drug application for REOLYSIN®. In addition to the milestone payments, royalty payments payable to the Vendors will become due and payable in accordance with the Share Purchase Agreement upon realization of sales of REOLYSIN®.

During the year, the Company completed amendments and revisions to the contingent obligations to the Vendors with respect to these other contingent payments. The amendments and revisions reduced the amount and clarified the determination of potential obligations of the Company to these shareholders. If

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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 Vendors an aggregate of 14.25% (formerly 20%) 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 payments referred to in the foregoing sentence will be amended to equal a royalty payment of 2.85% (formerly 4%) of net sales received by the Company for such products.

### **Employees**

As of December 31, 2003, the Company had 9 employees. The majority of the activities of the Company are conducted under contract with third party service providers.

### **Research and Development Expenditures**

For the period ended December 31, 2003, the Company incurred research and development expenditures of \$3,314,188, representing approximately 47.8% of the Company's total expenses for the year. See *Management's Discussion and Analysis - Review and Treatment of Research and Development Costs*.

## **SELECTED FINANCIAL INFORMATION**

### **Selected Annual Information and Selected Quarterly Information**

Reference is made to the information under the headings *Management Discussion and Analysis of Financial Conditions and Results of Operations - Selected Annual Information; Summary of Quarterly Results* in the 2003 Annual Report of the Company, which information is incorporated herein by reference.

### **Dividend Policy**

To date, the Company has not paid any dividends on its outstanding common shares. The future payment of dividends will be dependent upon the financial requirements of the Company to fund future growth, the financial condition of the Company and other factors which the Board of Directors of the Company may consider appropriate in the circumstances. It is unlikely that dividends will be paid in the foreseeable future.

## **MANAGEMENT'S DISCUSSION AND ANALYSIS**

Reference is made to the information under the heading *Management's Discussion and Analysis of Financial Conditions and Results of Operations* in the 2003 Annual Report of the Company, which information is incorporated herein by reference.



**MARKET FOR SECURITIES**

**Market for Common Shares**

The outstanding common shares of the Company are listed and posted for trading on the Toronto Stock Exchange under the trading symbol **ONC** and on the Nasdaq Small Cap Market under the trading symbol **ONCY**. The following table sets forth the market price ranges and the aggregate volume of trading of the common shares on the Toronto Stock Exchange and Nasdaq Small Cap Market for the periods indicated:

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<u>Period</u>	<u>Toronto Stock Exchange</u>				<u>Nasdaq Small Cap Market</u>			
	<u>High</u> (\$)	<u>Low</u> (\$)	<u>Close</u> (\$)	<u>Volume</u>	<u>High</u> (\$)	<u>Low</u> (\$)	<u>Close</u> (\$)	<u>Volume</u>
<b>2003</b>								
January	2.69	1.80	1.85	1,294,529	2.15	1.11	1.20	818,760
February	1.94	1.60	1.80	837,648	1.55	1.03	1.17	226,865
March	1.85	1.50	1.68	818,989	1.25	1.00	1.15	150,125
April	2.38	1.45	2.30	1,114,969	1.74	0.99	1.59	835,170
May	4.90	1.80	3.75	5,926,249	3.57	1.26	2.76	4,254,252
June	4.28	2.85	3.55	3,659,176	3.15	2.09	2.64	3,612,378
July	3.59	2.75	3.20	1,248,412	2.75	1.91	2.25	1,127,692
August	3.80	3.05	3.69	929,336	2.82	2.20	2.68	869,413
September	6.07	3.26	4.39	4,081,883	4.52	2.43	3.27	5,036,766
October	6.34	4.25	5.76	3,345,346	5.01	3.181	4.39	4,575,392
November	6.20	4.30	5.04	1,723,781	4.89	3.30	3.86	2,643,687
December	5.15	3.70	4.44	1,166,094	3.97	2.78	3.44	1,794,869

**Description of Common Shares**

The holders of the common shares of the Company are entitled to one vote per share at meetings of shareholders, to receive such dividends as declared by the Company and to receive the remaining property and assets of the Company upon dissolution or winding up of the Company. The common shares of the Company are not subject to any future call or assessment and there are no pre-emptive, conversion or redemption rights attached to such shares. The Company currently has outstanding stock options and common share purchase warrants to purchase common shares as set forth in Note 11 of the audited financial statements of the Company.

**DIRECTORS AND OFFICERS**

The directors of the Company are elected by the shareholders at each Annual General Meeting and typically hold office until the next Annual General Meeting at which time they may be re-elected or replaced. Casual vacancies on the board are filled by the remaining directors and the persons filling those vacancies hold office until the next Annual General Meeting at which time they may be re-elected or replaced. The officers

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are appointed by the Board of Directors and hold office indefinitely at the pleasure of the Board of Directors.

The following table sets forth the names and municipalities of residence of all directors and officers of the Company as at the date hereof, as well as the positions and offices with the Company held by such persons and their principal occupations.

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Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
Bradley G. Thompson Ph.D(2) Calgary, Alberta	President, Chief Executive Officer and Executive Chairman of the Board	Executive Chairman of the Board, President and Chief Executive Officer since April 1999. Executive Chairman of the Board of SYNSORB from February 1999 to July 1999.	April 21, 1999
Douglas A. Ball C.A. Calgary, Alberta	Chief Financial Officer and Director	Chief Financial Officer since May 2000. Mr. Ball was Vice President, Finance and Chief Financial Officer of SYNSORB from June 1997 to May 2000. Prior to this, he was the Vice President, Finance and Administration and Chief Financial Officer of ECL Group of Companies Ltd. Mr. Ball held this position from December 1995 until May 1997. Prior to ECL, he was Controller and then Vice President and Controller of Canadian Airlines International Ltd. from June 1993 until August 1995.	April 21, 1999
William A. Cochrane, OC, M.D. Calgary, Alberta	Director	President of W.A. Cochrane & Associates, Inc. (a consulting company) since 1989 and Chairman of Pheromone Sciences Corp. (a public biopharmaceutical company) and UTI at the University of Calgary since 2000. Dr. Cochrane sits on a number of boards of Canadian and American companies. Dr. Cochrane is an Officer of the Order of Canada and a 2002 recipient of the Queens Golden Jubilee Medal. Dr. Cochrane also served as the Deputy Minister of Health Services for the Province of Alberta from 1973 to 1974.	October 31, 2002
Matthew C. Coffey Ph.D. Calgary, Alberta	Vice-President, Product Development	Vice-President of Product Development of the Corporation since July 1999. Chief Financial Officer of the Corporation from September 1999 to May 2000. Project Manager of SYNSORB from March 1999 to July 1999. Prior to joining SYNSORB, Dr. Coffey completed his doctorate degree at the University of Calgary.	N/A
George M. Gill, M.D. Washington, D.C.	Senior Vice President, Clinical and Regulatory Affairs	Dr. Gill has been a consultant in clinical research and regulatory affairs to the pharmaceutical and biotechnology industries since he retired from Ligand Pharmaceuticals in 1999. During his 35 years in the industry, he also served in senior executive positions with ICI Pharmaceuticals (now Astrazeneca), Bristol-Myers Squibb, and Hoffmann-La Roche. Dr. Gill holds a B.Sc. in chemistry from Dickinson College in Pennsylvania and an M.D. from the School of Medicine of the University of Pennsylvania in Philadelphia.	N/A
George Masters (3)(4) Churchpoint, Nova Scotia	Director	Interim President and Chief Executive Officer for Signalgene (a public biopharmaceutical company) since May 30, 2002 and is also Chairman of the Board of the company since April 2001 and a director since	April 5, 2002

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Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
		September 2000. In addition, Mr. Masters is Chairman of the Board of Directors of Biocatalyst Yorkton Inc. (a private venture capital company) since December 1996. Mr. Masters is also the Vice Chairman of Hemosol Inc. (a public biopharmaceutical company), a position he has held since 1992.	

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Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
Antoine A. Noujaim Ph.D(1)(2) Edmonton, Alberta	Director	President and Chief Executive Officer of ViRexx Research Inc. (a public biopharmaceutical company) since July 2002. Formerly Chairman of the Board of AltaRex Corp. (a public biopharmaceutical company) from February 1998 to July 2002. President and Chief Executive Officer of AltaRex Corp., from November 1995 to February 1998 and from May 2003 to present. Prior thereto, Dr. Noujaim was the President of Biomira Research Inc., a division of Biomira Inc. (a public biopharmaceutical company) from 1994 to 1995 and Senior Vice-President of the Immunoconjugate Division of Biomira Inc. from 1989 to November 1995. Dr. Noujaim also served as a Director of Biomira Inc. from 1985 to 1995.	August 27, 1999
Robert B. Schultz, F.C.A.(1)(3) Toronto, Ontario	Lead Director	Chairman and Director of Rockwater Capital Corporation formerly McCarvill Corporation (a financial services company) since June 2001. Director and special advisor to Merrill Lynch Canada (a public financial services company) from May 1, 2000 to June 2001. Chairman and Chief Executive Officer of Merrill Lynch Canada from August 1998 until his retirement on May 1, 2000. Prior to this appointment, Mr. Schultz was Chief Executive Officer at Midland Walwyn since 1990. Since joining the investment industry in 1971, Mr. Schultz has held a variety of senior positions, and has participated on various industry-related boards and committees including Director and Chairman of the Investment Dealers Association of Canada.	June 30, 2000
Fred A. Stewart, Q.C.(1)(2) Bragg Creek, Alberta	Director	President of Fred Stewart & Associates Inc. (a government and corporate relations consulting company) since March 1996. Prior to that, Mr. Stewart was an associate with Milner Fenerty, Barristers and Solicitors from June 1993 to March 1996. Mr. Stewart served as Member of the Legislative Assembly of the Province of Alberta from 1986 to 1993.	August 27, 1999
Jim Dinning Calgary, Alberta	Director	Executive Vice President of TransAlta Corporation (power generation and wholesale marketing company) since 1997. Prior thereto, Mr. Dinning served as Member of the Legislative Assembly of the Province of Alberta from 1986 to 1997. Mr. Dinning is a director of Finning International Inc. and Shaw Communications Inc. and is Chairman of the Canadian Clean Power Coalition.	March 24, 2004
J. Mark Lievonon C.A. Toronto, Ontario	Director	President of Aventis Pasteur Limited (a vaccine development, manufacturing and marketing company) since October 1998 and holding various other positions with Aventis Pasteur Limited and its	April 5, 2004

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Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
		predecessors since 1983. Mr. Lievonen is a member of the Board of Directors of BIOTECCanada and served as Chair from January 2000 to May 2003. He has also served on a number of industry and community boards and councils, including as a member of the BIOCouncil, an Advisory Group to the Government of Ontario in biotechnology.	
<b>Notes:</b>			
(1) These persons are members of the Audit Committee. Mr. Stewart is the Chair of the Audit Committee.			
(2) These persons are members of the Compensation Committee. Dr. Noujaim is the Chair of the Compensation Committee.			
(3) These persons are members of the Corporate Governance and Nominating Committee. Mr. Schultz is the Chair of the Corporate Governance and Nominating Committee.			
(4) Mr. Masters is not standing for re-election as a director of the Company at the annual and special meeting to be held on May 26, 2004.			

As at the date hereof, the directors and senior officers as a group beneficially owned, directly or indirectly, 27,000 common shares of the Company, representing less than 0.1% of the issued and outstanding common shares.

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Certain directors of the Company are associated with other companies, which may give rise to conflicts of interest. In accordance with the ABCA, directors who have a material interest in any person who is a party to a material contract or a proposed material contract with the Company are required, subject to certain exceptions, to disclose that interest and abstain from voting on any resolution to approve that contract. In addition, the directors are required to act honestly and in good faith with a view to the best interests of the Company.

### RISK FACTORS

**All of the Company's potential products, including REOLYSIN®, are in the research and development stage and will require further development and testing before they can be marketed commercially.**

Prospects for companies in the biotechnology industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology companies should be regarded as speculative. The Company is currently in the research and development stage on one product, REOLYSIN®, for human application, the riskiest stage for a company in the biotechnology industry. It is not possible to predict, based upon studies in animals, whether REOLYSIN® will prove to be safe and effective in humans. REOLYSIN® will require additional research and development, including extensive clinical testing, before the Company will be able to obtain the approvals of the relevant regulatory authorities in applicable countries to market REOLYSIN® commercially. There can be no assurance that the research and development programs conducted by the Company will result in REOLYSIN® or any other products becoming commercially viable products, and in the event that any product or products result from the research and development program, it is unlikely they will be commercially available for a number of years.

To achieve profitable operations the Company, alone or with others, must successfully develop, introduce and market its products. To obtain regulatory approvals for products being developed for human use, and to achieve commercial success, human clinical trials must demonstrate that the product is safe for human use and that the product shows efficacy. Unsatisfactory results obtained from a particular study relating to a program may cause the Company to abandon its commitment to that program or the product being tested. No assurances can be provided that any current or future animal or human test, if undertaken, will yield favourable results. If the Company is unable to establish that REOLYSIN® is a safe, effective treatment for cancer, it may be required to abandon further development of the product and develop a new business strategy.

**There are inherent risks in pharmaceutical research and development**

Pharmaceutical research and development is highly speculative and involves a high and significant degree of risk. The marketability of any product developed by the Company will be affected by numerous factors beyond the Company's control, including:

the discovery of unexpected toxicities or lack of sufficient efficacy of products which make them unattractive or unsuitable for human use;

preliminary results as seen in animal and/or limited human testing may not be substantiated in larger controlled clinical trials;

manufacturing costs or other factors may make manufacturing of products impractical and non-competitive;

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proprietary rights of third parties or competing products or technologies may preclude commercialization;

requisite regulatory approvals for the commercial distribution of products may not be obtained; and

other factors may become apparent during the course of research, up-scaling or manufacturing which may result in the discontinuation of research and other critical projects.

The Company's product under development has never been manufactured on a commercial scale, and there can be no assurance that such products can be manufactured at a cost or in a quantity to render such products commercially viable. Production and utilization of the Company's products may require the development of new manufacturing technologies and expertise. The impact on the Company's business in the event that new manufacturing technologies and expertise are required to be developed is uncertain. There can be no assurance that the Company will successfully meet any of these technological challenges, or others that may arise in the course of development.

**Pharmaceutical products are subject to intense regulatory approval processes**

The regulatory process for pharmaceuticals, which includes preclinical studies and clinical trials of each compound to establish its safety and efficacy, takes many years and requires the expenditure of substantial resources. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Further, government policy may change, and additional government regulations may be established that could prevent or delay regulatory approvals for the Company's products. In addition, a marketed drug and its manufacturer are subject to continual review. Later discovery of previously unknown problems with the product or manufacturer may result in restrictions on such product or manufacturer, including withdrawal of the product from the market.

The FDA in the United States and Health Canada in Canada may deny approval of a NDA or NDS if required regulatory criteria are not satisfied, or may require additional testing. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA and Health Canada may require further testing and surveillance programs to monitor the pharmaceutical product that has been commercialized. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product withdrawals, product seizures, injunction actions and criminal prosecutions.

In addition to its own pharmaceuticals, the Company may supply active pharmaceutical ingredients and advanced pharmaceutical intermediates for use in its customers' drug products. The final drug products in which the pharmaceutical ingredients and advanced pharmaceutical intermediates are used, however, are subject to regulation for safety and efficacy by the FDA, Health Canada and other jurisdictions, as the case may be. Such products must be approved by such agencies before they can be commercially marketed. The process of obtaining regulatory clearance for marketing is uncertain, costly and time consuming. The Company cannot predict how long the necessary regulatory approvals will take or whether the Company's customers will ever obtain such approval for their products. To the extent that the Company's customers do not obtain the necessary regulatory approvals for marketing new products, the Company's product sales could be adversely affected.

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Health Canada, the FDA and other governmental regulators have increased requirements for drug purity and have increased environmental burdens upon the pharmaceutical industry. Because pharmaceutical drug manufacturing is a highly regulated industry, requiring significant documentation and validation of manufacturing processes and quality control assurance prior to approval of the facility to manufacture a specific drug, there can be considerable transition time between the initiation of a contract to manufacture a product and the actual initiation of manufacture of that product. Any lag time in the initiation of a contract to manufacture product and the actual initiation of manufacture could cause the Company to lose profits or incur liabilities.

The pharmaceutical regulatory regime in Europe and other countries is, by and large, generally similar to that of Canada and the United States. The Company could face similar risks in these other jurisdictions, as the risks described above.

#### **The Company's operations and products may be subject to other government manufacturing and testing regulations**

Securing regulatory approval for the marketing of therapeutics by Health Canada in Canada and the FDA in the United States and similar regulatory agencies in other countries is a long and expensive process, which can delay or prevent product development and marketing. Approval to market products may be for limited applications or may not be received at all.

The products anticipated to be manufactured by the Company will have to comply with the FDA's current Good Manufacturing Practices (cGMP) and other FDA, Health Canada and local government guidelines and regulations, including other international regulatory requirements and guidelines. Additionally, certain of the Company's customers may require the manufacturing facilities contracted by the Company to adhere to additional manufacturing standards, even if not required by the FDA. Compliance with cGMP regulations requires manufacturers to expend time, money and effort in production, and to maintain precise records and quality control to ensure that the product meets applicable specifications and other requirements. The FDA and other regulatory bodies periodically inspect drug-manufacturing facilities to ensure compliance with applicable cGMP requirements. If the manufacturing facilities contracted by the Company fail to comply with the cGMP requirements, the facilities may become subject to possible FDA or other regulatory action and manufacturing at the facility could consequently be suspended. The Company may not be able to contract suitable alternative or back-up manufacturing facilities on terms acceptable to the Company or at all.

The FDA or other regulatory agencies may also require the submission of any lot of a particular product for inspection. If the lot product fails to meet the FDA requirements, then the FDA could take any of the following actions: (i) restrict the release of the product; (ii) suspend manufacturing of the specific lot of the product; (iii) order a recall of the lot of the product; or (iv) order a seizure of the lot of the product.

The Company's operations and products may be subject to other government manufacturing and testing regulations.

The Company is subject to regulation by governments in many jurisdictions and, if the Company does not comply with healthcare, drug, manufacturing and environmental regulations, among others, the Company's existing and future operations may be curtailed, and the Company could be subject to liability.

In addition to the regulatory approval process, the Company may be subject to regulations under local, provincial, state, federal and foreign law, including requirements regarding occupational health, safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, provincial, state, federal and foreign regulations.

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**The biotechnology industry is extremely competitive and the Company must successfully compete with larger companies with substantially greater resources**

Technological competition in the pharmaceutical industry is intense and the Company expects competition to increase. Other companies are conducting research on therapeutics involving the Ras pathway as well as other novel treatments or therapeutics for the treatment of cancer which may compete with the Company's product. Many of these competitors are more established, benefit from greater name recognition and have substantially greater financial, technical and marketing resources than the Company. In addition, many of these competitors have significantly greater experience in undertaking research, preclinical studies and human clinical trials of new pharmaceutical products, obtaining regulatory approvals and manufacturing and marketing such products. In addition, there are several other companies and products with which the Company may compete from time to time, and which may have significantly better and larger resources than the Company. Accordingly, the Company's competitors may succeed in manufacturing and/or commercializing products more rapidly or effectively, which could have a material adverse effect on the Company's business, financial condition or results of operations.

The Company anticipates that it will face increased competition in the future as new products enter the market and advanced technologies become available. There can be no assurance that existing products or new products developed by the Company's competitors will not be more effective, or be more effectively manufactured, marketed and sold, than any that may be developed or sold by the Company. Competitive products may render the Company's products obsolete and uncompetitive prior to recovering research, development or commercialization expenses incurred with respect to any such products.

**The Company relies on patents and proprietary rights to protect its technology**

The Company's success will depend, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the rights of third parties. The Company has patents in the United States and Europe and has filed applications for patents in the United States and under the PCT, allowing it to file in other jurisdictions. See Item 4. *Information on the Company Patent and Patent Application Summary*. The Company's success will depend, in part, on its ability to obtain, enforce and maintain patent protection for its technology in Canada, the United States and other countries. The Company cannot be assured that patents will issue from any pending applications or that claims now or in the future, if any, allowed under issued patents will be sufficiently broad to protect its technology. In addition, no assurance can be given that any patents issued to or licensed by the Company will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide continuing competitive advantages to the Company.

The patent positions of pharmaceutical and biotechnology firms, including the Company, are generally uncertain and involve complex legal and factual questions. In addition, it is not known whether any of the Company's current research endeavours will result in the issuance of patents in Canada, the United States, or elsewhere, or if any patents already issued will provide significant proprietary protection or will be circumvented or invalidated. Since patent applications in the United States and Canada are maintained in secrecy until at least 18 months after filing of the original priority application, and since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by

several months, the Company cannot be certain that it or any licensor was the first to create inventions claimed by pending patent applications or that it was the first to file patent applications for such inventions. Loss of patent protection could lead to generic competition for these products, and others in the future, which would materially and adversely affect the financial prospects for these products and the Company.

Similarly, since patent applications filed before October, 2000 in the United States are maintained in secrecy until the patents issue or foreign counterparts, if any, publish, the Company cannot be certain that it or any licensor was the first creator of inventions covered by pending patent applications or that it or

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such licensor was the first to file patent applications for such inventions. There is no assurance that the Company's patents, if issued, would be held valid or enforceable by a court or that a competitor's technology or product would be found to infringe such patents.

Accordingly, the Company may not be able to obtain and enforce effective patents to protect its proprietary rights from use by competitors, and the patents of other parties could require the Company to stop using or pay to use certain intellectual property, and as such, the Company's competitive position and profitability could suffer as a result.

In addition, the Company may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to the Company. If the Company does not obtain such licenses, it could encounter delays in introducing one or more of its products to the market while it attempts to design around such patents, or could find that the development, manufacture or sale of products requiring such licenses could be foreclosed. In addition, the Company could incur substantial costs in defending itself in suits brought against the Company on such patents or in suits in which the Company attempts to enforce its own patents against other parties.

**The Company's products may fail or cause harm, subjecting the Company to product liability claims, which are uninsured**

The sale and use of products of the Company entail risk of product liability. The Company currently does not have any product liability insurance. There can be no assurance that it will be able to obtain appropriate levels of product liability insurance prior to any sale of its pharmaceutical products. An inability to obtain insurance on economically feasible terms or to otherwise protect against potential product liability claims could inhibit or prevent the commercialization of products developed by the Company. The obligation to pay any product liability claim or a recall of a product could have a material adverse effect on the business, financial condition and future prospects of the Company.

**The Company has limited manufacturing experience and intends to rely on third parties to commercially manufacture its products, if and when developed.**

To date, the Company has relied upon a sole contract manufacturer to manufacture small quantities of REOLYSIN®. The manufacturer may encounter difficulties in scaling up production, including production yields, quality control and quality assurance. Only a limited number of manufacturers can supply therapeutic viruses and failure by the manufacturer to deliver the required quantities of REOLYSIN® on a timely basis at a commercially reasonable price may have a material adverse effect on the Company. The Company has recently completed its program for the development of a commercial process for manufacturing REOLYSIN® and has filed a number of patent applications related to the process. There can be no assurance that the Company will successfully obtain sufficient patent protection related to its manufacturing process.

The Company's products may fail or cause harm, subjecting the Company to product liability claims, which are uninsured



**New products may not be accepted by the medical community or consumers.**

The Company's primary activity to date has been research and development and the Company has no experience in marketing or commercializing products. The Company will likely rely on third parties to market its products, assuming that they receive regulatory approvals. If the Company relies on third parties to market its products, the commercial success of such product may be outside of its control. Moreover, there can be no assurance that physicians, patients or the medical community will accept the Company's product, even if the Company's product proves to be safe and effective and is approved for marketing by Health Canada, the FDA and other regulatory authorities. A failure to successfully market its products would have a material adverse affect on the Company's revenue.

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**The Company's technologies may become obsolete**

The pharmaceutical industry is characterized by rapidly changing markets, technology, emerging industry standards and frequent introduction of new products. The introduction of new products embodying new technologies, including new manufacturing processes, and the emergence of new industry standards may render the Company's products obsolete, less competitive or less marketable. The process of developing the Company's products is extremely complex and requires significant continuing development efforts and third party commitments. The Company's failure to develop new technologies and products and the obsolescence of existing technologies could adversely affect its business.

The Company may be unable to anticipate changes in its potential customer requirements that could make the Company's existing technology obsolete. The Company's success will depend, in part, on its ability to continue to enhance its existing technologies, develop new technology that addresses the increasing sophistication and varied needs of the market, and respond to technological advances and emerging industry standards and practices on a timely and cost-effective basis. The development of the Company's proprietary technology entails significant technical and business risks. The Company may not be successful in using its new technologies or exploiting its niche markets effectively or adapting its businesses to evolving customer or medical requirements or preferences or emerging industry standards.

**The Company is highly dependent on third party relationships for research and clinical trials**

The Company relies upon third party relationships for assistance in the conduct of research efforts, pre-clinical development and clinical trials, and manufacturing. In addition, the Company expects to rely on third parties to seek regulatory approvals for and to market the Company's product. Although the Company believes that its collaborative partners will have an economic motivation to commercialize the Company's product included in any collaborative agreement, the amount and timing of resources diverted to these activities generally is expected to be controlled by the third party. Furthermore, if the Company cannot maintain these relationships, its business may suffer.

**The Company has no operating revenues and a history of losses.**

To date, the Company has not generated sufficient revenues to offset its research and development costs and accordingly has not generated positive cash flow or made an operating profit. As of December 31, 2003, the Company had an accumulated deficit of \$24,994,592. The Company incurred net losses of \$8.5 million, \$6.1 million and \$6.2 million for the years ended December 31, 2003, 2002 and 2001, respectively. The Company anticipates that it will continue to incur significant losses during 2004 and in the foreseeable future. The Company will not reach profitability until after successful and profitable commercialization of one or more of its products. Even if one or more of its products are profitably commercialized, the initial losses incurred by the Company may never be recovered.

During 2003, the Company had no operating revenues. The Company has benefited to date from the receipt of research grants. There can be no assurance that grants will continue to be available to the Company or, if so, at what levels.

**The Company may need additional financing in the future to fund the research and development of its products and to meet its ongoing capital requirements.**

As of December 31, 2003, the Company had cash and cash equivalents, including short-term investments, of \$20.8 million and working capital of approximately \$20.1 million. The Company anticipates that it may need additional financing in the future to fund research and development and to meet its on going capital requirements. The amount of future capital requirements will depend on many factors, including

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continued scientific progress in its drug discovery and development programs, progress in its pre-clinical and clinical evaluation of drug candidates, time and expense associated with filing, prosecuting and enforcing its patent claims and costs associated with obtaining regulatory approvals. In order to meet such capital requirements, the Company will consider contract fees, collaborative research and development arrangements, and additional public or private financings (including the incurrence of debt and the issuance of additional equity securities) to fund all or a part of particular programs as well as potential partnering or licensing opportunities. There can be no assurance that additional funding will be available or, if available, that it will be available on acceptable terms. If adequate funds are not available on terms favorable to the Company, the Company may have to reduce substantially or eliminate expenditures for research and development, testing, production and marketing of its proposed product, or obtain funds through arrangements with corporate partners that require the Company to relinquish rights to certain of its technologies or product. There can be no assurance that the Company will be able to raise additional capital if its current capital resources are exhausted.

**The cost of director and officer liability insurance may increase substantially and may affect the ability of the Company to retain quality directors and officers**

The Company carries liability insurance on behalf of its directors and officers. Given a number of large director and office liability insurance claims in the U.S. equity markets, director and officer liability insurance is becoming increasingly more expensive with increased restrictions. Consequently, there is no assurance that the Company will continue to be offered this insurance or be able to obtain adequate coverage. The inability to acquire the appropriate insurance coverage will limit the Company's ability to attract and maintain directors and officers as required to conduct its business.

**The Company is dependent on its key employees and collaborators**

The Company's ability to develop the product will depend, to a great extent, on its ability to attract and retain highly qualified scientific personnel and to develop and maintain relationships with leading research institutions. Competition for such personnel and relationships is intense. The Company is highly dependent on the principal members of its management staff, Dr. Thompson, Dr. Coffey, Mr. Ball and Dr. Gill, as well as its advisors and collaborators, the loss of whose services might impede the achievement of development objectives. The persons working with the Company are affected by a number of influences outside of the control of the Company. The loss of key employees and/or key collaborators may affect the speed and success of product development.

The Company presently carries insurance in the amounts of \$2,000,000, \$1,000,000 and \$500,000 for Dr. Thompson, Dr. Coffey and Mr. Ball, respectively.

**The Company's share price may be highly volatile**

Market prices for securities of biotechnology companies generally are volatile. This increases the risk of securities litigation. Factors such as announcements (publicly made or at scientific conferences) of technological innovations, new commercial products, patents, the development of proprietary rights, results of clinical trials, regulatory actions, publications, quarterly financial results, the Company's financial position, public concern over the safety of biotechnology, future sales of shares by the Company or by its current shareholders and other factors could have a significant effect on the market price and volatility of the common shares.

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**The Company incurs some of its expenses in foreign currencies and therefore is exposed to foreign currency exchange rate fluctuations**

The Company incurs some of its manufacturing, clinical and consulting expenses in foreign currencies (to date mainly the U.S. dollar). Over the past year the Canadian dollar has appreciated relative to the U.S. dollar thereby decreasing the Canadian dollar equivalent. However, if this trend reverses, the Company's Canadian dollar equivalent costs will increase.

Also, as the Company expands to other foreign jurisdictions there may be an increase in its foreign exchange exposure.

**The Company earns interest income on its excess cash reserves and is exposed to changes in interest rates**

The Company invests its excess cash reserves in investment vehicles that provide a rate of return with little risk to principal. As interest rates change the amount of interest income the Company earns will be directly impacted.

**ADDITIONAL INFORMATION**

**Legal Proceedings**

The Company is not aware of any material legal proceedings nor are any such proceedings known by the Company to be contemplated.

**Interest of Management and Others in Material Transactions**

Other than as discussed herein, there are no material interests, direct or indirect, of directors, executive officers, senior officers, any direct or indirect shareholder of the Company who beneficially owns, or who exercises control over, more than 10% of the outstanding common shares of the Company or any known associate or affiliate of such persons, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or will materially affect the Company.

**Transfer Agent and Registrar**

The transfer agent and registrar for the common shares of the Company is Computershare Trust Company of Canada at its principal offices in Calgary, Alberta and Toronto, Ontario.

**Material Contracts**

Other than as discussed herein, there are no material contracts, other than contracts entered into in the ordinary course of business, that are material to the Company that were entered into within the most recently completed financial year, or before the most recently completed financial year but are still in effect.

**Interests of Experts**

Ernst & Young LLP, Chartered Accountants, have audited the financial statements of the Company for the year ended December 31, 2003, as set forth in the Annual Report of the Company.

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As at the date hereof, the partners and associates of Ernst & Young LLP, Chartered Accountants, the independent auditors of the Company, as a group did not beneficially own any of the outstanding common shares of the Company.

**External Auditor Service Fees**

During the financial years ended December 31, 2003 and 2002, Ernst & Young LLP received the following fees from the Company:

	<b>December 31</b>	
	<b><u>2003</u></b>	<b><u>2002</u></b>
Audit fees	\$44,600	\$40,698
Audit-related fees(1),(3)	34,062	27,316
Tax fees(2)	9,946	3,802
All other fees	--	--

**Notes:**

- (1) Includes review of interim financial statements, accounting consultations and subscription to on-line accounting.
- (2) Comprised of tax return preparation, scientific research and development return and other compliance fees.
- (3) Includes fees associated with matters relating to prospectus offering by the Company in October 2003.

***Audit Fees***

Audit fees were for professional services rendered by Ernst & Young, LLP for the audit of the Company's annual financial statements and services provided in connection with statutory and regulatory filings or engagements.

***Audit-Related Fees***

Notes:

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Audit-related fees were for assurance and related services reasonably related to the performance of the audit or review of the annual statements and are not reported under the heading Audit Fees above. These services consisted of accounting consultations, assistance with prospectus filings and assistance with preparations for compliance with section 404 of the *Sarbanes-Oxley Act of 2002*.

### *Tax Fees*

Tax fees were for tax compliance and tax advice. These services consisted of tax compliance including the preparation of tax returns.

### *All Other Fees*

There were no fees paid to Ernst & Young, LLP that would be considered All Other Fees in 2003 or 2002. Fees to be disclosed under this category would be for products and services other than those described under the headings Audit Fees, Audit-Related Fees and Tax Fees above.

### **Audit Committee Matters**

#### *Mandate of the Audit Committee*

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#### **1. Policy Statement**

It is the policy of Oncolytics Biotech Inc. (the Corporation) to establish and maintain an Audit Committee, composed entirely of independent directors, to assist the Board of Directors (the Board) in carrying out their oversight responsibility for the Corporation's internal controls, financial reporting and risk management processes. The Audit Committee will be provided with resources commensurate with the duties and responsibilities assigned to it by the Board including administrative support. If determined necessary by the Audit Committee, it will have the discretion to institute investigations of improprieties, or suspected improprieties within the scope of its responsibilities, including the standing authority to retain special counsel or experts.

#### **2. Composition of the Committee**

- (a) The Audit Committee shall consist of a minimum of three (3) directors, at least half of whom shall be resident Canadians. The Board shall appoint the members of the Audit Committee and may seek the advice and assistance of the Corporate Governance and Nominating Committee in identifying qualified candidates. The Board shall appoint one member of the Audit Committee to be the Chair of the Audit Committee, or delegate such authority to appoint the Chair of the Audit Committee to the Audit Committee.
- (b) Each director appointed to the Audit Committee by the Board shall be an outside director who is unrelated. An outside, unrelated director is a director who is independent of management and is free from any interest, any business or other relationship which

could, or could reasonably be perceived, to materially interfere with the director's ability to act with a view to the best interests of the Corporation, other than interests and relationships arising from shareholding. In determining whether a director is independent of management, the Board shall make reference to the then current legislation, rules, policies and instruments of applicable regulatory authorities.

- (c) Each member of the Audit Committee shall be financially literate. In order to be financially literate, a director must be, at a minimum, able to read and understand basic financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Corporation's financial statements. At least one member shall have accounting or related financial management expertise, meaning the ability to analyze and interpret a full set of financial statements, including the notes attached thereto, in accordance with generally accepted accounting principles. In determining whether a member of the Audit Committee is financially literate or has accounting or related financial expertise, reference shall be made to the then current legislation, rules, policies and instruments of applicable regulatory authorities.
- (d) A director appointed by the Board to the Audit Committee shall be a member of the Audit Committee until replaced by the Board or until his or her resignation.

### 3. Meetings of the Committee

- (a) The Audit Committee shall convene a minimum of four times each year at such times and places as may be designated by the Chair of the Audit Committee and whenever a meeting is requested by the Board, a member of the Audit Committee, the auditors, or senior management of the Corporation. Scheduled meetings of the Audit Committee shall correspond with the review of the year-end and quarterly financial statements and management discussion and analysis.
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- (b) Notice of each meeting of the Audit Committee shall be given to each member of the Audit Committee and to the auditors, who shall be entitled to attend each meeting of the Audit Committee and shall attend whenever requested to do so by a member of the Audit Committee.
- (c) Notice of a meeting of the Audit Committee shall:
  - (i) be in writing, including by electronic communication facilities;
  - (ii) state the nature of the business to be transacted at the meeting in reasonable detail;
  - (iii) to the extent practicable, be accompanied by copies of documentation to be considered at the meeting; and
  - (iv) be given at least two business days prior to the time stipulated for the meeting or such shorter period as the members of the Audit Committee may permit.
- (d) A quorum for the transaction of business at a meeting of the Audit Committee shall consist of a majority of the members of the Audit Committee. However, it shall be the practice of the Audit Committee to require review, and, if necessary, approval of certain important matters by all members of the Audit Committee.
- (e) A member or members of the Audit Committee may participate in a meeting of the Audit Committee by means of such telephonic, electronic or other communication facilities, as permits all persons participating in the meeting to communicate adequately with each other. A member participating in such a meeting by any such means is deemed to be present at the meeting.

- (f) In the absence of the Chair of the Audit Committee, the members of the Audit Committee shall choose one of the members present to be Chair of the meeting. In addition, the members of the Audit Committee shall choose one of the persons present to be the Secretary of the meeting.
- (g) A member of the Board, senior management of the Corporation and other parties may attend meetings of the Audit Committee; however the Audit Committee (i) shall, at each meeting, meet with the external auditors independent of other individuals other than the Audit Committee and (ii) may meet separately with management.
- (h) Minutes shall be kept of all meetings of the Audit Committee and shall be signed by the Chair and the Secretary of the meeting.

#### **4. Duties and Responsibilities of the Committee**

- (a) The Audit Committee's primary duties and responsibilities are to:
    - (i) identify and monitor the management of the principal risks that could impact the financial reporting of the Corporation;
    - (ii) monitor the integrity of the Corporation's financial reporting process and system of internal controls regarding financial reporting and accounting compliance;
    - (iii) monitor the independence and performance of the Corporation's external auditors;
    - (iv) deal directly with the external auditors to approve external audit plans, other services (if any) and fees;
    - (v) directly oversee the external audit process and results (in addition to items described in Section 4(d) below);
    - (vi) provide an avenue of communication among the external auditors, management and the Board; and
    - (vii) carry out a review designed to ensure that an effective whistle blowing procedure exists to permit stakeholders to express any concerns regarding accounting or financial matters to an appropriately independent individual.
  - (b) The Audit Committee shall have the authority to:
    - (i) inspect any and all of the books and records of the Corporation and its affiliates;
    - (ii) discuss with the management of the Corporation and its affiliates, any affected party and the external auditors, such accounts, records and other matters as any member of the Audit Committee considers necessary and appropriate;
    - (iii) engage independent counsel and other advisors as it determines necessary to carry out its duties; and
    - (iv) to set and pay the compensation for any advisors employed by the Audit Committee.
  - (c) The Audit Committee shall, at the earliest opportunity after each meeting, report to the Board the results of its activities and any reviews undertaken and make recommendations to the Board as deemed appropriate.
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- (d) The Audit Committee shall:
- (i) review the audit plan with the Corporation's external auditors and with management;
  - (ii) discuss with management and the external auditors any proposed changes in major accounting policies or principles, the presentation and impact of material risks and uncertainties and key estimates and judgements of management that may be material to financial reporting;
  - (iii) review with management and with the external auditors material financial reporting issues arising during the most recent fiscal period and the resolution or proposed resolution of such issues;
  - (iv) review any problems experienced or concerns expressed by the external auditors in performing an audit, including any restrictions imposed by management or material accounting issues on which there was a disagreement with management;
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- (v) review with senior management the process of identifying, monitoring and reporting the principal risks affecting financial reporting;
  - (vi) review audited annual financial statements (including management discussion and analysis) and related documents in conjunction with the report of the external auditors and obtain an explanation from management of all material variances between comparative reporting periods;
  - (vii) consider and review with management, the internal control memorandum or management letter containing the recommendations of the external auditors and management's response, if any, including an evaluation of the adequacy and effectiveness of the internal financial controls of the Corporation and subsequent follow-up to any identified weaknesses;
  - (viii) review with financial management and the external auditors the quarterly unaudited financial statements and management discussion and analysis before release to the public;
  - (ix) before release, review and if appropriate, recommend for approval by the Board, all public disclosure documents containing audited or unaudited financial information, including any prospectuses, annual reports, annual information forms, management discussion and analysis and press releases; and
  - (x) oversee, any of the financial affairs of the Corporation or its affiliates, and, if deemed appropriate, make recommendations to the Board, external auditors or management.
- (e) The Audit Committee shall:
- (i) evaluate the independence and performance of the external auditors and annually recommend to the Board the appointment of the external auditor or the discharge of the external auditor when circumstances are warranted;
  - (ii) consider the recommendations of management in respect of the appointment of the external auditors;
  - (iii) pre-approve all non-audit services to be provided to the Corporation or its subsidiary entities by its external auditors, or the external auditors of affiliates of the Corporation subject to the over-riding principle that the external auditors not being



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permitted to be retained by the Corporation to perform specifically listed categories of non-audit services as set forth by the Securities and Exchange Commission as well as internal audit outsourcing services, financial information systems work and expert services. Notwithstanding, the foregoing the pre-approval of non-audit services may be delegated to a member of the Audit Committee, with any decisions of the member with the delegated authority reporting to the Audit Committee at the next scheduled meeting;

- (iv) approve the engagement letter for non-audit services to be provided by the external auditors or affiliates, together with estimated fees, and considering the potential impact of such services on the independence of the external auditors;

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- (v) when there is to be a change of external auditors, review all issues and provide documentation related to the change, including the information to be included in the Notice of Change of Auditors and documentation required pursuant to the then current legislation, rules, policies and instruments of applicable regulatory authorities and the planned steps for an orderly transition period; and
  - (vi) review all reportable events, including disagreements, unresolved issues and consultations, as defined by applicable securities policies, on a routine basis, whether or not there is to be a change of external auditors.
- (f) The Audit Committee shall enquire into and determine the appropriate resolution of any conflict of interest in respect of audit or financial matters, which are directed to the Audit Committee by any member of the Board, a shareholder of the Corporation, the external auditors, or senior management.
  - (g) The Audit Committee shall periodically review with management the need for an internal audit function.
  - (h) The Audit Committee shall review the Corporation's accounting and reporting of costs, liabilities and contingencies.
  - (i) The Audit Committee shall establish and maintain procedures for:
    - (i) the receipt, retention and treatment of complaints received by the Corporation regarding accounting controls, or auditing matters; and
    - (ii) the confidential, anonymous submission by employees of the Corporation or concerns regarding questionable accounting or auditing matters.
  - (j) The Audit Committee shall review and approve the Corporation's hiring policies regarding employees and former employees of the present and former external auditors.
  - (k) The Audit Committee shall review with the Corporation's legal counsel, on no less than an annual basis, any legal matter that could have a material impact on the Corporation's financial statements, and any enquiries received from regulators, or government agencies.
  - (l) The Audit Committee shall assess, on an annual basis, the adequacy of this Mandate and the performance of the Audit Committee.

### 5. Date of Mandate

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This Mandate was initially approved by the Board on September 3, 1999. Subsequent to that date, the Board has amended and restated this Mandate on each of December 13, 2002 and April 23, 2003. This Mandate is effective from and after March 5, 2004.

### *Composition of the Audit Committee*

The following table sets forth the name of each of the current members of the Audit Committee, whether such member is independent, whether such member is financially literate and the relevant education and experience of such member.

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Name	Independent	Financially Literate	Relevant Education and Experience
Fred A. Stewart, Q.C. (Chairman)	Yes	Yes	Mr. Stewart graduated with Bachelors of Commerce and Law degrees and is a Barrister and Solicitor (Queens Counsel). Mr. Stewart served as a Member of Cabinet in the Legislative Assembly of the Province of Alberta. Mr. Stewart has acquired significant financial experience and exposure to accounting and financial issues as a founding partner of his law firm, as a Member of Treasury Board of the Government of Alberta and while serving as a director and audit committee member of both private and public companies.
Antoine A. Noujaim Ph.D	Yes	Yes	Dr. Noujaim has a Ph.D. in Bionucleonics and is presently President and CEO of AltaRex Medical Corp. as well as Chairman of ViRexx Medical Corp., both being public companies trading on the TSX and TSXV. He is the founder of both organizations as well as co-founding Biomira Inc. (TSX, Nasdaq) in 1985. He served as senior VP of Biomira, Inc. Through his past experience, Dr. Noujaim has supervised the individuals engaged in the preparing, analyzing or evaluating financial statements. Dr. Noujaim has also served as a director and audit committee member with several other public companies.
Robert B. Schultz F.C.A	Yes	Yes	Mr. Schultz is a Fellow of the Chartered Accountants and is currently Chairman and Director of Rockwater Capital Corporation (a financial services company). Mr. Schultz has served as Chairman and Chief Executive Officer of Merrill Lynch Canada (a public financial services company) and as Chief Executive Officer of Midland Walwyn. Through his various roles as Chairman and Chief Executive Officer, Mr. Schultz has supervised the individual engaged in preparing, analyzing or evaluating financial statements. Mr. Schultz has also served as a director with several other public companies.

**Additional Information**

Additional information, including information as to directors and officers remuneration and indebtedness, principal holders of the Company's securities, options to purchase securities and interests of insiders in material transactions is contained in the Information Circular of the Company for the Company's most recent annual meeting of shareholders that involved the election of directors, which is incorporated herein by reference and forms an integral part of this Annual Information Form.

Additional financial information is contained in the financial statements of the Company for the year ended December 31, 2003, which are incorporated herein by reference and form an integral part of this Annual Information Form.

The Company will provide to any person, upon request:

- (a) when the securities of the Company are in the course of a distribution under a preliminary short form prospectus or a short form prospectus:

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- (i) one copy of this Annual Information Form, together with one copy of any document, or the pertinent pages of any document, incorporated by reference in this Annual Information Form;
  - (ii) one copy of the comparative financial statements of the Company for the year ended December 31, 2003, together with the accompanying report of the auditors and one copy of the most recent interim financial statements of the Company that have been filed, if any, for any period after December 31, 2003;
  - (iii) one copy of the Company's Information Circular in respect of the Company's most recent annual meeting of shareholders that involved the election of directors or one copy of any annual filing prepared instead of that Information Circular, as appropriate and any subsequent management Information Circular or annual filing; and
  - (iv) one copy of any other documents that are incorporated by reference into the preliminary short form prospectus or the short form prospectus and are not required to be provided under (i) to (iii) above; or
- (b) at any other time, one copy of the documents referred to in clauses (a) (i) to (iii), provided that the Company may require the payment of a reasonable charge if the request is made by a person who is not a holder of common shares of the Company.

**Any request for any documents referred to above should be made to the Chief Financial Officer, Oncolytics Biotech Inc., Suite 210, 1167 Kensington Crescent N.W., Calgary, Alberta, Canada, T2N 1X7 or by telecopier at (403) 283-0858.**

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## GLOSSARY

*In this Annual Information Form, unless the context otherwise requires, the following words and phrases shall have the meaning set forth below:*

**ABCA** *Business Corporations Act* (Alberta), as amended.

**ACB** Alberta Cancer Board.

**Activating mutations** a type of genetic mutation that results in a particular protein being active in the absence of an appropriate stimuli. This type of mutation typically leads to the development of a cancerous transformation of a cell.

**Adjuvant therapy** a form of therapy that is to be used in conjunction with one or more addition therapies.

**Alberta Heritage Foundation** the Alberta Heritage Foundation for Medical Research.

**Animal model** a human disease given to an animal which exhibits similar or identical characteristics to this disease in humans.

**Appropriate Regulatory Authority** means (a) Health Canada, (b) the Food and Drug Administration in the United States, or (c) the comparable authorities in the following countries or areas: United Kingdom, France, Germany, Japan, Benelux.

**Asymptomatic** without any signs or symptoms.

**Cancer** a heterogeneous group of diseases that is characterized by the uncontrolled or aberrant growth of cells. In addition to the uncontrolled growth of these tumor cells, these cells are able to invade and colonize other sites in the body; by definition these tumors are malignant.

**Carcinomas** a type of cancer that arises from epithelial tissue.

**Cellular proliferative disorder** a heterogeneous group of disease characterized by the uncontrolled or aberrant growth of cells; is distinct from cancer in that it does not necessarily imply a malignant state.

**Clinical Trial Agreement** the agreement among the Company, Dr. Don Morris and the ACB dated May 1, 1999, providing for, among other things, a repayable grant of \$200,000 to the Company to offset the future REOLYSIN® clinical trial expenditures.

**Cytostatic** any drug or agent that is capable of preventing a cell's growth and division.

**Cytotoxic** any drug or agent that is capable of causing cell death.

**Differentiation** a form of growth; a process whereby a cell develops different or more advanced processes than were possessed by the cell before.

**Epidermal growth factor** a compound that promotes the growth of cells.

**Epidermal growth factor receptor** the cellular receptor that interacts with the epidermal growth factor; a particular family of receptor tyrosine kinase.

**Epithelial** the tissue that forms the outer layer of the body surface or the tissue that lines the gut or other hollow structure.

**Etiology** the reason or causation of an illness, disease or disorder.

**FDA** the Food and Drug Administration

**Gastrointestinal tract** within the digestive system including the stomach, intestine, and all accessory organs.

**Glioblastoma** a specific form of cancer derived from brain tissue.

**Gliomas** a specific form of cancer derived from brain tissue.

**Good Manufacturing Practices** the current regulatory requirements and standards regarding quality assurance procedures to be adhered to in the manufacturing of therapeutic products established and monitored by various governments including Canada and the United States.

**Growth factor receptor** a form of receptor that interacts with growth factors.

**HER2/neu/ErbB2** a form of receptor tyrosine kinase that is frequently overexpressed in breast cancers.

**Immune competent** an animal with a fully functional immune system; an animal that can mount a response to a foreign or infectious agent.

**Immuno-compromised** an animal that is lacking an immune system.

**Investigational New Drug Submission (or IND)** documentation filed with government agencies responsible for evaluating and licensing pharmaceutical drugs. This documentation is necessary for the initiation of clinical trials.

**In Vivo** in the living body.

**Lesion** a morbid change in the functioning or texture of an organ or tissue.

**Metastasis** the process whereby a tumor cell is able to leave the original tumor mass and spread to secondary sites in the body forming additional tumor sites.

**Mitogenic** a drug or agent that promotes cellular division or growth.

**Neoplasia** a group of diseases characterized by uncontrolled cell growth, including, but not limited to, cancer.

**Nucleus** an organelle in the cell that contains genetic material.

**Oncology** the study and treatment of cancer and tumors.

**Patent Cooperation Treaty or PCT** an international patent treaty, of which Canada is a signatory, whereby a single international patent application can be filed in the applicant's or inventor's home country for possible protection of intellectual property in over 100 PCT member countries.

**PKR (or double stranded RNA dependent protein kinase)** a host protein that plays a key role in mediating the cell's antiviral activity.

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**Platelet-derived growth factor receptor (PDGFR)** the cellular receptor that interacts with the platelet-derived growth factor; a particular family of receptor tyrosine kinase.

**Ras** a cellular protein that is a key relay in the transmission of growth signals from the outside of the cell to the cell's nucleus. In a noncancerous cell, Ras is activated in the presence of an appropriate growth signal.

**Receptor** a cellular structure, usually found on the cell surface, that can interact with a certain compound to elicit a specific type of cellular response.

**Receptor tyrosine kinase (RTK)** a type of host receptor that uses a particular residue for cellular signaling to the nucleus. Mutation or overexpression of this type of receptor is frequently seen in the development of a variety of cancers.

**REOLYSIN®** is a trademark of the Company for the human reovirus for the treatment of a specific disease.

**Reovirus** a double stranded RNA virus first identified in 1959. The name is an acronym for Respiratory Enteric Orphan virus. The virus is given the designate of orphan virus since it is not associated with a known disease state. For the purpose of this prospectus, all reference to reovirus is to reovirus type III Dearing.

**Research Contract** an agreement between the Company and the Governors of the University of Calgary, providing for the aggregate sum of \$102,000 to be paid by the Company for a research project under the direction and supervision of Dr. Patrick Lee.

**Share Purchase Agreement** the share purchase agreement among the Vendors, SYNSORB and the Company dated April 21, 1999 providing for the purchase by SYNSORB of all of the issued and outstanding shares in the capital of the Company.

**Signal Transduction** The transmission of signals from the cell surface to the cell's nucleus.

**SYNSORB** SYNSORB Biotech Inc. (now Hawker Resources Inc. by name change), a public Company incorporated under the ABCA.

**Technology Commercialization Agreement** the agreement between the Company and the Alberta Heritage Foundation dated February 9, 1999 providing for a repayable grant of \$150,000 to the Company to offset reovirus clinical trial expenditures.

**Toxicology** the scientific determination of the quantity of a substance that is required to act adversely in the body.

**Tumor** an abnormal growth of tissue whether benign or malignant.

**Vendors** Dr. Patrick Lee, Dr. James Strong, Dr. Matthew Coffey, Dr. Bradley Thompson and University Technologies International Inc.

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Financial Statements

**Oncolytics Biotech Inc.**

December 31, 2003 and 2002

**AUDITORS REPORT**To the Shareholders of  
**Oncolytics Biotech Inc.**

We have audited the balance sheets of Oncolytics Biotech Inc. as at December 31, 2003 and 2002 and the statements of loss and deficit and cash flows for each of the years in the three-year period ended December 31, 2003 and for the cumulative period from inception on April 2, 1998. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in Canada and in the United States. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2003 and 2002 and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2003 and the cumulative period from inception on April 2, 1998 in accordance with Canadian generally accepted accounting principles.

As discussed in Note 4 to the financial statements, in 2003 the Company changed its method of accounting for stock-based compensation.

Calgary, Canada  
February 6, 2004

Chartered Accountants

**Oncolytics Biotech Inc.****BALANCE SHEETS**

As at December 31

	<u>2003</u>	<u>2002</u>
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	2,641,127	8,319,244
Short-term investments	18,111,608	--
Accounts receivable	64,224	48,536
Prepaid expenses	156,837	77,158
	<u>          </u>	<u>          </u>

BALANCE SHEETS

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	<b>2003</b>	<b>2002</b>
	<b>20,973,796</b>	8,444,938
<b>Capital assets [note 5]</b>	<b>4,965,379</b>	4,516,813
<b>Investments [notes 7 and 8]</b>	<b>111,425</b>	5,006,503
	<b>26,050,600</b>	17,968,254
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	<b>884,928</b>	1,260,239
<b>Alberta Heritage Foundation loan [note 6]</b>	<b>150,000</b>	150,000
<b>Commitments and contingency [notes 9 and 10]</b>		
<b>Shareholders' equity</b>		
Share capital [note 11]		
Authorized: unlimited		
Issued: 27,208,262 (2002 - 22,145,284)	<b>44,712,589</b>	30,191,572
Warrants [note 11]	<b>1,598,250</b>	114,286
Contributed surplus [notes 2, 7 and 11]	<b>3,699,425</b>	2,702,718
Deficit	<b>(24,994,592)</b>	(16,450,561)
	<b>25,015,672</b>	16,558,015
	<b>26,050,600</b>	17,968,254

See accompanying notes

On behalf of the Board:

Signed: *Brad Thompson*  
Director

Signed: *Doug Ball*  
Director

**Oncolytics Biotech Inc.**

**STATEMENTS OF LOSS AND DEFICIT**

For the years ended December 31

2003	2002	2001	Cumulative from inception on April 2, 1998 to December 31,
\$	\$	\$	



				2003 \$
<b>Revenue</b>				
Rights revenue	--	--	--	310,000
Interest income	<b>313,305</b>	208,867	655,212	2,085,983
	<b>313,305</b>	208,867	655,212	2,395,983
<b>Expenses</b>				
Research and development	<b>3,314,188</b>	4,283,743	5,116,661	16,891,069
Operating	<b>2,953,840</b>	2,102,272	1,555,128	7,760,913
Amortization	<b>663,524</b>	574,237	465,454	1,910,090
	<b>6,931,552</b>	6,960,252	7,137,243	26,562,072
<b>Loss before the following:</b>	<b>6,618,247</b>	6,751,385	6,482,031	24,166,089
<b>Gain on sale of BCY LifeSciences Inc. [note 8]</b>	<b>(264,453)</b>	--	--	(264,453)
<b>Loss on sale of Transition Therapeutics Inc. [note 8]</b>	<b>2,156,685</b>	--	--	2,156,685
<b>Loss before taxes</b>	<b>8,510,479</b>	6,751,385	6,482,031	26,058,321
<b>Capital tax</b>	<b>33,552</b>	(12,281)	30,000	51,271
<b>Future income tax recovery [note 13]</b>	<b>--</b>	(647,618)	(340,570)	(1,115,000)
<b>Net loss for the year</b>	<b>8,544,031</b>	6,091,486	6,171,461	24,994,592
<b>Deficit, beginning of year</b>	<b>16,450,561</b>	10,359,075	4,187,614	--
<b>Deficit, end of year</b>	<b>24,994,592</b>	16,450,561	10,359,075	24,994,592
<b>Basic and diluted loss per share [note 12]</b>	<b>(0.35)</b>	(0.30)	(0.34)	

See accompanying notes

## Oncolytics Biotech Inc.

## STATEMENTS OF CASH FLOWS

For the years ended December 31

	2003 \$	2002 \$	2001 \$	Cumulative from inception on April 2, 1998 to December 31, 2003 \$
<b>OPERATING ACTIVITIES</b>				
Net loss for the year	(8,544,031)	(6,091,486)	(6,171,461)	(24,994,592)
Deduct non-cash items				
Amortization	663,524	574,237	465,454	1,910,090
Non-cash compensation <i>[note 11]</i>	996,707	32,718	--	1,029,425
Gain on sale of BCY LifeSciences Inc.	(264,453)	--	--	(264,453)
Loss on sale of Transition Therapeutics Inc.	2,156,685	--	--	2,156,685
Future income tax recovery	--	(647,618)	(340,570)	(1,115,000)
Net changes in non-cash working capital	(486,170)	(1,123,551)	1,773,720	579,200
	<b>(5,477,738)</b>	<b>(7,255,700)</b>	<b>(4,272,857)</b>	<b>(20,698,645)</b>
<b>INVESTING ACTIVITIES</b>				
Intellectual property	(1,045,869)	(860,520)	(385,495)	(2,664,826)
Other capital assets	(50,729)	(191,694)	(200,018)	(510,972)
Short-term investments	(18,111,608)	--	--	(18,111,608)
Investment in BCY LifeSciences Inc.	450,151	(127,123)	--	323,028
Investment in Transition Therapeutics Inc.	2,552,695	(20,352)	--	2,532,343
	<b>(16,205,360)</b>	<b>(1,199,689)</b>	<b>(585,513)</b>	<b>(18,432,035)</b>
<b>FINANCING ACTIVITIES</b>				
Alberta Heritage Foundation loan	--	--	--	150,000
Proceeds from exercise of stock options and warrants	700,882	34,000	2,210,016	3,460,985
Proceeds from private placements	9,844,700	1,769,877	--	16,518,220
Proceeds from public offerings	5,459,399	--	--	21,642,602
	<b>16,004,981</b>	<b>1,803,877</b>	<b>2,210,016</b>	<b>41,771,807</b>
<b>Increase (decrease) in cash and cash equivalents during the year</b>	<b>(5,678,117)</b>	<b>(6,651,512)</b>	<b>(2,648,354)</b>	<b>2,641,127</b>
<b>Cash and cash equivalents, beginning of the year</b>	<b>8,319,244</b>	<b>14,970,756</b>	<b>17,619,110</b>	<b>--</b>
<b>Cash and cash equivalents, end of the year</b>	<b>2,641,127</b>	<b>8,319,244</b>	<b>14,970,756</b>	<b>2,641,127</b>
<b>Cash interest, received</b>	<b>187,843</b>	<b>218,129</b>	<b>655,212</b>	

	2003 \$	2002 \$	2001 \$	Cumulative from inception on April 2, 1998 to December 31, 2003 \$
<b>Cash taxes paid (net)</b>	1,552	18,114	39,870	

See accompanying notes

### Oncolytics Biotech Inc.

#### NOTES TO FINANCIAL STATEMENTS

December 31, 2003 and 2002

#### 1. INCORPORATION AND NATURE OF OPERATIONS

Oncolytics Biotech Inc. (the "Company") was incorporated on April 2, 1998 under the Business Corporations Act (Alberta) as 779738 Alberta Ltd. On April 8, 1998, the Company changed its name to Oncolytics Biotech Inc.

The Company is a development stage biopharmaceutical company that focuses on the discovery and development of pharmaceutical products for the treatment of cancers that have not been successfully treated with conventional therapeutics. The product being developed by the Company may represent a novel treatment for Ras mediated cancers which can be used as an alternative to existing cytotoxic or cytostatic therapies, as an adjuvant therapy to conventional chemotherapy, radiation therapy, or surgical resections, or to treat certain cellular proliferative disorders for which no current therapy exists.

#### 2. BASIS OF FINANCIAL STATEMENT PRESENTATION

On April 21, 1999, SYNSORB Biotech Inc. ( SYNSORB ) purchased all of the shares of the Company. In connection with the acquisition, the basis of accounting for the assets and liabilities of Oncolytics was changed to reflect SYNSORB 's cost of acquiring its interest in such assets and liabilities (i.e. reflecting SYNSORB 's purchase cost in the financial statements of the Company). The amount by which SYNSORB 's purchase price exceeded the underlying net book value of the Company 's assets and liabilities at April 21, 1999 was \$2,500,000. Such amount has been credited to contributed surplus and charged to intellectual property which will be amortized to income based on the established amortization policies for such assets. Subsequent to April 21, 1999 SYNSORB 's ownership has been diluted through public offerings of the Company 's common shares, sales of the Company 's shares by SYNSORB and a distribution of SYNSORB 's ownership interest in the Company to its shareholders [note 7]. As a result, SYNSORB no longer has any ownership in the Company.

#### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The financial statements of the Company have been prepared in accordance with Canadian generally accepted accounting principles. These policies are, in all material respects, in accordance with United States generally accepted accounting principles except as disclosed in note 16. The financial statements have, in management's opinion, been properly prepared within reasonable limits of materiality and within the framework of the accounting policies summarized below.

**Use of estimates**

Because a precise determination of many assets and liabilities is dependent upon future events, the preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Actual results could differ from those estimates and such differences could be significant. Significant estimates made by management affecting the Company's financial statements include the assessment of the net realizable value of long lived assets and the amortization period of intellectual property.

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2003 and 2002

**Cash and cash equivalents**

Cash and cash equivalents consists of cash on hand and balances with the Company's bank including interest bearing deposits earning an average interest rate of 2.89% (2002 2.2%).

**Short-term investments**

Short-term investments consisting primarily of bankers' acceptances, coupons and notes, are liquid investments that are readily convertible to known amounts of cash and are subject to an insignificant risk of changes in value and with original maturities less than one year at the time of purchase, are carried at the lower of amortized cost and market value. Gains and losses on disposal of short-term investments are included in income in the period of realization. Premiums or discounts are amortized over the remaining maturity of the instrument and reported in interest income.

**Capital assets**

Capital assets are recorded at cost. Amortization is provided on bases and at rates designed to amortize the cost of the assets over their estimated useful lives. Amortization is recorded using the declining balance method at the following annual rates:

Office equipment and furniture	20%
Medical equipment	20%
Computer equipment	30%
Leasehold improvements	Straight line over the term of the lease

Costs relating to acquiring and establishing intellectual property (mainly patents) are recorded at cost, net of recoveries. Amortization of the intellectual property is on a straight-line basis over seventeen years or estimated useful life, whichever is shorter, and begins on the earlier of a patent being granted or its utilization. The Company assesses potential impairment of its intellectual property when any events that might give rise to impairment are known to the Company by measuring the expected net recovery from products based on the use of the intellectual

property.

### **Investments**

Investments are accounted for at cost and written down only when there is evidence that a decline in value that is other than temporary has occurred.

### **Financial instruments**

Financial instruments of the Company consist of cash and cash equivalents, short term investments, accounts receivable, investments, accounts payable and accrued liabilities, and the Alberta Heritage Foundation loan. As at December 31, 2003 and 2002, there are no significant differences between the carrying values of these amounts and their estimated market values, with the exception of investments whose market value at December 31, 2003 was \$157,140 (2002 \$2,537,089), determined by the closing market value of the investees' shares.

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## **Oncolytics Biotech Inc.**

### **NOTES TO FINANCIAL STATEMENTS**

December 31, 2003 and 2002

### **Foreign exchange**

Transactions originating in foreign currencies are translated into Canadian dollars at the exchange rate in effect at the date of the transaction. Monetary assets and liabilities are translated at the year-end rate of exchange and non-monetary items are translated at historic exchange rates. Exchange gains and losses are included in net loss for the year.

### **Research and development**

Research costs are expensed as incurred. Development costs that meet specific criteria related to technical, market and financial feasibility will be capitalized. To date, all of the development costs have been expensed.

### **Loss per common share**

Basic loss per share is determined using the weighted average number of common shares outstanding during the period.

The Company uses the treasury stock method to calculate diluted loss per share. Under this method, diluted loss per share is computed in a manner consistent with basic loss per share except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of options and warrants, if dilutive. The number of additional shares is calculated by assuming that any outstanding in the money options and warrants were exercised at the later of the beginning of the period or the date of issue and that the proceeds from such exercises were used to acquire shares of common stock at the average market price during the reporting period.

### **Stock option plan**

The Company has one stock option plan (the Plan) available to officers, directors, employees, consultants and suppliers with grants under the Plan approved from time to time by the Board of Directors. Under the Plan, the exercise price of each option equals the market price of the Company's stock on the date of grant in accordance with Toronto Stock Exchange guidelines. Vesting is provided for at the discretion of the Board and the expiration of options is to be no greater than ten years from the date of grant.

**Non-employee stock based compensation**

Stock based compensation to non-employees is recorded at the fair market value based on the fair value of the consideration received, or the fair value of the equity instruments granted, or liabilities incurred, whichever is more reliably measurable, on the earlier of the date at which a performance commitment is reached, performance is achieved, or the vesting date of the options.

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**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2003 and 2002

**Future income taxes**

The Company follows the liability method of accounting for income taxes. Under the liability method, future income taxes are recognized for the difference between financial statement carrying values and the respective income tax basis of assets and liabilities (temporary differences). Future income tax assets and liabilities are measured using substantively enacted income tax rates expected to apply in the years in which temporary differences are expected to be recovered or settled. The effect on future income tax assets and liabilities of a change in tax rates is included in income in the period of the change.

**4. CHANGE IN ACCOUNTING POLICY****Stock based compensation**

Effective January 1, 2003, the Company elected to prospectively adopt the fair value based method of accounting for employee awards granted under its stock option plan (see note 11). Previously, the intrinsic value method was used. The following tables provide pro forma net loss and pro forma basic and diluted net loss per share had compensation expense, for awards granted in 2002, been based on the fair value method of accounting for stock based compensation:

	<b>2003</b>	<b>2002</b>
	<b>\$</b>	<b>\$</b>
Reported net loss	8,544,031	6,091,486
Compensation expense	46,533	689,373
Pro forma net loss	8,590,564	6,780,859
Reported basic and diluted net loss per share	0.35	0.30
Pro forma basic and diluted net loss per share	0.35	0.33

As this policy has been applied prospectively, comparative information has not been restated.

## Oncolytics Biotech Inc.

## NOTES TO FINANCIAL STATEMENTS

December 31, 2003 and 2002

## 5. CAPITAL ASSETS

	2003		
	Cost	Accumulated Amortization	Net Book Value
Intellectual property	6,364,495	1,689,617	4,674,878
Medical equipment	191,502	58,140	133,362
Office equipment	29,576	13,165	16,411
Office furniture	88,788	35,050	53,738
Computer equipment	92,730	58,480	34,250
Leasehold improvements	96,636	43,896	52,740
	<b>6,863,727</b>	<b>1,898,348</b>	<b>4,965,379</b>

	2002		
	Cost	Accumulated Amortization	Net Book Value
Intellectual property	5,303,134	1,095,263	4,207,871
Medical equipment	166,192	30,558	135,634
Office equipment	29,378	9,508	19,870
Office furniture	77,396	25,378	52,018
Computer equipment	86,443	49,203	37,240
Leasehold improvements	100,834	36,654	64,180
	<b>5,763,377</b>	<b>1,246,564</b>	<b>4,516,813</b>

## 6. ALBERTA HERITAGE FOUNDATION LOAN

The Company has received a loan of \$150,000 from the Alberta Heritage Foundation for Medical Research. Pursuant to the terms of the agreement, the Company is required to repay this amount in annual installments from the date of commencement of sales in an amount equal to the lesser of: (a) 5% of the gross sales generated by the Company; or (b) \$15,000 per annum until the entire loan has been paid in full.

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2003 and 2002

**7. RELATED PARTY TRANSACTIONS**

On May 7, 2002, the shareholders of SYNSORB and the Company approved an arrangement whereby the Company would release from escrow 4,000,000 common shares held by SYNSORB. As consideration, SYNSORB provided the Company with 1,500,000 common shares of BCY Life Sciences Inc. ( BCY ) along with the rights to receive an additional 400,000 common shares of BCY upon the attainment of certain milestones by BCY at no cash cost to the Company. The Company received 200,000 of these 400,000 common shares on November 27, 2002. These 1,700,000 common shares in BCY have been recorded as an investment at \$170,000 based on the quoted market price of the BCY common shares at that time with an offsetting credit recorded to contributed surplus.

**8. INVESTMENTS**

On April 23, 2002, the Company acquired 694,445 common shares of BCY, a public company, for \$0.18 per share, and warrants exercisable until April 23, 2004 to purchase up to 694,445 common shares in BCY at an exercise price of \$0.27 per share for total consideration of \$127,123 (including costs of \$2,123). After this transaction and the transaction described in note 7, the Company held a total of 2,394,445 BCY shares. During the fourth quarter of 2003, the Company sold 1,496,500 of its BCY shares for net cash proceeds of \$450,151 recording a gain on sale of investment of \$264,453. As at December 31, 2003, the Company's remaining ownership in BCY was 897,945 common shares with a market value of \$157,140 and the common share purchase warrants which have not been exercised.

On June 14, 2002, the Company acquired 6,890,000 common shares of Transition Therapeutics Inc. ( TTH ), a public company, through the issuance of 1,913,889 common shares of the Company from treasury. The investment was recorded at \$4,709,380 (including acquisition costs of \$20,352) based on the trading price of the Company's shares at the time of acquisition. On June 6, 2003, the Company sold all of its 6,890,000 common shares of TTH for net cash proceeds of \$2,552,695 recording a loss on sale of investment of \$2,156,685.

**9. COMMITMENTS**

The Company is committed to payments totaling \$1,569,739 during 2004 for activities primarily related to product manufacturing as well as continuing toxicology and process related costs.

The Company is committed to monthly rental payments (including the Company's portion of operating costs) of \$10,702 under the terms of a lease for office premises, which expires on May 31, 2006.

Under a clinical trial agreement entered into with the Alberta Cancer Board ( ACB ), the Company has agreed to repay the amount funded under the agreement together with a royalty, to a combined maximum amount of \$400,000 plus an overhead repayment of \$100,000, upon sales of a specified product. The Company agreed to repay the ACB in annual installments in an amount equal to the lesser of: (a) 5% of gross sales of a specified product; or (b) \$100,000 per annum.



**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2003 and 2002

**10. CONTINGENCY**

During 1999, the Company entered into an agreement that assumed certain obligations (the Assumption Agreement ) in connection with a Share Purchase Agreement (the Agreement ) between SYNSORB and the former shareholders of the Company to make milestone payments and royalty payments.

As of December 31, 2003, a milestone payment was still outstanding for \$1.0 million, due within 90 days of the first receipt from an Appropriate Regulatory Authority, for marketing approval to sell REOLYSIN® to the public or the approval of a new drug application for REOLYSIN®.

This milestone payment, when payable, will be accounted for as research and development expense and will not be deductible for tax purposes.

In addition to the milestone payment, payments may become due and payable in accordance with the Agreement upon realization of sales of REOLYSIN®. During the year, the Company completed amendments and revisions to the contingent obligations to its five founding shareholders with respect to these other contingent payments. The amendments and revisions reduced the amount and clarified the determination of potential obligations of the Company to these shareholders arising from the Agreement and Assumption Agreement entered into in 1999. 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 14.25% (formerly 20%) 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 payments referred to in the foregoing sentence will be amended to a royalty payment of 2.85% (formerly 4%) of Net Sales received by the Company for such products.

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**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2003 and 2002

**11. SHARE CAPITAL**

**Authorized:**

Unlimited number of common shares

**Issued**

**Shares**

**Warrants**

Authorized:

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Issued	Shares		Warrants	
	Number	Amount \$	Number	Amount \$
Balance, December 31, 1998	2,145,300	4	--	--
Issued on exercise of stock options	76,922	77	--	--
	2,222,222	81	--	--
July 29, 1999 share split (a)	6,750,000	81	--	--
Issued for cash pursuant to July 30, 1999 private placement (net of share issue costs of \$45,000) (b)	1,500,000	855,000	--	--
Issued for cash pursuant to August 24, 1999 private placement	1,399,997	1,049,998	--	--
Issued on initial public offering (net of share issue costs of \$317,897) (c)	4,000,000	3,082,103	--	--
Issued for cash pursuant to exercise of share purchase warrants	20,000	15,000	--	--
Balance, December 31, 1999	13,669,997	5,002,182	--	--
Issued on exercise of stock options and warrants	573,910	501,010	--	--
Issued for cash pursuant to July 17, 2000 private placement (d)	244,898	2,998,645	--	--
Issued on public offering (net of share issue costs of \$998,900) (e)	3,000,000	13,101,100	--	--
Balance, December 31, 2000	17,488,805	21,602,937	--	--
Issued on exercise of stock options and warrants	1,702,590			