

ONCOLYTICS BIOTECH INC  
Form 40-F  
March 04, 2005

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, 2004**

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.

Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

None  
(Title of Class)

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

None  
(Title of Class)

---

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, 2004, 31,915,496 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

---

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(R) and other products of the Company;

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

---

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, 2004, 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 \$1.2034.

#### **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 18 "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 has materially affected, or is 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 and procedures 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. A copy of the Code of Ethics for Chief Executive Officer, Chief Financial Officer and Controller is attached to this annual report as Exhibit 99.F, and is available in print to any shareholder who requests it by writing to the Company at Suite #210, 1167 Kensington Crescent N.W., Calgary, Alberta, Canada, T2N 1X7, Attention: Doug Ball. All amendments to the code, and all waivers of the code with respect to any of the officers covered by it, will be disclosed in the Company's annual report on Form 40-F or in current reports on Form 6-K and provided in print to any shareholder upon written request to the Company.

The Company has a separate Code of Ethics applicable to all employees, officers and directors of the Company, a copy of which is available in print to any shareholder who requests it by writing to the Company at Suite #210, 1167 Kensington Crescent N.W., Calgary, Alberta, Canada, T2N 1X7, Attention: Doug Ball. All amendments to the Code of Ethics applicable to all employees, officers and directors of the Company, and all waivers of the code with respect to any of the officers covered by it, will be disclosed in the Company's annual report on Form 40-F or in current reports on Form 6-K and provided in print to any shareholder upon written request to the Company.

**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 2004 Annual Report, and as at the date of this Report, the following individuals comprise the entire membership of the Company's Audit Committee, which have been established in accordance with Section 3(a)(58)(A) of the Exchange Act:

Fred Stewart  
Robert Schultz  
Jim Dinning

*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 previously mentioned directors have also been determined by the Company to be independent within the criteria referred to above under the subheading Independence .

**PRINCIPAL ACCOUNTING FEES AND SERVICES INDEPENDENT AUDITORS**

The table setting forth the Company's fees paid to its independent auditor, Ernst & Young LLP for the years ended December 31, 2004 and December 31, 2003 are set forth under the heading *Additional Information External Auditor Service Fees* of the Company's 2004 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. See, "Audit Committee Matters" in the Company's 2004 Annual Information Form included herein by reference.

**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 Contractual Obligations* , the Company has set forth its contractual commitments.

**NASDAQ CORPORATE GOVERNANCE**

The Company's common shares are quoted for trading on the Nasdaq SmallCap Market ( Nasdaq ). Section 4350 of the Nasdaq Marketplace Rules permits Nasdaq to grant exemptions to a foreign private issuer when provisions of Section 4350 related to qualitative listing requirements are contrary to a law, rule or regulation of any public authority exercising jurisdiction over such issuer or contrary to generally accepted business practices in the issuer's country of domicile. The Company is organized under the laws of Province of Alberta and its common shares are listed for trading on The Toronto Stock Exchange. The Company complies with the laws of Province of Alberta and rules and regulations of The Toronto Stock Exchange, including rules related to corporate governance practices. Section 4350 of the Nasdaq Marketplace Rules requires a foreign private issuer to provide a description of the significant ways in which the Company's governance practices differ from those followed by domestic companies pursuant to Section 4350 of the Nasdaq Marketplace Rules in annual reports for years beginning

---

December 31, 2003. A description of the significant ways in which the Company's governance practices differ from those followed by domestic companies pursuant to Section 4350 of the Nasdaq Marketplace Rules in the years ended December 31, 2003 and December 31, 2004 and currently is as follows:

*Shareholder Meeting Quorum Requirement:* The Nasdaq minimum quorum requirement for a shareholder meeting under Section 4350(b) of the Nasdaq Marketplace Rules is one-third of the outstanding shares of common stock. In addition, a company listed on Nasdaq is required to state its quorum requirement in its bylaws. The Company's quorum requirement is set forth in its corporate bylaws. A quorum for a meeting of members of the Company is two persons present and being, or representing by proxy, members holding not less than 5% of the issued shares entitled to be voted at such meeting. The foregoing quorum requirement is consistent with the laws, customs and practices in Canada and the rules of The Toronto Stock Exchange.

**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 previously 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.

---

**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**

Signatures

**Oncolytics Biotech Inc.**

By /s/ Doug Ball

Doug Ball  
Chief Financial Officer

Date: March 4, 2005

---

**DOCUMENTS FILED AS PART OF THIS REPORT**

1. Renewal Annual Information Form of the Registrant for the year ended December 31, 2004
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, 2004 and 2003;
  - Statements of Loss and Deficit for the years ended December 31, 2004, 2003, 2002 and cumulative from inception on April 2, 1998 to December 31, 2004;
  - Statements of Cash Flows for the years ended December 31, 2004, 2003, 2002 and cumulative from inception on April 2, 1998 to December 31, 2004;
  - 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**

- 99.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.
- 99.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.
- 99.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.
- 99.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.
- 99.E Consent of Ernst & Young LLP, Independent Chartered Accountants.

## RENEWAL ANNUAL INFORMATION FORM

for the Year Ended December 31, 2004

March 4, 2005

---

### TABLE OF CONTENTS

	<b>Page</b>
<b>CORPORATE STRUCTURE</b>	<b>1</b>
<b>GENERAL DEVELOPMENT OF THE BUSINESS</b>	<b>1</b>
General	1
Clinical Trials	2
Animal Studies	3
Manufacturing	4
Reovirus for Animal Use	5
Financings and Other Distributions	5
Shareholdings in Other Issuers	5
Publications and Presentations	5
Patents	6
Recent Developments	7
Future Development	7
<b>NARRATIVE DESCRIPTION OF THE BUSINESS</b>	<b>8</b>
Business of the Company	8
<b>TABLE OF CONTENTS</b>	<b>8</b>



	<b>Page</b>
Scientific Background	9
The Potential Cancer Product	9
Repayable Grants	10
Business Strategy	10
Regulatory Requirements	11
Market and Competition	12
Product Marketing Strategy	12
Third Party Advisor, Collaborators and Scientific Advisory Board	12
Intellectual Property Policy	14
Patent and Patent Application Summary	14
Acquisition of all of the Shares of the Company by SYNSORB	16
Employees	16
Research and Development Expenditures	17
Dividend Policy	17
<b>MARKET FOR SECURITIES</b>	<b>17</b>
Market for Common Shares	17
Description of Common Shares	17
<b>DIRECTORS AND OFFICERS</b>	<b>18</b>
<b>AUDIT COMMITTEE MATTERS</b>	<b>20</b>
Mandate of the Audit Committee	20
Composition of the Audit Committee	26
<b>RISK FACTORS</b>	<b>26</b>
<b>ADDITIONAL INFORMATION</b>	<b>28</b>
Legal Proceedings	34

	<b>Page</b>
Interest of Management and Others in Material Transactions	34
Transfer Agent and Registrar	34
Material Contracts	34
Interests of Experts	34
External Auditor Service Fees	35
Audit Fees	35
Audit-Related Fees	35
Tax Fees	35
All Other Fees	35
Other Additional Information	35
<b>GLOSSARY</b>	<b>36</b>

*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, regulatory 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 2<sup>nd</sup> 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 1990's. 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 February 27, 2004, the Company announced 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 is 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® is 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 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 announced the final update on its technical clinical study for T2 prostate cancer. On March 23, 2003, the Company previously reported results from an interim assessment of this clinical 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. This trial, which was approved by Health Canada on October 11, 2001, was 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 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 comprise 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 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 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 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 engages a toll manufacturer, Cobra Biomanufacturing Plc for the production of reovirus for human clinical trials and animal toxicology studies. 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 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

Since the initial public offering, the Company has completed 10 offerings for net cash proceeds of \$53,685,487. In 2004, the following offerings of securities were completed:

on April 7, 2004, the Company issued 1,077,100 units at \$6.25 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 \$7.75 per share until October 7, 2005);

on September 23, 2004, the Company issued 21,459 common shares valued at \$150,000 and \$250,000 cash to a non-management founding shareholder to cancel a portion of the Company's future contingent payments; and

on November 23, 2004, the Company issued 1,504,000 units at \$6.65 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 \$8.00 per share until November 23, 2007).

### Shareholdings in Other Issuers

During 2004, the Company sold 697,945 (2003 1,496,500) common shares of BCY for net cash proceeds of \$133,609 (2003 \$450,151) and reported a gain on sale of these shares of \$47,002 (2003 \$264,453). As at December 31, 2004, the Company's remaining ownership in BCY was 200,000 common shares which were still under escrow.

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 December 15, 2004, "Efficacy and Safety Evaluation of Human Reovirus Type 3 in Immunocompetent Animals" was published in *Clinical Cancer Research* Vol. 10. This publication concluded that the data showed the efficacy and safety of reovirus when it is used in the treatment of gliomas in immunocompetent hosts. As well, inoculation of reovirus into the brain of nonhuman primates did not produce significant toxicities.

---

-6-

On September 30, 2004, a poster was presented at the 16th EORTC-NCI-AACR 2004 Symposium on "Molecular Targets and Cancer Therapeutics" in Geneva, Switzerland entitled "The oncolytic reovirus, Reolysin, augments the anticancer effects of cytotoxic agents in vitro against the ras-mutated human colon cancer cell line HCT 116. The researchers were able to show that REOLYSIN® enhances the cytotoxicity of chemotherapeutic agents including 5-FU, gemcitabine, doxorubicin and cisplatin.

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 Institut 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.

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

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

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.

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

In 2004, the Company received notification of issuance of three additional patents in the U.S. for a total of 13 U.S. patents and one European patent. The new patents in 2004 continued to expand on previously issued patents in the area of using recombinant reovirus for the treatment of neoplasia (cancers), non-cancer cellular proliferative diseases, and various methods of production and processing of the reovirus. 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*.

---

-7-

### Recent Developments

#### *Recurrent Malignant Glioma Clinical Trial Study in the U.S.*

On February 28, 2005, the Company announced that it had received clearance from the US Food and Drug Administration (FDA) to begin a Phase I/II clinical trial to investigate the use of REOLYSIN® to treat patients with recurrent malignant gliomas.

This clinical trial is an open-label dose escalation Phase I/II study in which a single dose of REOLYSIN® will be administered by infusion to patients with recurrent malignant gliomas that are refractory to standard therapy. The administration involves the stereotactically-guided placement of a needle into the tumour, through which REOLYSIN® will be administered or infused into the tumour mass and surrounding tissue using a pump. 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 response to the virus and any evidence of antitumour activity. The enrolment in this study is expected to be up to 30 evaluable patients in the dose escalation phase with up to an additional 14 patients added at the maximum tolerated dose.

#### *REOLYSIN® in Combination with Radiation Therapy Clinical Trial Study in the U.K.*

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

On February 18, 2005, the Company announced that it had received a letter of approval from the U.K. regulatory authorities (Medicines and Healthcare products Regulatory Agency or MHRA) for its Clinical Trial Application to begin a Phase I clinical trial to evaluate the feasibility, safety and anti-tumour effects of intratumoural administration of REOLYSIN® in combination with radiation in patients with advanced cancers.

The trial is a Phase I open-label, dose-escalation study of REOLYSIN® combined with two different radiation dosages/schedules. The enrolment in this study is expected to be approximately thirty evaluable patients, and will depend upon the number of dose levels tested. Up to an additional fifteen patients will also be treated at the maximum tolerated dose. The primary objective of the study is to determine the maximum tolerated dose, dose limiting toxicity, and safety profile of REOLYSIN® when administered intratumourally to patients receiving radiation treatment. A secondary objective is to examine any evidence of anti-tumour activity. Patients who have been diagnosed with advanced or metastatic solid tumours that are refractory (have not responded) to standard therapy or for which no curative standard therapy exists will be eligible.

### **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 2005 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, expanding into other areas including utilizing its association with the NCI to broaden its clinical trial program. The Company also intends to expand 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.

---

-8-

**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 regulatory authorities such as the Food and Drug Administration in the United States, the Health Protection Branch in Canada, or MHRA in the UK as well as those factors detailed in the Company's regulatory filings.**

## **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.

---

-9-

## 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 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

---

-10-

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.

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

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 current new product development

---

-11-

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. The primary regulatory body in the United States is the FDA and in the UK is the MHRA. 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.

---

-12-

**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 2005 from the American Cancer Society, 1.37 million Americans are expected to be diagnosed with cancer in the year, and 57,000 Americans are forecast to die of cancer. In the United States cancer accounts for 22.8% 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 treatment are \$189.9 billion. Of this figure, \$69.4 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 December 15, 2004, "Efficacy and Safety Evaluation of Human Reovirus Type 3 in Immunocompetent Animals" was published in *Clinical Cancer Research* Vol. 10. This publication concluded that the data showed the efficacy and safety of reovirus when it is used in the treatment of gliomas in immunocompetent hosts. As well, inoculation of reovirus into the brain of nonhuman primates did not produce significant toxicities.

On September 30, 2004, a poster was presented at the 16th EORTC-NCI-AACR 2004 Symposium on "Molecular Targets and Cancer Therapeutics" in Geneva, Switzerland entitled "The oncolytic reovirus,"

---

-13-

Reolysin, augments the anticancer effects of cytotoxic agents in vitro against the ras-mutated human colon cancer cell line HCT 116. The researchers were able to show that REOLYSIN® enhances the cytotoxicity of chemotherapeutic agents including 5-FU, gemcitabine, doxorubicin and cisplatin.

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.

**Scientific Advisory Board**

The Company formed a Scientific Advisory Board in 2003 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 antitumoural 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 Section Chief of Hematology/Oncology in the department of pediatrics at the Children's Hospital at Montefiore 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.

---

-14-

Frank Tufaro, Ph.D., has extensive 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 13 patents issued in the United States (11 of the 13 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 consider leaving the Company for other employment. The Company intends that all staff be compensated through competitive salaries and all staff participate in the company stock option program.

### **Patent and Patent Application Summary**

Where a patent is filed in the United States there is an option to file a Patent Cooperation Treaty (PCT) application. The PCT application process is a means for technology patented in one of the PCT signatory countries to receive protection in other PCT countries. The PCT includes over 100 countries. Within one year of filing a patent in the United States, the applicant files for PCT coverage in all PCT countries. Approximately 18 months after the PCT filing, the applicant must pay individual filing fees in designated PCT countries and at that time the applicant may wish to restrict coverage to a subset of countries which have potential for the technology. At the time of filing the PCT application the applicant designates which of the member countries are to be covered by the application. The PCT application allows the applicant to defer national filings in the various designated countries for a period of up to 30 months from the original PCT application filing date. After the PCT application deferral period, the applicant must file for separate national or regional patents in one or more designated countries, depending on which specific markets the applicant intends to target.

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

The following table sets forth the Company's patent issuances, including its first European patent:

-15-

<u>Title</u>	<u>Ownership</u>	<u>Inventors</u>	<u>Status of Patent</u>	
Patent Number U.S. 6,110,461 Reovirus for the Treatment of Neoplasia	Oncolytics Biotech Inc.	Dr. Patrick W.K. Lee Dr. James E. Strong Dr. Matthew C. Coffey	Filing date: Issued:	Aug. 13, 1997 Aug. 29, 2000
Patent Number U.S. 6,136,307 Reovirus for the Treatment of cellular proliferative disorders	Oncolytics Biotech Inc.	Dr. Patrick W.K. Lee Dr. James E. Strong Dr. Matthew C. Coffey	Filing date: Issued:	Feb. 24, 1999 Oct. 24, 2000
Patent Number U.S. 6,261,555 Reovirus for the treatment of Neoplasia	Oncolytics Biotech Inc.	Dr. Patrick W. K. Lee Dr. James Strong Dr. Matthew C. Coffey	Filing date: Issued:	Aug. 12, 1998 July 17, 2001
Patent Number U.S. 6,344,195 Reovirus for the treatment of Neoplasia	Oncolytics Biotech Inc.	Dr. Patrick W. K. Lee Dr. James Strong Dr. Matthew C. Coffey	Filing date: Issued:	May 12, 2000 Feb. 5, 2002
European Application Number 98940002.3 Patent Number 1003534 Reovirus for the treatment of Neoplasia	Oncolytics Biotech Inc.	Dr. Patrick W. K. Lee Dr. James Strong Dr. Matthew Coffey	Filing date: Issued:	Aug 12, 1998 March 6, 2002
Patent Number U.S. 6,455,038 Reovirus for the treatment of Cellular Proliferative Disorders	Oncolytics Biotech Inc.	Dr. Patrick L. Lee Dr. James E. Strong Dr. Matthew C. Coffey	Filing date: Issued:	June 15, 2000 Sept. 24, 2002
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 <sup>(1)</sup>	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 <sup>(2)</sup>	Oncolytics Biotech Inc.	Dr. Matthew C. Coffey Dr. Bradley G. Thompson	Filing date: Issued:	Sept. 28, 2001 Nov 18, 2003

-16-

<u>Title</u>	<u>Ownership</u>	<u>Inventors</u>	<u>Status of Patent</u>	
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
Patent Number U.S. 6,808,916 Method of Extracting Virus from Cell Culture	Oncolytics Biotech Inc.	Dr. Matthew C. Coffey Dr. Bradley G. Thompson	Filing date: Issued:	March 14, 2002 Oct. 26, 2004
Patent Number U.S. 6,811,775 Reovirus for the Treatment of Cellular Proliferative Disorders	Oncolytics Biotech Inc.	Dr. Patrick L. Lee Dr. James E. Strong Matthew E. Coffee	Filing date: Issued:	August 15, 2002 Nov. 2, 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 reached an agreement that cancelled a portion of its future contingent obligation for consideration of \$400,000 consisting of \$250,000 cash and 21,459 common shares valued at \$150,000. As a result, the Company's future contingent obligations were reduced to 11.75% (formerly 14.25%) of royalty payments or other payments received as a result of entering into partnerships or other arrangements for the development of the reovirus technology. 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 2.35% (formerly 2.85%) of net sales received by the Company for such products.



**Employees**

As of December 31, 2004, the Company had 9 employees. The majority of the activities of the Company are conducted under contract with third party service providers.

-17-

**Research and Development Expenditures**

For the period ended December 31, 2004, the Company incurred research and development expenditures of \$7,107,998 representing approximately 51.9% of the Company's total expenses for the year. See *Management's Discussion and Analysis - Results of Operations - Research and Development Expenses*.

**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.

**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:

	Toronto Stock Exchange				Nasdaq Small Cap Market			
	High (\$)	Low (\$)	Close (\$)	Volume	High (US\$)	Low (US\$)	Close (US\$)	Volume
<b>Period</b>								
<b>2004</b>								
January	4.86	3.93	4.83	81,752	3.75	2.94	3.64	87,980
February	6.00	4.64	5.60	170,855	4.48	3.48	4.20	211,694
March	8.45	5.15	8.17	238,456	6.49	3.85	6.23	417,108
April	12.90	7.81	9.43	283,914	9.84	6.01	6.85	602,042
May	9.55	6.85	7.73	118,570	6.97	4.86	5.82	226,020
June	8.25	7.08	7.95	55,968	6.24	5.12	5.94	82,776
July	7.90	4.30	5.11	102,200	5.94	3.20	3.80	157,695
August	6.84	4.09	6.22	82,095	5.26	3.03	4.71	118,918

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

		Toronto Stock Exchange				Nasdaq Small Cap Market			
September	8.29	5.72	7.42	106,652	7.00	4.39	5.87	172,928	
October	7.90	6.57	7.27	55,115	6.25	5.24	5.94	113,942	
November	7.36	4.89	4.95	80,118	6.03	4.11	4.13	147,071	
December	6.06	4.82	5.55	81,752	4.95	4.04	4.59	118,990	

### 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 10 and 11 of the audited financial statements of the Company.

-18-

### 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 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.

Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
Bradley G. Thompson Ph.D. <sup>(2)</sup> 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.	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. <sup>(3)</sup> Calgary, Alberta	Director	President of W.A. Cochrane & Associates, Inc. (a consulting company) since 1989 and Chairman of Resverlogix Corp. (a public biopharmaceutical company) and University Technologies International Inc. (UTI) at the University of Calgary since 2000 and is a	October 31, 2002

Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
Matthew C. Coffey Ph.D. Calgary, Alberta	Chief Scientific Officer Officer	<p><del>Director of the Corporation since July 2000. Prior to 2000, he served as the Deputy Minister of Health Services for the Province of Alberta from 1973 to 1974 and President of the University of Calgary from 1974 to 1978.</del></p> <p>Vice-President of Product Development of the Corporation since July 1999. Chief Financial Officer of the Corporation from September 1999 to May 2000.</p>	N/A

-19-

Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
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
Antoine A. Noujaim Ph.D. <sup>(2)</sup> Edmonton, Alberta	Director	Chairman and Chief Executive Officer of ViRexx Medical Corp since February 1, 2005. Formerly Chairman, CEO & President of ViRexx Research Inc. (a public biopharmaceutical company which changed its name to ViRexx Medical Corp.) 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 2004 to the 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. <sup>(1)</sup> Toronto, Ontario	Lead Director	Chairman and Director of Rockwater Capital Corporation formerly McCarvill Corporation (a financial services company) since 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,	June 30, 2000

Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
Fred A. Stewart, Q.C. <sup>(1)(2)</sup> Bragg Creek, Alberta	Director	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 President Association of Canada (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 <sup>(1)</sup> Calgary, Alberta	Director	Chairman of Western Financial Group since September 2004. Prior thereto, Mr. Dinning was the Executive Vice President of TransAlta Corporation (power generation and wholesale marketing company) from 1997 to 2004 and 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.	March 24, 2004

-20-

Name and Municipality of Residence	Position with the Corporation	Principal Occupation	Director of the Corporation Since
J. Mark Lievonen C.A. <sup>(3)</sup> Markham, Ontario	Director	President of Sanofi Pasteur Limited (formerly known as Aventis Pasteur Limited), a vaccine development, manufacturing and marketing company, since October 1998 and holding various positions with Sanofi Pasteur Limited and its predecessors since 1983. Mr. Lievonen is a member of the Board of Directors of BIOTECCanada (served as Chair from 2000 to May 2003), Ontario Genomics Institute since December 2002 (appointed Chair in September 2004), and the Ontario Cancer Research Network since 2004. 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.	April 5, 2004

**Notes:**

- (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. Lievonen is the Chair of the Corporate Governance and Nominating Committee.

Notes:

As at the date hereof, the directors and senior officers as a group beneficially owned, directly or indirectly, 29,500 common shares of the Company, representing less than 0.1% of the issued and outstanding common shares.

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.

## AUDIT COMMITTEE MATTERS

### *Mandate of the Audit Committee*

#### **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

---

-21-

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.
- (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

---

-22-

- (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. This will include receipt, review and evaluation, at least annually, of a formal written statement from the independent auditors confirming their independence, and qualifications, including their compliance with the requirements of the relevant oversight boards;
  - (iv) deal directly with the external auditors to pre-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;

---

-23-

- (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;
  - (viii) pre-approve any related party transactions to be entered into by the Company, and ensure appropriate disclosure thereof; and
  - (ix) ensure financial disclosure incorporates inclusion of any material correcting adjustments required by the external auditors.
- (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.

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

- (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.
  - (d) The Audit Committee shall:
    - (i) review the audit plan with the Corporation's external auditors and with management;
    - (ii) Review with the independent auditors the matters required to be discussed relating to the conduct of the audit, including (a) the proposed scope of their examination, with emphasis on accounting and financial areas where the Committee, the independent auditors or management believes special attention should be directed; (b) the results of their audit, including their audit findings report and resulting letter, if any, of recommendations for management; (c) their evaluation of the adequacy and effectiveness of the Company's internal controls over financial reporting; (d) significant areas of disagreement, if any, with management; (e) co-operation received from management in the conduct of the audit; (f) significant accounting, reporting, regulatory or industry developments affecting the Company; and (g) review any proposed changes in major accounting policies or principles proposed or contemplated by the independent auditors or management, 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;
- 

-24-

- (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;
- (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. Without restricting the generality of the foregoing, the committee will discuss with management and the independent auditors to the extent required, any issues and disclosure requirements regarding (a) the use of pro forma or adjusted non-GAAP information, as well as financial information and earnings guidance provided to analysts and rating agencies, (b) any off balance sheet arrangements, and (c) any going concern qualification;
- (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)



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

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 and monitor the audit partners' rotation as required by law;
  - (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 permitted to be retained by the Corporation to perform specifically listed categories of non-audit services as set forth by the Securities and Exchange
- 

-25-

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;
  - (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

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

- (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.
- 

-26-

### 5. Date of Mandate

The Audit Committee 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 and March 5, 2004. This Mandate is effective from and after December 8, 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.

<b>Name</b>	<b>Independent</b>	<b>Financially Literate</b>	<b>Relevant Education and Experience</b>
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 the Treasury Board of the Government of Alberta and while serving as a director and audit committee member of both private and 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.

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

Name	Independent	Financially Literate	Relevant Education and Experience
			Mr. Schultz has also served as a director with several other public companies.
Jim Dinning	Yes	Yes	Mr. Dinning graduated with a bachelor of commerce honours degree and a master's degree in public administration from Queen's University. Mr. Dinning served as a Member of the Legislative Assembly of the Province of Alberta. Mr. Dinning has acquired significant financial experience and exposure to accounting and financial issues while serving as a director and audit committee member for other publicly traded companies and as Minister of Finance for the Alberta Provincial Government.

### 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

-27-

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;

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.

---

-28-

### **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 similar regulatory authorities in other countries 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 similar regulatory authorities in other countries 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 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.

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 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 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.

---

-29-

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, 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 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.

**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.

---

-30-

### **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 *Narrative Description 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 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

---

-31-

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 affect 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.

**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.

**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's technologies may become obsolete

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.

---

-32-

**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, 2004, the Company had an accumulated deficit of \$38.0 million. The Company incurred net losses of \$13.0, \$8.5 million, and \$6.1 million for the years ended December 31, 2004, 2003, and 2002, respectively. The Company anticipates that it will continue to incur significant losses during 2005 and in the foreseeable future. The Company will not reach profitability until after successful 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.

**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, 2004, the Company had cash and cash equivalents, including short-term investments, of \$33.9 million and working capital of approximately \$33.3 million. The Company presently anticipates that its average cash usage for 2005 will be approximately \$1.0 million per month and its existing capital resources are adequate to fund its current plans for research and development activities into 2007. Factors that will affect the Company's anticipated monthly cash usage include, but are not limited to, the number of manufacturing runs required to supply its clinical trial program and the cost of each run, the number of clinical trials ultimately approved, the timing of patient enrollment in the approved clinical trials, the actual costs incurred to support each clinical trial, the number of treatments each patient will receive, the timing of the NCI's R&D activity, and the level of pre-clinical activity required by a health authority.

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 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.

---

-33-

**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 \$1,500,000, \$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.

**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 in the U.S. and the UK). 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's share price may be highly volatile

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.

---

-34-

## **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, 2004, as set forth in the Annual Report of the Company.

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, 2004 and 2003, Ernst & Young LLP received the following fees from the Company:

<b>Item</b>	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
	<b>\$</b>	<b>\$</b>
Audit fees	60,460	44,600
Audit-related fees(1),(3),(4)	33,354	34,062
Tax fees(2)	22,150	9,946
All other fees	--	--

-35-

**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 tax consultation fees.
- (3) Includes fees associated with matters relating to the prospectus offerings in 2004 and 2003.
- (4) Includes fees associated with preliminary internal control work for Sarbanes Oxley Section 404.

***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***

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 professional tax consultations.

***All Other Fees***

Notes:

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

There were no fees paid to Ernst & Young, LLP that would be considered All Other Fees in 2004 or 2003. 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.

### Other 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, 2004 and under the heading Management's Discussion and Analysis of Financial Conditions and Results of Operations in the 2004 Annual Report of the Company, which are incorporated herein by reference and form an integral part of this Annual Information Form.

The documents referred to above as well as additional information relating to the Company is available through the Internet on the Canadian System for Electronic Document Analysis and Retrieval ( SEDAR ) at [www.sedar.com](http://www.sedar.com).

**Alternatively, a request for any documents referred to above may 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.**

---

-36-

## 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 additional 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.

---

-37-

**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.

---

-38-

**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.

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

**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.

---

**EXHIBIT 2**

Financial Statements

### **Oncolytics Biotech Inc.**

December 31, 2004 and 2003

---

#### **AUDITORS REPORT**

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

We have audited the balance sheets of Oncolytics Biotech Inc. as at December 31, 2004 and 2003 and the statements of loss and deficit and cash flows for each of the years in the three-year period ended December 31, 2004 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.

AUDITORS REPORT

47

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

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and auditing standards generally accepted in Canada. 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 consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, these financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2004 and 2003 and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2004 and the cumulative period from inception on April 2, 1998 in accordance with Canadian generally accepted accounting principles.

Calgary, Canada

February 11, 2005 [except note 20 which  
is as of February 21, 2005]

Chartered Accountants

### Oncolytics Biotech Inc.

#### BALANCE SHEETS

As at December 31

	<b>2004</b>	<b>2003</b>
	\$	\$
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	12,408,516	2,641,127
Short-term investments	21,510,707	18,111,608
Accounts receivable	47,767	64,224
Prepaid expenses	250,365	156,837
	<b>34,217,355</b>	20,973,796
<b>Capital assets [note 4]</b>	<b>5,259,286</b>	4,965,379
<b>Investments [notes 6 and 7]</b>	<b>12,000</b>	111,425
	<b>39,488,641</b>	26,050,600
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	949,258	884,928
	<b>150,000</b>	150,000
<b>Commitments and contingency [notes 8 and 9]</b>		
<b>Shareholders' equity</b>		
Share capital [note 10]		
Authorized: unlimited		
Issued: 31,915,496 (2003 - 27,208,262)	66,643,325	44,712,589



Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

	2004	2003
	\$	\$
Warrants [note 10]	3,347,630	1,598,250
Contributed surplus [notes 2, 6, 11 and 12]	6,349,139	3,699,425
Deficit	(37,950,711)	(24,994,592)
	<hr/>	<hr/>
	38,389,383	25,015,672
	<hr/>	<hr/>
	39,488,641	26,050,600
	<hr/>	<hr/>

See accompanying notes

On behalf of the Board:

/s/ Doug Ball  
Director

/s/ Fred Stewart  
Director

**Oncolytics Biotech Inc.**

**STATEMENTS OF LOSS AND DEFICIT**

For the periods ended December 31

	2004	2003	2002	Cumulative from inception on April 2, 1998 to December 31, 2004
	\$	\$	\$	\$
<b>Revenue</b>				
Rights revenue	--	--	--	310,000
Interest income	699,757	313,305	208,867	2,785,740
	<hr/>	<hr/>	<hr/>	<hr/>
	699,757	313,305	208,867	3,095,740
	<hr/>	<hr/>	<hr/>	<hr/>
<b>Expenses</b>				
Research and development [note 9]	7,107,998	2,818,962	4,251,025	23,526,528
Operating	2,803,669	2,449,478	2,102,870	10,005,794
Stock based compensation [note 11]	2,668,570	996,707	32,718	3,697,995
Foreign exchange loss (gain)	358,068	2,881	(598)	359,970
Amortization	751,756	663,524	574,237	2,661,846
	<hr/>	<hr/>	<hr/>	<hr/>
	13,690,061	6,931,552	6,960,252	40,252,133
	<hr/>	<hr/>	<hr/>	<hr/>

	2004	2003	2002	Cumulative from inception on April 2, 1998 to December 31, 2004
	\$	\$	\$	\$
Loss before the following:	12,990,304	6,618,247	6,751,385	37,156,393
Gain on sale of BCY LifeSciences Inc. [note 7]	(34,185)	(264,453)	--	(298,638)
Loss on sale of Transition Therapeutics Inc. [note 7]	--	2,156,685	--	2,156,685
Loss before taxes	12,956,119	8,510,479	6,751,385	39,014,440
Capital tax (recovery)	--	33,552	(12,281)	51,271
Future income tax recovery [note 14]	--	--	(647,618)	(1,115,000)
Net loss for the period	12,956,119	8,544,031	6,091,486	37,950,711
Deficit, beginning of period	24,994,592	16,450,561	10,359,075	--
Deficit, end of period	37,950,711	24,994,592	16,450,561	37,950,711
Basic and diluted loss per share [note 13]	(0.45)	(0.35)	(0.30)	

See accompanying notes

### Oncolytics Biotech Inc.

#### STATEMENTS OF CASH FLOWS

For the periods ended December 31

	2004	2003	2002	Cumulative from inception on April 2, 1998 to December 31, 2004
	\$	\$	\$	\$
<b>OPERATING ACTIVITIES</b>				
Net loss for the year	(12,956,119)	(8,544,031)	(6,091,486)	(37,950,711)
Deduct non-cash items				
Amortization	751,756	663,524	574,237	2,661,846
Non-cash compensation [note 11]	2,668,570	996,707	32,718	3,697,995
Gain on sale of BCY LifeSciences Inc.	(34,185)	(264,453)	--	(298,638)

Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

	2004	2003	2002	Cumulative from inception on April 2, 1998 to December 31, 2004
	\$	\$	\$	\$
Cancellation of contingent payment obligation settled in common shares <i>[note 9]</i>	150,000	--	--	150,000
Loss on sale of Transition Therapeutics Inc.	--	2,156,685	--	2,156,685
Foreign exchange loss	264,080	2,881	(598)	265,982
Future income tax recovery	--	--	(647,618)	(1,115,000)
Net changes in non-cash working capital	(69,065)	(489,051)	(1,122,953)	508,233
<b>Cash used in operating activities</b>	<b>(9,224,963)</b>	<b>(5,477,738)</b>	<b>(7,255,700)</b>	<b>(29,923,608)</b>
<b>INVESTING ACTIVITIES</b>				
Intellectual property	(958,809)	(1,045,869)	(860,520)	(3,623,635)
Other capital assets	(15,230)	(50,729)	(191,694)	(526,202)
Purchase of short-term investments	(6,777,179)	(18,111,608)	--	(24,888,787)
Redemption of short-term investments	3,114,000	--	--	3,114,000
Investment in BCY LifeSciences Inc.	133,609	450,151	(127,123)	456,637
Investment in Transition Therapeutics Inc.	--	2,552,695	(20,352)	2,532,343
<b>Cash used in investing activities</b>	<b>(4,503,609)</b>	<b>(16,205,360)</b>	<b>(1,199,689)</b>	<b>(22,935,644)</b>
<b>FINANCING ACTIVITIES</b>				
Alberta Heritage Foundation loan	--	--	--	150,000
Proceeds from exercise of stock options and warrants	8,121,296	700,882	34,000	11,582,281
Proceeds from private placements	6,223,763	9,844,700	1,769,877	22,741,983
Proceeds from public offerings	9,150,902	5,459,399	--	30,793,504
<b>Cash provided by financing activities</b>	<b>23,495,961</b>	<b>16,004,981</b>	<b>1,803,877</b>	<b>65,267,768</b>
<b>Increase (decrease) in cash and cash equivalents during the period</b>	<b>9,767,389</b>	<b>(5,678,117)</b>	<b>(6,651,512)</b>	<b>12,408,516</b>
<b>Cash and cash equivalents, beginning of the period</b>	<b>2,641,127</b>	<b>8,319,244</b>	<b>14,970,756</b>	<b>--</b>
<b>Cash and cash equivalents, end of the period</b>	<b>12,408,516</b>	<b>2,641,127</b>	<b>8,319,244</b>	<b>12,408,516</b>
<b>Cash interest received</b>	<b>459,757</b>	<b>187,843</b>	<b>218,129</b>	
<b>Cash taxes paid (net)</b>	<b>--</b>	<b>1,552</b>	<b>18,114</b>	

See accompanying notes

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

**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 6]. 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 18. 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, 2004 and 2003

### 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 2.26% (2003 2.89%).

### Short-term investments

Short-term investments consisting primarily of bankers' acceptances, coupons and notes, and 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 two years at the time of purchase, and 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	Staight 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 (currently estimated to be ten years) 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.

### 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.

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

**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.

**Stock based compensation**

***Officers, Directors and Employees***

Effective January 1, 2003, the Company prospectively adopted the fair value based method of accounting for employee awards granted under its stock option plan (see note 11). The fair value of each stock option grant is calculated using the Black Scholes Option Pricing Model and is recorded over the option's vesting period on a straight line basis. 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:

---

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

2004	2003	2002
\$	\$	\$

Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

	2004 \$	2003 \$	2002 \$
Reported net loss	12,956,199	8,544,031	6,091,486
Compensation expense	4,425	46,533	689,373
Pro forma net loss	12,960,624	8,590,564	6,780,859
Reported basic and diluted net loss per share	(0.45)	(0.35)	(0.30)
Pro forma basic and diluted net loss per share	(0.45)	(0.35)	(0.33)

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

**Non-employees**

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.

**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. CAPITAL ASSETS**

	2004		
	Cost	Accumulated Amortization	Net Book Value
Intellectual property	\$ 7,373,742	\$ 2,376,144	\$ 4,997,598
Medical equipment	191,502	82,498	109,004
Office equipment	29,576	16,163	13,413
Office furniture	88,788	43,046	45,742
Computer equipment	126,322	66,205	60,117
Leasehold improvements	96,636	63,224	33,412
	\$ 7,906,566	\$ 2,647,280	\$ 5,259,286

Oncolytics Biotech Inc.

## NOTES TO FINANCIAL STATEMENTS

December 31, 2004 and 2003

<b>2003</b>			
	<b>Cost</b>	<b>Accumulated Amortization</b>	<b>Net Book Value</b>
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>

**5. 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.

**6. 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 were 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.

**7. 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 6, the Company held a total of 2,394,445 BCY shares. During the first six months of 2004, the Company sold 697,945 (2003 1,496,500) of its BCY shares for net cash proceeds of \$133,609 (2003 \$450,151) recording a gain on sale of investment of \$47,002 (2003 \$264,453). In the third quarter of 2004, the Company recorded a write down of its remaining investment in BCY of \$12,817 to reflect the investment's market value (as estimated based on its publicly traded share price) at that time. As at December 31, 2004, the Company's remaining ownership



**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

in BCY was 200,000 common shares with a book value (net of write down) of \$12,000. The warrants expired out of the money.

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.

**8. COMMITMENTS**

The Company is committed to payments totaling \$943,815 during 2005 for activities related to its clinical trial program and collaborations.

The Company is committed to monthly rental payments (including the Company's portion of operating costs) of \$11,087 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.

**9. 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®. In 2003, 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. Also, on September 23, 2004, the Company reached an agreement that further reduced its contingent payments to its founding shareholders through the cancellation of a portion of these contingent payments from one of its non-management founding shareholders. The consideration paid by the Company consisted of \$250,000 cash and 21,459 common shares valued at \$150,000 and has

---

**Oncolytics Biotech Inc.**

## NOTES TO FINANCIAL STATEMENTS

December 31, 2004 and 2003

been recorded as research and development expense. The value of the common shares was based on the closing market price on September 23, 2004.

As a result of the amendments and the cancellation agreement, if the Company receives royalty payments or other payments as a result of entering into partnerships or other arrangements for the development of the reovirus technology, the Company is obligated to pay to the founding shareholders 11.75% (formerly in 2003 14.25% and 2002 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 2.35% (formerly in 2003 2.85% and 2002 4%) of Net Sales received by the Company for such products.

**10. SHARE CAPITAL****Authorized:**

Unlimited number of common shares

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 <sup>(a)</sup>	6,750,000	81		
Issued for cash pursuant to July 30, 1999 private placement (net of share issue costs of \$45,000) <sup>(b)</sup>	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) <sup>(c)</sup>	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 <sup>(d)</sup>	244,898	2,998,645		
Issued on public offering (net of share issue costs of \$998,900) <sup>(e)</sup>	3,000,000	13,101,100		

Authorized:

**Oncolytics Biotech Inc.****NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

Balance, December 31, 2000	17,488,805	21,602,937		
Issued on exercise of stock options and warrants	1,702,590	2,210,016		
Balance, December 31, 2001	19,191,395	23,812,953		
Issued on exercise of stock options	40,000	34,000		
Issued on acquisition of the interest in Transition Therapeutics Inc. [note 7]	1,913,889	4,689,028		
Issued for cash pursuant to December 11, 2002 private placement <sup>(f)</sup>	1,000,000	1,896,714	550,000	114,286
Share issue costs		(241,123)		
Balance, December 31, 2002	22,145,284	30,191,572	550,000	114,286
Issued for cash pursuant to February 10, 2003 private placement <sup>(g)</sup>	140,000	265,540	77,000	16,000
Issued for cash pursuant to June 19, 2003 private placement <sup>(h)</sup>	2,120,000	5,912,113	1,272,000	543,287
Issued for cash pursuant to August 21, 2003 private placement <sup>(i)</sup>	1,363,900	3,801,778	813,533	349,176
Issued for cash pursuant to October 14, 2003 public offering <sup>(j)</sup>	1,200,000	5,528,972	720,000	617,428
Exercise of options	64,700	149,615		
Exercise of warrants	174,378	593,194	(174,378)	(41,927)
Share issue costs		(1,730,195)		

**Oncolytics Biotech Inc.****NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

Balance, December 31, 2003	27,208,262	44,712,589	3,258,155	1,598,250
Issued for cash pursuant to April 7, 2004 private placement <sup>(k)</sup>	1,077,100	5,924,050	646,260	1,028,631
Issued for cash pursuant to November 23, 2004 public offering <sup>(l)</sup>	1,504,000	8,693,120	864,800	1,521,672
Issued pursuant to cancellation of contingent payment <i>[note 9]</i>	21,459	150,000		
Exercise of warrants	1,907,175	8,178,546	(1,907,175)	(798,096)
Expired warrants		2,827	(6,700)	(2,827)
Exercise of options	197,500	778,951		
Share issue costs		(1,796,758)		
Balance, December 31, 2004	31,915,496	66,643,325	2,855,340	3,347,630

- (a) Pursuant to subsection 167(1)(f) of the Business Corporations Act (Alberta), the Articles of the Company were amended by subdividing the 2,222,222 issued and outstanding common shares of the Company into 6,750,000 common shares.
- (b) Pursuant to a private placement, 1,500,000 common share purchase warrants were issued entitling the holders thereof to acquire one additional share at \$0.75 per share until November 8, 2001. At December 31, 2001, all of the warrants had been exercised.
- (c) Pursuant to the initial public offering, the agent was issued common share purchase warrants entitling it to acquire 400,000 common shares at \$0.85 per share until May 8, 2001. At December 31, 2001, all of the warrants had been exercised.
- (d) Pursuant to the private placement, 244,898 common shares were issued at an issue price of \$12.25 per share net of issue costs of \$1,355.
- (e) Pursuant to a special warrant offering, the Company sold 3,000,000 special warrants for \$4.70 per warrant for net proceeds of \$13,101,100. Each warrant entitled the holder to one common share upon exercise. At December 31, 2001, all of the warrants had been exercised.
- (f) Pursuant to a private placement, 1,000,000 units were issued at an issue price of \$2.00 per unit net of issue costs of \$241,123. Each unit included one common share (ascribed value of \$1.897) and one-half of one common share purchase warrant (ascribed value of \$0.103) for a total of 500,000 warrants. Each whole common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$3.00 per share until June 11, 2004. In addition, the Company issued 50,000 common share purchase warrants on the same terms to the brokerage firm assisting with the transaction. The ascribed value of these broker warrants was \$11,000 (\$0.22 per

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

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

broker warrant) and has been included in the issue costs. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.

- (g) Pursuant to a private placement, 140,000 units were issued at an issue price of \$2.00 per unit net of issue costs of \$37,369. Each unit included one common share (ascribed value of \$1.897) and one-half of one common share purchase warrant (ascribed value of \$0.103) for a total of 70,000 warrants. Each whole common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$3.00 per share until August 10, 2004. In addition, the Company issued 7,000 common share purchase warrants on the same terms to the brokerage firm assisting with the transaction. The ascribed value of these broker warrants was \$1,540 (\$0.22 per broker warrant) and has been included in the issue costs. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.
- (h) Pursuant to a private placement, 2,120,000 units were issued at an issue price of \$3.00 per unit net of issue costs of \$637,986. Each unit included one common share (ascribed value of \$2.789) and one-half of one common share purchase warrant (ascribed value of \$0.211) for a total of 1,060,000 warrants. Each whole common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$4.00 per share until December 19, 2004. In addition, the Company issued 212,000 common share purchase warrants on the same terms to the brokerage firms assisting with the transaction. The ascribed value of these broker warrants was \$95,400 (\$0.45 per broker warrant) and has been included in the issue costs. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.
- (i) Pursuant to a private placement, 1,363,900 common shares and 681,943 common share purchase warrants were issued for gross proceeds of \$4,091,738. Each common share and whole common share purchase warrant have ascribed values of \$2.787 and \$0.425 respectively. Each common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$4.00 per share until February 21, 2005. Share issue costs related to this private placement were \$367,839. In addition, the Company issued 131,590 common share purchase warrants on the same terms to the advisors assisting with the transaction. The ascribed value of these additional warrants was \$59,216 (\$0.45 per additional warrant) and has been included in the issue costs. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.
- (j) Pursuant to a public offering, 1,200,000 units were issued at an issue price of \$5.00 per unit net of issue costs of \$687,001. Each unit included one common share (ascribed value of \$4.607) and one-half of one common share purchase warrant (ascribed value of \$0.393) for a total of 600,000 warrants. Each whole common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$6.25 per share until April 14, 2005. In addition, the Company issued 120,000 common share purchase warrants with an exercise price of \$5.00 that expires on April 14, 2005 to the brokerage firms assisting with the transaction. The ascribed value of these broker warrants was \$146,400 (\$1.19 per broker warrant) and has been included in the issue costs. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.
- (k) Pursuant to a private placement, the Company sold 1,077,100 units at an average price of \$6.25 per unit for gross cash proceeds of \$6,731,875. The units were comprised of 1,077,100 common shares and 538,550 common share purchase warrants and have ascribed values of \$5.50 and \$1.50 respectively. Each common share purchase warrant entitles the holder to acquire one common share

---

### Oncolytics Biotech Inc.

#### NOTES TO FINANCIAL STATEMENTS

December 31, 2004 and 2003

in the capital of the Company upon payment of \$7.75 per share until October 7, 2005. Share issue costs related to the private placement were \$728,918. In addition, the Company issued 107,710 common share purchase warrants to its advisor entitling the holder to acquire one common share of the capital of the Company upon payment of \$7.00 per share until October 7, 2005. The ascribed value of these additional warrants was \$220,806 (\$2.05 per additional warrant) and has been included in the share issue costs above. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.

Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

- (l) Pursuant to a public offering, the Company sold 1,504,000 units at an issue price of \$6.65 per unit for gross cash proceeds of \$10,001,600. Each unit included one common share (ascribed value of \$5.78) and one-half of one common share purchase warrant (ascribed value of \$0.87) for a total of 752,000 warrants. Each whole common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$8.00 per share until November 23, 2007. Share issue costs related to this public offering were \$1,063,890. In addition, the Company issued 112,800 common share purchase warrants with an exercise price of \$7.06 that expires on May 23, 2006 to the brokerage firm assisting with the transaction. The ascribed value of these broker warrants was \$213,192 (\$1.89 per broker warrant) and has been included in the share issue costs above. The ascribed values of the warrants were based on the Black Scholes Option Pricing Model.

The following table summarizes the Company's outstanding warrants as at December 31, 2004:

Exercise Price	Outstanding, Beginning of the Year	Granted During the Year	Exercised During the Year	Expired During the Year	Outstanding, End of Year	Weighted Average Remaining Contractual Life (years)
\$3.00	480,755		480,755			
\$4.00	1,243,867		1,237,167	6,700		
\$4.00	813,533		44,561		768,972	0.17
\$5.00	120,000		74,442		45,558	0.29
\$6.25	600,000		70,250		529,750	0.29
\$7.00		107,710			107,710	0.75
\$7.06		112,800			112,800	1.40
\$7.75		538,550			538,550	0.75
\$8.00		752,000			752,000	2.90
	3,258,155	1,511,060	1,907,175	6,700	2,855,340	1.09

Oncolytics Biotech Inc.

NOTES TO FINANCIAL STATEMENTS

December 31, 2004 and 2003

11. STOCK BASED COMPENSATION

Stock Option Plan

The Company has issued stock options to acquire common stock through its stock option plan of which the following are outstanding at December 31:

	2004		2003
Stock Options	Weighted Average Share Price \$	Stock Options	Weighted Average Share Price \$

Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

	2004		2003	
Outstanding at beginning of year	2,800,800	3.81	2,653,500	4.40
Granted during year	1,202,250	5.63	599,000	3.71
Cancelled during year			(387,000)	7.97
Exercised during year	(197,500)	3.77	(64,700)	2.31
<hr/>				
Outstanding at end of year	3,805,550	4.39	2,800,800	3.81
<hr/>				
Options exercisable at end of year	3,717,050	4.41	2,720,383	3.87
<hr/>				

The following table summarizes information about the stock options outstanding and exercisable at December 31, 2004:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price \$	Number Exercisable	Weighted Average Exercise Price \$
\$0.75 - \$1.00	982,550	4.8	0.85	982,550	0.85
\$1.65 - \$2.37	281,000	6.5	1.85	231,000	1.88
\$2.70 - \$3.33	478,750	8.0	3.04	473,750	3.07
\$4.00 - \$5.00	1,211,750	9.5	4.79	1,185,250	4.89
\$6.77 - \$9.76	708,500	7.1	8.67	701,500	8.67
\$12.15 - \$13.50	143,000	5.8	12.63	143,000	12.63
<hr/>					
	3,805,550	7.5	4.39	3,717,050	4.41
<hr/>					

The outstanding options vest annually or after the completion of certain milestones. The Company has reserved 4,012,461 common shares for issuance relating to outstanding stock options.

As the Company is following the fair value based method of accounting for stock option awards, compensation expense related to options granted to employees and consultants was \$2,537,088 (2003 \$812,711) and \$131,482 (2003 \$102,466) respectively with an offsetting credit to contributed surplus.

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

The estimated fair value of stock options issued during the year was determined using the Black-Scholes model using the following weighted average assumptions and fair value of options:

2004	2003
<hr/>	<hr/>

	<b>2004</b>	<b>2003</b>
Risk-free interest rate	2.83%	3.09%
Expected hold period to exercise	2 years	2 years
Volatility in the price of the Company's shares	71%	69%
Dividend yield	zero	zero
Weighted average fair value of options	\$ 2.26	\$ 1.47

In 2002, the Company granted 48,000 share incentive rights to a non-employee which, when exercised by the holder, would require payment in cash or shares, at the sole option of the Company for amounts in excess of \$2.31 based on the weighted average trading price for the ten trading days prior to the exercise. The Company accounted for this transaction with a non-employee at fair value determined using the Black-Scholes model. The related compensation expense recorded in 2003 was \$81,530, with an offsetting credit to contributed surplus. As at December 31, 2004, these share incentive rights are still outstanding.

## 12. CONTRIBUTED SURPLUS

The following table summarizes the change in contributed surplus for the period ending December 31:

	<b>2004</b>	<b>2003</b>
	\$	\$
Balance, beginning of year	\$ 3,699,425	\$ 2,702,718
Stock based compensation	2,683,869	996,707
Exercise of stock options	(34,155)	
Balance end of year	\$ 6,349,139	\$ 3,699,425

## 13. LOSS PER COMMON SHARE

Loss per common share is calculated using the weighted average number of common shares outstanding for the year ended December 31, 2004 of 29,028,391 (2003 24,242,845; 2002 20,311,238). The effect of any potential exercise of the Company's stock options and warrants outstanding during the year has been excluded from the calculation of diluted earnings per share, as it would be anti-dilutive.

### Oncolytics Biotech Inc.

#### NOTES TO FINANCIAL STATEMENTS

December 31, 2004 and 2003



**14. INCOME TAXES**

The provision for income taxes recorded in the financial statements differs from the amount which would be obtained by applying the statutory income tax rate to the loss before tax as follows:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
Loss before taxes	<b>(12,956,119)</b>	(8,510,479)	(6,751,385)
Statutory Canadian corporate tax rate	<b>33.87%</b>	36.75%	39.24%
Anticipated tax recovery	<b>(4,388,238)</b>	(3,127,601)	(2,649,243)
Non-taxable portion of net capital loss (gain)	<b>(16,717)</b>	347,698	--
Employee stock based compensation	<b>903,845</b>	366,290	--
Cancellation of contingent payment obligation settled in common shares	<b>50,805</b>	--	--
Change in tax rate	<b>198,610</b>	272,506	228,892
Non-deductible expenses	<b>8,976</b>	9,739	10,398
Change in valuation allowance(a)	<b>3,242,719</b>	2,131,368	1,762,335
Future income tax recovery	--	--	(647,618)

(a) As of December 31, 2004, the Company has non-capital losses for income tax purposes of approximately \$23,814,000, which are available for application against future taxable income and expire in 2006 (\$663,000) 2007 (\$1,033,000), 2008 (\$2,898,000), 2009 (\$4,483,000), 2010 (\$4,483,000) and 2014 (\$10,254,000). In addition to the loss carry forward amounts above, the Company has scientific research and development claims and related investment tax credits of approximately \$7,772,000 as at December 31, 2004 which are available for application against future taxable income. The potential benefits resulting from these tax pools have been recognized in the financial statements only to the extent they are more likely than not of being realized.

The components of the Company's future income tax asset are as follows:

	<b>2004</b>	<b>2003</b>
	<b>\$</b>	<b>\$</b>
Non-capital loss carryforwards	<b>8,010,356</b>	4,633,861
Scientific research and development	<b>3,099,863</b>	3,167,981
Net capital loss carryforwards	<b>283,627</b>	308,929
Undepreciated capital costs in excess of book value of capital assets	<b>93,596</b>	72,305
Net book value of intellectual property in excess of tax value	<b>(71,327)</b>	(310,315)
Share issue costs	<b>683,239</b>	509,411
Valuation allowance	<b>(12,099,354)</b>	(8,382,172)
Future tax asset	--	--

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

**15. INDEMNIFICATION OF OFFICERS AND DIRECTORS**

The Company's corporate by-laws require that, except to the extent expressly prohibited by law, the Company will indemnify its officers and directors against all costs, charges and expenses, including an amount paid to settle an action or satisfy a judgment reasonably incurred in respect of any civil, criminal or administrative action or proceeding as it relates to their services to the Company. The by-laws provide no limit to the amount of the indemnification. The Company has purchased directors' and officers' insurance coverage to cover claims made against the directors and officers during the applicable policy periods. The amounts and types of coverage have varied from period to period as dictated by market conditions. The Company believes that it has adequate insurance coverage; however there is no guarantee that all indemnification payments will be covered under the Company's existing insurance policies.

There is no pending litigation or proceeding involving any officer or director of the Company as to which indemnification is being sought, nor is the Company aware of any threatened litigation that may result in claims for indemnification.

**16. FINANCIAL INSTRUMENTS**

Financial instruments of the Company consist of cash and cash equivalents, short term investments, accounts receivable, investments, accounts payable, and the Alberta Heritage Foundation loan. As at December 31, 2004 and 2003, 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, determined by the closing market value of the investees' shares.

***Credit risk***

The Company is exposed to credit risk on its short-term investments in the event of non-performance by counterparties, but does not anticipate such non-performance. The Company mitigates its exposure to credit risk by restricting its portfolio to investment grade securities with short term maturities and by monitoring the credit risk and credit standing of counterparties.

***Interest rate risk***

The Company has exposure to interest income risk through its short-term investments in fixed-income securities that are sensitive to interest rate fluctuations.

***Foreign exchange risk***

The Company purchases goods and services denominated primarily in Canadian, U.S. and UK currencies. To manage its foreign exchange risk, the Company, from time to time, acquires short-term investments denominated in these securities.

---

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

**17. ECONOMIC DEPENDENCE**

The Company contracts the production and currently receives its supplies of REOLYSIN® from one toll manufacturer based in the United Kingdom. There are a limited number of potential producers and suppliers of REOLYSIN®. As a result, any significant disruption of the services provided by this toll manufacturer has the potential to delay the progress of the Company's clinical trial program. Management is aware of and is taking actions to minimize this exposure.

**18. RECONCILIATION OF CANADIAN GAAP TO US GAAP**

The financial statements of the Company are prepared in accordance with Canadian GAAP which, in most respects, conforms to US GAAP. Significant differences between Canadian and US GAAP are as follows:

	Notes	2004 \$	2003 \$	2002 \$	Cumulative from inception on April 2, 1998 to December 31, 2004 \$
Net loss - Canadian GAAP		<b>12,956,119</b>	8,544,031	6,091,486	37,950,119
Amortization of intellectual property	(1)	<b>(361,500)</b>	(361,500)	(361,500)	(1,626,750)
In process research and development	(1)	--	--	--	2,500,000
Future income tax recovery	(1)	--	--	647,618	1,115,000
Net loss - US GAAP		<b>12,594,619</b>	8,182,531	6,377,604	39,938,369
Unrealized loss (gain) on available-for-sale securities	(2)	--	(45,715)	2,469,414	2,423,699
Reclassification of unrealized gain (loss) on available-for-sale securities	(2)	<b>45,715</b>	(2,469,414)	--	(2,423,699)
Comprehensive loss - US GAAP		<b>12,640,334</b>	5,667,402	8,847,018	39,938,369
Basic and diluted loss per common share - US GAAP		<b>(0.43)</b>	(0.34)	(0.31)	--

There are no differences between Canadian GAAP and US GAAP in amounts reported as cash flows from (used in) operating, financing and investing activities.

**Oncolytics Biotech Inc.****NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

Balance sheet items in accordance with US GAAP are as follows:

December 31, 2004

December 31, 2003

	Notes	Canadian GAAP	US GAAP	Canadian GAAP	US GAAP
Capital assets	(1)	5,259,286	3,271,036	4,965,379	2,615,629
Investments	(2)	12,000	12,000	111,425	157,140
Future income taxes	(1)	--	--	--	--
Deficit	(1)	37,950,711	39,938,961	24,994,592	27,344,342
Other comprehensive loss (income)	(2)	--	--	--	(45,715)

## 1. Push-Down Accounting and In Process Research and Development

Intellectual property of \$2,500,000 recorded as a consequence of SYNORB's acquisition of the Company's shares comprises intangible assets related to research and development activities. Under US GAAP, these items are expensed on acquisition.

As a result of charging \$2,500,000 to expense in 1999 for US GAAP purposes, the amortization of the intellectual property and the future income tax recovery and future income tax liability related to intellectual property recorded for Canadian GAAP purposes has been reversed.

## 2. Unrealized Gains and Losses on Investments

Under U.S. GAAP, equity securities, having a readily determinable fair value and not classified as trading securities, are classified as available-for-sale securities and reported at fair value, with unrealized gains and losses included in comprehensive income or loss and reported as a separate component of shareholders' equity net of related deferred income taxes. Declines in the fair value of individual available-for-sale securities below their cost that are other than temporary result in write-downs of the individual securities to their fair value. The related write-downs are included in earnings as realized losses. Under Canadian GAAP, these securities are carried at cost and written down only when there is evidence that a decline in value that is other than temporary has occurred.

## Stock Based Employee Compensation

On January 1, 2003, the Company prospectively adopted the fair value based method for its employee options (see note 3). Consequently there were no differences between Canadian GAAP and U.S. GAAP with respect to options granted in 2004 and 2003.

In 2002, the Company applied the intrinsic value method for employee stock options and the fair value method for non-employee options granted after January 1, 2002. Prior to January 1, 2002, for US GAAP, the Company applied the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related interpretations in accounting for its employee stock option plans. As well, the Company provided pro forma disclosure as required by FAS 123 for those options granted prior to January 1, 2002.

Oncolytics Biotech Inc.

## NOTES TO FINANCIAL STATEMENTS

December 31, 2004 and 2003

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

The following additional pro-forma disclosure would be provided under US GAAP with respect to the fair value of employee options granted prior to January 1, 2002. The fair value for these options granted was estimated at the date of grant using a Black-Scholes Option Pricing Model with the following weighted-average assumptions:

	2001
Risk free interest rate	5.0%
Dividend yield	0%
Volatility factors of expected market price	87%
Weighted average expected life of the options	2 years

Pro forma disclosures of loss and loss per common share are presented below as if the Company had adopted the cost recognition requirements under FAS 123 from inception.

		2004 \$	2003 \$	2002 \$
Net Loss	Pro forma - Canadian GAAP	12,960,624	8,590,564	6,780,859
	As reported - US GAAP	12,594,619	8,182,531	6,377,604
	Pro forma - US GAAP	12,599,044	8,236,440	7,186,991
Basic and diluted net loss per common share	Pro forma - Canadian GAAP (\$/share)	(0.45)	(0.35)	(0.33)
	As reported - US GAAP	(0.43)	(0.34)	(0.31)
	Pro forma - US GAAP (\$/share)	(0.43)	(0.34)	(0.35)

### Newly Issued U.S. Accounting Standards

#### *Share Based Payments*

On December 16, 2004, the Financial Accounting Standards Board ( FASB ) issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. Statement 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, Statement of Cash Flows. Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted no later than July 1, 2005

The Company adopted the fair value based method of accounting for share-based payments effective January 1, 2003 using the prospective method described in FASB Statement No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. Currently, the Company uses the Black Scholes model to estimate the value of stock options granted to employees and expects to continue to use this acceptable option valuation model upon the required adoption of Statement 123(R). The Company does not anticipate that adoption of Statement 123(R) will have a material impact on its results of operations or

**Oncolytics Biotech Inc.**

**NOTES TO FINANCIAL STATEMENTS**

December 31, 2004 and 2003

its financial position.

**19. COMPARATIVE FIGURES**

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

**20. SUBSEQUENT EVENT**

During the January 1, to February 21, 2005 period, the Company received proceeds of \$3,075,888 from the exercise of 768,972 warrants previously issued on August 21, 2003. As of February 21, 2005, all of the 813,533 warrants issued as part of the August 21, 2003 private placement have been exercised.

---

**EXHIBIT 3**

**March 2, 2005**

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

The following information should be read in conjunction with the Company's 2004 audited financial statements and notes thereto, which were prepared in accordance with Canadian generally accepted accounting principles (GAAP).

**FORWARD-LOOKING STATEMENTS**

The following discussion contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company's belief as to the potential of REOLYSIN® as a cancer therapeutic and the Company's expectations as to the success of its research and development programs in 2005 and beyond, future financial position, business strategy and plans for future operations, and statements that are not historical facts, involve known and unknown risks and uncertainties, which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the need for and availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN® as a cancer treatment, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN®, uncertainties related to the research and development of pharmaceuticals, uncertainties related to competition, changes in technology, the regulatory process and general changes to the economic environment. Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Forward looking statements are based on assumptions, projections, estimates and/or expectations of management at the time such forward looking statements are made, and such assumptions, projections, estimates and/or expectations could change or prove to be incorrect or inaccurate. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements.

## OVERVIEW

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

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

### *General Risk Factors*

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

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

---

In developing a product for approval, the Company will rely upon its employees, contractors, consultants and collaborators and other third party relationships, including the ability to obtain appropriate product liability insurance. There can be no assurance that these reliances and relationships will continue as required.

In addition to developmental and operational considerations, market prices for securities of biotechnology companies generally are volatile, and may or may not move in a manner consistent with the progress being made by the Company.

### *Highlights*

In 2004, the Company's net loss was \$12,956,119 compared to a net loss of \$8,544,031 in 2003 and \$6,091,486 in 2002. The increase in the Company's net loss was due to an increase in research and development (R&D) activity as well as non-cash compensation expense. Cash used in operating activities in 2004 was \$9,224,963 compared to \$5,477,738 and \$7,255,700 in 2003 and 2002 respectively.

During 2004, the Company received approval and commenced patient enrollment in a systemic (intravenous) delivery clinical trial in the United Kingdom (UK). In conjunction with this new trial, the Company provided a final update on the T2 prostate clinical study undertaken to provide technical information to support a systemic delivery clinical trial application. For manufacturing and related process development activity, the Company continued to focus on supplying its clinical trial and research programs with REOLYSIN® as well as the transfer of its manufacturing process to a UK based supplier. Finally, the Company continued to incur expenses for research collaborations. In particular, animal model data was reported from the examination of the use of REOLYSIN® with radiation therapy and also with approved chemotherapeutics.

In 2004, the Company raised \$23,495,961 through a private placement, a public offering and the exercise of warrants and options. In 2003, the Company raised \$19,007,827 through three private placements, one public offering, exercises of warrants and options, and the sale of all of its investments in Transition Therapeutics Inc. (TTH) and a majority of its investment in BCY LifeSciences Inc. (BCY). As a result of these financing activities, the Company ended the year with cash and cash equivalents (including short-term investments) of \$33,919,223 at December 31, 2004 (2003 \$20,752,735).

During 2004, the Company was granted three additional U.S. patents for a total of 13 U.S. patents and one European patent. The Company expended \$958,809 in 2004 associated with its intellectual property compared to \$1,045,869 in 2003.

### *Recent Developments*

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

### *Recurrent Malignant Glioma Clinical Trial Study in the U.S.*

On February 28, 2005, the Company announced that it had received clearance from the US Food and Drug Administration (FDA) to begin a Phase I/II clinical trial to investigate the use of REOLYSIN® to treat patients with recurrent malignant gliomas.

This clinical trial is an open-label dose escalation Phase I/II study in which a single dose of REOLYSIN® will be administered by infusion to patients with recurrent malignant gliomas that are refractory to standard therapy. The administration involves the stereotactically-guided placement of a needle into the tumour, through which REOLYSIN® will be administered or infused into the tumour mass and surrounding tissue using a pump. 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 response to the virus and any evidence of antitumour activity. The enrolment in this study is expected to be up to 30 evaluable patients in the dose escalation phase with up to an additional 14 patients added at the maximum tolerated dose.

---

### *REOLYSIN® in Combination with Radiation Therapy Clinical Trial Study in the U.K.*

On February 18, 2005, the Company announced that it had received a letter of approval from the U.K. regulatory authorities (Medicines and Healthcare products Regulatory Agency or MHRA) for its Clinical Trial Application to begin a Phase I clinical trial to evaluate the feasibility, safety and anti-tumour effects of intratumoural administration of REOLYSIN® in combination with radiation in patients with advanced cancers.

The trial is a Phase I open-label, dose-escalation study of REOLYSIN® combined with two different radiation dosages/schedules. The enrolment in this study is expected to be approximately thirty evaluable patients, and will depend upon the number of dose levels tested. Up to an additional fifteen patients will also be treated at the maximum tolerated dose. The primary objective of the study is to determine the maximum tolerated dose, dose limiting toxicity, and safety profile of REOLYSIN® when administered intratumourally to patients receiving radiation treatment. A secondary objective is to examine any evidence of anti-tumour activity. Patients who have been diagnosed with advanced or metastatic solid tumours that are refractory (have not responded) to standard therapy or for which no curative standard therapy exists will be eligible.

## **ACCOUNTING POLICIES**

### **Critical Accounting Policies and Estimates**

In preparing the Company's financial statements, management is required to make certain estimates, judgments and assumptions that the Company believes are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets at the date of the financial statements and the reported amounts of expenses during the periods presented. Significant estimates are used for, but not limited to, the treatment of the Company's research and development expenditures, the assessment of realizable value of long-lived assets, the amortization period of intellectual property and the calculation of stock based compensation.

The significant accounting policies which the Company believes are the most critical to aid in fully understanding and evaluating its reported financial results include the following:

#### ***Research and Development***

The research and development costs of the Company are expensed as they are incurred. Under Canadian generally accepted accounting principles, development costs should be capitalized if certain criteria are met. Companies with products in clinical trials do not necessarily meet these criteria. The Company's development costs do not meet the following two criteria: (i) the technical feasibility of the product or process has been established; and (ii) the future market for the product or process is clearly defined. With regard to (i), the Company has completed enrollment in a Phase I clinical study for REOLYSIN®, its product being developed for human use, is presently enrolling patients in a systemic (intravenous) delivery human clinical study, is also conducting a human clinical study for brain cancer, and is planning additional clinical studies. Until the appropriate clinical studies have been completed, the technical feasibility of this product will not be known. With regard to (ii), the future market for the product will not be clearly defined until the completion of the clinical studies. Clinical studies not only determine the technical feasibility of the product, but also provide information regarding the proper use of the product and, therefore, the future market. Once the feasibility is determined a New Drug Application, or equivalent, is made to the appropriate regulatory body. Regulatory approval is required



before the product can be marketed. For these reasons, the Company's development costs are expensed and not capitalized.

#### ***Capitalization and Amortization of Patent Costs***

The Company treats third party costs incurred (primarily legal and registration costs) in the development of its Patent portfolio as limited-life intangible assets, and amortizes the costs related to these assets over the

---

lesser of 17 years or their estimated useful life. The Company also reviews the valuation of its Patent costs for impairment when any events that might give rise to impairment are known to the Company. If there is an indication of impairment, the Company would assess the fair value of its Patents and would record a reduction if the fair value were less than the book value.

In capitalizing these costs, the Company is recognizing the inherent future benefit of Patents, not only in protection of its own potential products, but also as a possible asset that could give rise to revenues in the future through licensing agreements. While Patent life is different in different jurisdictions it is normally considered to be 20 years from date of application. With an assumption of an average of three years from initial Patent application to Patent issuance, the Company has set a maximum of 17 years to amortize the costs from the date of issuance. The Company has then assessed the nature of the market and the continuing efforts to develop and market new and better products, as well as the incurrence of costs associated with Patents that have been issued and, as a result, the Company has chosen to amortize the costs on a straight-line basis over ten years.

As the product to which the Patents relate is in the development stage, with commercial recognition and revenue potential highly uncertain, should the Company experience a significant failure in its clinical trial program or other areas of risk, then the value of the Patents could be in serious question, giving rise to a possible write-down or write-off of the asset.

In the event that the Company is successful in its product development and sale, or other parties enter into licensing agreements with the Company, then it is also possible that the Patents may have a life and value beyond the ten years assumed for the amortization policy.

In any event, the revision to any of these policies or estimates outlined above would impact losses but not impact cash flows.

#### **Changes in Accounting Policy including Initial Adoption**

##### *Canadian GAAP - Financial Instruments*

On January 27, 2005, the Canadian Institute of Chartered Accountants (the "CICA") issued new accounting standards CICA Section 1530, Comprehensive Income, CICA Section 3855, Financial Instruments, and CICA Section 3865, Hedges, affecting the accounting treatment for financial instruments. Under the new standards, all financial instruments are to be included on a company's balance sheet (including derivatives) and initially measured, either at fair market value or, in limited circumstances when fair value may not be considered most relevant, at cost or amortized cost.

After initial recognition, the measurement of financial instruments will vary depending on the category of the financial instrument: financial assets held for trading, held-to-maturity investments, loans and receivables, and available-for-sale financial assets. The standards have also introduced "other comprehensive income", a new location for recognizing certain gains and losses. This provides an ability for certain gains and losses arising from changes in fair value to be temporarily recorded outside the income statement, but in a transparent manner.

The effective date for this standard is for annual and interim periods in fiscal years beginning on or after October 1, 2006.

##### *U.S. GAAP - Share Based Payment*

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. Statement 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, Statement of Cash Flows. Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be

recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted no later than July 1, 2005

The Company adopted the fair value based method of accounting for share-based payments effective January 1, 2003 using the prospective method described in FASB Statement No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. Currently, the Company uses the Black Scholes model to estimate the value of stock options granted to employees and expects to continue to use this acceptable option valuation model upon the required adoption of Statement 123(R). The Company does not anticipate that adoption of Statement 123(R) will have a material impact on its results of operations or its financial position.

### **Fair Presentation**

The Company prepares its financial statements in accordance with GAAP. As a result of complying with GAAP, the Company believes that the following should be mentioned in an effort to understand and fairly present its financial information:

#### ***Stock Based Compensation***

As required by the fair value based method for measuring stock based compensation, the Company uses the Black Scholes Option Pricing Model ( Black Scholes or the Model ) to calculate the fair value of its options. Though there are other models available to calculate the option values (for example, the binomial model), Black Scholes is currently widely used and accepted by other publicly traded companies. Therefore, the Company has concluded that Black Scholes is the appropriate option pricing model to use for its stock options at this time.

Black Scholes uses inputs in its calculation of fair value that requires the Company to make certain estimates and assumptions. For 2004, the Company used the following weighted average assumptions:

	<b>2004</b>
Risk-free interest rate	2.83%
Expected hold period to exercise	2 years
Volatility in the price of the Company's shares	71%
Dividend yield	Zero

A change in these estimates and assumptions will impact the value calculated by the Model. For instance, the volatility in the price of the Company's shares is based on the quoted trading price. The Company assumes that weekly trading prices best reflects the Company's trading price volatility. However, an entity can choose between daily, weekly, monthly or quarterly trading prices in the volatility calculation. For example, based upon periods chosen, if the Company were to use daily trading prices, volatility would increase 31%, resulting in an option value increase of 25% from that calculated from the stated volatility. If the Company were to use monthly trading prices over the same period, volatility would increase 11%, resulting in an option value increase of 8%. Also, volatility would change based on the period chosen and the frequency of price points chosen.

The Model also uses an expected hold period to exercise in its calculation of fair value. The Company, when estimating the expected hold period to exercise takes into consideration past history, the current trading price and volatility of the Company's common shares and has concluded that 2 years is an appropriate estimate. However, the Company's options have a 10 year life and given the fluctuations in its stock price the expected hold period could be different. If the hold period was to increase 1 year, there would have been a 20% increase in the Company's stock based compensation expense.

Consequently, in complying with GAAP and selecting what the Company believes are the most appropriate assumptions under the circumstances, the Company has increased its reported non-cash employee stock

based compensation expense for the year by \$2,537,088. However, given the above discussion this expense could be increased between 8% and 25% and still be in accordance with GAAP.

### *Warrant Values*

During 2004 the Company continued to raise cash through the issue of units. Typically, each unit consisted of one common share and a fraction of one common share purchase warrant with each whole warrant exercisable at a specified price for one additional common share for up to 36 months from the issue date. GAAP requires that when recording the issued units, a value should be ascribed to each component of the units based on the component's fair value. For the Company, the fair value of its common shares is established based on trading on stock exchanges in Canada and the U.S. However as the warrants do not trade on an exchange, the Black Scholes Option Pricing Model was used to determine the fair value of the warrants. In the event that the total calculated value of each individual component is greater than the price paid for the unit the value of each component is reduced on a relative basis until the total is equal to the unit's issue price.

For reasons discussed above under "Stock Based Compensation", the Model can produce a wide range of calculated values for the Company's warrants.

### *Initial Value of the Company's Intellectual Property*

The Company was acquired by SYNSORB Biotech Inc. (SYNSORB) in 1999. At that time, SYNSORB purchased all of the share capital of the Company for \$2,500,000 and subsequently applied "push down" accounting and revalued the Company's assets. As the only asset owned by the Company was its intellectual property, the \$2,500,000 was allocated to this asset with the corresponding credit to contributed surplus. This accounting treatment permitted under GAAP, increased the value of the Company's assets and shareholders' equity. As of December 31, 2004, the net book value of the Company's original intellectual property was \$1,083,333. Consequently, without the application of push down accounting applied to the Company by SYNSORB the value of the Company's intellectual property and shareholders' equity would be \$1,083,333 lower than presented in the 2004 audited financial statements.

### **Selected Annual Information**

	<b>2004</b>	<b>2003</b>	<b>2002</b>
	\$	\$	\$
Revenues <sup>(1)</sup>	699,757	313,305	208,867
Net loss <sup>(2),(3),(5)</sup>	12,956,119	8,544,031	6,091,486
Basic and diluted loss per share <sup>(2),(3),(5),(6)</sup>	0.45	0.35	0.30
Total assets <sup>(4),(6)</sup>	39,488,641	26,050,600	17,968,254
Total long term financial liabilities <sup>(7)</sup>	150,000	150,000	150,000
Cash dividends declared per share <sup>(8)</sup>	Nil	Nil	Nil

#### Notes:

- (1) Revenue is comprised of interest income and income from short term investments.
- (2) Included in net loss and net loss per share for 2004 is a net gain (net loss) from sale of investments of \$34,185 (2003 \$(1,892,232); 2002 \$nil).
- (3) Included in net loss and net loss per share for 2002 is a future income tax recovery of \$647,618 (2004 and 2003 \$nil).
- (4) Subsequent to the acquisition of the Company by SYNSORB in April 1999, the Company applied push down accounting. See note 2 to the audited financial statements for 2004.
- (5) Included in net loss and net loss per share is stock based compensation expense of \$2,668,570 (2003 \$996,707, and 2002 \$32,718)
- (6) The Company issued 4,685,775 common shares for cash proceeds of \$23,495,961 in 2004 (2003 5,062,978 common shares for \$16,004,981; 2002 1,040,000 common shares for \$1,803,877). In addition, 21,459 common shares were issued in 2004 as partial consideration for the cancellation of a portion of the Company's contingent payments (see note 9 to the audited financial statements for 2004). In 2002, the Company issued 1,913,889 common shares as consideration for the acquisition of the Company's investment in Transition Therapeutics Inc. with an ascribed value of \$4,689,028.
- (7) The long-term debt recorded in 2003, 2002 and 2001 represents repayable loans from the Alberta Heritage Foundation.
- (8) The Company has not declared or paid any dividends since incorporation.

**RESULTS OF OPERATIONS**

Net loss for the year ended December 31, 2004 was \$12,956,119 compared to \$8,544,031 and \$6,091,486 for 2003 and 2002, respectively.

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

	<b>2004</b>	<b>2003</b>	<b>2002</b>
	\$	\$	\$
Manufacturing and related process development expenses	<b>3,835,685</b>	1,328,480	1,892,517
Clinical trial expenses	<b>799,990</b>	130,034	504,260
Pre-clinical trial expenses and collaborations	<b>824,889</b>	322,060	663,012
Cancellation of contingent payment obligation	<b>400,000</b>		
Quebec scientific research and experimental development refund	<b>(21,436)</b>	(255,905)	
Other R&D expenses	<b>1,268,870</b>	1,294,293	1,191,236
<b>Research and development expenses</b>	<b>7,107,998</b>	2,818,962	4,251,025

In 2004, R&D was \$7,107,998 compared to \$2,818,962 and \$4,251,025 in 2003 and 2002 respectively.

**Manufacturing & Related Process Development ( M&P )**

M&P expenses include product manufacturing expenses and process development. Production manufacturing expenses include third party direct manufacturing costs, quality control testing, and vial fill costs. Process development expenses include costs associated with studies that examine components of the Company's manufacturing process and costs associated with the creation of master and working viral and cell banks.

	<b>2004</b>	<b>2003</b>	<b>2002</b>
	\$	\$	\$
Product manufacturing expenses	<b>2,179,387</b>	924,456	761,359
Technology transfer expenses	<b>656,346</b>		
Process development expenses	<b>999,952</b>	404,024	1,131,158
<b>Manufacturing and related process development expenses</b>	<b>3,835,685</b>	1,328,480	1,892,517

In 2004, the Company incurred production costs of \$2,179,387 compared to \$924,456 and \$761,359 in 2003 and 2002 respectively. The increase in production activity is a result of the need to supply the Company's existing and planned clinical trial programs and its other research activity (see *Clinical Trial Program*).

At the beginning of 2004, the Company entered into a manufacturing contract with a UK based supplier and incurred technology transfer costs of \$656,346 associated with this contract throughout the year. This technology transfer was completed in the fourth quarter of 2004.

In 2004, the Company incurred process development expenses of \$999,952 compared to \$404,024 and \$1,131,158 in 2003 and 2002 respectively. In 2002, the Company incurred process development expenses as it created a manufacturing process that should comply with cGMP manufacturing regulatory guidelines and should be scaleable to a commercial level. In 2003, the Company's process development activity related to the establishment of an independent supply of its master and working viral and cell banks. These banks provide the foundation of the Company's manufacturing process. Finally in 2004, the Company's process development activity continued to focus on the master and working viral and cell banks as well as including studies that examined ways to continue to improve the Company's manufacturing process (in particular

the virus yield).

In 2005, the Company expects that it will continue to produce REOLYSIN® and that a majority of its M&P expenses will relate directly to manufacturing. Also, future manufacturing costs may be impacted by

the need to supply additional clinical trials to be run by the Company as well by the U.S. National Cancer Institute and to continue to supply future pre-clinical trial studies and research collaborations. In addition, with respect to process development expenses, the Company expects to incur these types of costs as it continues to examine ways to improve its manufacturing process.

### Clinical Trial Program

Clinical trial expenses include those costs associated with the Company's clinical trial program in the UK and Canada as well as those incurred in the preparation of commencing other clinical trials. Included in clinical trial expenses are direct patient costs, CRO expenses, clinical trial site costs and other costs associated with the Company's clinical trial program.

	2004	2003	2002
	\$	\$	\$
Direct clinical trial expenses	<b>649,405</b>	64,559	504,260
Other clinical trial expenses	<b>150,585</b>	65,475	
Clinical trial expenses	<b>799,990</b>	130,034	504,260

In 2004, the Company incurred costs directly associated with ongoing clinical trials of \$649,405 compared to \$64,559 and \$504,260 in 2003 and 2002 respectively.

At the beginning of 2004, the Company received authorization to commence a systemic (intravenous) delivery trial in the UK and enrolled the first patient in May, 2004. The Company continued to enroll patients throughout 2004 and also opened up a second clinical trial site in the latter part of the year. In Canada, the Company continued to enroll patients in its malignant glioma study. Finally, with respect to the Company's Canadian T2 prostate cancer trial, the final update was provided in February 2004.

In 2002, the Company incurred clinical trial expenses associated with the malignant glioma and T2 prostate trials that were actively enrolling patients. In 2003, patient enrollment for these trials was temporarily postponed causing the decrease in direct clinical trial expenses.

In 2005, the Company expects to expand its clinical trial program to include other applications and other jurisdictions. If the Company's clinical trial program expands, it expects to incur additional clinical trial costs. Also, in accordance with the Company's agreement with the National Cancer Institute of America (the NCI), the Company will provide REOLYSIN® to the NCI as the NCI and the Company together determine when and which clinical trials will be carried out.

### Pre-Clinical Trial Expenses and Research Collaborations

Pre-clinical trial expenses include toxicology studies and are incurred by the Company in support of expanding its clinical trial program into other jurisdictions and other applications. Research collaborations are intended to expand the Company's intellectual property related to reovirus and other viruses and identify potential licensing opportunities arising from the Company's technology base.

	2004	2003	2002
	\$	\$	\$
Research collaboration expenses	<b>262,910</b>	120,026	
Pre-clinical trial expenses	<b>561,979</b>	202,034	663,012
Pre-clinical trial expenses and research collaborations	<b>824,889</b>	322,060	663,012

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

In 2004, the Company's research collaboration expenses increased to \$262,910 from \$120,026 in 2003. In 2004 the Company continued to enter into collaborations with universities and research hospitals in Europe and the US. In 2004, data from the Company's collaboration examining the use of REOLYSIN® with approved chemotherapeutics in animal models was presented.

In 2004, the Company incurred pre-clinical trial expenses of \$561,979 compared to \$202,034 and \$663,012 in 2003 and 2002 respectively. The increase in pre-clinical trial expenses in 2004 related to toxicology and equivalency studies that were performed in 2004 but not in 2003. In 2002, pre-clinical toxicology studies were also performed. The frequency of these types of studies change from year to year as the Company moves through its clinical trial program. Pre-clinical trial expenses are expected to continue as the Company moves into different jurisdictions and different types of clinical trials.

### Cancellation of Contingent Payment Obligation

On September 23, 2004, the Company reached an agreement that cancelled a portion of its future contingent obligation to one of its non-management founding shareholders for consideration of \$400,000. The consideration paid included cash of \$250,000 and non-cash consideration of 21,459 common shares valued at \$150,000 and was recorded as additional research and development expense. The value of the common shares was based on the September 23, 2004 closing price of \$6.99. As a result, the Company's future contingent payment obligations have been reduced to 11.75% (formerly in 2003 14.25% and 2002 20%) of payments received associated with a partnership or other arrangement for development. Similarly, if the Company develops the reovirus treatment to the point where it may be marketed at a commercial level, the payment referred to in the foregoing sentence has been amended to a royalty payment of 2.35% (formerly in 2003 2.85% and 2002 4%) of Net Sales received by the Company for such products.

### Other R&D Expenses

Other R&D expenses include compensation expenses for employees (excluding stock based compensation), consultant fees, travel and other miscellaneous R&D expenses.

In 2004, the Company incurred other R&D expenses of \$1,268,871 compared to \$1,294,291 and \$1,191,236 in 2003 and 2002 respectively. These costs have remained consistent over the past three years as there has been no significant change in the costs associated with the Company's R&D employees and consultants. The Company expects these cost will remain relatively constant in 2005.

### Operating Expenses

	2004	2003	2002
	\$	\$	\$
Public company related expenses	1,910,611	1,633,849	1,374,172
Office expenses	893,058	815,629	728,698
Operating expenses	2,803,669	2,449,478	2,102,870

In 2004, the Company incurred operating expenses of \$2,803,669 compared to \$2,449,478 and \$2,102,870 in 2003 and 2002 respectively. The reason for the change is as follows:

### Public Company Related Expenses

Public company related expenses include costs associated with investor relations activities, legal and accounting fees, corporate insurance, and transfer agent and other fees relating to the Company's two stock listings. In 2004, the Company incurred public company related expenses of \$1,910,611 compared to \$1,633,849 and \$1,374,172 in 2003 and 2002 respectively. The increase in 2003 and 2004 relates to the rising cost of directors' and officers' liability insurance which has increased due to general market conditions for companies with a US stock listing. As well, investor relation expenses increased compared to 2003 and 2002 due to the Company's shareholder base that has expanded to include US and European shareholders.

**Office Expenses**

Office expenses include compensation costs (excluding stock based compensation), office rent, and other office related costs. In 2004, the Company incurred office expenses of \$893,058 compared to \$815,629 and \$728,698 for 2003 and 2002 respectively. The increase in office expenses in 2004 and 2003 relate to office rent expense and compensation costs associated with increased staff levels.

**Stock Based Compensation**

	2004 \$	2003 \$	2002 \$
Stock based compensation	2,668,570	996,707	32,718

Non-cash stock based compensation recorded for 2004 increased to \$2,668,570 compared to \$966,707 and \$32,718 for 2003 and 2002 respectively associated with the granting of stock options to its employees, directors, and certain consultants.

**Foreign Exchange Loss (Gain)**

	2004 \$	2003 \$	2002 \$
Foreign exchange loss (gain)	358,068	2,881	(598)

The Company acquires investments in foreign currency to pay for anticipated expenses that are to be incurred in the United States ( U.S. ) and the United Kingdom ( U.K. ). As a result of recent movements in the U.S. and U.K. exchange rates the Company recorded a non-cash loss of \$358,068 for the year ending December 31, 2004. In 2003 and 2002, the Company's foreign exchange exposure was limited to the U.S. dollar.

**Sale of Investments**

	2004 \$	2003 \$	2002 \$
Gain on partial sale of investment in BCY LifeSciences Inc.	(34,185)	(264,453)	
Loss on sale of investment in Transition Therapeutics Inc.		2,156,685	
Net (gain) loss from sale of investments	(34,185)	1,892,232	

**BCY LifeSciences Inc. ( BCY )**

In 2004, the Company sold 697,945 (2003 1,496,500) common shares of BCY for net cash proceeds of \$133,609 (2003 \$450,151). This resulted in an accounting gain of \$47,002 (2003 \$264,453). The cash outlay for its investment in BCY was \$127,123.

The Company still owns 200,000 common shares of BCY that are currently in escrow and are scheduled to be released in 2005 and 2006. In the third quarter of 2004, the Company recorded a write down of \$12,817 against its remaining ownership in BCY to reflect the investment's market value (as estimated based on its remaining investment in BCY) at that time. As at December 31, 2004, the market value of the Company's remaining BCY common shares approximates the current book value of \$12,000.

**Transition Therapeutics Inc. ( TTH )**

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

In 2003, the Company sold 6,890,000 common shares of TTH for net cash proceeds of \$2,552,695. As a result of the sale, an accounting loss of \$2,156,685 was recorded. The Company's cash expenses with respect to its investment in TTH were limited to acquisition legal costs of \$20,352.

### Commitments

As at December 31, 2004, the Company has committed to payments totaling \$943,815 during 2005 for activities related to clinical trial activity and collaborations. All of these committed payments are considered to be part of the Company's normal course of business.

Subsequent to 2004, the Company has entered into another research and development agreement and under this contract has committed to payments totaling \$1,801,000.

### SUMMARY OF QUARTERLY RESULTS

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

	2004				2003			
	Dec.	Sept.	June	March	Dec.	Sept.	June	March
Revenue <sup>(1)</sup>	205	194	183	117	127	102	41	43
Net loss <sup>(2),(5)</sup>	3,992	3,096	3,192	2,676	1,696	1,823	3,911	1,114
Basic and diluted loss per common share <sup>(2),(5)</sup>	\$ 0.14	\$ 0.11	\$ 0.11	\$ 0.10	\$ 0.06	\$ 0.07	\$ 0.17	\$ 0.05
Total assets <sup>(3),(6)</sup>	39,489	29,471	31,221	25,435	26,051	21,532	18,815	16,702
Total cash <sup>(4),(6)</sup>	33,919	23,806	25,522	20,298	20,753	15,843	13,486	6,887
Total long-term debt <sup>(7)</sup>	150	150	150	150	150	150	150	150
Cash dividends declared <sup>(8)</sup>	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil

(1) Revenue is comprised of interest income and income from short term investments.

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

(3) Subsequent to the acquisition of the Company by SYNSORB in April 1999, the Company applied push down accounting. See note 2 to the audited financial statements for 2004.

(4) Included in total cash are cash and cash equivalents plus short-term investments.

(5) Included in net loss and loss per common share is stock based compensation of \$5,426, \$734,670, \$48,878, and \$1,870,596 for March, June, September, and December of 2004 respectively (2003 \$471, \$68,318, \$437,554 and 490,364).

(6) The Company issued 4,685,775 common shares for cash proceeds of \$23,495,961 in 2004 (2003 5,062,978 common shares for \$16,004,981). In addition, 21,459 common shares were issued in September 2004 as partial consideration for the cancellation of a portion of the Company's contingent payments (see note 9 to the audited financial statements for 2004).

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

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

### FOURTH QUARTER

Statement of loss for the three month period ended December 31, 2004 and 2003

	2004 \$ (unaudited)	2003 \$ (unaudited)
Interest income	204,941	126,697
Research and development expenses	1,425,286	767,053
Operating expenses	690,628	628,412
Stock based compensation	1,879,596	490,364
Foreign exchange loss (gain)	4,104	(6,781)
Amortization	197,280	175,033



Edgar Filing: ONCOLYTICS BIOTECH INC - Form 40-F

	2004 \$ (unaudited) 4,196,894	2003 \$ (unaudited) 2,054,081
Loss before the following:	3,991,953	1,927,384
Gain on sale of investment in BCY		(264,453)
Loss before taxes	3,991,953	1,662,931
Capital tax		32,610
Net loss	3,991,953	1,695,541

**Review of Operations**

For the three month period ended December 31, 2004, the Company's net loss increased to \$3,991,953 compared to \$1,695,541 for the three month period ended December 31, 2003. The reasons for the increase are as follows:

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

	2004 \$ (unaudited)	2003 \$ (unaudited)
Manufacturing and related process development expenses ("M&P")	492,388	215,885
Clinical trial expenses	366,852	73,331
Pre-clinical trial expenses and research collaborations	89,425	83,743
Other R&D expenses	476,621	394,094
Research and development expenses	1,425,286	767,053

The Company's R&D expenses increased to \$1,425,286 in the fourth quarter of 2004 compared to \$767,053 for the fourth quarter of 2003.

During the fourth quarter of 2004, the Company's M&P expenses were \$492,388 compared to \$215,885 in 2003. The increase in M&P expenses was a result of increased manufacturing activity in support of the Company's clinical trial and research programs. During the fourth quarter of 2003, the Company's M&P activity was focused on the development of the Company's master and working viral and cell banks.

The Company's clinical trial expenses increased to \$366,852 in the fourth quarter compared to \$73,331 for the fourth quarter of 2003. The increase in the fourth quarter of 2004 relates to the continued patient enrollment and the addition of a second clinical trial site for its UK systemic (intravenous) delivery clinical trial.

**Operating Expenses**

	2004 \$ (unaudited)	2003 \$ (unaudited)
Public company related expenses	438,349	378,103
Office expenses	252,279	250,309
Operating expenses	690,628	628,412

The Company's operating expenses for the fourth quarter of 2004 increased to \$690,628 compared to \$628,412 for the fourth quarter of 2003.

During the fourth quarter of 2004, the Company's public company related expenses increased to \$438,349 compared to \$378,103 for the fourth quarter of 2003. This increase corresponds to an increase in investor relations activity in the fourth quarter of 2004 compared to the fourth quarter of 2003.

**Stock Based Compensation**

	2004 \$ (unaudited)	2003 \$ (unaudited)
Stock based compensation	1,879,596	490,364

Non-cash stock based compensation recorded for the fourth quarter of 2004 increased to \$1,879,596 compared to \$490,364 for the fourth quarter of 2003 associated with the granting of stock options to its employees, directors, and certain consultants.

**Financing Activities**

During the fourth quarter of 2004, the Company received cash proceeds of \$3,362,580 from the exercise of 840,645 previously issued warrants. These warrants related to the private placement entered into on June 19, 2003 and had an exercise price of \$4.00.

On November 23, 2004, the Company closed a public offering whereby it issued 1,504,000 units at an issue price of \$6.65 per unit for net cash proceeds of \$9,150,902. Each unit was comprised of one common share and one-half of one common share purchase warrant. Each whole common share purchase warrant entitles the holder to acquire one common share in the capital of the Company upon payment of \$8.00 per share until November 23, 2007. In addition, the Company issued 112,800 common share purchase warrants with an exercise price of \$7.06 that expires on May 23, 2006.

On October 14, 2003, the Company closed a public offering whereby it issued 1,200,000 units for net cash proceeds of \$5,459,399. Each unit was comprised of one common share and one half of one common share purchase warrant. Each whole warrant entitles the holder to purchase an additional common share for \$6.25 and expires on April 14, 2005. In addition, the Company issued 120,000 broker warrants with an exercise price of \$5.00 that expire on April 14, 2005.

**LIQUIDITY AND CAPITAL RESOURCES**

**Liquidity**

As at December 31, 2004, the Company had cash and cash equivalents (including short-term investments) and working capital positions of \$33,919,223 and \$33,268,097 respectively compared to \$20,752,735 and \$20,088,868 respectively for 2003. The increase in 2004 reflects the cash inflows from the one private placement, one public offering and the exercise of options and warrants that raised \$23,495,961. Cash

outflows during the year arose from research and development expenses, operational expenses, and intellectual property expenditures.

The Company desires to maintain adequate cash and short-term investment reserves to support its planned activities which include its clinical trial program, production manufacturing, and its intellectual property expansion and protection. The Company presently anticipates that its average cash usage for 2005 will be approximately \$1,000,000 per month and its existing capital resources are adequate to fund its current plans for research and development activities well into 2007. Factors that will affect the Company's anticipated monthly burn rate include, but are not limited to, the number of manufacturing runs required to supply its clinical trial program and the cost of each run, the number of clinical trials ultimately approved, the timing of patient enrollment in the approved clinical trials, the actual costs incurred to support each clinical trial, the

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

number of treatments each patient will receive, the timing of the NCI's R&D activity, and the level of pre-clinical activity undertaken.

In the event that the Company chooses to seek additional capital, the Company will look to fund additional capital requirements primarily through the issue of additional equity. The Company recognizes the challenges and uncertainty inherent in the capital markets and the potential difficulties it might face in raising additional capital. Market prices and market demand for securities in biotechnology companies are volatile and there are no assurances that the Company would have the ability to raise funds when required.

### Capital Expenditures

The Company spent \$958,809 on intellectual property in 2004 compared to \$1,045,869 in 2003. The change in intellectual property expenditures reflects the timing of filing costs associated with its expanded patent base. As well, the Company has benefited from a stronger Canadian dollar as its patent costs are typically denominated in U.S. currency. The Company received three U.S. patents in 2004 bringing its total patents issued to 13 in the U.S. and one in Europe.

### Contractual Obligations

The Company has the following contractual obligations as at December 31, 2004:

Contractual Obligations	Payments Due by Period				
	Total \$	Less than 1 year \$	1-3 years \$	4-5 years \$	After 5 years \$
Long term debt <sup>(1)</sup>	\$ 150,000				\$ 150,000
Capital lease obligations	Nil				
Operating leases <sup>(2)</sup>	188,479	\$ 133,044	\$ 55,435		
Purchase obligations	943,815	943,815			
Other long term obligations	Nil				
<b>Total contractual obligations</b>	<b>\$ 1,282,294</b>	<b>\$ 1,076,859</b>	<b>\$ 55,435</b>		<b>\$ 150,000</b>

#### Note:

- (1) The Company's long term debt is a \$150,000 loan from the Alberta Heritage Foundation. Repayments are required upon the realization of sales (see note 6 of the Company's audited 2003 financial statements).
- (2) The Company's operating leases are comprised of its office lease.

Subsequent to the year end, the Company entered into a toll manufacturing agreement that will increase the Company's purchase obligations by \$1,801,000 to \$2,744,815. The combined purchase obligations include activities associated with the Company's clinical trial and manufacturing programs and research collaborations. These purchase obligations are assumed to all occur in 2005.

The Company will fund its capital expenditure requirements and commitments with existing working capital.

### Investing Activities

Under its Investment Policy, the Company is permitted to invest in short-term instruments with a rating no less than R-1 (DBRS) with terms less than two years. The Company has \$21,510,707 invested under this policy and is currently earning interest at an effective rate of 2.26%.

## OFF-BALANCE SHEET ARRANGEMENTS

As at December 31, 2004, the Company has not entered into any off-balance sheet arrangements.

## TRANSACTIONS WITH RELATED PARTIES

In 2004 and 2003 the Company did not enter into any related party transactions.

## FINANCIAL INSTRUMENTS AND OTHER INSTRUMENTS

The Company does not use financial derivatives or other financial instruments .

## RISKS FACTORS AFFECTING FUTURE PERFORMANCE

**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, or early studies in humans, 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 approval of the United States Food and Drug Administration (the "FDA") or from similar regulatory authorities in other 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 favorable 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;  
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 other relevant regulatory authorities may deny approval of a new drug application ( NDA ) or its equivalent in the relevant jurisdiction 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 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 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.

---

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 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 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 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.

**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'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 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, 2004, the Company had an accumulated deficit of \$38.0 million. The Company incurred net losses of \$13.0 million, \$8.5 million, and \$6.1 million for the years ended December 31, 2004, 2003, and 2002, respectively. The Company anticipates that it will continue to incur significant losses during 2005 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.

**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, 2004, the Company had cash and cash equivalents (including short-term investments) of \$33.9 million and working capital of approximately \$33.3 million. The Company anticipates that it may need additional financing in the future to fund research and development and to meet its ongoing capital requirements. The amount of future capital requirements will depend on many factors, including 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 continue to increase substantially or may not be available to the Company 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 may limit the Company's ability to attract and maintain directors and officers as required to conduct its business.

**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, primarily the U.S. dollar and the Great British pound ( GBP ). Over the past year the Canadian dollar has appreciated relative to the U.S. dollar and the GBP 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 principle. As interest rates change the amount of interest income the Company earns will be directly impacted.

#### **OTHER MD&A REQUIREMENTS**

The Company has 32,684,468 common shares outstanding at March 2, 2005. If all of the Company's warrants and options were exercised the Company would have 38,576,386 common shares outstanding.

The Company's 2004 Annual Information Form is available on [www.sedar.com](http://www.sedar.com).