ONCOLYTICS BIOTECH INC
Form 6-K
April 07, 2008

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer

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

For the month of April 2008

Commission File Number 000-31062

Oncolytics Biotech Inc.

(Translation of registrant s name into English)

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

(Address of principal executive offices)

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

Form 20-F þ Form 40-F o

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

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

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

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

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

Yes o No þ

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

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SIGNATURES

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

Oncolytics Biotech Inc.
(Registrant)

Date: April 7, 2008

By: /s/ Doug Ball

Doug Ball
Chief Financial Officer

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RENEWAL ANNUAL INFORMATION FORM
for the Year Ended December 31, 2007
March 5, 2008

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This Annual Information Form contains forward-looking statements, including statements that may contain words such as anticipate, estimate, expect, project, intend, plan, believe and similar expressions and statements relating to matters that are not historical facts. Forward-looking statements, including our belief as to the potential of REOLYSIN® as a cancer therapeutic and our expectations as to the success of our research and development and manufacturing programs in 2008 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 our 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, our ability to successfully commercialize REOLYSIN®, uncertainties related to the research, development and manufacturing of pharmaceuticals, uncertainties related to competition, changes in technology, the regulatory process and general changes to the economic environment. Investors should consult our quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Forward-looking statements are based on assumptions, projections, estimates and expectations of management at the time such forward-looking statements are made, and such assumptions, projections, estimates and/or expectations could change or prove to be incorrect or inaccurate. Investors are cautioned against placing undue reliance on forward-looking statements. We do not undertake to update these forward-looking statements.

CORPORATE STRUCTURE

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

GENERAL DEVELOPMENT OF THE BUSINESS

General

We focus 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 we are presently developing may represent a novel treatment for Ras-mediated cancers which can be used as an alternative to existing cytotoxic or cytostatic therapies or as an adjuvant therapy to conventional chemotherapy, radiation therapy, or surgical resections. It could also potentially be used to treat certain cellular proliferative disorders for which no current therapy exists.

Our technologies are based primarily on discoveries in the Department of Microbiology and Infectious Diseases at the University of Calgary in the 1990s. Oncolytics Biotech Inc. 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 us may represent a novel treatment for certain tumour types and some cellular proliferative disorders. Our lead product is a virus that is able to replicate specifically in, and hence kill, certain tumour cells both in tissue culture as well as in a number of animal models without damaging normal cells. See *Narrative Description of the Business Our Business; Scientific Background.*

We are also assessing the potential opportunities for product candidates resulting from issued patents received for Ras-targeted adenovirus and herpes virus.

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2007 REOLYSIN® DEVELOPMENT

Clinical Trial Program

We began 2007 with five clinical trials of which three were actively enrolling patients and two had been recently approved to commence. During the year, we received approval to commence another three clinical trials, commenced patient enrollment in four trials and completed enrollment in one trial. We exited 2007 with a clinical trial program of eight active clinical trials of which seven are being conducted by us and one is being sponsored by the U.S. National Cancer Institute (NCI). As well in 2007, we announced positive clinical trial results from two clinical trials.

2007 Clinical Trial Results

U.K. Phase Ia/Ib Combination REOLYSIN® and Radiation Clinical Trial

The primary objective of this Phase Ia/Ib trial was to determine the maximum tolerated dose (MTD), dose limiting toxicity (DLT), and safety profile of REOLYSIN® when administered intratumourally to patients receiving radiation treatment. A secondary objective was to examine any evidence of anti-tumour activity. Eligible patients include those who have been diagnosed with late stage advanced or metastatic solid tumours that are refractory (have not responded) to standard therapy or for which no curative standard therapy exists. In the third quarter of 2007, we announced positive interim results from this clinical trial for patients with advanced or metastatic cancers and completed enrollment in the fourth quarter. At the time we announced our interim results, 22 patients had been treated with 15 having completed the study. Five patients had withdrawn from the study, and two patients were still on study.

A total of 11 patients in the Ia portion of the trial received two intratumoural treatments of REOLYSIN® at dosages of $1x10^8$, $1x10^9$, or $1x10^{10}$ $TCID_{50}$ with a constant localized radiation dose of 20 Gy given in five fractions. Of these 11 patients, three patients (one with oesophageal, one with squamous skin carcinoma and one with squamous cell scalp cancer) experienced significant partial responses.

One month following treatment, the oesophageal patient experienced a 28.5% reduction in the target tumour, with stable disease noted in four, non-treated tumours. At two and three months, the target tumour had shrunk 64%, with stable disease continuing in the four non-treated tumours, including a 15% volume reduction in non-treated mediastinal disease that was maintained for more than six months. The squamous skin cancer patient experienced a 50% reduction in the target tumour, as well as stable disease in two, non-treated tumours at one, two and three months post treatment. The patient with squamous cell scalp cancer experienced stable disease in the target tumour for two months which then became a partial response at three months. This patient also experienced stable disease in one non-treated tumour measured at three months post-treatment.

Patients in the Ib portion of the trial received either two, four or six intratumoural doses of REOLYSIN® at $1x10^{10}$ $TCID_{50}$ with a constant localized radiation dose of 36 Gy given in 12 fractions. Of the six patients who had completed the study, at the time, three patients (one with colorectal, one with melanoma and one with lung cancer) experienced tumour regression in the target tumour, as well as stable disease in non-treated tumours.

The patient with colorectal cancer experienced a partial response with a more than 50% regression in the target tumour as well as stable disease in four, non-treated tumours measured at one month following treatment. The patient with melanoma cancer experienced minor regression in the target tumour as well as stable disease in two, non-treated tumours at one and two months following treatment. The patient with lung cancer experienced minor regression in the target tumour, as well as stable disease in three, non-treated tumours at two months following treatment.

The treatment has been well tolerated, with mostly Grade 1 or 2 toxicities noted including fatigue, lymphopenia, fever, and neutropenia. Grade 3 toxicities including cellulitis, dysphasia and diarrhoea were related to disease progression and not to the combination treatment. Viral replication was unaffected by cellular irradiation.

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U.S. Phase I Systemic Clinical Trial

The primary objective of our U.S. Phase I clinical trial examining the systemic administration of REOLYSIN® was to determine the MTD, DLT, and safety profile of REOLYSIN® when administered systemically to patients. A secondary objective was to examine any evidence of anti-tumour activity. Eligible patients included those who had 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. In 2007, we announced positive results from this trial in patients with advanced cancers. The results indicated that REOLYSIN® can be delivered systemically to patients with advanced and metastatic cancers and cause anti-tumour activity.

A total of 18 patients were treated in the escalating dosage trial to a maximum daily dose of $3x10^{10}$ $TCID_{50}$ in a one-hour infusion. Of the 18 patients treated, eight demonstrated stable disease or better, as measured by RECIST (Response Evaluation Criteria in Solid Tumours a measure used by regulatory agencies in determining efficacy) including a patient with progressive breast cancer who experienced a 34% shrinkage in tumour volume.

The trial was originally designed to demonstrate the safety of a single, one-hour infusion of REOLYSIN®. During the treatment of the 4th cohort of patients, we applied for and were granted approval to allow subsequent patients to receive repeat monthly treatments of REOLYSIN®. Of the patients eligible for retreatment, three patients received a range of two to seven one-hour infusions of REOLYSIN®. Toxicities possibly related to REOLYSIN® treatment in this trial were generally mild (grade 1 or 2) and included chills, fever and fatigue.

Clinical Trials Actively Enrolling

Throughout 2007, we continued to enroll patients in our Phase II and Phase Ib combination REOLYSIN®/radiation clinical trials in the U.K. and in our Phase I/II recurrent malignant glioma clinical trial in the U.S. As well in 2007, we commenced enrollment in the following studies:

U.S. Phase II Sarcoma Clinical Trial

We received approval to commence and initiated patient enrollment in our U.S. Phase II trial to evaluate the intravenous administration of REOLYSIN® in patients with various sarcomas that have metastasized to the lung. Patients are being enrolled at the Montefiore Medical Center/Albert Einstein College of Medicine in the Bronx, New York, the University of Michigan Comprehensive Cancer Center in Ann Arbor, and the Cancer Therapy and Research Center, Institute for Drug Development in San Antonio, Texas.

This trial is a Phase II, open-label, single agent study whose primary objective is to measure tumour responses and duration of response, and to describe any evidence of antitumour activity of intravenous, multiple dose REOLYSIN® in patients with bone and soft tissue sarcomas metastatic to the lung. REOLYSIN® is being given intravenously to patients at a dose of $3x10^{10}$ $TCID_{50}$ for five consecutive days. Patients may receive additional five-day cycles of therapy every four weeks for a maximum of eight cycles.

Up to 52 patients will be enrolled in the study. Eligible patients must have a bone or soft tissue sarcoma metastatic to the lung deemed by their physician to be unresponsive to or untreatable by standard therapies.

U.K. Combination REOLYSIN® Paclitaxel and Carboplatin Clinical Trial

We commenced patient enrolment in our U.K. clinical trial to evaluate the anti-tumour effects of systemic administration of REOLYSIN® in combination with paclitaxel and carboplatin in patients with advanced cancers including head and neck, melanoma, lung and ovarian.

This trial has two components. The first is an open-label, dose-escalating, non-randomized study of REOLYSIN® given intravenously with paclitaxel and carboplatin every three weeks. Standard dosages of paclitaxel and carboplatin will be delivered with escalating dosages of REOLYSIN® intravenously. A maximum of three cohorts will be enrolled in the REOLYSIN® dose escalation portion. The second component of the trial will immediately follow and will include the enrolment of a further 12 patients at the maximum dosage of REOLYSIN® in combination with a standard dosage of paclitaxel and carboplatin.

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Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours such as head and neck, melanoma, lung and ovarian cancers that are refractory to standard therapy or for which no curative standard therapy exists. The primary objective of the trial is to determine the MTD, DLT, recommended dose and dosing schedule and safety profile of REOLYSIN® when administered in combination with paclitaxel and carboplatin. Secondary objectives include the evaluation of immune response to the drug combination, the body s response to the drug combination compared to chemotherapy alone and any evidence of anti-tumour activity.

U.K. Combination REOLYSIN® Gemcitabine Clinical Trial

We commenced patient enrolment in our U.K. clinical trial to evaluate the anti-tumour effects of systemic administration of REOLYSIN® in combination with gemcitabine (Gemzar®) in patients with advanced cancers including pancreatic, lung and ovarian. The combination of reovirus and gemcitabine has been shown in preclinical studies to be more effective than gemcitabine or reovirus alone at killing certain cancer cell lines.

This trial has two components. The first is an open-label, dose-escalating, non-randomized study of REOLYSIN® given intravenously with gemcitabine every three weeks. A standard dosage of gemcitabine will be delivered with escalating dosages of REOLYSIN® intravenously. A maximum of three cohorts will be enrolled in the REOLYSIN® dose escalation portion. The second component of the trial will immediately follow and will include the enrolment of a further 12 patients at the maximum dosage of REOLYSIN® in combination with a standard dosage of gemcitabine.

Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours such as pancreatic, lung and ovarian cancers that are refractory to standard therapy or for which no curative standard therapy exists. The primary objective of the trial is to determine the MTD, DLT, recommended dose and dosing schedule and safety profile of REOLYSIN® when administered in combination with gemcitabine. Secondary objectives include the evaluation of immune response to the drug combination, the body s response to the drug combination compared to chemotherapy alone and any evidence of anti-tumour activity.

U.K. Combination REOLYSIN® Docetaxel Clinical Trial

We commenced patient enrolment in our U.K. clinical trial to evaluate the anti-tumour effects of systemic administration of REOLYSIN® in combination with docetaxel (Taxotere®) in patients with advanced cancers including bladder, prostate, lung and upper gastro-intestinal. In preclinical studies, the combination of REOLYSIN® and various taxanes including docetaxel has been shown to be synergistic against a variety of cancer cell lines.

The trial has two components. The first is an open-label, dose-escalating, non-randomized study of REOLYSIN® given intravenously with docetaxel every three weeks. A standard dosage of docetaxel will be delivered with escalating dosages of REOLYSIN® intravenously. A maximum of three cohorts will be enrolled in the REOLYSIN® dose escalation portion. The second component of the trial will immediately follow and will include the enrolment of a further 12 patients at the maximum dosage of REOLYSIN® in combination with a standard dosage of docetaxel.

Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours such as bladder, prostate, lung or upper gastro-intestinal cancers that are refractory to standard therapy or for which no curative standard therapy exists. The primary objective of the trial is to determine the MTD, DLT, recommended dose and dosing schedule and safety profile of REOLYSIN® when administered in combination with docetaxel. Secondary objectives include the evaluation of immune response to the drug combination, the body s response to the drug combination compared to chemotherapy alone and any evidence of anti-tumour activity.

Clinical Trial Approved to Commence

U.K. REOLYSIN® in Combination with Cyclophosphamide

In 2007, we announced receipt of a letter of approval to commence our clinical trial using intravenous administration of REOLYSIN® in combination with cyclophosphamide, a chemotherapeutic agent as well as immune modulator, in patients with advanced cancers.

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The trial is an open-label, dose-escalating, non-randomized trial of REOLYSIN® given intravenously with escalating doses of cyclophosphamide. A standard dose of REOLYSIN® is administered intravenously over five consecutive days, while an intravenous dose of cyclophosphamide is administered three days before REOLYSIN® treatment and continues through the course of the treatment cycle. The total number of patients studied will depend on the number of dose levels tested, but it is anticipated to be approximately 30 patients.

Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours including pancreatic, lung and ovarian cancers that are refractory to standard therapy or for which no curative standard therapy exists. The primary objectives of the trial include determining the Minimum Effective Immunomodulatory Dose of cyclophosphamide to obtain successful immune modulation. Secondary objectives include the safety profile of the combination and gathering any evidence of anti-tumour activity.

U.S. National Cancer Institute Phase II Melanoma Clinical Trial

In 2007, the NCI filed a protocol with the U.S. Food and Drug Administration for a Phase II clinical trial for patients with metastatic melanoma using systemic administration of REOLYSIN®. The NCI is sponsoring the trial under our Clinical Trials Agreement that requires us to provide clinical supplies of REOLYSIN®. The trial is expected to enroll up to 47 patients with metastatic melanoma.

Pre-Clinical Trial and Collaborative Program

We perform pre-clinical studies and engage in collaborations to help support our clinical trial programs and expand our intellectual property base. Throughout 2007, we continued with studies examining the interaction between the immune system and the reovirus, the use of the reovirus as a co-therapy with existing chemotherapeutics and radiation, the use of new RAS active viruses as potential therapeutics, and to investigate new uses for the reovirus in therapy. During 2007, in conjunction with our various collaborators, we reported the results of a number of research collaborations.

We announced that a poster presentation entitled Reovirus Infection of Human Melanoma Cells Supports Priming of Anti-Tumour Cytotoxic T Cell Immunity was presented by Dr. Robin Prestwich of CR-UK Clinical Centre, Leeds Institute of Molecular Medicine, University of Leeds, U.K at the National Cancer Research Institute Cancer Conference in Birmingham, U.K. In this study, the investigators infected melanoma cell lines with reovirus. The reovirus-infected cell lines stimulated the maturation of dendritic cells, which in turn educated cancer-killing T cells to attack and kill the melanoma cells.

Dr. Maureen E. Lane et al. of Cornell University, New York, presented a poster entitled In Vivo Synergy between Oncolytic Reovirus and Gemcitabine in Ras-Mutated Human HCT116 Xenografts at the American Association for Cancer Research Annual Meeting in Los Angeles, CA. The researchers found that treatment of human colon cancer cell lines with the combination of REOLYSIN® and gemcitabine resulted in both *in vitro* and *in vivo* synergy. There was no additional toxicity associated with the combined treatment. Tumours treated with the combination were significantly smaller (by area and weight) than tumours in control groups or tumours treated with either agent alone. The researchers concluded that the synergistic combination of REOLYSIN® and gemcitabine is a promising therapeutic regimen for study in clinical trials.

An oral presentation entitled Reovirus as a Potentially Immunogenic as well as Cytotoxic Therapy for Metastatic Colorectal Cancer was given by one of our collaborators, Dr. Sheila Fraser of St. James s University Hospital in Leeds, U.K. The investigators tested reovirus *in vitro* against recently resected colorectal cancer liver metastases. The results showed that a significant proportion of tumour cell cultures showed susceptibility to death following reovirus infection, and also demonstrated effective replication of reovirus within these cells. In addition, dendritic cells that prime the immune system to fight cancer cells were activated by exposure to the reovirus. The investigators concluded that the data supports the development of reovirus as a novel therapy for colorectal cancer, with the potential to direct the immune system to target cancer cells.

Professor Hardev Pandha of The Royal Surrey Hospital, U.K. presented a poster entitled Synergistic Antitumour Activity of Oncolytic Reovirus and Cisplatin in Malignant Melanoma at the 4th International Conference on Oncolytic Viruses as Cancer Therapeutics in Carefree, Arizona. The results of the preclinical study showed that the combination

of reovirus and cisplatin was significantly more effective than cisplatin or reovirus alone at killing

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melanoma cancer cells in a mouse model. The investigators concluded that the addition of chemotherapeutic agents can enhance the efficacy of reovirus therapy.

Finally, Dr. Richard Vile of the Mayo College of Medicine, Rochester, Minnesota delivered an oral presentation at the 4th International Conference on Oncolytic Viruses as Cancer Therapeutics in Carefree, Arizona that covered a study of systemic administration of reovirus in combination with cyclophosphamide, an immune modulator. The work demonstrated that systemic administration of reovirus in combination with cyclophosphamide enhanced tumour regression in a melanoma animal model without increasing toxicity. In addition, the investigators were able to demonstrate that the addition of cyclophosphamide significantly increased the amount of reovirus replicating within the tumour. The investigators concluded that the addition of cyclophosphamide may lead to improved efficacy of REOLYSIN® treatment.

Manufacturing and Process Development

In 2007, we completed multiple production runs to build up a supply of REOLYSIN® for our current clinical trial program. Our process development activity examined the scale up of our manufacturing process, increasing the batch size from our present cGMP scale of 20-litres to 40-litres and then to 100-litres. Finally, towards the end of 2007, we commenced the technology transfer of our 40-litre production run to a second toll manufacturer in the U.S.

Intellectual Property

During 2007, eight U.S. and one Canadian patents were issued. At the end of 2007, we had been issued over 160 patents including 25 U.S. and six Canadian patents as well as issuances in other jurisdictions. We also have over 180 patent applications filed in the U.S., Canada and other jurisdictions.

2006 REOLYSIN® DEVELOPMENT

Clinical Trial Program

U.K. Phase I Systemic Administration Clinical Trial

During 2006, we completed patient enrollment in our U.K. phase I systemic delivery clinical trial. The primary objective of our U.K. Phase I trial was to determine the maximum tolerated dose (MTD), dose limiting toxicity (DLT), and safety profile of REOLYSIN® when administered systemically to patients. A secondary objective was to examine any evidence of anti-tumour activity. Eligible patients included those who had been diagnosed with advanced or metastatic solid tumours that were refractory (have not responded) to standard therapy or for which no curative standard therapy exists.

A total of 33 patients were treated in this clinical trial to a maximum daily dose of $1x10^{11}$ $TCID_{50}$. These 33 patients have received 77 courses of therapy, for a total of 338 daily treatments. Patients were entered into the study at the following dose levels (all $TCID_{50}$): $1x10^8$ for 1 day, $1x10^8$ for 3 days, $1x10^8$, $3x10^8$, $1x10^9$, $3x10^9$, $1x10^{10}$ and $3x10^{10}$ for five days, and $1x10^{11}$ for three days. An MTD was not reached and the treatment appears to have been well tolerated by the patients.

Toxicities possibly related to REOLYSIN® treatment in this trial were generally mild (grade 1 or 2) and included chills, fever, headache, cough, runny nose, sore throat and fatigue. Transient grade 3 toxicities included lymphopenia, neutropenia and troponin I. These symptoms were more frequently observed from day two of treatment and usually lasted less than six hours.

Of the thirty two patients assessed, anti-tumour activity was noted in seven patients. Patients were assessed with CTR scans, and where possible tumour marker assessment, and histopathology of tumour biopsies. Two patients with colorectal cancer had tumour stabilization (one for three months, the other classified as stable disease for six months) and had CEA tumour marker reduction of 27% and 60% respectively. One patient with metastatic prostate cancer had stable disease for four months, had a 50% decrease in PSA, and had extensive product-induced necrosis with associated intratumoural viral replication in metastatic lesions in the lymph nodes. One patient with metastatic bladder cancer had stable disease for four months and had a minor tumour response in a metastatic lesion in a lymph

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node (reduction from 2.5 to 1.9 cm). A patient with pancreatic cancer and a patient with lung cancer had stable disease for four months. A patient with endometrial cancer had stable disease for five months.

Phase Ia/Ib Combination REOLYSIN®/Radiation Clinical Trial

In 2006, we completed patient enrollment in our Phase Ia combination REOLYSIN®/radiation clinical trial. The primary objective of this trial was to determine the MTD, DLT, and safety profile of REOLYSIN® when administered intratumourally to patients receiving radiation treatment. A secondary objective was to examine any evidence of anti-tumour activity. Eligible patients included those who had been diagnosed with advanced or metastatic solid tumours that were refractory to standard therapy or for which no curative standard therapy exists.

A total of 11 patients were treated in this Phase Ia trial with two intratumoural treatments of REOLYSIN® at dosages of $1x10^8$, $1x10^9$, or $1x10^{10}$ $TCID_{50}$ with a constant localized radiation dose of 20 Gy in five fractions. Preliminary results in the first seven patients showed that the combination of intratumoural REOLYSIN® and radiation was well-tolerated and an MTD had not been reached. Most toxicities were mild, generally grade 1 and 2, and included fever, sweating and skin erythema. One patient in the second cohort developed grade 3 fatigue and grade 2 flu-like symptoms and could not receive the second REOLYSIN® injection. There was no evidence that the REOLYSIN® injections exacerbated the acute reactions expected from the radiation. There was also no evidence of viral shedding in the blood, urine, stool or sputum on day eight post-REOLYSIN® injection.

Interim analysis also showed evidence of local responses and an indication of systemic effects. Amongst the first five patients that completed treatment, three patients had partial tumour responses. There was one case of progressive disease at one month, one case of stable disease at one month, two cases of partial responses at one, two and three months and one case of stable disease at one and two months, which became a pathological partial response at three months. CT scans from the treated lymph node tumour in the first patient in the trial clearly show the partial response, which at the time of the interim analysis, had lasted for over eight months. A metastatic tumour in this patient that was outside the radiation field also showed a partial response.

Subsequent to completion of the Phase Ia portion of this trial, we commenced patient enrolment in the Phase Ib portion. The Phase Ib trial will treat patients with a range of two to six intratumoural doses of REOLYSIN® at $1x10^{10}$ $TCID_{50}$ with a constant radiation dose of 36 Gy in 12 fractions.

The primary objective of our Phase Ib trial is to determine the MTD, DLT, 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. Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours that are refractory to standard therapy or for which no curative standard therapy exists. An additional group of patients is planned to be treated at the maximum dose regimen reached in this Ib trial.

U.K. Phase II Combination REOLYSIN®/Radiation Clinical Trial

In 2006, we received a letter of approval from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) for our Clinical Trial Application (CTA) to begin a Phase II clinical trial to evaluate the anti-tumour effects of intratumoural administration of REOLYSIN® in combination with low-dose radiation in patients with advanced cancers. In December 2006, we initiated patient enrollment.

The trial is an open-label, single-arm, multi-centre Phase II study of REOLYSIN® delivered via intratumoural injection to patients during treatment with low-dose radiotherapy. Up to 40 evaluable patients, including approximately 20 patients with head and neck and esophageal cancers, and approximately 20 patients with other advanced cancers, will be treated with two intratumoural doses of REOLYSIN® at $1x10^{10}$ $TCID_{50}$ with a constant localized radiation dose of 20 Gy in five consecutive daily fractions. Eligible patients include those who have been diagnosed with advanced or metastatic cancers including head, neck and esophageal tumours that are refractory (have not responded) to standard therapy or for which no curative standard therapy exists.

The primary objective of the trial is to assess the anti-tumour activity of the combination of REOLYSIN® and low dose radiotherapy in treated and untreated lesions. Secondary objectives include the evaluation of viral replication, immune response to the virus and to determine the safety and tolerability of intratumoural administration of REOLYSIN® in patients with advanced cancers who are receiving radiation treatment.

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U.K. REOLYSIN® in Combination with Paclitaxel and Carboplatin

In 2006, we received a letter of approval from the MHRA to begin our clinical trial using intravenous administration of REOLYSIN® in combination with paclitaxel and carboplatin in patients with advanced cancers including melanoma, lung, and ovarian. The combination of paclitaxel and carboplatin chemotherapy is used in cancer patients with ovarian and lung cancers, and is also used widely in the treatment of many other types of cancer.

In studies conducted by the U.S. National Cancer Institute (NCI), the combination of REOLYSIN® and paclitaxel was uniformly synergistic against six non-small cell lung cancer cell lines examined, including cell lines resistant to paclitaxel or REOLYSIN®. Preclinical studies conducted at Cornell University also found that REOLYSIN® in combination with platinum drugs enhanced the cytotoxicity of the chemotherapeutic agents.

This trial has two components. The first is an open-label, dose-escalating, non-randomized study of REOLYSIN® given intravenously with paclitaxel and carboplatin every three weeks. Standard dosages of paclitaxel and carboplatin will be delivered with escalating dosages of REOLYSIN® intravenously. A maximum of three cohorts will be enrolled in the REOLYSIN® dose escalation portion. The second component of the trial will immediately follow and will include the enrolment of a further 12 patients at the maximum dosage of REOLYSIN® in combination with standard dosages of paclitaxel and carboplatin.

Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours such as melanoma, lung and ovarian cancers that are refractory to standard therapy or for which no curative standard therapy exists. The primary objective of the trial is to determine the MTD, DLT, recommended dose and dosing schedule and safety profile of REOLYSIN® when administered in combination with carboplatin and paclitaxel. Secondary objectives include the evaluation of immune response to the drug combination, the body s response to the drug combination compared to chemotherapy alone and any evidence of anti-tumour activity.

U.S. Phase I Systemic Administration Clinical Trial

In 2006, we completed patient enrolment in our U.S. Phase I clinical trial investigating the systemic delivery of REOLYSIN® to treat patients with advanced cancers. A total of 18 patients were treated in the Phase I trial with REOLYSIN® at escalating dosages of $1x10^8$, $3x10^8$, $1x10^9$, $3x10^9$, $1x10^{10}$ or $3x10^{10}$ $TCID_{50}$. An MTD was not reached and the treatment appears to have been well tolerated by the patients.

The clinical trial was an open-label, dose-escalation Phase I study in which a single dose of REOLYSIN® was administered intravenously to patients diagnosed with selected advanced or metastatic solid tumours that are refractory 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 anti-tumour activity.

U.S. Phase I/II Recurrent Malignant Glioma Clinical Trial

In 2006, we began patient enrolment in our clinical trial to investigate the use of REOLYSIN® for patients with recurrent malignant gliomas. This clinical trial is an open-label dose escalation Phase I/II trial in which a single dose of REOLYSIN® is 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 anti-tumour activity.

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U.S. National Cancer Institute

In 2006, the NCI commenced its solicitation process for two clinical trial studies, a Phase II study of REOLYSIN® administered systemically in patients with melanoma and a Phase I/II study of REOLYSIN® co-administered both systemically and intraperitoneally (IP) in patients with ovarian cancer. The purpose of the Phase I portion of the trial is to determine the MTD of REOLYSIN® given by IP administration in combination with a constant systemic dose and dosing regimen.

Pre-Clinical Trial and Collaborative Program

We perform pre-clinical studies and engage in collaborations to help support our clinical trial programs and expand our intellectual property base. Throughout 2006, we continued with studies examining the interaction between the immune system and the reovirus, the use of the reovirus as a co-therapy with existing chemotherapeutics and radiation, the use of new RAS active viruses as potential therapeutics, and to investigate new uses for the reovirus in therapy.

During 2006, in conjunction with our various collaborators, we reported the results of a number of research collaborations. One of our collaborators presented a poster at the British Society of Gene Therapy 3rd annual conference in London U.K. Our investigators concluded that immune interventions which prolong local viral replication, and/or enhance levels of tumour specific T cells, should have significant therapeutic impacts both against the local, injected tumour and against systemic metastatic disease not accessible to direct viral injection.

As well, a poster by Dr. E. Anders Kolb was presented at the AACR annual meeting in Washington D.C. The investigators tested reovirus against various pediatric sarcoma cell lines *in vitro* and *in vivo*. In all tumour lines evaluated, the reovirus exhibited significant antitumour activity. The investigators concluded that REOLYSIN® demonstrates excellent anti-tumor activity *in vitro* and *in vivo* in childhood sarcoma cell lines, and that these promising results suggest that a clinical trial of systemic reovirus in pediatric solid tumours is warranted.

In the fourth quarter of 2006, Dr. Shizuko Sei of SAIC-Frederick, Inc., prime contractor to the U.S. National Cancer Institute at Frederick presented a poster at the 18th EORTC-NCI-AACR symposium on Molecular Targets and Cancer Therapeutics in Prague, Czech Republic. The research focused on work conducted by the NCI with reovirus in combination with a number of common chemotherapeutic agents. In general, the combination of reovirus with cisplatin, gemcitabine, mitomycin or vinblastine was synergistic against NSCLC cell lines sensitive to anti-cancer drugs. Of particular interest to the researchers, the combination of reovirus and paclitaxel was uniformly synergistic in all six cell lines examined, including in those with high-level resistance to paclitaxel or reovirus. The data suggest that the combination of reovirus and paclitaxel may help in promoting cell-death signaling, resulting in a more efficient and synergistic anti-cancer effect against these cell lines than using each agent on its own.

Manufacturing and Process Development

At the beginning of 2006, we completed the production runs that were ongoing at the end of 2005, providing us with sufficient product to complete our U.K. Phase II combination REOLYSIN®/radiation clinical trial and our existing Phase I clinical trials. At the same time, our process development activity helped improve virus yields from our manufacturing process. These improvements were transferred to our cGMP manufacturer and we began production runs under this improved process. These production runs are expected to provide sufficient REOLYSIN® to expand our Phase II clinical trial program. Our process development activity has now shifted focus to the examination of the potential scale up of our manufacturing process.

2005 REOLYSIN® DEVELOPMENT

Clinical Trial Program

In the first part of 2005, we reported that we received regulatory clearance to commence three additional clinical trial studies. The first trial approved in 2005 was our first co-therapy study that is investigating REOLYSIN® in combination with radiation therapy in the United Kingdom (U.K.). Our second and third trials that received regulatory clearance were two United States (U.S.) clinical trial studies. The first of these trials was a Phase I/II recurrent malignant glioma clinical trial. The second was a Phase I systemic delivery clinical trial.

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During 2005, we commenced patient enrollment in the U.K. combination radiation therapy and the U.S. systemic delivery clinical trials while continuing to enroll patients in our ongoing U.K. systemic delivery and Canadian glioma clinical trials. In the fourth quarter of 2005, we ended patient treatment in the Canadian glioma study and exited 2005 with three actively enrolling clinical trials.

In the fourth quarter of 2005, we reported interim results from two of our clinical trials. The first report was in conjunction with a poster presentation at the AACR-NCI-EORTC conference in Philadelphia by our principal investigator for our Phase I systemic delivery clinical trial in the U.K. Our principal investigator presented data on 22 patients and reported that REOLYSIN® is well tolerated when administered intravenously with minimal toxicity observed and that reovirus replication in tumours has been identified with evidence of tumor necrosis. The principal investigator also reported that there have been encouraging hints of activity in prostate and colorectal cancer. This trial continues to enroll and we expect that patient enrollment will be completed in 2006. We also reported on the Canadian glioma clinical trial. In this trial a total of 12 patients were enrolled. A maximum tolerated dose was not reached and REOLYSIN® was well tolerated.

Pre-Clinical Trial and Collaborative Program

We perform pre-clinical studies and engage in collaborations to help support our clinical trial programs and expand our intellectual property base. In 2005, we investigated the interaction of the reovirus with the immune system and the use of reovirus as a co-therapy with existing chemotherapies and radiation. In the fourth quarter of 2005, we reported in conjunction with one of our collaborators at the AACR-NCI-EORTC conference in Philadelphia, that reovirus enhances radiation cytotoxicity in vitro and in vivo. The results of this collaboration were also used to support our radiation co-therapy clinical trial application in the U.K.

Manufacturing and Process Development

During 2005, we contracted cGMP (current good manufacturing practices)production runs that we believe produced sufficient REOLYSIN® to supply our existing clinical trials in the U.S. and the U.K. We also entered into process development activities that examined ways to improve the process yields.

Financings and Other Distributions

Since inception we have raised net cash proceeds of $96,253,751 through public offerings, private placements and the exercise of warrants and options.

Recent 2008 Developments

Clinical Trial Program

U.S. Phase II Interim Update

On January 31, 2008, we announced that we met the initial criteria to proceed to full enrolment in our U.S. Phase II trial to evaluate the intravenous administration of REOLYSIN® in patients with various sarcomas that have metastasized to the lung. According to the trial protocol, to proceed to full enrolment of 52 patients, we had to demonstrate that at least one patient in the first 38 patients treated experienced a complete or partial response, or stable disease for greater than six months. The third patient treated in the study was demonstrated to have stable disease by RECIST criteria for more than six months as measured by CT scan. A PET scan taken at the same time showed that any residual tumour mass was metabolically inert.

A total of 12 patients have received REOLYSIN® treatment to date, with five remaining on study. The trial is a Phase II, open-label, single agent study whose primary objective is to measure tumour responses and duration of response, and to describe any evidence of antitumour activity of intravenous, multiple dose REOLYSIN® in patients with bone and soft tissue sarcomas metastatic to the lung. REOLYSIN® is delivered intravenously to patients at a dose of $3x10^{10}$ $TCID_{50}$ for five consecutive days. Patients may receive additional five-day cycles of therapy every four weeks for a maximum of eight cycles.

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Eligible patients must have a bone or soft tissue sarcoma metastatic to the lung deemed by their physician to be unresponsive to or untreatable by standard therapies. These include patients with osteosarcoma, Ewing sarcoma family tumours, malignant fibrous histiocytoma, synovial sarcoma, fibrosarcoma and leiomyosarcoma.

U.S. National Cancer Institute Phase Clinical Trial

On January 3, 2008, the U.S. National Cancer Institute (NCI) filed a protocol with the U.S. Food and Drug Administration for a Phase 1/2 clinical trial for patients with metastatic ovarian, peritoneal or fallopian tube cancers using concurrent systemic and intraperitoneal administration of REOLYSIN®. The NCI is sponsoring the trial under our Clinical Trials Agreement that requires us to provide clinical supplies of REOLYSIN®. The trial, which is being carried out at The Ohio State University Comprehensive Cancer Center, is expected to enroll up to 70 patients with metastatic ovarian, peritoneal or fallopian tube cancers.

COLLABORATIVE PROGRAM

On January 7, 2008, we reported that a research group led by Dr. Richard Vile of the Mayo Clinic College of Medicine in Rochester, Minnesota, published the results of their work testing the antitumor efficacy and safety of various combinations of reovirus and cyclophosphamide *in vivo*. The paper is entitled Cyclophosphamide Facilitates Antitumor Efficacy against Subcutaneous Tumors following Intravenous Delivery of Reovirus and appeared online in the January 1, 2008 issue of Clinical Cancer Research.

The purpose of the research study was to investigate whether it was possible to use cyclophosphamide, an immune modulator, to enhance the delivery and replication of the reovirus when delivered intravenously. After testing various doses and dosing regimens of reovirus and cyclophosphamide in mice, a metronomic dosing regimen was developed that resulted in increased survival, high levels of reovirus recovered from regressing tumors, levels of neutralizing antibodies that were protective, and only very mild toxicities. The data support investigation in human clinical trials of the use of cyclophosphamide prior to systemic reovirus administration to modulate, but not ablate, the immune system.

On February 4, 2008, we reported that Dr. Kevin Harrington and his research group at The Institute of Cancer Research, London, U.K. published the results of their work testing combination treatment schedules of reovirus and radiation in human and murine tumour cells in vitro and in vivo. The paper, entitled Enhanced *In vitro* and *In vivo* Cytotoxicity of Combined Reovirus and Radiotherapy appeared online in the February 1, 2008 issue of Clinical Cancer Research. The effect of different schedules of reovirus and radiotherapy on viral replication and cytotoxicity was tested in vitro and the combination was assessed in three tumour models in vivo. The results demonstrated that combining reovirus and radiotherapy significantly increased cancer cell killing both in vitro and in vivo, particularly in cell lines with moderate susceptibility to reovirus alone.

Future Developments

We plan to continue to enroll patients in our clinical trials throughout 2008 and expect to complete enrollment in our chemotherapy co-therapy trials in the U.K. and our sarcoma study in the U.S. We believe that the results from these trials will allow us to broaden our phase II clinical trial program. As well, we believe that the NCI will commence enrollment in its Phase II melanoma clinical trial and commence additional trials with REOLYSIN®.

We expect to complete the technology transfer of our 40-litre manufacturing process to our U.S. toll manufacturer and produce REOLYSIN® for our clinical trial program throughout 2008. We believe we will complete our 100-litre scale up studies and will begin to examine a lyophilization (freeze drying) process for REOLYSIN®.

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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 our control. Any of these factors may cause our actual results, performance or achievement 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 FDA in the United States, the HPB in Canada, or MHRA in the UK as well as those factors detailed in our regulatory filings.

NARRATIVE DESCRIPTION OF THE BUSINESS

Our Business

Our potential product for human use, REOLYSIN®, is developed from the reovirus. This virus has been demonstrated to replicate specifically in tumour cells bearing an activated Ras pathway. Activating mutations of Ras occur in approximately 30% of all human tumours directly, but considering its central role in signal transduction, activation of the Ras pathway has been shown to play a role in approximately two-thirds of all tumours.

The functionality of the product is based upon the finding that tumours 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, tumour 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 tumour cell with an activated Ras pathway, reovirus is able to freely replicate and hence kill the host tumour 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 tumour cells carrying an activated Ras pathway available.

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

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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 tumour 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 tumour types in which Ras mutations are relatively rare. Although activating mutations of Ras itself are thought to occur in only about 30% of all tumours it is expected that approximately two-thirds of all tumours 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 us 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 tumours, expanded animal models as well as human brain, breast, and prostate tumours implanted in immuno-compromised mice have yielded promising results. In animals where tumour regression was noted, a single injection of reovirus is often enough to cause complete tumour regression. More importantly, it was demonstrated that this treatment is effective in causing tumour regression in immune competent animals. We believe that the nature of this virus, combined with its selective replication makes it an attractive candidate as a cancer therapy.

We also believe 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 tumour 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 tumours that can disrupt and impinge on normal tissue and organ function. In many instances, cells from

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these tumours can break away from the original tumour and travel through the body to form new tumours through a process referred to as metastasis.

Our cancer product is a potential therapeutic for tumours possessing an activated Ras pathway. In tumour 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 tumours 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 tumours may respond to this treatment.

Repayable Grants

Pursuant to the Technology Commercialization Agreement with the Alberta Heritage Foundation, we received $150,000 to offset the REOLYSIN® development costs. Under the Technology Commercialization Agreement, we agreed to repay the amount of the grant from our gross sales. We 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, we received funding and overhead support from the ACB to offset the REOLYSIN® clinical trial expenditures. Under the Clinical Trial Agreement, we 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. We 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.

Business Strategy

Our 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 we believe is best for our development. We intend to achieve our business strategy by focusing on these key areas:

- Develop REOLYSIN® by continuing to progress the product through our clinical trial program assessing the safety and efficacy in human subjects.
- Establish collaborations with experts to assist us with scientific and clinical developments of this new potential pharmaceutical product.
- Implement strategic alliances with selected pharmaceutical and biotechnology companies and selected laboratories, at a time and in a manner where such alliances may complement and expand our research and development efforts on the product and provide sales and marketing capabilities.
- Utilize our broadening patent base and collaborator network as a mechanism to meet our strategic objectives.
- Develop relationships with companies that could be instrumental in assisting us to access other innovative therapeutics.

Our business strategy is based on attaining a number of commercial objectives, which, in turn, are supported by a number of product development goals. Our new product development presently being conducted is primarily of a research and development nature. In the context of this Annual Information Form, statements of our belief are based primarily upon our results derived to date from our research and development program with animals, and early stage human trials, and upon which we believe that we

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have 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 us will occur. See *Risk Factors.*

At this time we do not intend to become a fully integrated pharmaceutical company with substantial in-house research and development, marketing and distribution or manufacturing capabilities. We are pursuing a strategy of establishing relationships with larger companies as strategic partners. We intend to partner or joint venture with larger pharmaceutical companies that have existing and relevant marketing capability for our products. It is anticipated that future clinical development into large international or pivotal trials 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 our products, the strategic partners would be expected to share in gross proceeds from the sale of our product or products and potentially share in various market or manufacturing opportunities. 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 current Good Manufacturing Practices and submit marketing materials before being allowed to market pharmaceutical products. While we plan to pursue or support the pursuit of the approval of our product, success in acquiring regulatory approval for any product is not assured.

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

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

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

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

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

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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 2007 from the American Cancer Society, 1.4 million Americans are expected to be diagnosed with cancer in the year, and 559,650 Americans are forecast to die of cancer. In the United States cancer accounts for 25% of all deaths, second only to heart 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 $206.3 billion. Of this figure, $78.2 billion can be attributed to direct patient costs.

It has been estimated that approximately 30% of all tumours 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 tumours with activated Ras (either through direct activating mutation or mutation or over-expression of elements upstream of Ras) is approximately two thirds.

We are aware of large pharmaceutical companies developing small molecule programs for the development of therapeutics to treat Ras mediated tumours. 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 us may be large and could require substantial sales and marketing capability. Before or upon successful completion of the development of a cancer product, we intend 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, we will establish arrangements with various partners for different geographical areas or specific applications at various times in the development process. Our management and consultants have relevant experience with the partnering process.

Third Party Advisor, Collaborators and Scientific Advisory Board

We use various third party advisors, scientific collaborators and our scientific advisory board to assist us with the advancement of REOLYSIN®. We typically report on the activity of these groups once their work is completed.

Scientific Advisory Board

Our Scientific 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

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the Gene and Viral Therapy Group at the Institut Catala d Oncologia in Barcelona. Dr. Alemany has collaborated with us in the past in developing 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 Chairman and CEO of NeuroPhysics Corporation, a brain scanning technology company. From 1997 to 2001 Dr. Tuchman was the Senior Vice President of Equity Research for Oscar Gruss & Son, where he conducted investment research and helped develop marketing strategies for healthcare companies. He also held senior neurology positions at New York Medical College and Lincoln Medical and Mental Health Center.

Frank Tufaro, Ph.D., has extensive 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

At the end of 2007, we had been issued over 160 patents including 25 U.S. and six Canadian patents as well as issuances in other jurisdictions. We also have over 180 patent applications filed in the U.S., Canada and other jurisdictions. All potentially valuable intellectual property is identified by the inventor, and classified by us 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 us. We believe that we apply our 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 we perceive to be essential.

We believe 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 us for other employment. We intend that all staff be compensated through competitive salaries and participation in our 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

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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. For a list of certain patents go to our website at www.oncolyticsbiotech.com.

Acquisition of all of the Shares of Oncolytics Biotech Inc. by SYNSORB

In April 1999, Oncolytics Biotech Inc., the Vendors and SYNSORB entered into the Share Purchase Agreement whereby SYNSORB acquired all of our then outstanding common shares 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 us. We 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, we have 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®.

In 2004, we reached an agreement that cancelled a portion of our 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, our 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 we develop 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 us for such products.

Employees

As of December 31, 2007, we had 14 employees. The majority of our activities are conducted under contract with third party service providers.

Research and Development Expenditures

For the period ended December 31, 2007, we incurred research and development expenditures of $11,315,088 representing approximately 67.1% of our total expenses for the year. See *Management s Discussion and Analysis Results of Operations Research and Development Expenses* .

Dividend Policy

To date, we have not paid any dividends on our outstanding common shares. The future payment of dividends will be dependent upon our financial requirements to fund future growth, our financial

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condition and other factors which our Board of Directors may consider appropriate in the circumstances. It is unlikely that dividends will be paid in the foreseeable future.

MARKET FOR SECURI