ONCOLYTICS BIOTECH INC
Form 6-K
April 08, 2008

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 - _____

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

EXHIBIT INDEX

1. Annual Report
2. Notice of Annual and Special Meeting of Shareholders
3. Proxy Card

EXHIBIT 1

Oncolytics Biotech Inc. is focused on the development of oncolytic viruses as a novel and effective approach to cancer treatment. Oncolytics clinical program includes a variety of Phase I/II and Phase II human trials using REOLYSIN®, its proprietary formulation of the human reovirus, alone and in combination with radiation or chemotherapy.

Oncolytics trades on the Toronto Stock Exchange (symbol ONC) and on the NASDAQ (symbol ONCY).

Contents

Annual and Special Meeting The Annual and Special Meeting of the Shareholders will be held at The Yale Club of New York City, 50 Vanderbilt Avenue, New York at 9:00 a.m. on Wednesday, May 7, 2008.

Letter to Shareholders

2007 marked a significant expansion of the Company s clinical trial program for REOLYSIN® with Phase II studies and combination drug therapy studies being expanded and initiated. This activity was supported by further advances in our preclinical development program, manufacturing, and intellectual property.

Clinical Program Developments

This past year was our most active year to date, with the announcement of results from three separate clinical trials, the approval of three additional trials in the U.S. and the U.K., and the start of enrolment in four new trials; three combination REOLYSIN® and chemotherapy trials in the U.K., and a Phase II sarcoma trial in the U.S.

In January 2007, we announced that the Medicines and Healthcare products Regulatory Agency (MHRA) had approved two, intravenous, combination trials using REOLYSIN® in combination with gemcitabine or docetaxel. These trials are in addition to the intravenous, combination REOLYSIN®/paclitaxel and carboplatin trial approved late in 2006. These three trials all began enrolling patients in the first half of 2007. The trials have two components; a small, dose escalation component that will enroll three cohorts of patients and a second component that will include the enrolment of a further 12 patients at the maximum dosage of REOLYSIN®.

The Company received clearance in April 2007 to begin a U.S. Phase II trial in patients with various sarcomas (bone and soft tissue cancers) that have metastasized to the lung. Patient enrolment began in June, and in January 2008 the Company announced that it had met the criteria to proceed to full enrolment of 52 patients. According to the trial protocol, to proceed to full enrolment Oncolytics 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 Response Evaluation Criteria in Solid Tumours (RECIST) for more than six months as measured by CT scan. A PET scan taken at the same time showed that any residual mass was metabolically inactive. At the time, 12 patients had been treated and five remained on study.

After conducting extensive preclinical work with the reovirus over the past few years, the U.S. National Cancer Institute (NCI) moved its REOLYSIN® program forward in May 2007 when it filed a protocol with the U.S. Food & Drug Administration (FDA) to conduct a Phase II systemic administration trial with REOLYSIN® for patients with metastatic melanoma. In January 2008, the NCI also filed a protocol for a Phase I/II systemic and intraperitoneal administration trial with REOLYSIN® for patients with advanced ovarian, peritoneal or fallopian tube cancers. Under its clinical trial agreement, the NCI will pay for all costs of these trials, while Oncolytics will provide REOLYSIN®. Both of these trials have received clearance from the FDA and are expected to start enrolling patients this year.

Positive final results from our Phase I U.K. systemic administration trial were presented at the American Society of Clinical Oncology (ASCO) in June. The results indicate that REOLYSIN® can be delivered systemically to patients with advanced and metastatic cancers and causes anti-tumour activity. Positive results from our U.S. Phase I systemic administration trial were also presented at ASCO. Of the 18 patients treated in the U.S. trial, eight demonstrated stable

disease, including a patient with progressive breast cancer who experienced a 34% shrinkage in tumour volume, or a partial response. 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 however, Oncolytics applied for and was 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®.

We were also very pleased to announce positive interim results of our Phase Ia/Ib combination REOLYSIN® and radiation trial in September. Of the 11 patients treated in the Ia portion of the trial, three patients experienced significant partial responses, with stable disease noted in other, non-treated tumours. Of the 6 patients that had completed treatment in the Ib portion, three patients experienced tumour regression, as well as stable disease in non-treated tumours. The treatment was well tolerated, with mostly Grade 1 or 2 toxicities noted including fatigue, lymphopenia, fever, and neutropenia. A total of 23 patients were treated in the trial, which concluded enrolment in December 2007.

Oncolytics is also planning to initiate enrolment in another combination trial in the U.K. In October, the MHRA approved a clinical trial that will examine intravenous administration of REOLYSIN® in combination with cyclophosphamide, a chemotherapeutic agent as well as immune modulator, in patients with advanced cancers. Patients will receive REOLYSIN® intravenously with escalating doses of cyclophosphamide. 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.

Pre-Clinical Program Developments

Oncolytics has research collaborations in place with numerous leading institutions in North America and Europe, and 2007 was an active year for our collaborators. The research that continues to support our clinical program focused on immune interaction with the reovirus, as well as the effect of combinations of chemotherapy and/or immune modulation with the reovirus.

Intellectual Property Portfolio

We continue a sustained effort to expand and broaden our intellectual property portfolio. In 2007, we secured an additional eight U.S. patents and one Canadian patent, bringing our total to more than 165 patents issued worldwide, including 25 U.S. patents and six Canadian patents. In January 2008, we secured an additional two Canadian patents.

Scaling Up Production

Last year, Oncolytics successfully completed initial scale up of our manufacturing process for REOLYSIN® to the 40-litre level, and also investigated further increases in scale to the 100-litre level. The process at the 40-litre scale can deliver 20,000 doses of REOLYSIN® at the maximum clinical dose for intravenous use, or 60,000 doses for local use. Testing at the 100-litre level is ongoing. The enhanced process allows us to keep pace with the rapidly expanding clinical program, while preparing for commercial demand in future.

Financial Resources

The Company completed a public offering in February 2007 that added gross proceeds of $12 million to our financial reserves. An over-allotment option was also fully exercised in March 2007, increasing the gross proceeds to $13.8 million. With the successful completion of the financing, cash reserves are estimated to carry the Company well into 2009.

Looking Ahead

Although 2007 was our most productive year to date, 2008 is already shaping up to surpass the many achievements in 2007 as we move forward with our Phase II program, and begin to focus our efforts in the clinical program in key indications. We expect to conclude enrolment in several of our Phase II trials in 2008. With solid preclinical and Phase I results, a scalable manufacturing process, a comprehensive intellectual property portfolio and the financial resources to support our Phase II program, we look forward to an exciting and productive 2008.

On behalf of our Board of Directors and staff at Oncolytics, we would like to thank all shareholders for their continued support.

Brad Thompson, PhD
President & CEO

March 5, 2008

Management s Discussion and Analysis
of Financial Condition and Results of Operations
March 5, 2008
The following information should be read in conjunction with our 2007 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 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.

Overview

Oncolytics Biotech Inc. is a Development Stage Company
Since our inception in April of 1998, Oncolytics Biotech Inc. has been a development stage company and we have focused our research and development efforts on the development of REOLYSIN®, our potential cancer therapeutic. We have not been profitable since our inception and expect to continue to incur substantial losses as we continue research and development efforts. We do not expect to generate significant revenues until, if and when, our 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 we 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 pharmaceutical product, we rely upon our 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 Oncolytics.

REOLYSIN® Development Update For 2007

We have been developing our product REOLYSIN® as a possible cancer therapy since our inception in 1998. Our goal each year is to advance REOLYSIN® through the various steps and stages of development required for potential pharmaceutical products. In order to achieve this goal, we believe that we have to actively manage the development of our clinical trial program, our pre-clinical and collaborative programs, our manufacturing process and REOLYSIN® supply, and our intellectual property.

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 enrolment in four trials and completed enrolment 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

We announced positive interim results from our U.K. Phase Ia/Ib combination REOLYSIN® and radiation clinical trial for patients with advanced or metastatic cancers in the third quarter of 2007 and completed enrolment 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.

The primary objective of the 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.

U.S. Phase I Systemic Clinical Trial

We announced positive results from our U.S. Phase I clinical trial examining the systemic administration of REOLYSIN® 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.

The primary objective of this 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 are refractory (have not responded) to standard therapy or for which no curative standard therapy exists.

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 enrolment in the following studies:

U.S. Phase II Sarcoma Clinical Trial

We received approval to commence and initiated patient 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. 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.

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 Trials - 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.

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 objective of the trial includes 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, 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 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.

Financing Activity

In 2007, we issued 4,600,000 units at a price of $3.00 per unit for net cash proceeds of $12,063,394. Each unit consisted of one common share and one-half of one common share purchase warrant. Each whole common share purchase warrant shall entitle the holder thereof to acquire one common share upon payment of $3.50 expiring on February 22, 2010. The net proceeds from this offering will be used for our clinical trial program, manufacturing activities in support of the clinical trial program and for general corporate purposes.

Financial Impact

We estimated at the beginning of 2007 that our monthly cash usage would be approximately $1,400,000 for 2007. Our cash usage for the year was $13,569,594 from operating activities and $944,719 for the purchases of intellectual property and capital assets which is in line with our estimate. Our net loss for the year was $15,642,191.

REOLYSIN® Development For 2008

We plan to continue to enroll patients in our clinical trials throughout 2008 and expect to complete enrolment 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 enrolment 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®.

We estimate, based on our expected activity for 2008 that our monthly cash usage will increase to $1,660,000 per month (see Liquidity and Capital Resources).

Recent 2008 Progress

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 examined was metabolically inert.

A total of 12 patients had received REOLYSIN® treatment at that time, 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.

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 I/II 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.

Accounting Policies

Critical Accounting Policies and Estimates

In preparing our financial statements, we are required to make certain estimates, judgments and assumptions that we believe 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 our 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 we believe are the most critical to aid in fully understanding and evaluating our reported financial results include the following:

Research and Development

Our research and development costs 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. Our 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), we have completed six Phase I clinical trials and are presently enrolling or have permission to commence seven additional clinical trial studies for REOLYSIN®. We are also planning to add additional trials to our clinical trial program. 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, our development costs are expensed and not capitalized.

Capitalization and Amortization of Patent Costs

We treat third party costs incurred (primarily legal and registration costs) in the development of our Patent portfolio as limited-life intangible assets, and we amortize the costs related to these assets over the lesser of 17 years or their estimated useful life. We also review the valuation of our Patent costs for impairment when any events that might give rise to impairment are known to us. If there is an indication of impairment, we would assess the fair value of our Patents and would record a reduction if the fair value were less than the book value.

In capitalizing these costs, we are recognizing the inherent future benefit of our Patents, not only in protection of our own potential products, but also as a possible asset that could give rise to revenues in the future through licensing agreements. While Patent life varies 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, we have set a maximum of 17 years to amortize the costs from the date of issuance. We have 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, we have 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 we experience a significant failure in our 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 we are successful in our product development and sales, or other parties enter into licensing agreements with us, 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

International Financial Reporting Standards

In 2006, the CICA announced that accounting standards in Canada will converge with International Financial Standards (IFRS). The Company will need to begin reporting under IFRS in the first quarter of 2011 with comparative data for the prior year. IFRS uses a conceptual framework similar to GAAP, but there could be significant differences on recognition, measurement and disclosures that will need to be addressed. The Company is currently assessing the impact of these standards on its financial statements.

Capital Disclosures

The CICA has issued new accounting recommendations for capital disclosures which require disclosure of both qualitative and quantitative information that enables users of financial statements to evaluate the Company s objectives, policies, and processes for managing capital. These recommendations are effective for the Company beginning January 1, 2008.

Disclosure and Presentation of Financial Instruments

The CICA has issued new accounting recommendations for disclosure and presentation of financial instruments which require disclosures of both qualitative and quantitative information that enables users of financial statements to evaluate the nature and extent of risks arising from financial instruments to which the Company is exposed. These recommendations are effective for the Company beginning January 1, 2008.

Goodwill and Intangible Assets

The CICA has issued new accounting recommendations for the treatment of goodwill and intangible assets that are intended to reduce the differences between IFRS in the accounting for intangible assets and results in closer alignment with U.S. GAAP. The objectives of these recommendations are to reinforce the principle-based approach to the recognition of assets only in accordance with the definition of an asset and the criteria for asset recognition; and clarify the application of the concept of matching revenues and expenses such that the current practice of recognizing asset items that do not meet the definition and recognition criteria is eliminated. The standard also provides guidance for the recognition of internally developed intangible assets, whether separately acquired or internally developed. These changes are effective for fiscal years beginning on or after October 1, 2008, with early adoption encouraged. The Company is evaluating the effects of adopting these recommendations.

Fair Presentation

We prepare our financial statements in accordance with GAAP. As a result of complying with GAAP, we believe that the following should be mentioned in an effort to understand and fairly present our financial information:

(iii) The Managing General Partner’s beneficial ownership of 383,986 shares of Common Stock represents 0.26% of the outstanding shares of Common Stock.

(iv) Steadfast Capital’s beneficial ownership of 383,986 shares of Common Stock represents 0.26% of the outstanding shares of Common Stock.

(v) American Steadfast’s beneficial ownership of 2,290,955 shares of Common Stock represents 1.58% of the outstanding shares of Common Stock.

(vi) The Offshore Fund's beneficial ownership of 4,540,859 shares of Common Stock represents 3.12% of the outstanding shares of Common Stock.

(vii) Collectively, the Reporting Persons' beneficial ownership of 7,215,800 shares of Common Stock represents 4.96% of the outstanding shares.

(c) Number of shares as to which such person has:

(i) Sole power to vote or to direct the vote

Not applicable.

(ii) Shared power to vote or to direct the vote of shares of Common Stock:

Steadfast Capital has shared power with the Managing General Partner and Mr. Pitts to vote or direct the vote of the 383,986 shares of Common Stock beneficially owned by Steadfast Capital.

American Steadfast has shared power with the Investment Manager and Mr. Pitts to vote or direct the vote of the 2,290,955 shares of Common Stock beneficially owned by American Steadfast.

The Offshore Fund has shared power with the Investment Manager and Mr. Pitts to vote or direct the vote of the 4,540,859 shares of Common Stock beneficially owned by the Offshore Fund.

(iii) Sole power to dispose or to direct the disposition of shares of Common Stock:

Not applicable.

(iv) Shared power to dispose or to direct the disposition of shares of Common Stock:

Steadfast Capital has shared power with the Managing General Partner and Mr. Pitts to dispose or direct the disposition of the 383,986 shares of Common Stock beneficially owned by Steadfast Capital.

American Steadfast has shared power with the Investment Manager and Mr. Pitts to dispose or direct the disposition of the 2,290,955 shares of Common Stock beneficially owned by American Steadfast.

The Offshore Fund has shared power with the Investment Manager and Mr. Pitts to dispose or direct the disposition of the 4,540,859 shares of Common Stock beneficially owned by the Offshore Fund.

ITEM 5. OWNERSHIP OF FIVE PERCENT OR LESS OF A CLASS.

If this statement is being filed to report the fact that as of the date hereof the Reporting Persons have ceased to be the beneficial owner of more than five percent of the class of securities, check the following [X].

ITEM 10. CERTIFICATION.

By signing below the undersigned certifies that, to the best of its or his knowledge and belief, the securities referred to above were not acquired and are not held for the purpose of or with the effect of changing or influencing the control of the issuer of the securities and were not acquired and are not held in connection with or as a participant in any transaction having that purpose or effect.

SIGNATURE

After reasonable inquiry and to the best of its knowledge and belief, each of the undersigned certifies that the information set forth in this statement is true, complete, and correct.

Dated: February 14, 2012

STEADFAST CAPITAL MANAGEMENT LP

By: /s/ Robert S. Pitts, Jr.
Robert S. Pitts, Jr., President

STEADFAST ADVISORS LP

By: /s/ Robert S. Pitts, Jr.
Robert S. Pitts, Jr., President

STEADFAST CAPITAL, L.P.
By: STEADFAST ADVISORS LP, as Managing General Partner

By: /s/ Robert S. Pitts, Jr.
Robert S. Pitts, Jr., President

AMERICAN STEADFAST, L.P.
By: STEADFAST CAPITAL MANAGEMENT LP, Attorney-in-Fact

By: /s/ Robert S. Pitts, Jr.
Robert S. Pitts, Jr., President

STEADFAST INTERNATIONAL MASTER FUND LTD.

By: /s/ Robert S. Pitts, Jr.
Robert S. Pitts, Jr., Director

/s/ Robert S. Pitts, Jr.
Robert S. Pitts, Jr.