ONCOLYTICS BIOTECH INC
Form 6-K
November 06, 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 November 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: November 6, 2008

By: /s/ Doug Ball

Doug Ball
Chief Financial Officer

Third Quarter Report
September 30, 2008

Oncolytics Biotech Inc.
TSX: ONC
NASDAQ: ONCY

Third Quarter Report

For the quarter ended September 30, 2008

Letter to Shareholders

Pivotal Trial Program Selected

Oncolytics made a decision in early November to pursue a pivotal (Phase II/III) randomized trial using the combination of REOLYSIN® with paclitaxel/carboplatin in refractory patients with head and neck cancers. The decision was made following a review of results by the Company s Board of Directors from the Company s ongoing U.K. Phase I and Phase II combination REOLYSIN® and paclitaxel/carboplatin clinical trials. The results were presented November 1 at the International Society for Biological Therapy of Cancer (iSBTc) annual meeting in San Diego, CA.

Compelling Clinical Results

Interim results of both the Phase I and Phase II U.K. clinical trials examining REOLYSIN® in combination with paclitaxel and carboplatin were announced at the iSBTc annual meeting on November 1. Of 14 patients treated so far in the two trials, four patients have had dramatic partial responses, five have had stable disease, four have had progressive disease and one is too early to evaluate. Nine of the evaluable patients are head and neck cancer patients. Eight of nine patients have responded, with four patients experiencing a partial response, while four have had stable disease ranging from two to eight cycles.

During the quarter, we announced the completion of the dose escalation portion of 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. On November 1, interim results of the trial were also presented at the iSBTc annual meeting. The researchers demonstrated that 9 of 11 evaluable patients have experienced stable disease or better for at least four cycles. These include one complete resolution of the target lesion in a breast cancer patient with stable disease (SD) of non-target lesions; one partial response in gastric cancer; and stable disease or better in a variety of cancers. The second component of the trial, which is ongoing, includes the enrolment of a further nine patients at the top dose of REOLYSIN® in combination with a standard dosage of docetaxel.

During the quarter, the U.S. National Cancer Institute (NCI) started patient enrolment in a Phase 2 clinical trial for patients with metastatic melanoma using systemic administration of REOLYSIN®. The trial is being carried out by the Mayo Phase II Consortium under the NCI s Clinical Trials Agreement with Oncolytics, while Oncolytics will provide clinical supplies of REOLYSIN®. The primary objectives of the study are to assess the antitumour effects of REOLYSIN® in patients with metastatic malignant melanoma, as well as the safety profile of REOLYSIN®. The trial is expected to enroll up to 47 patients with metastatic melanoma.

It was particularly gratifying to announce during the quarter that following U.S. Food and Drug Administration (FDA) review, we initiated a U.S. Phase II clinical trial using intravenous administration of REOLYSIN® as a first-line therapy in combination with paclitaxel and carboplatin in patients with non-small cell lung cancer (NSCLC) with K-RAS or EGFR-activated tumours. Lung cancer is the

second most common cancer in men and women and is the leading cause of cancer death. More people die of lung cancer than of colon, breast and prostate cancers combined. According to the American Cancer Society, this year there will be about 215,020 new cases of lung cancer in the U.S., of which 85% to 90% will be NSCLC. Only about 15% of people diagnosed with lung cancer are still alive after five years.

The trial is a single arm, two-stage, open-label, Phase 2 study of REOLYSIN® given intravenously with paclitaxel and carboplatin every 3 weeks. Patients will receive four to six cycles of paclitaxel and carboplatin in conjunction with REOLYSIN®, at which time REOLYSIN® may be continued as a monotherapy. It is anticipated that up to 36 patients will be treated in this trial. Previous preclinical data indicates that reovirus tends to localize in the lungs, and we have seen clinical responses in metastatic lung lesions with REOLYSIN® as a monotherapy as well as in combination with paclitaxel and carboplatin. A significant clinical opportunity for REOLYSIN® exists in the treatment of patients with metastatic cancers, including NSCLC, who have a mutated K-RAS gene and are unlikely to respond to treatment with EGF receptor inhibitors.

Commercial Scale Manufacturing

Subsequent to the quarter-end, we also announced that we had completed the initial scale up of our manufacturing process for REOLYSIN® to commercial scale. While our manufacturing capacity at 40 litres allowed us to support future pivotal clinical studies with REOLYSIN®, a 100-litre manufacturing facility has the potential to produce more than one million doses a year for intravenous use.

Growing IP Portfolio

Oncolytics intellectual property portfolio continues to grow. On the last day of the quarter, we were granted our 28th U.S. patent, followed one week later by our 29th U.S. patent. Our portfolio now includes more than 190 issued patents worldwide.

Outlook

In the quarters ahead, we expect to be submitting our protocol for our first pivotal trial for REOLYSIN®, as well as announcing additional results from our 12 active clinical trials.

I would like to thank all our stakeholders for their continued support, and I look forward to updating all of you on our progress.

Brad Thompson, PhD
President and CEO
November 4, 2008

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

This discussion and analysis should be read in conjunction with the unaudited interim consolidated financial statements of Oncolytics Biotech Inc. as at and for the three and nine months ended September 30, 2008 and 2007, and should also be read in conjunction with the audited financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) contained in our annual report for the year ended December 31, 2007. The financial statements have been prepared in accordance with Canadian generally accepted accounting principles (GAAP).

FORWARD-LOOKING STATEMENTS

The following discussion contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including 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 except as required by applicable laws.

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 activities 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 our research and development. 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 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 our 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.

See also *RISK Factors Affecting Future Performance* in our 2007 MD&A.

REOLYSIN® DEVELOPMENT UPDATE FOR THE THIRD QUARTER OF 2008

We continue to develop our lead product REOLYSIN® as a potential cancer therapy. 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 actively manage the development of our clinical trial program, our pre-clinical and collaborative programs, our manufacturing process and supply, and our intellectual property.

Clinical Trial Program

During the third quarter of 2008, our clinical trial program expanded to 12 clinical trials of which ten are being conducted by us and two are being sponsored by the U.S. National Cancer Institute (NCI).

Clinical Trials Completed Enrollment

During the third quarter of 2008, we completed patient enrolment in the dose escalation portion of 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. The combination of REOLYSIN® and Taxotere® was well tolerated with no obvious toxicity related specifically to REOLYSIN®. Efficacy of the combination was encouraging with both objective anti-tumour responses and disease stabilization observed radiologically.

This trial (REO 010) has two components. The first component is an open-label, dose-escalating, non-randomized study of REOLYSIN® given intravenously with docetaxel every three weeks. Standard dosages of docetaxel were delivered to patients with escalating dosages of REOLYSIN® intravenously. The second component of the trial includes the enrolment of a further nine patients at the top dose of REOLYSIN® in combination with a standard dosage of docetaxel. Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours including bladder, lung, prostate or upper gastro-intestinal cancers 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 determine the Maximum Tolerated Dose (MTD), Dose-Limiting Toxicity (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 Actively Enrolling

During the third quarter of 2008, we enrolled and treated our 200th cancer patient in our clinical trial program. As well,

we commenced enrollment in our previously approved U.S. Phase II clinical trial investigating REOLYSIN® in combination with paclitaxel and carboplatin and the NCI began enrollment in its Phase II systemic melanoma clinical trial. At the end of the third quarter of 2008, nine of our ten sponsored trials and both our NCI sponsored trials were enrolling and treating patients.

Clinical Trials Expanded Trial Program

U.S. Phase II Combination REOLYSIN® Paclitaxel and Carboplatin Clinical Trial for Non-Small Cell Lung Cancer

During the third quarter of 2008, we announced that following U.S. Food and Drug Administration review, we initiated a U.S. Phase II clinical trial using intravenous administration of REOLYSIN® in combination with paclitaxel and carboplatin in patients with non-small cell lung cancer (NSCLC) with K-RAS or EGFR-activated tumours. This trial is a single arm, two-stage, open-label, Phase 2 study of REOLYSIN® given intravenously with paclitaxel and carboplatin every 3 weeks. Patients will receive four to six cycles of paclitaxel and carboplatin in conjunction with REOLYSIN®, at which time REOLYSIN® may be continued as a monotherapy. It is anticipated that up to 36 patients will be treated in this trial. Eligible patients include those with metastatic or recurrent NSCLC with K-RAS or EGFR-activated tumours, who have not received chemotherapy treatment for their metastatic or recurrent disease. Patients must have demonstrated mutations in K-RAS or EGFR, or EGFR gene amplification in their tumours (metastatic or primary) in order to qualify for the trial.

The primary objectives of this trial are to determine the objective response rate of REOLYSIN® in combination with paclitaxel and carboplatin in patients with metastatic or recurrent NSCLC with K-RAS or EGFR-activated tumours, and to measure progression-free survival at 6 months. The secondary objectives are to determine the median survival and duration of progression-free survival in patients, and to evaluate the safety and tolerability of REOLYSIN® in combination with paclitaxel and carboplatin in this patient population.

Pre-Clinical Trial and Collaborative Program

Presentations

During the third quarter of 2008, we announced the participation of five of our collaborators and their schedule of presentations at four conferences through November 15, 2008 covering clinical trial results and preclinical research on REOLYSIN®.

A poster entitled Phase I Trial of Oncolytic Reovirus (Reolysin) in Combination with Carboplatin/Paclitaxel in Patients with Advanced Solid Cancers authored by Dr. Kevin Harrington and colleagues was presented at the International Society for Biological Therapy of Cancer (iSBTc) annual meeting, being held in San Diego, California from October 31-November 2, 2008.

A poster entitled A Phase I Study to Evaluate the Feasibility, Safety, and Biological Effects of Intravenous Administration of a Wild-Type Reovirus (REOLYSIN®) in Combination with Docetaxel to Patients with Advanced Malignancies authored by Prof. Hardev Pandha and colleagues was presented at the iSBTc annual meeting, as well a preclinical poster also authored by Prof. Pandha entitled Synergistic Anti-Tumour Activity of Oncolytic Reovirus and Docetaxel in a PC-3 Prostate Cancer Mouse Model.

Two oral presentations, both entitled A Phase II Study of Intravenous Reolysin (Wild Type Reovirus) in the Treatment of Patients with Bone and Soft Tissue Sarcomas Metastatic to the Lung authored by Dr. Monica Mita et al. are to be presented at the Chemotherapy Foundation Symposium XXVI, being held in New York from November 4-8, 2008 and also at the Connective Tissue Oncology Society (CTOS) meeting, being held in London, U.K. from November 13-15, 2008.

A poster entitled Systemic Administration of Reolysin Inhibits Growth of Human Sarcoma Xenografts Alone and in Combination with Cisplatin and Radiation authored by Dr. Anders Kolb and colleagues is to be presented at the CTOS meeting.

A poster entitled In Vivo Efficacy and Replication Dynamics of Intravenously Administered Oncolytic Reovirus in Nude Mice Bearing Human Melanoma Xenografts authored by Dr. Shizuko Sei et al, was presented at the EORTC-AACR-NCI Symposium on Molecular Targets and Cancer Therapeutics, held in Geneva, Switzerland from October 21-24, 2008.

A poster entitled Synergistic Anti-Tumour Activity of Oncolytic Reovirus and Cisplatin in a B16.F10 Mouse Melanoma Model authored by Prof. Hardev Pandha and colleagues is scheduled to be presented at the EORTC-AACR-NCI Symposium on Molecular Targets and Cancer Therapeutics.

Manufacturing and Process Development

During the third quarter of 2008, we completed our final 40-litre production run for 2008 and began the fill and packaging process of the REOLYSIN® we produced in 2008. As well, we continued our process development work examining further scale-up to the 100-litre level, lyophilization, and process validation.

Intellectual Property

During the third quarter of 2008, one U.S. patent was issued. At the end of the third quarter of 2008, we had been issued over 190 patents including 28 U.S. and nine 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.

Financial Impact

We estimated at the beginning of 2008 that our average monthly cash usage would be approximately $1,660,000 for 2008. Our cash usage for the nine month period ending September 30, 2008 was $12,463,995 from operating activities which includes our intellectual property expenditures which is lower than our expected monthly average. Our net loss for the nine month period ending September 30, 2008 was $12,789,735.

Cash Resources

We exited the third quarter of 2008 with cash resources totaling $12,680,162 (see *Liquidity and Capital Resources*).

EXPECTED REOLYSIN® DEVELOPMENT FOR THE REMAINDER OF 2008

We plan to continue to enroll patients in our clinical trials throughout 2008. We expect to complete enrollment in a number of our 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 and choose a pivotal trial path.

We expect to produce REOLYSIN® for our clinical trial program throughout 2008. We believe we will complete our 100-litre scale up activities and will continue our examination of a lyophilization (freeze drying) process for REOLYSIN®.

We now expect, based on our expected activity for the remainder of 2008 that our average monthly cash usage will range between $1,400,000 to $1,500,000 per month (see *Liquidity and Capital Resources*).

RECENT DEVELOPMENTS

Clinical Trial Results

U.K. Phase I/II Combination REOLYSIN® and Paclitaxel/Carboplatin Clinical Trial

On October 23, 2008 we announced that an abstract entitled Phase I Trial of Oncolytic Reovirus (REOLYSIN®) in Combination with Carboplatin/Paclitaxel in Patients with Advanced Solid Cancers would be available in the November/December issue of the Journal of Immunotherapy, the official journal of the International Society for Biological Therapy of Cancer (iSBTc). The principal investigator for the trial is Dr. Kevin Harrington of The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust. The abstract covers results of the trial (REO 011) up to July 2008. On November 1, 2008, a poster presentation was presented that included current results of the trial at the iSBTc annual meeting. The meeting was held in San Diego, California from October 31-November 2, 2008.

The results of the fourteen patients treated to date are as follows:

Primary Tumour	REOLYSIN Dose $TCID_{50}$	Cycles	Best Response
Phase I patients			
Melanoma	$3x10^9$	2	PD
Squamous cell carcinoma (SCC) head & neck	$3x10^9$	8	Clinical CR, SD per CT scan
Peritoneal	$3x10^9$	3	PD
Melanoma (eye)	$1x10^{10}$	2	PD
Head & neck	$1x10^{10}$	8	PR
Nasopharynx	$1x10^{10}$	8	PR
Endometrial	$3x10^{10}$	8	SD
SCC nasopharynx	$3x10^{10}$	1	PD
Head & neck (laryngeal carcinoma)	$3x10^{10}$	2	SD
Phase II patients			
Nasopharynx	$3x10^{10}$	8*	SD
Nasopharynx with liver mets	$3x10^{10}$	7*	PR
SCC nasolabial fold	$3x10^{10}$	5*	SD
SCC nasopharynx	$3x10^{10}$	4*	PR
SCC nasopharynx	$3x10^{10}$	2*	Too early to evaluate

* still on study CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease

U.K. Phase I/II Combination REOLYSIN® and Docetaxel Clinical Trial

On October 23, 2008 we announced that an abstract entitled A Phase I Study to Evaluate Systemic Wild-Type Reovirus (REOLYSIN®) in Combination with Docetaxel in Patients with Advanced Malignancies would be available in the November/December issue of the Journal of Immunotherapy, the official journal of the International Society for Biological Therapy of Cancer (iSBTc). The principal investigator for the trial is Professor Hardev Pandha of the Royal Surrey County Hospital, U.K.

On November 1, 2008, a poster presentation was presented by Prof. Pandha that included current results of this trial, at the iSBTc annual meeting. The results of the fourteen patients treated to date are as follows:

Primary Tumour	REOLYSIN Dose $TCID_{50}$	Cycles	Best Response
Breast	$1x10^{10}$	8	PR CR in liver
Gastric	$3x10^{10}$	8*	PR 32% reduction in lymph nodes
Mesothelioma	$1x10^{10}$	6	Minor response 23% reduction in lymph nodes
Prostate	$3x10^9$	6	SD on scans 30% reduction in PSA
Squamous Cell Carcinoma Head and Neck	$3x10^9$	3	Minor response 26% reduction in

			lymph node
Unknown	$3x10^9$	6	SD
Pancreas	$3x10^{10}$	6*	SD
Prostate	$3x10^{10}$	5*	SD
Prostate	$3x10^{10}$	5	SD
Melanoma	$1x10^{10}$	4	SD
Pancreas	$3x10^{10}$	2	SD, but progressed clinically

* patients still on study CR=complete response, PR=partial response, SD=stable disease

The researchers concluded that REOLYSIN® can be safely combined with docetaxel, that there was objective radiological evidence of anticancer activity and that Phase II studies with this combination are justified. Any significant toxicities observed were consistent with those expected with docetaxel alone.

Phase II/III Program

On November 4, 2008 we announced that we will be pursuing a Phase II/III, randomized trial using the combination of REOLYSIN® with paclitaxel and carboplatin in patients with head and neck cancers.

Pre-Clinical and Collaborative Programs

On October 23, 2008 we announced that Dr. Shizuko Sei of SAIC-Frederick, Inc., delivered a poster presentation entitled In Vivo Efficacy and Replication Dynamics of Intravenously Administered Oncolytic Reovirus in Nude Mice Bearing Human Melanoma Xenografts at the 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics. SAIC-Frederick is the prime contractor to the National Cancer Institute at Frederick (NCI-F) in the United States. The conference is being held in Geneva, Switzerland, from October 21-24, 2008.

Mice bearing human melanoma tumours each received a single injection of reovirus at various dose levels, administered intravenously. Dose-dependent tumor growth delay was observed in the treated animals, with the effect most pronounced for the first seven days. Reovirus was demonstrated to be in all biopsied tumors and the level consistently increased from day 2 through day 7 in all dose groups.

The investigators concluded that a single IV administration of reovirus led to substantial tumor growth delay in melanoma-bearing nude mice, and the extent of acute phase reovirus replication in tumor tissues appeared to predict the subsequent tumor response. This proof-of-principle study demonstrates that systemically administered reovirus can reach and replicate in distant tumor tissues, resulting in virus-induced oncolysis.

On October 22, 2008, we announced that a poster presentation authored by Prof. Hardev Pandha of The Royal Surrey Hospital, U.K., entitled Synergistic Anti-Tumour Activity of Oncolytic Reovirus and Cisplatin in a B16.F10 Mouse Melanoma Model was presented at the 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics.

In the study, the researchers examined the in vitro and in vivo oncolytic activity of reovirus in combination with cisplatin against a mouse melanoma cell line. The researchers demonstrated that the combined therapy results in significantly increased cell death in vitro compared to either agent alone. In the mouse model, combined therapy suppressed tumour growth and significantly prolonged median survival time. The researchers concluded that the addition of chemotherapeutic agents can significantly enhance the anti-tumour efficacy of reovirus therapy and justify formal clinical evaluation.

On November 1, 2008, Prof. Pandha made a poster presentation on November 1, 2008 at the iSBTc meeting entitled Synergistic Anti-Tumour Activity of Oncolytic Reovirus and Docetaxel in a PC-3 Prostate Cancer Mouse Model. This preclinical research, which demonstrated that combining reovirus and docetaxel treatment resulted in markedly reduced tumour growth compared to single agent treatments, provided support for the ongoing U.K. clinical trial examining the combination of REOLYSIN® and docetaxel in patients with advanced cancers. An abstract covering these preclinical results will also be available in the November/December issue of the Journal of Immunotherapy.

Manufacturing Program

On October 8, 2008 we announced that we had successfully completed initial scale up of our manufacturing process for REOLYSIN® to commercial scale. The scale up of primary production and downstream processing development was undertaken by the National Research Council Biotechnology Research Institute (NRC-BRI) located in Montreal, Canada.

INITIAL ADOPTION OF NEW ACCOUNTING STANDARD

On April 1, 2008, we early adopted the new Canadian Institute of Chartered Accountants (the CICA) Handbook Section 3064 *Goodwill and Intangible Assets*. Pursuant to the transitional provisions set out in Section 3064, we retroactively adopted this standard with restatement.

The adoption of Section 3064 impacted the treatment of our patent costs. Prior to Section 3064, we accounted for our patent costs as an intangible asset under CICA Handbook Section 3450 *Research and Development Costs*. Section 3450 allowed us to capitalize our third party legal costs associated with our patent portfolio as a limited-life intangible asset which was then amortized over the estimated useful life of the patents. Section 3064 does not permit the capitalization of these third party legal costs. Consequently, the third party legal costs previously capitalized as intellectual property are required to be expensed and any previously recorded related amortization charges are to be reversed. The intellectual property costs which remain capitalized and subject to amortization relate to the initial acquisition of our business by SYNSORB Biotech Inc.

In order for us to capitalize our intellectual property expenditures we would be required to demonstrate all of the following:

1. The technical feasibility of completing the intangible asset so that it will be available for use or sale.

2. Our intention to complete the intangible asset and use or sell it.

3. Our ability to use or sell the intangible asset.

4. How the intangible asset will generate probable future economic benefits. Among other things, we are able to demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset.

5. The availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.

6. Our ability to measure reliably the expenditure attributable to the intangible asset during its development.

Therefore, all of our future intellectual property expenditures will be expensed as incurred until we meet all of the capitalization criteria set out above. We plan to regularly monitor our research and development activity in conjunction with these six criteria to ensure we record our intellectual property expenditures in line with Section 3064.

The impact of the early adoption of Section 3064 on our previously reported consolidated balance sheets prior to adoption on April 1, 2008 is as follows:

Consolidated Balance Sheet	**March 31, 2008** $	**December 31, 2007** $	**December 31, 2006**
Intellectual Property			
Intellectual property, previously reported	5,006,297	5,026,540	5,079,805
Adjustment, adoption of Section 3064	(4,554,422)	(4,484,290)	(4,176,055)
Intellectual property, restated	451,875	542,250	903,750
Deficit			
Deficit, previously reported	(83,846,498)	(80,522,257)	(65,030,066)

Adjustment, adoption of Section 3064	(4,554,422)	(4,484,290)	(4,176,055)
Deficit, restated	(88,400,920)	(85,006,547)	(69,206,121)

The impact of the early adoption of Section 3064 on our previously reported consolidated statements of loss, comprehensive loss and cash flows prior to the adoption on April 1, 2008 is as follows:

Consolidated Statements of Loss and Comprehensive Loss	Three Month Period Ending March 31, 2008 $	Year Ended December 31, 2007 $	Year Ended December 31, 2006 $	Cumulative from inception on April 2, 1998 to December 31, 2007 $
Net loss and comprehensive loss, previously reported	3,324,241	15,642,191	14,297,524	80,522,257
Adjustment, adoption of Section 3064	70,132	308,235	330,767	4,484,290
Net loss and comprehensive loss, restated	3,394,373	15,950,426	14,628,291	85,006,547
Basic and diluted loss per share, previously reported	(0.08)	(0.39)	(0.39)	
Basic and diluted loss per share, restated	(0.08)	(0.39)	(0.40)	

Consolidated Statements of Cash Flows	Three Month Period Ending March 31, 2008 $	Year Ended December 31, 2007 $	Year Ended December 31, 2006 $	Cumulative from inception on April 2, 1998 to December 31, 2007 $
Operating activities, previously reported	(2,991,234)	(13,569,594)	(12,155,372)	(66,551,036)
Adjustment, adoption of Section 3064	(257,304)	(852,498)	(842,610)	(6,365,180)
Operating activities, restated	(3,248,538)	(14,422,092)	(12,997,982)	(72,916,216)
Investing activities, previously reported	3,602,844	4,678,785	11,894,126	(22,987,619)
Adjustment, adoption of Section 3064	257,304	852,498	842,610	6,365,180
Investing activities, restated	3,860,148	5,531,283	12,736,736	(16,622,439)

THIRD QUARTER RESULTS OF OPERATIONS

(for the three months ended September 30, 2008 and 2007)

Net loss for the three month period ending September 30, 2008 was $4,140,832 compared to $3,786,456 for the three month period ending September 30, 2007.

Research and Development Expenses (R&D)

	2008 **$**	**2007** **$** ***[Restated]***
Manufacturing and related process development expenses	**632,594**	879,937
Clinical trial expenses	**1,475,915**	1,278,175
Pre-clinical trial and research collaboration expenses	**218,929**	293,785
Intellectual property(1)	**265,700**	243,696
Other R&D expenses	**617,156**	438,747
Research and development expenses	**3,210,294**	3,134,340

Note: 1) Upon adoption of CICA Handbook Section 3064, intellectual property expenditures are now recorded as an expense for the period.

For the third quarter of 2008, R&D increased to $3,210,294 compared to $3,134,340 for the third quarter of 2007. The increase in R&D was due to the following:

Manufacturing & Related Process Development (M&P)

	2008 **$**	**2007** **$** ***[Restated]***
Product manufacturing expenses	**632,594**	610,842
Process development expenses		269,095
Manufacturing and related process development expenses	**632,594**	879,937

During the third quarter of 2008, our M&P expenses decreased to $632,594 compared to $879,937 for the third quarter of 2007. In the third quarter of 2008 we completed the 40-litre production run that had commenced at the end of the second quarter of 2008. In the third quarter of 2007, we were in the process of filling, testing, and packaging the REOLYSIN® that was produced earlier in the year.

Our process development activity in the third quarter of 2008 focused on planning the studies required to obtain a commercial scale manufacturing process that can be used during our pivotal trial program. These studies will include 100-litre scale up and technology transfer activities along with validation, stability and lyophilization studies. In the third quarter of 2007, we focused on increasing the scale of our production runs from batch sizes of 20 litres to 40 and then 100 litres.

Clinical Trial Program

	2008 **$**	**2007** **$** ***[Restated]***
Clinical trial expenses	**1,475,915**	1,278,175

During the third quarter of 2008, our clinical trial expenses increased to $1,475,915 compared to $1,278,175 for the third quarter of 2007. In the third quarter of 2008, we incurred patient enrollment and treatment costs in our nine

enrolling clinical trials compared to only seven actively enrolling clinical trials in the third quarter of 2007. As well, the patients enrolled in our Phase II clinical trials and those enrolled at the top dose of the dose escalation component of our Phase I trials received more re-treatments in the third quarter of 2008 compared to the third quarter of 2007.

Pre-Clinical Trial Expenses and Research Collaborations

	2008 **$**	**2007** **$** ***[Restated]***
Research collaboration expenses	**218,929**	293,785
Pre-clinical trial expenses		
Pre-clinical trial expenses and research collaborations	**218,929**	293,785

During the third quarter of 2008, our research collaboration expenses were $218,929 compared to $293,785 for the third quarter of 2007. Our research collaboration activity continues to focus on the interaction of the immune system and the reovirus and the use of the reovirus as a co-therapy with existing chemotherapeutics and radiation. In the third quarter of 2008, we continued to review our collaborations, only renewing certain contracts. In the third quarter of 2007, we incurred costs associated with a number of previously contracted collaborations.

Intellectual Property Expenditures

	2008	**2007**