

ONCOLYTICS BIOTECH INC

Form 6-K

June 05, 2006

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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 June 2006

Commission File Number 000-31062

**Oncolytics Biotech Inc.**

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*(Translation of registrant's name into English)*

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

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*(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

Form 40-F

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):

**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):

**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

No

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

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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: June 5, 2006

By: /s/ Doug Ball

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Doug Ball  
Chief Financial Officer

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**FOR IMMEDIATE RELEASE**

**Oncolytics Biotech Inc. s Research Collaborators Present  
Positive REOLYSIN® Clinical Trial Data at ASCO Conference**

**CALGARY, AB, June 5, 2006** - Oncolytics Biotech Inc. ( Oncolytics ) (TSX:ONC, NASDAQ:ONCY) today announced that two of its research collaborators presented positive interim and final results of two Phase I clinical trials at poster sessions at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 4, 2006 in Atlanta, Georgia. The data cover interim results of Oncolytics Phase I systemic administration trial being conducted in the U.K. and final results of Oncolytics Phase I recurrent malignant glioma trial conducted in Canada.

The results of these trials and previously completed and reported trials are consistent in showing that REOLYSIN® is well tolerated and can demonstrate activity in tumours when delivered locally or systemically to patients with a wide variety of advanced cancers, said Dr. Brad Thompson, President and CEO of Oncolytics.

Interim results of the Company s UK Phase I systemic administration clinical trial investigating the use of REOLYSIN® to treat patients with advanced cancers indicated that REOLYSIN® can be delivered systemically to various tumour types and cause virus-mediated tumour responses. A total of 30 patients have been treated to date in the escalating frequency and dosage portion of the trial to a maximum daily dose of  $1 \times 10^{11}$  TCID<sub>50</sub>. To date these 30 patients have received 65 courses of therapy, for a total of 284 daily treatments. Patients have been entered into the study at the following dose levels (all TCID<sub>50</sub>):  $1 \times 10^8$  for 1 day,  $1 \times 10^8$  for 3 days,  $1 \times 10^8$ ,  $3 \times 10^8$ ,  $1 \times 10^9$ ,  $3 \times 10^9$ ,  $1 \times 10^{10}$  and  $3 \times 10^{10}$  for five days, and  $1 \times 10^{11}$  for three days. A maximum tolerated dose (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 have generally been mild (grade 1 or 2) and have included chills, fever, headache, cough, runny nose, sore throat and fatigue. Transient grade 3 toxicities include 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 cohorts whose patients have completed treatment (seven), anti-tumour activity was noted in patients with colorectal, prostate, pancreatic, bladder, and NSCL cancer. 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 at six months) and had CEA tumour marker reduction of 27% and 60% respectively. One patient with metastatic prostate cancer had stable disease at 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 at four months and had a minor tumour response in a metastatic lesion in a lymph node (reduction from 2.5 to 1.9 cm). A patient with pancreatic cancer and a patient with NSCL cancer had stable disease at four months.

The primary objective of the Company s UK Phase I trial is to determine the MTD, dose limiting toxicity (DLT), and safety profile of REOLYSIN® when administered systemically to patients. A secondary objective is to examine any evidence of anti-tumour activity. Eligible patients include 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.

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In a second poster presentation, final results of a Canadian Phase I trial for recurrent malignant glioma indicated that intratumoural administration of REOLYSIN<sup>®</sup> was well tolerated by the patients and a maximum tolerated dose was not reached. A total of 12 patients were treated with a single, intratumoural injection of REOLYSIN<sup>®</sup> at dosages of 1x10<sup>7</sup>, 1x10<sup>8</sup>, and 1x10<sup>9</sup> TCID<sub>50</sub> in a delivery volume of 0.9 ml.

Toxicities possibly related to the REOLYSIN<sup>®</sup> treatment in this trial were generally mild (grade 1 and 2) and included fever, headache and neutropenia. A transient grade 3 elevation in GGT was noted. Three patients lived longer than one year, and one of these patients is still alive approximately 45 months post-treatment.

The primary objective of the Company's Canadian Phase I trial was to determine the MTD, DLT, and safety profile of REOLYSIN<sup>®</sup> when administered intratumourally to patients. A secondary objective was to examine any evidence of anti-tumour activity. The study examined the use of a single, intratumoural injection of REOLYSIN<sup>®</sup>, delivered using imaging-guided surgery, in patients with malignant glioma that had recurred despite other treatments, including surgery and radiation therapy.

Both ASCO posters can be found on the Oncolytics website at [www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com)

**About Oncolytics Biotech Inc.**

Oncolytics is a Calgary-based biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. Oncolytics' clinical program includes a variety of Phase I and Phase I/II human trials using REOLYSIN<sup>®</sup>, its proprietary formulation of the human reovirus, alone and in combination with radiation. For further information about Oncolytics, please visit [www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com)

*This press release contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company's expectations related to the interim results of the Phase I UK Systemic Administration clinical trial investigating delivery of REOLYSIN<sup>®</sup> for advanced cancers, and the final results of the Phase I Canadian trial for recurrent malignant glioma and the Company's belief as to the potential of REOLYSIN<sup>®</sup> as a cancer therapeutic, involve known and unknown risks and uncertainties, which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN<sup>®</sup> as a cancer treatment, the success and timely completion of clinical studies and trials, actual patient tolerance, the Company's ability to successfully commercialize REOLYSIN<sup>®</sup>, uncertainties related to the research and development of pharmaceuticals and uncertainties related to the regulatory process. Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward looking statements. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements.*

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