ONCOLYTICS BIOTECH INC
Form 6-K
February 27, 2004

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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 February 2004

Commission File Number 000-31062

Oncolytics Biotech Inc.

(Translation of registrant s name into English)

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

(Address of principal executive offices)

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

Form 20-F þ Form 40-F o

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

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

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

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

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

Yes o No þ

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

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SIGNATURES

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

Oncolytics Biotech Inc.
(Registrant)

Date February 27, 2004

By: /s/ Douglas A. Ball

Douglas A. Ball
Chief Financial Officer

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210, 1167 Kensington Cr. N.W.
Calgary, Alberta
Canada T2N 1X7

FOR IMMEDIATE RELEASE

Oncolytics Biotech Receives Approval To Initiate UK Phase I Cancer Trial Investigating Systemic Delivery of REOLYSIN®

CALGARY, AB, February 27, 2004 Oncolytics Biotech Inc. (Oncolytics) (TSX:ONC, NASDAQ:ONCY) announced today that it has received a letter of approval from the UK regulatory authorities (Medicines and Healthcare products Regulatory Agency or MHRA) for its Clinical Trial Exemption (CTX) to begin a Phase I clinical trial to investigate the systemic delivery of REOLYSIN® as a treatment for patients with advanced or metastatic solid tumours. The principal investigator for the study is Dr. J. de Bono of the Royal Marsden Hospital.

This clinical trial will be the first to examine the systemic delivery of REOLYSIN®, which is expected to result in delivery of the virus throughout the body to both the primary tumour and metastatic disease sites, said Dr. Brad Thompson, President and CEO of Oncolytics. The approval of this trial is the culmination of an extensive program in the areas of manufacturing and preclinical toxicology.

This clinical trial is an open-label, dose-escalation Phase I study in which REOLYSIN® will be administered intravenously to patients diagnosed with advanced or metastatic solid tumours that are refractory to standard therapy (has not responded) or for which no curative standard therapy exists. The primary objective of the study is to determine the maximum tolerated dose (MTD), dose limiting toxicity (DLT) and safety profile of REOLYSIN®. Secondary objectives include the evaluation of viral replication, immune response to the virus and any evidence of antitumour activity. The enrolment in this study is expected to be up to forty evaluable patients and will depend upon the number of dose levels tested.

About Oncolytics Biotech Inc.

Oncolytics is a Calgary-based biotechnology company focused on the development of REOLYSIN®, its proprietary formulation of the human reovirus, as a potential cancer therapeutic. Oncolytics researchers have demonstrated that the reovirus is able to selectively kill human cancer cells *in vitro* that are derived from many types of cancer, including breast, prostate, pancreatic and brain tumours, and have also demonstrated successful cancer treatment results in a number of animal models. Phase I clinical trial results have indicated that there were no toxicology-related issues with the administration of the reovirus, and that the reovirus demonstrated activity in tumours injected with REOLYSIN®.

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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 results of the UK Phase I trial investigating systemic delivery of REOLYSIN® and the Company s belief as to the potential of REOLYSIN® 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® as a cancer treatment, the success and timely completion of clinical studies and trials, the Company s ability to successfully commercialize REOLYSIN®, uncertainties related to the research and development of pharmaceuticals, uncertainties related to the regulatory process and general changes to the economic environment. Investors should consult the Company s quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward looking statements. 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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FOR IMMEDIATE RELEASE

Oncolytics Biotech Provides Final Update on T2 Prostate Cancer Study

CALGARY, AB, February 27, 2004 Oncolytics Biotech Inc. (Oncolytics) (TSX:ONC, NASDAQ:ONCY) provided a final update today on its technical clinical study evaluating the efficacy and safety of REOLYSIN® for the treatment of T2 prostate cancer.

This clinical trial has met its histopathological objective of showing that REOLYSIN® selectively infects and kills tumour cells in humans without damaging adjacent healthy tissue, said Dr. Brad Thompson, Oncolytics President and CEO. The data generated was helpful in gaining approval to commence systemic administration studies. Our clinical program for REOLYSIN® will focus on the initiation of a systemic delivery clinical trial, our collaborative program with the US National Cancer Institute and our other local delivery studies.

Oncolytics previously reported results from an interim assessment of this clinical study (March 31, 2003). There was evidence of viral activity in five of six patients and there were no safety concerns, from either a clinical or histopathological perspective, in all six patients. The preliminary data showed clear histopathological evidence of apoptotic tumour cell death, one measure of viral activity, in four of the six patients. In a fifth patient, the PSA level dropped by 53% and the prostate gland shrank by 67% from just prior to treatment to the time of surgical removal. There was no evidence of viral activity in the sixth patient. In all six patients, there was no histopathological evidence of any viral effect on healthy prostatic tissue. Additional histopathological analysis has demonstrated immune cell infiltration (B and T cells) into virus infected tumour mass. This infiltration was not noted in adjacent normal tissue. Further histopathological analysis including microarray (a measure of gene expression) is currently being conducted. Information obtained in these studies is intended to be utilized in future systemic studies to assess optimal dosing and response.

The T2 prostate cancer trial was intended to evaluate the safety and histopathological efficacy of intra-tumoural administration of REOLYSIN® for the treatment of cancer that is restricted to the prostate gland. Patients received a single injection of REOLYSIN® and were monitored for approximately three weeks, at which time the prostate was surgically removed. The primary efficacy endpoint was the response rate as measured by pathological examination of the tumour.

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