ONCOLYTICS BIOTECH INC
Form 6-K
February 28, 2005

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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, 2005

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 o Form 40-F þ

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 28, 2005

By: /s/ Doug Ball, CFO

Doug Ball, CFO
Chief Financial Officer

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Calgary, Alberta
Canada T2N 1X7

FOR IMMEDIATE RELEASE

Oncolytics Biotech Receives FDA Clearance to Initiate Phase I/II Recurrent Malignant Gliomas Clinical Trial

CALGARY, AB, February 28, 2005 - Oncolytics Biotech Inc. (Oncolytics) (TSX:ONC, NASDAQ:ONCY) announced today that it has received clearance from the US Food and Drug Administration (FDA) to begin a Phase I/II clinical trial to investigate the use of REOLYSIN® to treat patients with recurrent malignant gliomas. The principal investigator for the trial is Dr. James Markert, Professor, Neurosurgery and Physiology, the University of Alabama at Birmingham.

Treatment of specific cancers, such as brain cancer, with local or regional administration of REOLYSIN® is part of Oncolytics clinical strategy, said Dr. Brad Thompson, President and CEO of Oncolytics. The U.S. study will complement our Canadian recurrent malignant gliomas study by employing an alternative method of product delivery to the tumour site in the brain.

This clinical trial is an open-label dose escalation Phase I/II study in which a single dose of REOLYSIN® will be administered by infusion to patients with recurrent malignant gliomas that are refractory to standard therapy. The administration involves the stereotactically-guided placement of a needle into the tumour, through which REOLYSIN® will be administered or infused into the tumour mass and surrounding tissue using a pump. The primary objective of the study is to determine the maximum tolerated dose (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 30 evaluable patients in the dose escalation phase with up to an additional 14 patients added at the maximum tolerated dose (MTD).

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 cancer cells and, *in vitro*, kill human cancer cells 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 REOLYSIN® was well tolerated 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 Canadian and US Phase 1/II trials investigating delivery of REOLYSIN® for recurrent malignant gliomas, 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.

FOR FURTHER INFORMATION PLEASE CONTACT:

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