ONCOLYTICS BIOTECH INC
Form 6-K
April 07, 2005

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 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 - _____

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, 2005

By: /s/ Brad Thompson

Brad Thompson
President & CEO

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

FOR IMMEDIATE RELEASE

Oncolytics Biotech Inc. Receives FDA Clearance to Initiate Phase I Systemic Delivery Clinical Trial

CALGARY, AB, April 7, 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 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 trial is Dr. Sanjay Goel, Assistant Professor and Attending Physician in the Department of Medical Oncology, Montefiore Medical Center and Albert Einstein College of Medicine, New York City.

This is our second clinical trial investigating the systemic administration of REOLYSIN® in patients with advanced cancers, said Dr. Brad Thompson, President and CEO of Oncolytics. Systemic administration of REOLYSIN® for the treatment of advanced or metastatic cancer, either as a monotherapy or in combination with radiation therapy or chemotherapy, addresses the largest patient population and market opportunity.

This clinical trial is an open-label, dose-escalation Phase I study in which a single dose of REOLYSIN® will be administered intravenously to patients diagnosed with selected advanced or metastatic solid tumours that are refractory (have not responded) to standard therapy 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 anti-tumour activity. The enrolment in this study is expected to be up to 36 evaluable patients and will depend in part upon the number of cohorts 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 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®.

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 US Phase I trial investigating systemic delivery of REOLYSIN®; the Company s belief as to the nature of the market opportunity that REOLYSIN® is intended to address; 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, competitive risks associated with research and development initiatives of the Company s competitors, 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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