

ONCOLYTICS BIOTECH INC

Form 6-K

February 18, 2005

**Table of Contents**

---

---

**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

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

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 - \_\_\_\_\_

---

---

---

**TABLE OF CONTENTS**

Signatures

Press Release

---

**Table of Contents**

**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 18, 2005

By: /s/ Doug Ball, CFO

\_\_\_\_\_  
Doug Ball, CFO  
Chief Financial Officer

**Table of Contents**

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

---

**FOR IMMEDIATE RELEASE**

**Oncolytics Biotech Inc. Announces Approval for U.K. Clinical Trial Investigating REOLYSIN® in Combination with Radiation Therapy**

**CALGARY, AB, February 18, 2005** Oncolytics Biotech Inc. ( Oncolytics ) (TSX:ONC, NASDAQ:ONCY) announced today that it has received a letter of approval from the U.K. regulatory authorities (Medicines and Healthcare products Regulatory Agency or MHRA) for its Clinical Trial Application (CTA) to begin a Phase I clinical trial to evaluate the feasibility, safety and anti-tumour effects of intratumoural administration of REOLYSIN® in combination with radiation in patients with advanced cancers. The Principal Investigators are Dr. Kevin Harrington of the Cancer Research U.K. Centre for Cell and Molecular Biology, The Institute of Cancer Research, London, and Dr. Alan Melcher of the Cancer Research U.K. Clinical Centre at St. James' s University Hospital in Leeds. The trial will enroll patients at the Royal Marsden and St. James' s Hospitals in the U.K.

In animal models, radiation therapy used in combination with REOLYSIN® had more effect than either agent by itself. said Dr. Brad Thompson, President and CEO of Oncolytics. This clinical trial will be the first to examine the effects of intratumoural delivery of REOLYSIN® in combination with radiation.

The trial is a Phase I open-label, dose-escalation study of REOLYSIN® combined with two different radiation dosages/schedules. The enrolment in this study is expected to be approximately thirty evaluable patients, and will depend upon the number of dose levels tested. Up to an additional fifteen patients will also be treated at the maximum tolerated dose (MTD). The primary objective of the study is to determine the MTD, dose limiting toxicity (DLT), and safety profile of REOLYSIN® when administered intratumourally to patients receiving radiation treatment. A secondary objective is to examine any evidence of anti-tumour activity. Patients who have 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 will be eligible.

**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 patient enrolment and the results of the UK Phase I trial investigating delivery of REOLYSIN® in combination with radiation 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:**

***For Canada:***

Oncolytics Biotech Inc.  
Dr. Brad Thompson  
210, 1167 Kensington Cr NW  
Calgary, Alberta T2N 1X7

Tel: 403.670.7377  
Fax: 403.283.0858  
[www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com)

***For Canada:***

The Equicom Group Inc.  
Joanna Longo  
20 Toronto Street  
Toronto, Ontario M5C 2B8

Tel: 416.815.0700 ext. 233  
Fax: 416.815.0080  
[jlongo@equicomgroup.com](mailto:jlongo@equicomgroup.com)

***For United States:***

The Investor Relations Group  
Gino De Jesus or Dian Griesel, Ph.D.  
11 Stone Street, 3rd Floor  
New York, NY 10004

Tel: 212.825.3210  
Fax: 212.825.3229  
[mail@investorrelationsgroup.com](mailto:mail@investorrelationsgroup.com)