

ONCOLYTICS BIOTECH INC

Form 6-K

December 23, 2002

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# FORM 6-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

For the month of December 23, 2002

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 ☒ [X]

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 ☒ [X]

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 December 23, 2002

By: /s/ Douglas A. Ball

\_\_\_\_\_  
Douglas A. Ball

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

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**FOR IMMEDIATE RELEASE**

**Oncolytics Biotech Announces Positive Interim Safety Results from REOLYSIN®  
Phase I Malignant Glioma Study**

**CALGARY, Alberta, December 23, 2002** Oncolytics Biotech Inc. (TSX: ONC, NASDAQ: ONCY) ( Oncolytics ) today announced positive interim safety results from the Phase I component of its clinical study examining the use of REOLYSIN® in the treatment of recurrent malignant glioma, the most aggressive form of brain cancer. The Company reported that REOLYSIN® appeared to be well tolerated when surgically delivered into the brain during the treatment of the first six patients.

Determination of the safety of REOLYSIN® is the primary purpose of the Phase I study. The study is examining the use of a single, intratumoural injection of REOLYSIN® delivered using imaging-guided surgery, in patients with malignant glioma that has recurred despite other treatments, including surgery and radiation therapy. After treatment with REOLYSIN®, the Phase I patients are monitored and evaluated for safety for a period of six months. Five of the six treated patients remain alive and on study with duration after treatment ranging between 10 and 25 weeks. One patient died of progressive disease after leaving the study, but no severe adverse effects attributable to the virus were seen in this patient.

An independent data safety monitoring board was established at the start of the trial and recently completed its first scheduled review, which included the results seen in the first six patients. The board has recommended continuing the trial. It further recommended changes be made to enhance the measurement of the safety and efficacy of REOLYSIN® in the intended patient population in future studies. The physician investigators have also made observations during the care of the six patients that may lead to protocol changes. As is standard practice, until the clinical data and proposed changes have been reviewed and approved by the regulatory agencies, no new patients are being enrolled.

We are very pleased with the interim safety data from this human study, said George M. Gill, M.D., Oncolytics Senior Vice President of Clinical and Regulatory Affairs. We have learned a great deal about the use of REOLYSIN® and, after discussing these clinical results with the regulatory agencies, our data safety monitoring board and our advisors, we plan to incorporate this experience into our current study and in the design of future trials during the continued clinical development of REOLYSIN®.

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**About Oncolytics Biotech Inc.**

Oncolytics is a Calgary-based biotechnology company focused on the development of the human reovirus (REOLYSIN®) 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 derived from many types of cancer including breast, prostate, pancreatic and brain tumours. Research has also yielded 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 injected tumours.

*This news 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 belief as to the potential of REOLYSIN® as a component of the treatment for recurrent malignant glioma and other cancers, and the Company's expectations as to the design, timing and success of its planned clinical trial programs, 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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