ONCOLYTICS BIOTECH INC
Form 6-K
September 02, 2008

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 September 2008

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 - _____

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: September 2, 2008

By: /s/ Doug Ball

Doug Ball
Chief Financial Officer

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FOR IMMEDIATE RELEASE

Oncolytics Biotech Inc. Announces U.S. Phase 2 Combination Clinical Trial for Non-Small Cell Lung Cancer Patients with K-RAS or EGFR-Activated Tumours

CALGARY, AB, September 2, 2008 - Oncolytics Biotech Inc. (Oncolytics) (TSX:ONC, NASDAQ:ONCY) announced today that following U.S. Food and Drug Administration (FDA) review, the Company is initiating a U.S. Phase 2 clinical trial using intravenous administration of REOLYSIN® in combination with paclitaxel and carboplatin in patients with non-small cell lung cancer (NSCLC) with K-RAS or EGFR-activated tumours. The Principal Investigator is Dr. Miguel Villalona-Calero, Professor Division of Hematology/Oncology and Department of Internal Medicine and Pharmacology at The Ohio State University Comprehensive Cancer Center.

In this era of personalized cancer treatment, we are quite excited about this trial, said Dr. Villalona-Calero. Although we have had for some time treatments that target EGFR, K-RAS has been an elusive target. REOLYSIN® has the potential to target K-RAS activated tumors, possibly enhancing the beneficial effects produced by chemotherapy.

This trial gives Oncolytics the opportunity to treat NSCLC patients in a first-line clinical setting, said Dr. Brad Thompson, President and CEO of Oncolytics. Assuming we achieve an acceptable response rate, the combination of REOLYSIN® with paclitaxel and carboplatin for NSCLC would be a strong candidate for registration studies.

This trial is a single arm, two-stage, open-label, Phase 2 study of REOLYSIN® given intravenously with paclitaxel and carboplatin every 3 weeks. Patients will receive four to six cycles of paclitaxel and carboplatin in conjunction with REOLYSIN®, at which time REOLYSIN® may be continued as a monotherapy. It is anticipated that up to 36 patients will be treated in this trial.

Eligible patients include those with metastatic or recurrent NSCLC with K-RAS or EGFR-activated tumours, who have not received chemotherapy treatment for their metastatic or recurrent disease. Patients must have demonstrated mutations in K-RAS or EGFR, or EGFR gene amplification in their tumours (metastatic or primary) in order to qualify for the trial.

The primary objectives of the Phase 2 trial are to determine the objective response rate of REOLYSIN® in combination with paclitaxel and carboplatin in patients with metastatic or recurrent NSCLC with K-RAS or EGFR-activated tumours, and to measure progression-free survival at 6 months. The secondary objectives are to determine the median survival and duration of progression-free survival in patients, and to evaluate the safety and tolerability of REOLYSIN® in combination with paclitaxel and carboplatin in this patient population.

REOLYSIN® preferentially replicates in cancer cells that have an activated RAS pathway. Approximately two thirds of all cancers have an activated RAS pathway, including most metastatic disease. A large number of mutations, including mutations in EGFR, Her2 or K-RAS along the RAS pathway lead to RAS pathway activation.
Recent clinical studies in NSCLC with EGFR-based therapies have shown that patients with mutations or overexpression of EGFR, which are commonly found in NSCLC, derive clinical benefit from these therapies. An agent such as REOLYSIN® that selectively replicates in cancers with an activated RAS pathway resulting from EGFR mutations or overexpression may show similar benefit. However, patients with mutant
K-RAS, or up to 20% of the more than 180,000 patients diagnosed every year in the U.S. with NSCLC, do not derive benefit from EGFR-based therapies. The introduction of screening for K-RAS mutations, and the exclusion of K-RAS mutated patients will lead to higher response rates in EGFR-mutated or overexpressed patients treated with EGFR-based therapies. This excluded patient group is therefore prescreened for RAS pathway activation resulting from mutations in K-RAS, and an agent such as REOLYSIN® may be indicated for this patient group. This study targets patients with either EGFR-activated tumours or K-RAS mutations.

Previous preclinical data indicates that reovirus tends to localize in the lungs, and we have seen clinical responses in metastatic lung lesions with REOLYSIN® as a monotherapy or in combination with paclitaxel and carboplatin, said Dr. Brad Thompson, President and CEO of Oncolytics. A significant clinical opportunity for REOLYSIN® is in the treatment of patients with metastatic cancers including NSCLC who have a mutated K-RAS gene and are unlikely to respond to treatment with EGF receptor inhibitors.

About Lung Cancer

Lung cancer is the second most common cancer in men and women and is the leading cause of cancer death. More people die of lung cancer than of colon, breast and prostate cancers combined. During 2008, there will be about 215,020 new cases of lung cancer in the U.S., of which 85% to 90% will be NSCLC. Only about 15% of people diagnosed with lung cancer are still alive after five years. There is no single, first-line therapy approved for NSCLC in the U.S., but first-line combination treatments include avastin/paclitaxel/carboplatin, vinorelbin/cisplatin, gemcitabine/cisplatin, paclitaxel/cisplatin and docetaxel/cisplatin. Other therapies approved for second and third-line treatments are used as well. For more information about lung cancer, please go to www.cancer.org.

About Oncolytics Biotech Inc.

Oncolytics is a Calgary-based biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. Oncolytics clinical program includes a variety of Phase 1/2 and Phase 2 human trials using REOLYSIN®, its proprietary formulation of the human reovirus, alone and in combination with radiation or chemotherapy. For further information about Oncolytics, please visit www.oncolyticsbiotech.com.

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 U.S. Phase 2 combination REOLYSIN® /paclitaxel and carboplatin clinical trial for patients with recurrent or metastatic NSCLC with K-RAS or EGFR-activated tumours, 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 tolerability of REOLYSIN® outside a controlled test, 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 and uncertainties related to the regulatory process. 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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