

ONCOLYTICS BIOTECH INC

Form 6-K

March 08, 2004

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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 March 2004

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 -

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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.

Date March 8, 2004

Oncolytics Biotech Inc.  
(Registrant)

By: /s/ Douglas A. Ball

Douglas A. Ball  
Chief Financial Officer

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210, 1167 Kensington Cr. N.W  
Calgary, Alberta  
Canada T2N 1X7

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**FOR IMMEDIATE RELEASE**

**Oncolytics Biotech Inc. Reports Highlights and Financial Results for 2003**

**Calgary, AB, March 8, 2004** Oncolytics Biotech Inc. (TSX:ONC, NASDAQ:ONCY) (Oncolytics or the Company) today reported its financial results for the year ended December 31, 2003.

**The Company Also Reported Selected Highlights from 2003;**

Strengthened the balance sheet by raising net proceeds of \$19.0 million;

Advanced REOLYSIN®'s development with positive interim results for the T2 prostate cancer clinical trial, and successfully completing further animal toxicology studies and a manufacturing development program;

Entered into a collaboration with the U.S. National Cancer Institute to conduct multiple clinical trials with REOLYSIN®;

Broadened the Company's intellectual property base with the issue of five U.S. patents, including patents covering modified herpes and adenoviruses targeting the Ras pathway; and

Expanded external research collaborations, including one with Dr. Ramon Alemany of the Institut Catala d'Oncologia, Barcelona, Spain, and established an internationally based Scientific Advisory Board.

During 2003, Oncolytics advanced the development of REOLYSIN® in several key areas, said Dr. Brad Thompson, President and CEO of Oncolytics Biotech Inc. We made progress in advancing and expanding our clinical trial program, broadening our intellectual property portfolio and strengthening our financial resources in anticipation of supporting multiple clinical trials including the commencement of systemic administration studies.

**YEARS ENDED DECEMBER 31, 2003 AND 2002**

**RESULTS OF OPERATIONS**

Net loss for the year ended December 31, 2003 was \$8,544,031 compared to \$6,091,486 for 2002. The increase in the Company's net loss was due to the following:

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**Table of Contents****Research and Development Expenses ( R&D )**

	<b>2003</b>	<b>2002</b>
	<b>\$</b>	<b>\$</b>
Manufacturing and process expenses	<b>1,328,480</b>	1,892,517
Clinical trial expenses	<b>130,034</b>	504,260
Pre-clinical trial expenses	<b>202,034</b>	663,012
Other R&D expenses	<b>1,405,360</b>	1,191,236
	<hr/>	<hr/>
Research and development expenses before the following	<b>3,065,908</b>	4,251,025
Stock based compensation	<b>504,185</b>	32,718
Quebec scientific research and experimental development refund	<b>(255,905)</b>	
	<hr/>	<hr/>
Research and development expenses	<b>3,314,188</b>	4,283,743
	<hr/>	<hr/>

In 2003, R&D decreased to \$3,065,908 compared to \$4,251,025 in 2002. The decline in R&D was due to the following:

***Manufacturing & Related Process Development***

In 2003, the Company shifted its focus from process development to REOLYSIN® production and securing its supply of critical raw materials. The Company wants to produce sufficient product as it moves forward with its clinical trial program and other activities. Consequently, it incurred expenses primarily associated with production runs and reduced the amount of manufacturing process work compared to 2002. Costs associated with the production of REOLYSIN® represented almost 45% of the Company's manufacturing and process expenses in 2003 compared to almost 37% in 2002.

Offsetting the decrease associated with the reduced process development work was the creation of the Company's own viral and cell banks. In prior years the Company had relied on third party suppliers to create and maintain the required viral and cell banks to make REOLYSIN®. In 2003, the Company established an independent supply of its master and working viral and cell banks to ensure that it has independent access to REOLYSIN®'s critical raw materials, particularly in light of its planned expansion into other jurisdictions. These types of expenses represent approximately 28% of the manufacturing and process expenses in 2003 and were not incurred in 2002.

***Clinical Trial Program***

Clinical trial costs decreased compared to 2002 as direct costs associated with patient enrollment in the T2 prostate and the glioma trials were reduced. The Company also incurred costs associated with its applications to commence additional studies in other jurisdictions.

If the Company's clinical trial program expands, as presently anticipated, it expects to incur additional clinical trial R&D costs in 2004. Also, in accordance with the Company's agreement with the National Cancer Institute of America (the NCI), the Company will provide REOLYSIN® to the NCI as the NCI and the Company together determine which clinical trials will be carried out.

***Pre-Clinical Trial Expenses***

Pre-clinical trial costs in 2003 declined compared to 2002 as a result of the Company moving into its clinical trial program in 2002. Pre-clinical costs relate primarily to toxicology studies and frequency of these types of studies decreases as the Company moves through the clinical trial program. However, pre-

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clinical costs are expected to continue as the Company moves into different jurisdictions and different types of clinical trials.

***New Collaborations***

Included in other R&D expenses are costs associated with research collaborations, salary and other compensation costs, and R&D related travel. The increase in other R&D costs in 2003 compared to 2002, primarily relates to research collaborations entered into in 2003. These costs represented almost 10% of other R&D expenses in 2003 compared to zero in 2002. The intent of these collaborations is to expand the Company's intellectual property related to the reovirus and other viruses as well as identify potential licensing opportunities arising from the Company's expanding technology base.

In 2004, the Company presently expects to incur additional R&D expenses associated with other collaborations that would be intended to bring value to the Company, including such objectives as expanded intellectual property or additional product candidates.

**Operating Expenses**

	<b>2003</b>	<b>2002</b>
	\$	\$
Public company related expenses	<b>971,156</b>	999,305
Office costs	<b>1,167,147</b>	743,206
Stock based compensation	<b>488,097</b>	
Other operating expenses	<b>327,440</b>	359,761
	<b>2,953,840</b>	2,102,272

In 2003, the Company's operating expenses increased to \$2,953,840 compared to \$2,102,272 in 2002. The primary reason for the increase in 2003 relates to the stock based compensation recorded in 2003 that was not recorded in 2002. As well, the Company's insurance premiums associated with directors' and officers' liability insurance and general corporate insurance increased compared to 2002. In 2003, insurance costs represented almost 40% of the Company's office costs compared to almost 20% in 2002. The Company's insurance premiums increased dramatically in 2002 when the insurance policies were renewed reflecting the increased exposure that relates to listing and trading in the U.S. Finally, the Company has increased its staff levels primarily in support of its corporate requirements including those associated with public company regulatory requirements.

In 2004, the Company expects to incur additional operating costs associated with its compliance with the Sarbanes-Oxley internal control certification and related auditors' attestation requirements in 2005 and other possible increases in insurance premiums.

***Sale of Investments***

2003	2002	2001
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	\$	\$	\$
	<u>          </u>	<u>          </u>	<u>          </u>
Loss on sale of investment in Transition Therapeutics Inc.	<b>2,156,685</b>		
Gain on partial sale of investment in BCY LifeSciences Inc.	<b>(264,453)</b>		
	<u>          </u>	<u>          </u>	<u>          </u>
Net loss from sale of investments	<b>1,892,232</b>		
	<u>          </u>	<u>          </u>	<u>          </u>

A significant component of the increase in the Company's 2003 net loss compared to 2002 was the sale of the Company's investments in 2003. The net loss from sale of investments in 2003 was \$1,892,232 with no corresponding amounts in 2002.

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### *Transition Therapeutics Inc. ( TTH )*

In June 2003, the Company sold 6,890,000 common shares of TTH for net cash proceeds of \$2,552,695. The sale of TTH provided the Company with additional operating capital to Oncolytics as it continues with its development of REOLYSIN®. As a result of the sale, an accounting loss of \$2,156,685 was recorded. The Company's cash expenses with respect to its investment in TTH were limited to acquisition legal costs of \$20,352.

### *BCY LifeSciences Inc. ( BCY )*

In the fourth quarter of 2003, the Company sold 1,496,500 common shares of BCY for net cash proceeds of \$450,151. This resulted in an accounting gain of \$264,453. The Company's cash investment was \$127,123. As at December 31, 2003, the Company owned 897,945 common shares and 694,995 common share purchase warrants of BCY. The common share purchase warrants are exercisable at \$0.27 and expire in April of 2004.

## **Commitments**

As at December 31, 2003, the Company has committed to payments totaling \$1,569,739 for activities primarily related to product manufacturing and continued toxicology and process related work. The Company anticipates that these committed payments will occur in 2004. Subsequent to 2003, the Company has entered into another research and development agreement and under this contract has committed to payments totaling \$875,000. All of these committed payments are considered to be part of the Company's normal course of business.

## **CAPITAL EXPENDITURES**

During 2003, the Company was granted five additional U.S. patents, including patents covering modified herpes and adenoviruses targeting the Ras pathway, for a total of ten issued U.S. patents and one issued European patent. The Company expended \$1,045,869 in 2003 associated with its intellectual property compared to \$860,520 in 2002.

## **FINANCING ACTIVITIES**

Throughout 2003, the Company raised net proceeds of \$19,007,827 through three private placements, one public offering, exercises of warrants and options, and the sale of all of its investment in Transition Therapeutics Inc. ( TTH ) and a majority of its investment in BCY LifeSciences Inc. ( BCY ). As a result of these financing activities, the Company closed the year with cash and cash equivalents (including short-term investments) of \$20,752,735 (2002 - \$8,319,244). The Company believes that its existing capital resources are adequate to fund its current plans into 2006.

## **THREE MONTH PERIODS ENDED DECEMBER 31, 2003 AND 2002**

## **RESULTS OF OPERATIONS**

For the three month period ended December 31, 2003, the Company's net loss increased to \$1,695,541 compared to \$1,542,184 for the three month period ended December 31, 2002. R&D expenses incurred in the fourth quarter of 2003 were similar to those incurred in 2002 except for the stock based compensation expense. In the fourth quarter of 2003, the Company recorded stock based compensation of \$296,475 compared to \$32,718 recorded in the fourth quarter of 2002.

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Operating expenses in the fourth quarter of 2003 were similar to operating expenses in the fourth quarter of 2002 except for the stock based compensation expense of \$193,889 recorded in the fourth quarter of 2003 with no corresponding amount in the fourth quarter of 2002.

The effect of the increase in stock based compensation was reduced by the gain on sale of investment in BCY of \$264,453 recorded in 2003 and a future income tax recovery of \$161,905 recorded in 2002.

## **FINANCING ACTIVITIES**

On October 14, 2003, the Company closed a public offering whereby it issued 1,200,000 units for net cash proceeds of \$5,459,399. Each unit was comprised of one common share and one half of one common share purchase warrant. Each whole warrant entitles the holder to purchase an additional common share for \$6.25 and expires on April 14, 2005. In addition, the Company issued 120,000 broker warrants with an exercise price of \$5.00 that expire on April 14, 2005.

## **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 human cancer cells *in vitro* 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 belief as to the potential of REOLYSIN® as a cancer therapeutic; the Company's expectations as to the success of its research and development programs in 2004 and beyond, the Company's planned expansion in additional jurisdictions, the value of the additional patents and intellectual property; the Company's expectations related to the applications of the patented technology; the ability of the technology to strengthen the core technology; the Company's expectations as to adequacy of its existing capital resources; the design, timing, success of planned clinical trial programs and the Company's planned expansion of such programs; and other statements related to anticipated developments in the Company's business and technologies 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.  
Doug Ball

***For Canada:***

The Equicom Group Inc.  
Joanna Longo

***For United States:***

The Investor Relations Group  
Gino De Jesus or Dian Griesel, Ph.D.

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**Table of Contents****Oncolytics Biotech Inc.****BALANCE SHEETS**

As at December 31

	<b>2003</b>	<b>2002</b>
	<b>\$</b>	<b>\$</b>
	<b>(audited)</b>	<b>(audited)</b>
	<hr/>	<hr/>
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	2,641,127	8,319,244
Short-term investments	18,111,608	
Accounts receivable	64,224	48,536
Prepaid expenses	156,837	77,158
	<hr/>	<hr/>
	<b>20,973,796</b>	8,444,938
<b>Capital assets</b>	<b>4,965,379</b>	4,516,813
<b>Investments</b>	<b>111,425</b>	5,006,503
	<hr/>	<hr/>
	<b>26,050,600</b>	17,968,254
	<hr/>	<hr/>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	884,928	1,260,239
	<hr/>	<hr/>
<b>Alberta Heritage Foundation loan</b>	<b>150,000</b>	150,000
	<hr/>	<hr/>
<b>Commitments and contingency</b>		
<b>Shareholders equity</b>		
Share capital		
Authorized: unlimited		
Issued: 27,208,262 (2002 22,145,284)	44,712,589	30,191,572
Warrants	1,598,250	114,286
Contributed surplus	3,699,425	2,702,718
Deficit	(24,994,592)	(16,450,561)
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	<b>25,015,672</b>	16,558,015
	<hr/>	<hr/>

**26,050,600**

**17,968,254**



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## Oncolytics Biotech Inc.

## STATEMENTS OF LOSS AND DEFICIT

	Twelve months ended December 31, 2003 \$ (audited)	Twelve months ended December 31, 2002 \$ (audited)	Three months ended December 31, 2003 \$ (unaudited)	Three months ended December 31, 2002 \$ (unaudited)	Cumulative from inception on April 2, 1998 to December 31, 2003 \$ (audited)
<b>Revenue</b>					
Rights revenue					310,000
Interest income	<b>313,305</b>	208,867	<b>126,697</b>	44,451	2,085,983
	<b>313,305</b>	208,867	<b>126,697</b>	44,451	2,395,983
<b>Expenses</b>					
Research and development	<b>3,314,188</b>	4,283,743	<b>1,222,378</b>	1,087,525	16,891,069
Operating	<b>2,953,840</b>	2,102,272	<b>656,670</b>	516,317	7,760,913
Amortization	<b>663,524</b>	574,237	<b>175,033</b>	155,397	1,910,090
	<b>6,931,552</b>	6,960,252	<b>2,054,081</b>	1,759,239	26,562,072
<b>Loss before the following:</b>	<b>6,618,247</b>	6,751,385	<b>1,927,384</b>	1,714,788	24,166,089
<b>Gain on sale of BCY LifeSciences Inc.</b>	<b>(264,453)</b>		<b>(264,453)</b>		(264,453)
<b>Loss on sale of Transition Therapeutics Inc.</b>	<b>2,156,685</b>				2,156,685
	<b>8,510,479</b>	6,751,385	<b>1,662,931</b>	1,714,788	26,058,321
<b>Capital tax</b>	<b>33,552</b>	(12,281)	<b>32,610</b>	(10,699)	51,271
<b>Future income tax recovery</b>		(647,618)		(161,905)	(1,115,000)
	<b>8,544,031</b>	6,091,486	<b>1,695,541</b>	1,542,184	24,994,592
<b>Deficit, beginning of period</b>	<b>16,450,561</b>	10,359,075	<b>23,299,051</b>	14,908,377	



<b>Deficit, end of period</b>	<b><u>24,994,592</u></b>	<u>16,450,561</u>	<b><u>24,994,592</u></b>	<u>16,450,561</u>	<u>24,994,592</u>
<b>Basic and diluted loss per share</b>	<b><u>(0.35)</u></b>	<u>(0.30)</u>	<b><u>(0.06)</u></b>	<u>(0.07)</u>	<u></u>

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## Oncolytics Biotech Inc.

## STATEMENTS OF CASH FLOWS

	Twelve months ended December 31, 2003 \$ (audited)	Twelve months ended December 31, 2002 \$ (audited)	Three months ended December 31, 2003 \$ (unaudited)	Three months ended December 31, 2002 \$ (unaudited)	Cumulative from inception on April 2, 1998 to December 31, 2003 \$ (audited)
<b>OPERATING ACTIVITIES</b>					
Net loss for the year	(8,544,031)	(6,091,486)	(1,695,541)	(1,542,184)	(24,994,592)
Deduct non-cash items					
Amortization	663,524	574,237	175,033	155,397	1,910,090
Non-cash compensation	996,707	32,718	490,364	32,718	1,029,425
Gain on sale of BCY LifeSciences Inc.	(264,453)		(264,453)		(264,453)
Loss on sale of Transition Therapeutics Inc.	2,156,685				2,156,685
Future income tax recovery		(647,618)		(161,905)	(1,115,000)
Net changes in non-cash working capital	(486,170)	(1,123,551)	211,660	653,176	579,200
	<u>(5,477,738)</u>	<u>(7,255,700)</u>	<u>(1,082,937)</u>	<u>(862,176)</u>	<u>(20,698,645)</u>
<b>INVESTING ACTIVITIES</b>					
Intellectual property	(1,045,869)	(860,520)	(153,337)	(317,758)	(2,664,826)
Other capital assets	(50,729)	(191,694)	(4,299)	3,411	(510,972)
Short term investments	(18,111,608)		(6,082,116)		(18,111,608)
Investment in BCY LifeSciences Inc.	450,151	(127,123)	450,151		323,028
Investment in Transition Therapeutics Inc.	2,552,695	(20,352)		(20,352)	2,532,343
	<u>(16,205,360)</u>	<u>(1,199,689)</u>	<u>(5,789,601)</u>	<u>(334,699)</u>	<u>(18,432,035)</u>
<b>FINANCING ACTIVITIES</b>					
Alberta Heritage Foundation loan					150,000
Proceeds from exercise of stock options and warrants	700,882	34,000	240,987		3,460,985
Proceeds from private placements	9,844,700	1,769,877		1,769,877	16,518,220
Proceeds from public offerings	5,459,399		5,459,399		21,642,602

	<u>16,004,981</u>	<u>1,803,877</u>	<u>5,700,386</u>	<u>1,769,877</u>	<u>41,771,807</u>
<b>Increase (decrease) in cash and cash equivalents during the year</b>	<b>(5,678,117)</b>	<b>(6,651,512)</b>	<b>(1,172,152)</b>	<b>573,002</b>	<b>2,641,127</b>
<b>Cash and cash equivalents, beginning of the year</b>	<u><b>8,319,244</b></u>	<u>14,970,756</u>	<u><b>3,813,279</b></u>	<u>7,746,242</u>	
<b>Cash and cash equivalents, end of the year</b>	<u><b>2,641,127</b></u>	<u>8,319,244</u>	<u><b>2,641,127</b></u>	<u>8,319,244</u>	<u>2,641,127</u>