ONCOLYTICS BIOTECH INC
Form 6-K
May 03, 2004

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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 May 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 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 -_____

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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: May 3, 2004

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

FOR IMMEDIATE RELEASE

Oncolytics Biotech Inc. Announces 2004 First Quarter Results

CALGARY, AB, May 3, 2004 Oncolytics Biotech Inc. (Oncolytics) (TSX:ONC, NASDAQ:ONCY) today announced its financial results for the three-month period ending March 31, 2004.

First Quarter Highlights:

Received approval to commence a Phase I systemic (intravenous) administration clinical trial at the Royal Marsden Hospital, Surrey, U.K.

Provided a final update on the T2 prostate cancer clinical trial

Strengthened the Board of Directors with the addition of Mr. Jim Dinning

Added an 11th U.S. patent covering manufacturing of REOLYSIN®

Announced a $6.73 million private placement with a European institutional investor

During the quarter, we made a number of significant advancements in the development of REOLYSIN® as a potential cancer therapeutic, said Dr. Brad Thompson, President and CEO of Oncolytics.

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion and analysis should be read in conjunction with the unaudited financial statements of Oncolytics Biotech Inc. (Oncolytics or the Company) as at and for the three months ended March 31, 2004 and 2003, and should also be read in conjunction with the audited financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) contained in Oncolytics annual report for the year ended December 31, 2003. The financial statements have been prepared in accordance with Canadian generally accepted accounting principles (GAAP).

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FORWARD-LOOKING STATEMENTS

The following discussion 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 expectation regarding the adequacy of its existing capital resources, and the Company s expectations as to the success of its research and development programs in 2004 and beyond, future financial position, business strategy and plans for future operations, and statements that are not historical facts, 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 competition, changes in technology, 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. Forward looking statements are based on assumptions, projections, estimates and expectations of management at the time such forward looking statements are made, and such assumptions, projections, estimates and/or expectations could change or prove to be incorrect or inaccurate. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements.

OVERVIEW

Oncolytics Biotech Inc. is a Development Stage Company

Since its inception in April of 1998, Oncolytics Biotech Inc. (the Company) has been a development stage company and has focused its research and development efforts on the development of REOLYSIN®, its potential cancer therapeutic. The Company has not been profitable since its inception and expects to continue to incur substantial losses from its research and development. The Company does not expect to generate significant revenues until, if and when, its cancer product becomes commercially viable.

General Risk Factors

Prospects for biotechnology companies in the research and development stage should generally be regarded as speculative. It is not possible to predict, based upon studies in animals, or early studies in humans, whether a new therapeutic will ultimately prove to be safe and effective in humans, or whether necessary and sufficient data can be developed through the clinical trial process to support a successful product application and approval.

If a product is approved for sale, product manufacturing at a commercial scale and significant sales to end users at a commercially reasonable price may not be successful. There can be no assurance that the Company will generate adequate funds to continue development, or will ever achieve significant revenues or profitable operations. Many factors (e.g. competition, patent protection, appropriate regulatory approvals) can influence the revenue and product profitability potential.

In developing a product for approval, the Company will rely upon its employees, contractors, consultants and collaborators and other third party relationships, including the ability to obtain appropriate product liability insurance. There can be no assurance that these reliances and relationships will continue as required.

In addition to developmental and operational considerations, market prices for securities of biotechnology companies generally are volatile, and may or may not move in a manner consistent with the progress being made by the Company.

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Highlights

During the first quarter of 2004, the Company s net loss was $2,676,236 compared to $1,114,314 for the first quarter of 2003. The increase in the net loss primarily reflects the increased manufacturing costs incurred by the Company in preparation for its planned clinical trial program and other supporting activities. Also, the Company took action to further diminish its economic dependence related to having only one manufacturer of REOLYSIN® by entering into a manufacturing contract with a second supplier and incurred costs in the quarter associated with the transfer of its manufacturing process to the additional supplier. In addition, the Company s clinical trial, pre-clinical trial, and research collaboration expenses increased compared to the first quarter of 2003.

Recent Developments

On April 7, 2004, the Company sold 1,077,100 units, pursuant to a private placement, at an average price of $6.25 per unit. Net cash proceeds after issue costs were approximately $6,206,875. The units are comprised of 1,077,100 common shares and 538,550 common share purchase warrants. Each whole common share purchase warrant entitles the holder to acquire one common share of the capital of the Company upon payment of $7.75 per share until October 7, 2005. In addition, the Company issued 107,710 common share purchase warrants to its adviser entitling the holder to acquire one common share of the capital of the Company upon payment of $7.00 per share until October 7, 2005. The Company will use the proceeds from this financing for general corporate purposes.

RESULTS OF OPERATIONS

Net loss for the three month period ended March 31, 2004 was $2,676,236 compared to $1,114,314 for 2003. The increase in the Company s net loss was due to the following:

Research and Development Expenses (R&D)

	2004	2003
	$	$
Manufacturing and process expenses	**1,376,430**	66,108
Clinical trial expenses	**125,645**	10,643
Pre-clinical trial and research collaboration expenses	**178,960**	57,826
Other R&D expenses	**273,362**	345,058
Research and development expenses	**1,954,397**	479,635

For the first quarter of 2004, R&D increased to $1,954,397 compared to $479,635 for the first quarter of 2003. The increase in R&D was due to the following:

Manufacturing & Related Process Development

During the first quarter of 2004, the Company continued to focus on the production of REOLYSIN® in order to supply its R&D activity. Approximately 75% of the manufacturing and process development costs incurred in the first quarter of 2004 relate to the production of REOLYSIN® compared to nil in the first quarter of 2003. The increase in production costs also relates to technology transfer and set up costs associated with the addition of a second supplier in the first quarter of 2004.

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The majority of the remaining costs incurred in the first quarter of 2004 and all of the costs incurred in the first quarter of 2003 relate to process development expenses. The increase in process development expenses is due to the continued development of the Company s viral and cell banks which did not occur in 2003.

For the remainder of 2004, the Company expects that it will continue to produce REOLYSIN® and that a majority of these costs will relate directly to manufacturing.

Clinical Trial Programs

The Company s clinical trial expenses increased to $125,645 in the first quarter of 2004 compared to $10,643 for the first quarter of 2003. The increase was primarily due to the costs incurred in obtaining the approval to commence a systemic (intravenous) delivery clinical trial in the United Kingdom and continuing enrollment in its recurrent malignant glioma brain cancer study.

Pre-Clinical Trial and Research Collaboration Expenses

During the first quarter of 2004, the Company incurred increased pre-clinical and research collaboration expense that may assist in future clinical trial applications.

Operating Expenses

	2004	2003
	$	$
Salary, insurance and other office expenses	**378,417**	215,279
Public company and other operating expenses	**322,757**	306,275
Stock based compensation	**5,426**	471
	706,600	522,025

For the first quarter of 2004, the Company s operating expenses increased to $706,600 compared to $522,025 for the first quarter of 2003. Specifically, the Company incurred additional salary and insurance costs in the first quarter of 2004 compared to the first quarter of 2003. The increase in salary costs relates to additional staff levels that occurred in the second quarter of 2003 primarily in support of its corporate requirements including those associated with public company requirements. The increase in insurance premiums relates to the increased premiums for Directors and Officers liability insurance that began in the second quarter of 2003.

Sale of Investments

	2004	2003
	$	$
Gain on sale of investment in BCY LifeSciences Inc. (BCY)	**47,648**	

In the first quarter of 2004, the Company sold 676,945 common shares of BCY for net cash proceeds of $131,650. This resulted in an accounting gain of $47,648. As at March 31, 2004, the Company owned 221,000 common shares and 694,995 common share purchase warrants of BCY. The common share purchase warrants were exercisable at $0.27 and expired out of the money on April 23, 2004.

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Commitments

As at March 31, 2004, the Company has committed to payments totaling $1,704,102 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. All of these committed payments are considered to be part of the Company s normal course of business.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity

As at March 31, 2004, the Company had cash and cash equivalents, short-term investments and working capital positions of $2,941,266, $17,356,874 and $18,493,690 respectively compared to $2,641,127, $18,111,608 and $20,088,868 as at December 31, 2003. The decrease in the first quarter of 2004 reflects the operating and investing activities of the Company offset by the cash received from the exercise of warrants and options. For the three month period ended March 31, 2004, the Company had received proceeds from the exercise of warrants and options of $944,745. Cash outflows during the first quarter of 2004 were due to research and development expenses, operational expenses, and intellectual property expenditures.

The Company desires to maintain adequate cash and short-term investment reserves to support its planned activities which include its clinical trial program, production manufacturing, and its intellectual property expansion and protection as well as administrative activities. The Company believes that its existing capital resources, including the recently closed private placement (see *Recent Developments*) are adequate to fund its current plans for research and development activities through 2006 without presuming the further exercise of outstanding warrants and options. In the event that the Company chooses to seek additional capital, the Company will look to fund additional capital requirements primarily through the issue of additional equity. The Company recognizes the challenges and uncertainty inherent in the capital markets and the potential difficulties it might face in today s environment. Market prices for securities in biotechnology companies are volatile and the ability to raise funds will be dependent on a number of factors, including the progress of R&D, availability of clinical trial information, and general market conditions.

Capital Expenditures and Commitments

During the first quarter of 2004 the Company spent $130,540 on intellectual property compared to $459,660 in the first quarter of 2003. The difference relates to variances in filing fees on existing patent applications.

Investing Activities

Under its Investment Policy, the Company is permitted to invest in short-term instruments with a rating no less than R-1 (DBRS) with terms less than two years. As at March 31, 2004, the Company invested $17,356,874 under this policy and is currently earning interest at an effective rate of 2.67%.

OTHER MD&A REQUIREMENTS

The Company has 29,010,171 common shares outstanding at April 29, 2004. If all of the Company s warrants and options were exercised the Company would have 35,090,577 common shares outstanding.

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Oncolytics Biotech Inc.

BALANCE SHEETS

As at,

	March 31, 2004	December 31, 2003
	$ (unaudited)	$ (audited)
ASSETS		
Current		
Cash and cash equivalents	**2,941,266**	2,641,127
Short-term investments	**17,356,874**	18,111,608
Accounts receivable	**62,305**	64,224
Prepaid expenses	**129,102**	156,837
	20,489,547	20,973,796
Capital assets	**4,918,494**	4,965,379
Investments ***[note 3]***	**27,423**	111,425
	25,435,464	26,050,600
LIABILITIES AND SHAREHOLDERS EQUITY		
Current		
Accounts payable and accrued liabilities	**1,995,857**	884,928
Alberta Heritage Foundation loan	**150,000**	150,000
Shareholders equity		
Share capital *[note 2]*		
Authorized: unlimited		
Issued: 27,450,389 (2003 27,208,262)	**45,765,630**	44,712,589
Warrants *[note 2]*	**1,489,954**	1,598,250
Contributed surplus	**3,704,851**	3,699,425
Deficit	**(27,670,828)**	(24,994,592)
	23,289,607	25,015,672
	25,435,464	26,050,600

See accompanying notes

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Oncolytics Biotech Inc.

STATEMENTS OF LOSS AND DEFICIT

For the three month periods ended March 31,

	2004	2003	Cumulative from inception on April 2, 19981 to March 31, 2004
	$ (unaudited)	$ (unaudited)	$ (unaudited)
Revenue			
Rights revenue			310,000
Interest income	**117,356**	43,170	2,203,339
	117,356	43,170	2,513,339
Expenses			
Research and development	**1,954,397**	479,635	18,845,466
Operating	**706,600**	522,025	8,467,513
Amortization	**179,023**	155,224	2,089,113
	2,840,020	1,156,884	29,402,092
Loss before the following:	**2,722,664**	1,113,714	26,888,753
Gain on sale of BCY LifeSciences Inc. ***[note 3]***	**(47,648)**		(312,101)
Loss on sale of Transition Therapeutics Inc.			2,156,685
Loss before taxes	**2,675,016**	1,113,714	28,733,337
Capital tax	**1,220**	600	52,491
Future income tax recovery			(1,115,000)
Net loss for the period	**2,676,236**	1,114,314	27,670,828
Deficit, beginning of period	**24,994,592**	16,450,561	
Deficit, end of period	**27,670,828**	17,564,875	27,670,828
Basic and diluted loss per share	**0.10**	0.05	
Weighted average number of shares	**27,255,740**	22,221,506	

See accompanying notes

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Oncolytics Biotech Inc.

STATEMENTS OF CASH FLOWS

For the three month periods ended March 31,

	2004	2003	Cumulative from inception on April 2, 19981 to March 31, 2004
	$ (unaudited)	$ (unaudited)	$ (unaudited)
OPERATING ACTIVITIES			
Net loss for the period	**(2,676,236)**	(1,114,314)	(27,670,828)
Deduct non-cash items			
Amortization	**179,023**	155,224	2,089,113
Non-cash compensation	**5,426**	471	1,034,851
Gain on sale of BCY LifeSciences Inc.	**(47,648)**		(312,101)
Loss on sale of Transition Therapeutics Inc.			2,156,685
Future income tax recovery			(1,115,000)
Net changes in non-cash working capital	**1,140,583**	(257,136)	1,719,783
	(1,398,852)	(1,215,755)	(22,097,497)
INVESTING ACTIVITIES			
Intellectual property	**(130,540)**	(459,660)	(2,795,366)
Other capital assets	**(1,598)**	(622)	(512,570)
Purchase of short-term investments	**(245,266)**		(18,356,874)
Redemption of short-term investments	**1,000,000**		1,000,000
Investment in BCY LifeSciences Inc.	**131,650**		454,678
Investment in Transition Therapeutics Inc.			2,532,343
	754,246	(460,282)	(17,677,789)
FINANCING ACTIVITIES			
Alberta Heritage Foundation loan			150,000
Proceeds from exercise of warrants and stock options	**944,745**		4,405,730
Proceeds from private placements		244,171	16,518,220
Proceeds from public offerings			21,642,602
	944,745	244,171	42,716,552
Increase (decrease) in cash and cash equivalents during the period	**300,139**	(1,431,866)	2,941,266
Cash and cash equivalents, beginning of the period	**2,641,127**	8,319,244	
Cash and cash equivalents, end of the period	**2,941,266**	6,887,378	2,941,266

See accompanying notes

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Oncolytics Biotech Inc.

NOTES TO FINANCIAL STATEMENTS

March 31, 2004 and 2003 *(unaudited)*

1. ACCOUNTING POLICIES

These unaudited interim financial statements do not include all of the disclosures included in the Company s annual financial statements. Accordingly, these unaudited interim financial statements should be read in conjunction with the Company s most recent annual financial statements. The information for the year ended December 31, 2003 has been derived from the Company s audited financial statements for the year then ended.

The accounting policies used in the preparation of these unaudited interim financial statements conform with those used in the Company s most recent annual financial statements.

2. SHARE CAPITAL

Authorized:

Unlimited number of common shares

Issued:

	Shares		Warrants	
	Number	Amount $	Number	Amount $
Balance, December 31, 2002	22,145,284	30,191,572	550,000	114,286
Issued for cash pursuant to February 10, 2003 private placement	140,000	265,540	77,000	16,000
Issued for cash pursuant to June 19, 2003 private placement	2,120,000	5,912,113	1,272,000	543,287
Issued for cash pursuant to August 21, 2003 private placement	1,363,900	3,801,778	813,533	349,176
Issued for cash pursuant to October 14, 2003 public offering	1,200,000	5,528,972	720,000	617,428
Exercise of options	64,700	149,615		
Exercise of warrants	174,378	593,194	(174,378)	(41,927)
Share issue costs		(1,730,195)		
Balance, December 31, 2003	27,208,262	44,712,589	3,258,155	1,598,250
Exercise of warrants	235,377	1,038,228	(235,377)	(108,296)
Exercise of options	6,750	14,813		