

ONCOLYTICS BIOTECH INC

Form 6-K

May 30, 2003

Table of Contents

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 May 2003

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.

TABLE OF CONTENTS

Signatures

First Quarter Report

Management's Discussion and Analysis

Balance Sheets

Statement of Loss and Deficit

Statement of Cash Flows

Notes to Financial Statements

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Table of Contents

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-_____

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 29, 2003

By: /s/ Douglas A. Ball

Douglas A. Ball
Chief Financial Officer

Table of Contents

First Quarter Report

For the quarter ended March 31, 2003

LETTER TO SHAREHOLDERS

In the first quarter of 2003, Oncolytics made several important advancements in its development of REOLYSIN®.

Interim results from Oncolytics T2 prostate cancer trial were presented late in the quarter. The interim results showed clear evidence of apoptotic tumour cell death, one measure of viral activity, in four of the first six patients. In a fifth patient, the PSA level dropped by 53% and the prostate gland shrank by 67% from just prior to REOLYSIN® treatment to the time of surgical removal.

The current T2 prostate trial will continue to enroll patients.

Oncolytics also announced that it had successfully completed a program for the development of a commercial process to make REOLYSIN®. A single production run using this process, for example, should supply sufficient quantities of REOLYSIN® for all of the Company's anticipated clinical studies for the next two years.

The Company also reported within the quarter that it had been granted a sixth U.S. patent covering a method of producing infectious mammalian reovirus. This patent further expands the Company's intellectual property portfolio.

An animal toxicology program examining systemic delivery of REOLYSIN® was successfully completed in the quarter. Three animal species have now received REOLYSIN® via three different routes of administration. In all nine studies, the product has been well tolerated and no product-related serious adverse events were observed.

We look forward to providing further updates and thank you for your continued support.

Brad Thompson, PhD
Chairman, President and CEO

Table of Contents

Management's Discussion and Analysis

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, 2003 and 2002, and should also be read in conjunction with the audited financial statements and Management's Discussion and Analysis (MD&A) contained in Oncolytics' annual report for the year ended December 31, 2002. The financial statements have been prepared in accordance with Canadian generally accepted accounting principles (GAAP).

FIRST QUARTER HIGHLIGHTS

Presented interim results from its T2 prostate cancer trial;

Successfully completed a program for the commercial manufacturing of REOLYSIN®;

Received sixth U.S. patent, which covers the manufacturing of reovirus;

Successfully completed an animal toxicology study examining systemic delivery of REOLYSIN®; and

Announced publication on the utilization of the reovirus for the removal of cancer cells from human blood products.

RESULTS OF OPERATIONS

The Company incurred a net loss for the first quarter of \$1,114,314 compared to a net loss of \$1,273,820 for the first quarter of 2002. Basic and diluted loss per common share decreased from \$0.07 in the first quarter of 2002 to \$0.05 for the first quarter of 2003. The reasons for the decrease are as follows:

Research and Development Expenses (R&D)

During the first quarter of 2003, the Company incurred R&D expenses of \$479,635 compared to \$871,519 in the first quarter of 2002. R&D expenses decreased in the first quarter primarily due to a reduction in the costs associated with the development of a commercial process for the manufacturing of REOLYSIN®. The Company continued to incur R&D expenses as it studied the efficacy and safety of REOLYSIN® in its clinical trial program and completed its animal toxicology study examining systemic delivery of REOLYSIN®.

Operating Expenses

During the first quarter of 2003, the Company incurred operating expenses of \$522,025 compared to \$489,478 in the first quarter of 2002. Operating expenses for the first quarter of 2003 increased due to strategic additions to Oncolytics' staff after the first quarter of 2002 and increased professional fees and filing costs associated with public company filing requirements.

Future Income Taxes

The future income tax recovery of \$161,905 recorded in the first quarter of 2002 related to reversal of the Company's future tax liability, as its future tax assets relating to non-capital losses, scientific research and development pools and other tax pools exceeded the value of the future tax liability. No similar recovery was recorded in the first quarter of 2003.

CAPITAL EXPENDITURES

The Company continues to expand and protect its intellectual property as further evidenced by the issue of its sixth U.S. patent during the first quarter of 2003. As a result, Oncolytics expended \$459,660 for professional fees associated with its patent base in the first quarter of 2003 compared to \$149,130 in the first quarter of 2002.

INVESTMENTS

The Company continues to hold its investment of 6,890,000 common shares in Transition Therapeutics Inc. (TTH). The current market value based on quoted market prices at March 31, 2003 was \$2,204,800 compared to a carrying value of \$4,709,380. The Company has assessed this decline in value as temporary as at March 31, 2003. However, the Company believes that should this decline in value continue without further evidence of significant progress it would anticipate treating this valuation decline as other than temporary.

Table of Contents

FINANCING ACTIVITIES

The Company issued 140,000 units on February 10, 2003 for net proceeds of \$244,171. Each unit was convertible into one common share of the Company and one half of one share purchase warrant. Each full warrant entitles the holder to purchase an additional common share for \$3 per share. There were no such financing activities in the first quarter of 2002.

LIQUIDITY AND CAPITAL RESOURCES

The Company's cash and working capital positions at the end of the first quarter of 2003 were \$6,887,378 and \$6,147,192 respectively compared to cash and working capital positions as at December 31, 2002 of \$8,319,244 and \$7,184,699 respectively. The reduction in cash for the first quarter of 2003 was primarily due to R&D, operational expenses and legal costs required to broaden the Company's patent portfolio.

Management believes that its existing capital resources are adequate to fund ongoing R&D activities in support of its current plans into early 2004. In the event that the Company chooses to alter its present plans, or seek additional capital, it 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 and availability of clinical trial information.

FUTURE OUTLOOK

The Company presently expects to continue its clinical development of REOLYSIN® during 2003, including:

Continuing and completing the Phase I component of the Phase I/II Malignant Glioma Study;

Progressing into Phase II of the Malignant Glioma Study;

Initiating a Phase I/II systemic administration study; and

Completing the T2 prostate cancer study.

FORWARD-LOOKING STATEMENTS

The MD&A 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 and the Company's expectations as to the success of its research and development programs in 2003 and beyond, 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.

Table of Contents**Balance Sheets**

	\$	UNAUDITED March 31, 2003	AUDITED DECEMBER 31, 2002
ASSETS			
Current assets:			
Cash		6,887,378	8,319,244
Accounts receivable		45,686	48,536
Prepaid expenses		77,433	77,158
		<u>7,010,497</u>	<u>8,444,938</u>
Capital assets		4,684,648	4,516,813
Investments (note 3)		5,006,503	5,006,503
		<u>16,701,648</u>	<u>17,968,254</u>
LIABILITIES			
Accounts payable and accrued liabilities		863,305	1,260,239
Alberta Heritage Foundation loan		150,000	150,000
Shareholders' equity:			
Share capital (note 2)		30,550,029	30,305,858
Contributed surplus		2,703,189	2,702,718
Deficit		(17,564,875)	(16,450,561)
		<u>15,688,343</u>	<u>16,558,015</u>
		<u>16,701,648</u>	<u>17,968,254</u>

See accompanying notes

Table of Contents

Statement of Loss and Deficit

FOR THE THREE MONTHS ENDED MARCH 31	\$	2003	2002	CUMULATIVE FROM INCEPTION ON APRIL 2, 1998
Revenue				
Rights revenue				310,000
Interest income		43,170	57,180	1,815,848
		<u>43,170</u>	<u>57,180</u>	<u>2,125,848</u>
Expenses				
Research and development		479,635	871,519	14,056,516
Operating		522,025	489,478	5,329,098
Amortization		155,224	131,612	1,401,790
		<u>1,156,884</u>	<u>1,492,609</u>	<u>20,787,404</u>
Loss before income tax		1,113,714	1,435,429	18,661,556
Capital tax		600	296	18,319
Future income tax recovery			(161,905)	(1,115,000)
		<u>1,114,314</u>	<u>1,273,820</u>	<u>17,564,875</u>
Net loss for the period		1,114,314	1,273,820	17,564,875
Deficit, beginning of the year		16,450,561	10,359,075	
		<u>17,564,875</u>	<u>11,632,895</u>	<u>17,564,875</u>
Deficit, end of period		17,564,875	11,632,895	17,564,875
Basic and diluted loss per common share		0.05	0.07	
Weighted average number of shares		22,221,506	19,191,395	

See accompanying notes

Table of Contents

Statement of Cash Flows

FOR THE THREE MONTHS ENDED MARCH 31	\$	2003	2002	CUMULATIVE FROM INCEPTION ON APRIL 2, 1998
OPERATING ACTIVITIES				
Net loss for the period		(1,114,314)	(1,273,820)	(17,654,875)
Deduct non-cash items				
Amortization		155,224	131,612	1,401,790
Future income tax recovery			(161,905)	(1,115,000)
Non-cash compensation		471		33,189
Net changes in non-cash working capital		(257,136)	(1,341,393)	808,234
		(1,215,755)	(2,645,506)	(16,436,662)
INVESTING ACTIVITIES				
Intellectual property expenditures		(459,660)	(149,130)	(2,078,617)
Purchase of capital assets		(622)	(158,325)	(460,865)
Investment in Transition Therapeutics Inc.				(20,352)
Investment in BCY LifeSciences Inc.				(127,123)
		(460,282)	(307,455)	(2,686,957)
FINANCING ACTIVITIES				
Alberta Heritage Loan				150,000
Proceeds from exercise of warrants and options				2,760,103
Proceeds from private placement		244,171		6,917,691
Proceeds from public offering				16,183,203
		244,171		26,010,997
Increase (decrease) in cash during period		(1,431,866)	(2,952,961)	6,887,378
Cash, beginning of period		8,319,244	14,970,756	
Cash, end of period		6,887,378	12,017,795	6,887,378

See accompanying notes

Table of Contents**Notes to Financial Statements**

For the three months ended March 31, 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 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

	Number of Common Shares	Amount \$
Balance, December 31, 2002	22,145,284	30,305,858
Issued for cash pursuant to February 10, 2003 private placement (net of share issue costs of \$35,829) ^(a)	140,000	244,171
Balance, March 31, 2003	22,285,284	30,550,029

- (a) Pursuant to a private placement, 140,000 common shares were issued at an issue price of \$2 per share net of issue costs of \$35,829. Each common share had an associated one-half of one common share purchase warrant for a total of 70,000 warrants. Each whole common share purchase warrant will entitle the holder to acquire one common share in the capital of the Company upon payment of \$3 per share until August 10, 2004. In addition, the Company issued 7,000 common share purchase warrants on the same terms to the brokerage firm assisting with the transaction.

Options and Warrants As at March 31, 2003, the Company has outstanding stock options of 2,653,500 with a weighted average exercise price of \$4.40. There were no options exercised, granted or surrendered during the three month period ended March 31, 2003.

As at March 31, 2003, the Company has 627,000 warrants whereby two warrants entitle the holder to purchase a common share of the Company for \$3 per share. None of the warrants were exercised during the three month period ended March 31, 2003.

Pro Forma Disclosures Pro forma compensation expense, net loss and loss per share relating to the options granted in 2002 are as follows:

	3 MONTHS ENDED MARCH 31, 2003
\$	
Reported net loss	1,114,314
Compensation expense	11,521
Pro forma net loss	1,125,835
Reported basic and basic and diluted net loss per share	0.05
Pro forma basic and diluted net loss per share	0.05

3. INVESTMENTS

The Company owns 6,890,000 common shares of Transition Therapeutics Inc. (TTH) with a cost of \$4,709,380. The value of the Company's investment in TTH on March 31, 2003 was \$2,204,800 based on quoted market prices.

Table of Contents

SHAREHOLDER INFORMATION

For annual and quarterly reports, news releases and other investor information, please contact:

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Officers

Bradley Thompson, PhD

Chairman, President and Chief Executive Officer

Doug Ball, CA

Chief Financial Officer

George M Gill, MD

Senior Vice President, Clinical and Regulatory Affairs

Matt Coffey, PhD

Vice President, Product Development

Wayne Schnarr, PhD, MBA

Vice President, Corporate Development

Directors

Bradley Thompson, PhD

Chairman, President & CEO, Oncolytics Biotech Inc.

Doug Ball, CA

CFO, Oncolytics Biotech Inc.

William A Cochrane, OC, MD

Biotech Consultant

George Masters

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Tony Noujaim, PhD

President & CEO of Virexx Research Inc.

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Chairman of Rockwater Capital Corporation.

Fred Stewart, QC

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