

ONCOLYTICS BIOTECH INC
Form 20-F
May 23, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2007

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of the event requiring this shell company report _____

Commission file number **000-31062**

ONCOLYTICS BIOTECH INC.

(Exact name of Registrant as specified in its charter)

Alberta, Canada

(Jurisdiction of incorporation or organization)

Suite 210, 1167 Kensington Crescent, N. W. Calgary, Alberta, T2N 1X7, (403) 670-7377

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each Class	Name of each exchange on which registered
Common Shares, no par value	Nasdaq, Capital Market

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None.

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

Not Applicable

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Indicate the number of outstanding shares of each of the Registrant's classes of capital of common stock as of December 31, 2007:
41,180,748 Common Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual report or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes No

ONCOLYTICS BIOTECH INC.

FORM 20-F

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this document and the documents attached as exhibits to this annual report constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks,

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uncertainties and other factors which may cause the actual results, performance or achievements of Oncolytics Biotech Inc., or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Forward-looking statements are statements that are not historical facts, and include, but are not limited to, estimates and their underlying assumptions; statements regarding plans, objectives and expectations with respect to the efficacy of our technologies; the timing and results of clinical studies related to our technologies; future operations, products and services; the impact of regulatory initiatives on our operations; the size of and opportunities related to the markets for our technologies; general industry and macroeconomic growth rates; expectations related to possible joint and/or strategic ventures and statements regarding future performance. Forward-looking statements generally, but not always, are identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “projects”, “potential”, “possible” and similar expressions, or that even conditions “will,” “may,” “could” or “should” occur.

The forward-looking statements in this annual report are subject to various risks and uncertainties, most of which are difficult to predict and generally beyond our control, including without limitation:

- uncertainty as to our ability to achieve the goals and satisfy assumptions of management;
- the uncertainties related to the outcome of clinical studies and the long process related to such studies;
- the need for regulatory approvals to market REOLYSIN® and other products;
- our need for additional financing which may not be available on acceptable terms or at all;
- uncertainty as to whether we will be able to complete any licensing, partnering or marketing arrangements for our technologies;
- uncertainty as to the market acceptance of our products and our ability to generate sufficient revenues to make our products and technologies commercially viable;
- the intense competition in the biotechnology industry and risks related to changing technology that may render our technology obsolete; and
- other factors identified under the heading “Risk Factors” in our Renewal Annual Information Form, and those that are discussed or identified in our other public filings with the SEC.

If one or more of these risks or uncertainties materializes, or if underlying assumptions prove incorrect, our actual results may vary materially from those expected, estimated or projected. Forward-looking statements in this document are not a prediction of future events or circumstances, and those future events or circumstances may not occur. Given these uncertainties, users of the information included herein, including investors and prospective investors are cautioned not to place undue reliance on such forward-looking statements. We do not assume responsibility for the accuracy and completeness of these statements.

Forward-looking statements are based on our beliefs, opinions and expectations at the time they are made, and we do not assume any obligation to update our forward-looking statements if those beliefs, opinions, or expectations, or other circumstances, should change

All references in this annual report on Form 20-F to the terms “we”, “our”, “us”, “the Company” and “Oncolytics” refer to Oncolytics Biotech Inc.

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CURRENCY AND EXCHANGE RATES

Canadian Dollars Per U.S. Dollar

The following table sets out the exchange rates for one United States dollar (“US\$”) expressed in terms of one Canadian dollar (“Cdn\$”) in effect at the end of the following periods, and the average exchange rates (based on the average of the exchange rates on the last day of each month in such periods) and the range of high and low exchange rates for such periods.

Canadian Dollars Per U.S. Dollars

	2007	2006	2005	2004	2003
Average for the period	0.9309	0.8818	0.8254	0.7682	0.7139
Low for the period	1.0120	0.9100	0.8579	0.8310	0.7738

For the Month of

	April 2008	March 2008	February 2008	January 2008	December 2007	November 2007
High for the period	1.0268	1.0275	1.0291	1.0010	1.0221	1.0908
Low for the period	1.0021	0.9847	0.9815	0.9714	0.9789	0.9993

Exchange rates are based upon the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York. The noon rate of exchange on May 22, 2008 as reported by the United States Federal Reserve Bank of New York for the conversion of United States dollars into Canadian dollars was US\$1.00 = Cdn\$0.9861. Unless otherwise indicated, in this annual report on Form 20-F, all references herein are to Canadian Dollars.

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PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable

ITEM 3. KEY INFORMATION**A. Selected Financial Data**

The following table of selected financial data of has been derived from financial statements prepared in accordance with Canadian generally accepted accounting principles ("GAAP") which have been reconciled with U.S. GAAP in accordance with Item 18 (see note 21 of the audited financial statements). The data is qualified by reference to, and should be read in conjunction with, the audited financial statements, and related notes thereto, prepared in accordance with Canadian GAAP (See Item 18, "Financial Statements"). All dollar amounts are expressed in Canadian dollars.

	2007	2006	2005	2004	2003
	\$	\$	\$	\$	\$
Revenues	—	—	—	—	313,305
Net loss, Canadian GAAP ⁽²⁾	15,642,191	14,297,524	12,781,831	12,956,119	8,544,031
Net loss, U.S. GAAP ⁽²⁾	15,280,691	13,936,024	12,420,331	12,594,619	8,182,531
Basic and diluted loss per share, Canadian GAAP ^{(2), (3)}	0.39	0.390.39	0.45	0.35	
Basic and diluted loss per share, U.S. GAAP ^{(2), (3)}	0.38	0.38	0.38	0.43	0.34
Total assets, Canadian GAAP ^{(1), (3)}	30,781,857	33,565,692	46,294,326	39,488,641	26,050,600
Total assets, U.S. GAAP ^{(1), (3)}	30,239,607	32,661,942	45,029,076	37,500,391	23,746,565
Shareholders' equity, Canadian GAAP	27,960,630	30,799,271	44,451,845	38,389,383	25,015,672
Shareholders' equity, U.S. GAAP	27,418,380	29,895,521	43,186,595	36,401,133	22,711,637
Cash dividends declared per share ⁽⁴⁾	Nil	Nil	Nil	Nil	Nil
	40,428,825	36,346,266	32,804,540	29,028,391	24,242,845

Weighted average number of common shares
outstanding
Notes:

- 1) Subsequent to the acquisition of Oncolytics Biotech Inc. by SYNSORB in April 1999, we applied push down accounting. See note 2 to the audited financial statements for 2007.
- 2) Included in net loss and net loss per share is stock based compensation expense of \$539,156 (2006 – \$403,500; 2005 – \$64,104).
- 3) We issued 4,660,000 common shares for cash proceeds of \$12,114,394 (2006 – 284,000 common shares for cash proceeds of \$241,400; 2005 – 4,321,252 common shares for cash proceeds of \$18,780,189).
- 4) We have not declared or paid any dividends since incorporation.

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B. Capitalization and Indebtedness

Not Applicable

C. Reasons for the Offer and Use of Proceeds

Not Applicable

D. Risk Factors

Investment in shares of our common stock ("Common Shares") involves a degree of risk. These risks should be carefully considered before any investment decision is made. The following are some of the key risk factors generally associated with our business. However, the risks described below are not the only ones that we face. Additional risks not currently known to us, or that we currently deem immaterial, may also impair our business operations.

All of our potential products, including REOLYSIN[®], are in the research and development stage and will require further development and testing before they can be marketed commercially.

Prospects for companies in the biotechnology industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in biotechnology companies should be regarded as speculative. We are currently in the research and development stage on one product, REOLYSIN[®], for human application, the riskiest stage for a company in the biotechnology industry. It is not possible to predict, based upon studies in animals and early stage human clinical trials, whether REOLYSIN[®] will prove to be safe and effective in humans. REOLYSIN[®] will require additional research and development, including extensive additional clinical testing, before we will be able to obtain the approvals of the relevant regulatory authorities in applicable countries to market REOLYSIN[®] commercially. There can be no assurance that the research and development programs we conducted will result in REOLYSIN[®] or any other products becoming commercially viable products, and in the event that any product or products result from the research and development program, it is unlikely they will be commercially available for a number of years.

To achieve profitable operations we, alone or with others, must successfully develop, introduce and market our products. To obtain regulatory approvals for products being developed for human use, and to achieve commercial success, human clinical trials must demonstrate that the product is safe for human use and that the product shows efficacy. Unsatisfactory results obtained from a particular study relating to a program

may cause us to abandon our commitment to that program or the product being tested. No assurances can be provided that any current or future animal or human test, if undertaken, will yield favourable results. If we are unable to establish that REOLYSIN® is a safe, effective treatment for cancer, we may be required to abandon further development of the product and develop a new business strategy.

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There are inherent risks in pharmaceutical research and development.

Pharmaceutical research and development is highly speculative and involves a high and significant degree of risk. The marketability of any product we develop will be affected by numerous factors beyond our control, including but not limited to:

- the discovery of unexpected toxicities or lack of sufficient efficacy of products which make them unattractive or unsuitable for human use;
- preliminary results as seen in animal and/or limited human testing may not be substantiated in larger, controlled clinical trials;
- manufacturing costs or other production factors may make manufacturing of products ineffective, impractical and non-competitive;
- proprietary rights of third parties or competing products or technologies may preclude commercialization;
- requisite regulatory approvals for the commercial distribution of products may not be obtained; and
- other factors may become apparent during the course of research, up-scaling or manufacturing which may result in the discontinuation of research and other critical projects.

Our products under development have never been manufactured on a commercial scale, and there can be no assurance that such products can be manufactured at a cost or in a quantity to render such products commercially viable. Production and utilization of our products may require the development of new manufacturing technologies and expertise. The impact on our business in the event that new manufacturing technologies and expertise are required to be developed is uncertain. There can be no assurance that we will successfully meet any of these technological challenges or others that may arise in the course of development.

Pharmaceutical products are subject to intense regulatory approval processes.

The regulatory process for pharmaceuticals, which includes preclinical studies and clinical trials of each compound to establish its safety and efficacy, takes many years and requires the expenditure of substantial resources. Moreover, if regulatory approval of a drug is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Further, government policy may change, and additional government regulations may be established that could prevent or delay regulatory approvals for our products. In addition, a marketed drug and its manufacturer are subject to continual review. Later discovery of previously unknown problems with the product or manufacturer may result in restrictions on such product or manufacturer, inc