

ONCOLYTICS BIOTECH INC

Form 20-F

March 24, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

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 fiscal year ended
December 31, 2015

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 event requiring this shell company report:

Commission file number: 000-31062

ONCOLYTICS BIOTECH INC.

(Exact name of Registrant as specified in its charter)

Province of Alberta, Canada

(Jurisdiction of incorporation or organization)

Suite 210, 1167 Kensington Crescent, N.W. Calgary, Alberta, T2N 1X7

(Address of principal executive offices)

Kirk Look
Suite 210, 1167 Kensington Crescent, N.W. Calgary, Alberta, T2N 1X7
Tel: (403) 670-7377
E-mail: info@oncolytics.ca

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Shares, no par value

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the Registrant's classes of capital or common stock as of the close of the period covered by the annual report: 118,151,622 common shares as at December 31, 2015

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 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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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. (Check one)

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

US GAAP	International Financial Reporting Standards as issued by the International Accounting Standards Board	Other
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

If "Other" has been checked in response to the previous question, 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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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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.

Certain statements in this annual report on Form 20-F 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, as amended. Such forward-looking statements involve known and unknown risks, 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 events or conditions “will,” “may,” “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:

- risks related to all of our products, including REOLYSIN[®], being in the research and development stage and requiring further development and testing before they can be marketed commercially;

- risks inherent in pharmaceutical research and development;

- risks related to timing and possible delays in our clinical trials;

- risks related to some of our clinical trials being conducted in, and subject to the laws of foreign countries;

- risks related to our pharmaceutical products being subject to intense regulatory approval processes in the United States and other foreign jurisdictions;

- risks related to being subject to government manufacturing and testing regulations;

- risks related to the extremely competitive biotechnology industry and our competition with larger companies with greater resources;

- risks related to our reliance on patents and proprietary rights to protect our technology;

- risks related to potential products liability claims;

- risks related to our limited manufacturing experience and reliance on third parties to commercially manufacture our products, if and when developed;

- risks related to our new products not being accepted by the medical community or consumers;

risks related to our technologies becoming obsolete;

risks related to our dependence on third party relationships for research and clinical trials;

risks related to our lack of operating revenues and history of losses;

- uncertainty regarding our ability to obtain third-party reimbursement for the costs of our product;

risks related to other third-party arrangements;

risks related to our ability to obtain additional financing to fund future research and development of our products and to meet ongoing capital requirements;

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- risks related to potential increases in the cost of director and officer liability insurance;
- risks related to our dependence on key employees and collaborators;
- risks related to Barbados law;
- risks related to the effect of changes in the law on our corporate structure;
- risks related to expenses in foreign currencies and our exposure to foreign currency exchange rate fluctuations;
- risks related to our compliance with the Sarbanes-Oxley Act of 2002, as amended;
- risks related to our status as a foreign private issuer;
- risk related to possible “passive foreign investment company” status;
- risks related to fluctuations in interest rates;
- risks related to information technology systems; and
- risks related to our common shares.

This list is not exhaustive of the factors that may affect any of the Company’s forward-looking statements. Some of the important risks and uncertainties that could affect forward-looking statements are described further under the section heading “Item 3. Key Information – D. Risk Factors” below. 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. Investors should consult our quarterly and annual filings with the Canadian and US securities commissions for additional information on risks and uncertainties relating to 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, except as required by applicable law.

CURRENCY AND EXCHANGE RATES

Canadian Dollars Per US Dollar

The following table sets out the exchange rates for United States dollars ("US\$") expressed in terms of Canadian dollars ("Cdn\$") including 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 One US Dollar					
	2015	2014	2013	2012	2011	
Average for the period	1.2787	1.1045	1.0299	0.9996	0.9893	
For the Month of						
	February 2016	January 2016	December 2015	November 2015	October 2015	September 2015
High for the period	1.3523	1.3969	1.3360	1.3095	1.2904	1.3147
Low for the period	1.4040	1.4589	1.3990	1.3360	1.3242	1.3413

Exchange rates are based on the Bank of Canada nominal noon exchange rates. The nominal noon exchange rate on March 23, 2016 as reported by the Bank of Canada for the conversion of United States dollars into Canadian dollars was US\$1.00 = Cdn\$1.3203. Unless otherwise indicated, in this annual report on Form 20-F, all references herein are to Canadian Dollars.

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 selected financial data presented below for the five years ended December 31, 2015 is presented in Canadian dollars and is derived from our consolidated financial statements in Canadian dollars and in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). The information set forth below should be read in conjunction with our consolidated financial statements (including notes thereto) included under Item 18 and "Operating and Financial Review and Prospects" included under Item 5. For exchange rate data please see the section heading "Currency and Exchange Rates" above.

	2015	2014	2013	2012	2011
	\$	\$	\$	\$	\$
Revenues	—	—	—	—	—
Net loss ^{(1), (3)}	(13,722,995)	(18,619,335)	(23,532,647)	(36,373,521)	(29,044,701)
Net comprehensive loss	(13,242,060)	(18,418,990)	(23,395,834)	(36,313,135)	(29,005,542)
Basic and diluted loss per share ⁽²⁾	(0.12)	(0.21)	(0.28)	(0.48)	(0.41)
Total assets ⁽²⁾	27,383,798	17,193,190	28,222,027	22,078,090	36,024,617
Shareholders' equity ⁽²⁾	24,674,306	13,819,193	22,213,366	14,786,780	29,520,379
Cash dividends declared per share ⁽⁴⁾	Nil	Nil	Nil	Nil	Nil
Weighted average number of common shares outstanding	112,613,845	87,869,149	83,530,981	76,102,062	70,911,526

Notes:

- 1) Included in net loss and net loss per share for the year ended December 31, 2015 is stock based compensation expense of \$429,537 (2014 - \$980,325; 2013 - \$424,384; 2012 - \$730,751; 2011 - \$1,805,503).
We issued 24,639,128 common shares for net cash proceeds of \$23,667,654 in 2015 (2014 - 8,708,676 common shares for net cash proceeds of \$9,044,492; 2013 - 8,093,533 common shares for net cash proceeds of \$30,398,036; 2012 - 5,458,950 common shares for net cash proceeds of \$20,848,785; 2011 - 3,293,033 common shares for net cash proceeds of 14,824,658).
- 2) Included in the net loss and net loss per share for the years ended December 31, 2015, 2014, 2013, and 2012 is a change in fair value of warrant liability of \$nil (2011 change in fair value of warrant liability loss of \$36,000).
- 3) We have not declared or paid any dividends since incorporation.

B. Capitalization and Indebtedness

Not Applicable

C. Reasons for the Offer and Use of Proceeds

Not Applicable

D. Risk Factors

Investment in our common shares ("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