

ONCOLYTICS BIOTECH INC  
Form 20-F  
March 23, 2012

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, 2011

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)

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

(Address of principal executive offices)

Doug Ball  
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:

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

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

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: 71,251,335 common shares as at December 31, 2011

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:

U.S. GAAP  Other

International Financial Reporting  
Standards as issued by the  
International Accounting Standards  
Board

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

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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. 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,” “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:

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

risks related to potential increases in the cost of director and officer liability insurance;

risks related to our dependence on key employees and collaborators;

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- 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 status as a foreign private issuer;
  - risks related to our compliance with the Sarbanes-Oxley Act of 2002, as amended;
- risk related to possible “passive foreign investment company” status;
- risks related to fluctuations in interest rates;
- 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 U.S. 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 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 One U.S. Dollar					
	2011	2010	2009	2008	2007	
Average for the period	0.9893	1.0299	1.1420	1.0660	1.0748	
For the Month of						
	February	January	December	November	October	September
	2012	2012	2011	2011	2011	2011
High for the period	1.0158	1.0034	0.9948	0.9945	1.0109	1.0271
Low for the period	0.9960	0.9713	0.9594	0.9504	0.9383	0.9540

Exchange rates are based on the Bank of Canada nominal noon exchange rates. The nominal noon exchange rate on March 22, 2012 as reported by the Bank of Canada for the conversion of United States dollars into Canadian dollars was US\$1.00 = Cdn\$1.00. 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

Prior to January 1, 2011, we prepared our financial statements in accordance with Canadian generally accepted accounting principles as defined in the Handbook of the Canadian Institute of Chartered Accountants (“CICA Handbook”). In 2010, the CICA Handbook was revised to incorporate International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”) and to require publicly accountable enterprises to apply these standards effective for the years beginning on or after January 1, 2011. Accordingly, the 2011 financial statements are our first annual consolidated financial statements prepared in accordance with IFRS as issued by the IASB. The term “Canadian GAAP” as used in this 20F refers to Canadian GAAP before the adoption of IFRS.



The 2011 and 2010 consolidated financial statements have been prepared in compliance with IFRS. Subject to certain transition elections and exceptions disclosed in Note 3 to our consolidated financial statements for the year ended December 31, 2011, we have also consistently applied the accounting policies used in preparation of our opening IFRS statement of financial position at January 1, 2010. Note 3 to our consolidated financial statements for the year ended December 31, 2011, discloses the impact of our transition to IFRS on our reported financial position, financial performance and cash flows, including the nature and effect of significant changes in accounting policies from those used in our consolidated financial statements for the year ended December 31, 2010 prepared under Canadian GAAP.

The selected financial data presented below for the two years ended December 31, 2011 is presented in Canadian dollars and is derived from our consolidated financial statements in Canadian dollars and in accordance with IFRS. 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.

	2011	2010
	\$	\$
Revenues	—	—
Net loss <sup>(1), (3), (4)</sup>	(29,044,701	)(24,659,061 )
Net comprehensive loss	(29,005,542	)(24,815,721 )
Basic and diluted loss per share <sup>(2)</sup>	(0.41	)(0.39 )
Total assets <sup>(2)</sup>	36,024,617	44,432,442
Shareholders' equity <sup>(2)</sup>	29,520,379	36,394,960
Cash dividends declared per share <sup>(5)</sup>	Nil	Nil
Weighted average number of common shares outstanding	70,911,526	62,475,403

Notes:

- 1) Included in net loss and net loss per share is stock based compensation expense of \$1,805,503 (2010 - \$3,251,041). We issued 3,293,033 common shares for net cash proceeds of \$14,824,658 in 2011 (2010 - 6,408,333 common shares for net cash proceeds of \$27,288,132).
- 2)
- 3) Included in net loss and net loss per share is change in fair value of warrant liability gain of \$36,000 in 2011 (2010 - change in fair value of warrant liability loss of \$4,841,949).
- 4) Included in net loss and net loss per share is a write down of asset available for sale of \$735,681 (2010 - \$nil).
- 5) 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 shares of our 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<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup> will prove to be safe and effective in humans. REOLYSIN<sup>®</sup> 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<sup>®</sup> commercially. There can be no assurance that the research and development programs we conduct will result in REOLYSIN<sup>®</sup> 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.

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.

Any failure or delay in clinical trials for our products, including REOLYSIN<sup>®</sup>, may cause us to incur additional costs or delay or prevent the commercialization of our products and could severely harm our business.

We must conduct extensive clinical trials to demonstrate the safety and efficacy of our products in humans. Clinical testing, in particular, is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process, which could delay or prevent us from receiving marketing approval or commercializing our product candidates, including the following:

- Our clinical trials may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials or we may abandon projects that we expect to be promising;
- The number of subjects required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate;
- We might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- Regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or our clinical protocols;
- Regulators may refuse to accept or consider data from clinical trials for various reasons, including noncompliance with regulatory requirements or our clinical protocols;
- The cost of our clinical trials may be greater than we anticipate; and
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The supply or quality of our products or other materials necessary to conduct our clinical trials may be insufficient or inadequate.

Additionally, subject enrollment, which is a significant factor in the timing of clinical trials, is affected by a variety of factors, including the following:

- The size and nature of the subject population;
- The proximity of subjects to clinical sites;
- The eligibility criteria for the trial;
- The design of the clinical trial;
- Competing clinical trials; and
- Clinicians' and subjects' perceptions as to the potential advantages of the medication being studied in relation to other available therapies, including any new medications that may be approved for the indications we are investigating.

Furthermore, we plan to rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have

agreements governing their committed activities, we have limited influence over their actual performance. Any delays or unanticipated problems during clinical testing, such as enrollment in our clinical trials being slower than we anticipate or participants dropping out of our clinical trials at a higher rate than we anticipate, could increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues.

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, including withdrawal of the product from the market.

The United States Food and Drug Administration (“FDA”) and similar regulatory authorities in other countries may deny approval of a new drug application if required regulatory criteria are not satisfied, or may require additional testing. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA and similar regulatory authorities in other countries may require further testing and surveillance programs to monitor the pharmaceutical product that has been commercialized. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product withdrawals, product seizures, injunction actions and criminal prosecutions.

In addition to our own pharmaceuticals, we may supply active pharmaceutical ingredients and advanced pharmaceutical intermediates for use in our customers’ drug products. The final drug products in which the pharmaceutical ingredients and advanced pharmaceutical intermediates are used, however, are subject to regulation for safety and efficacy by the FDA and possibly other regulatory authorities in other jurisdictions. Such products must be approved by such agencies before they can be commercially marketed. The process of obtaining regulatory clearance for marketing is uncertain, costly and time consuming. We cannot predict how long the necessary regulatory approvals will take or whether our customers will ever obtain such approval for their products. To the extent that our customers do not obtain the necessary regulatory approvals for marketing new products, our product sales could be adversely affected.

The FDA and other governmental regulators have increased requirements for drug purity and have increased environmental burdens upon the pharmaceutical industry. Because pharmaceutical drug manufacturing is a highly regulated industry, requiring significant documentation and validation of manufacturing processes and quality control assurance prior to approval of the facility to manufacture a specific drug, there can be considerable transition time between the initiation of a contract to manufacture a product and the actual initiation of manufacture of that product. Any lag time in the initiation of a contract to manufacture product and the actual initiation of manufacture could cause us to lose profits or incur liabilities.

The pharmaceutical regulatory regime in Europe and other countries is generally similar to that of the United States. We could face similar risks in these other jurisdictions as the risks described above.

Our operations and products may be subject to other government manufacturing and testing regulations.

Securing regulatory approval for the marketing of therapeutics by the FDA in the United States and similar regulatory agencies in other countries is a long and expensive process, which can delay or prevent product development and marketing. Approval to market products may be for limited applications or may not be received at all.

The products we anticipate manufacturing will have to comply with the FDA's current Good Manufacturing Practices ("cGMP") and other FDA and local government guidelines and regulations, including other international regulatory requirements and guidelines. Additionally, certain of our customers may require the manufacturing facilities contracted by us to adhere to additional manufacturing standards, even if not required by the FDA. Compliance with cGMP regulations requires manufacturers to expend time, money and effort in production and to maintain precise records and quality control to ensure that the product meets applicable specifications and other requirements. The FDA and other regulatory bodies periodically inspect drug-manufacturing facilities to ensure compliance with applicable cGMP requirements. If the manufacturing facilities contracted by us fail to comply with the cGMP requirements, the facilities may become subject to possible FDA or other regulatory action and manufacturing at the facility could consequently be suspended. We may not be able to contract suitable alternative or back-up manufacturing facilities on terms acceptable to us or at all.

The FDA or other regulatory agencies may also require the submission of any lot of a particular product for inspection. If the lot product fails to meet the FDA requirements, then the FDA could take any of the following actions: (i) restrict the release of the product; (ii) suspend manufacturing of the specific lot of the product; (iii) order a recall of the lot of the product; or (iv) order a seizure of the lot of the product.

We are subject to regulation by governments in many jurisdictions. If we do not comply with healthcare, drug, manufacturing and environmental regulations, among others, in such jurisdiction, our existing and future operations may be curtailed, and we could be subject to liability.

In addition to the regulatory approval process, we may be subject to regulations under local, provincial, state, federal and foreign law, including, but not limited to, requirements regarding occupational health, safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, provincial, state, federal and foreign regulations.

The biotechnology industry is extremely competitive and we must successfully compete with larger companies with substantially greater resources.

Technological competition in the pharmaceutical industry is intense and we expect competition to increase. Other companies are conducting research on therapeutics involving the Ras pathway as well as other novel treatments or therapeutics for the treatment of cancer which may compete with our product. Many of these competitors are more established, benefit from greater name recognition and have substantially greater financial, technical and marketing resources than us. In addition, many of these competitors have significantly greater experience in undertaking research, preclinical studies and human clinical trials of new pharmaceutical products, obtaining regulatory approvals and manufacturing and marketing such products. In addition, there are several other companies and products with which we may compete from time to time, and which may have significantly better and larger resources than we do. Accordingly, our competitors may succeed in manufacturing and/or commercializing products more rapidly or effectively, which could have a material adverse effect on our business, financial condition or results of operations.

We anticipate that we will face increased competition in the future as new products enter the market and advanced technologies become available. There can be no assurance that existing products or new products developed by our competitors will not be more effective, or be more effectively manufactured, marketed and sold, than any that may be developed or sold by us. Competitive products may render our products obsolete and uncompetitive prior to recovering research, development or commercialization expenses incurred with respect to any such products.

We rely on patents and proprietary rights to protect our technology.

Our success will depend, in part, on our ability to obtain patents, maintain trade secret protection and operate without infringing the rights of third parties. We have received Granted Patents in countries throughout the world, including the United States, Canada, Europe, and Japan. We file our Applications for Patent in the United States and under the PCT, allowing us to subsequently file in other jurisdictions. See “Narrative Description—Patent and Patent Application Summary”. Our success will depend, in part, on our ability to obtain, enforce and maintain patent protection for our technology in Canada, the United States and other countries. We cannot be assured that patents will issue from any pending applications or that claims now or in the future, if any, allowed under issued patents will be sufficiently broad to protect our technology. In addition, no assurance can be given that any patents issued to, or licensed by us, will not be challenged, invalidated, infringed or circumvented, or that the rights granted there under will provide continuing competitive advantages to us.



The patent positions of pharmaceutical and biotechnology firms, including us, are generally uncertain and involve complex legal and factual questions. In addition, it is not known whether any of our current research endeavours will result in the issuance of patents in Canada, the United States, or elsewhere, or if any patents already issued will provide significant proprietary protection or will be circumvented or invalidated. Since patent applications in the United States and Canada may be maintained in secrecy until at least 18 months after filing of the original priority application, and since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we or any licensor were the first to create inventions claimed by pending patent applications or that we or the licensor were the first to file patent applications for such inventions. Loss of patent protection could lead to generic competition for these products, and others in the future, which would materially and adversely affect our financial prospects for these products.

Similarly, since patent applications filed before November 29, 2000 in the United States may be maintained in secrecy until the patents issue or foreign counterparts, if any, publish, we cannot be certain that we or any licensor were the first creator of inventions covered by pending patent applications or that we or such licensor were the first to file patent applications for such inventions. There is no assurance that our patents, if issued, would be held valid or enforceable by a court or that a competitor's technology

or product would be found to infringe such patents.

Accordingly, we may not be able to obtain and enforce effective patents to protect our proprietary rights from use by competitors. If other such parties obtain patents for certain information relied on by us in conducting our business, then we may be required to stop using, or pay to use, certain intellectual property, and as such, our competitive position and profitability could suffer as a result.

In addition, we may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to us. If we do not obtain such licenses, we could encounter delays in introducing one or more of our products to the market while we attempt to design around such patents, or we could find that the development, manufacture or sale of products requiring such licenses could be foreclosed. In addition, we could incur substantial costs in defending ourselves in suits brought against us on such patents or in suits in which our attempts to enforce our own patents against other parties.

Our products may fail or cause harm, subjecting us to product liability claims.

Use of our product during current clinical trials may entail risk of product liability. We maintain clinical trial liability insurance; however, it is possible this coverage may not provide full protection against all risks. Given the scope and complexity of the clinical development process, the uncertainty of product liability litigation, and the shrinking capacity of insurance underwriters, it is not possible at this time to assess the adequacy of current clinical trial coverage, nor the ability to secure continuing coverage at the same level and at reasonable cost in the foreseeable future. While we carry, and intend to continue carrying amounts believed to be appropriate under the circumstances, it is not possible at this time to determine the adequacy of such coverage.

In addition, the sale and commercial use of our product entails risk of product liability. We currently do not carry any product liability insurance for this purpose. There can be no assurance that we will be able to obtain appropriate levels of product liability insurance prior to any sale of our pharmaceutical products. An inability to obtain insurance on economically feasible terms or to otherwise protect against potential product liability claims could inhibit or prevent the commercialization of products developed by us. The obligation to pay any product liability claim or a recall of a product could have a material adverse effect on our business, financial condition and future prospects.

We have limited manufacturing experience and intend to rely on third parties to commercially manufacture our products, if and when developed.

To date, we have relied upon a contract manufacturer to manufacture small quantities of REOLYSIN®. The manufacturer may encounter difficulties in scaling up production, including production yields, quality control and quality assurance. Only a limited number of manufacturers can supply therapeutic viruses and failure by the manufacturer to deliver the required quantities of REOLYSIN® on a timely basis at a commercially reasonable price may have a material adverse effect on us. We have completed a program for the development of a commercial process for manufacturing REOLYSIN® and have filed a number of patent applications related to the process. There can be no assurance that we will successfully obtain sufficient patent protection related to our manufacturing process.

New products may not be accepted by the medical community or consumers.

Our primary activity to date has been research and development and we have no experience in marketing or commercializing products. We will likely rely on third parties to market our products, assuming that they receive regulatory approvals. If we rely on third parties to market our products, the commercial success of such product will

be subject to a number of risks that may be outside of our control, including:

- competition in relation to alternative treatments, including efficacy advantages and cost advantages;
- perceived ease of use;
- the availability of coverage or reimbursement by third-party payors;
- uncertainties regarding marketing and distribution support;
- distribution or use restrictions imposed by regulatory authorities.

Moreover, there can be no assurance that physicians, patients or the medical community will accept our product, even if it proves to be safe and effective and is approved for marketing by Health Canada, the FDA and other regulatory authorities. A failure to successfully market our product would have a material adverse effect on our revenue.

Our technologies may become obsolete.

The pharmaceutical industry is characterized by rapidly changing markets, technology, emerging industry standards and frequent introduction of new products. The introduction of new products embodying new technologies, including new manufacturing processes and the emergence of new industry standards may render our products obsolete, less competitive or less marketable. The process of developing our products is extremely complex and requires significant continuing development efforts and third party commitments. Our failure to develop new technologies and products and the obsolescence of existing technologies could adversely affect our business.

We may be unable to anticipate changes in our potential customer requirements that could make our existing technology obsolete. Our success will depend, in part, on our ability to continue to enhance our existing technologies, develop new technology that addresses the increasing sophistication and varied needs of the market, and respond to technological advances and emerging industry standards and practices on a timely and cost-effective basis. The development of our proprietary technology entails significant technical and business risks. We may not be successful in using our new technologies or exploiting our niche markets effectively or adapting our businesses to evolving customer or medical requirements or preferences or emerging industry standards.

We are highly dependent on third-party relationships for research and clinical trials.

We rely upon third party relationships for assistance in the conduct of research efforts, pre-clinical development and clinical trials, and manufacturing. In addition, we expect to rely on third parties to seek regulatory approvals for and to market our product. Although we believe that our collaborative partners will have an economic motivation to commercialize our product included in any collaborative agreement, the amount and timing of resources diverted to these activities generally is expected to be controlled by the third party. Furthermore, if we cannot maintain these relationships, our business may suffer.

We have no operating revenues and a history of losses.

To date, we have not generated sufficient revenues to offset our research and development costs and accordingly have not generated positive cash flow or made an operating profit. As of December 31, 2011, we had an accumulated deficit of \$171.4 million and we incurred net losses of \$29.0 million and \$24.7 million, for the years ended December 31, 2011 and 2010, respectively. We anticipate that we will continue to incur significant losses during 2012 and in the foreseeable future. We do not expect to reach profitability at least until after successful and profitable commercialization of one or more of our products. Even if one or more of our products are profitably commercialized, the initial losses incurred by us may never be recovered.

We may not be able to obtain third-party reimbursement for the cost of our product.

Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Uncertainty exists regarding the reimbursement status of newly-approved pharmaceutical products and reimbursement may not be available for REOLYSIN<sup>®</sup>. Any reimbursements granted may not be maintained or limits on reimbursements available from third-party payors may reduce the demand for, or negatively affect the price of, these products. If REOLYSIN<sup>®</sup> does not qualify for reimbursement, if reimbursement levels diminish, or if reimbursement is denied, our sales and profitability would be adversely affected.

Third-Party Risk

In the normal course of our business, we have entered into contractual arrangements with third parties which subject us to the risk that such parties may default on their obligations. Oncolytics may be exposed to third party credit risk through our contractual arrangements with our current contract manufacturer, the institutions which operate our clinical trials, or our contract research organizations and other parties. In the event such entities fail to meet their contractual obligations to Oncolytics, such failures could have a material adverse effect on Oncolytics and our operations.

We may need additional financing in the future to fund the research and development of our products and to meet our ongoing capital requirements.

As of December 31, 2011, we had cash and cash equivalents (including short-term investments) of \$34.9 million and working capital of approximately \$29.1 million. We anticipate that we will need additional financing in the future to fund research and development and to meet our ongoing capital requirements. The amount of future capital requirements will depend on many factors, including continued scientific progress in our drug discovery and development programs, progress in our pre-clinical and clinical evaluation of drug candidates, time and expense associated with filing, prosecuting and enforcing our patent claims and

costs associated with obtaining regulatory approvals. In order to meet such capital requirements, we will consider contract fees, collaborative research and development arrangements, and additional public or private financings (including the incurrence of debt and the issuance of additional equity securities) to fund all or a part of particular programs as well as potential partnering or licensing opportunities.

As a result of the weakened global economic situation, Oncolytics, along with all other pharmaceutical research and development entities, may have restricted access to capital, bank debt and equity, and is likely to face increased borrowing costs. Although our business and asset base have not changed, the lending capacity of all financial institutions has diminished and risk premiums have increased. As future operations will be financed out of funds generated from financing activities, our ability to do so is dependent on, among other factors, the overall state of capital markets and investor appetite for investments in the pharmaceutical industry and our securities in particular.

Should we elect to satisfy our cash commitments through the issuance of securities, by way of either private placement or public offering or otherwise, there can be no assurance that our efforts to raise such funding will be successful, or achieved on terms favourable to us or our existing shareholders. If adequate funds are not available on terms favorable to us, we may have to reduce substantially or eliminate expenditures for research and development, testing, production and marketing of our proposed product, or obtain funds through arrangements with corporate partners that require us to relinquish rights to certain of our technologies or product. There can be no assurance that we will be able to raise additional capital if our current capital resources are exhausted.

The cost of director and officer liability insurance may increase substantially and may affect our ability to retain quality directors and officers.

We carry liability insurance on behalf of our directors and officers. Given a number of large director and officer liability insurance claims in the U.S. equity markets, director and officer liability insurance has become increasingly more expensive with increased restrictions. Consequently, there is no assurance that we will continue to be offered this insurance or be able to obtain adequate coverage. The inability to acquire the appropriate insurance coverage may limit our ability to attract and maintain directors and officers as required to conduct our business.

We are dependent on our key employees and collaborators.

Our ability to develop the product will depend, to a great extent, on our ability to attract and retain highly qualified scientific personnel and to develop and maintain relationships with leading research institutions. Competition for such personnel and relationships is intense. We are highly dependent on the principal members of our management staff as well as our advisors and collaborators, the loss of whose services might impede the achievement of development objectives. The persons working with us are affected by a number of influences outside of our control. The loss of key employees and/or key collaborators may affect the speed and success of product development.

Barbados law differs from the laws in effect in Canada and the United States and may afford less protection to holders of our securities.

Certain of our assets and intellectual property are held by our wholly-owned subsidiary, Oncolytics Barbados, which is organized under the laws of Barbados. It may not be possible to enforce court judgments obtained in Canada or the United States against Oncolytics Barbados in Barbados based on the civil liabilities provisions of applicable securities laws. In addition, there is some doubt as to whether the courts of Barbados would recognize or enforce judgments of courts in Canada or the United States obtained against us or our directors or officers based on the civil liabilities provisions of Canadian and United States securities laws or hear actions against us or those persons based on such laws.

Changes in law could adversely affect our business and corporate structure.

There can be no assurances that changes will not occur in corporate, tax, property and other laws in Canada and/or Barbados (or the interpretation thereof by regulatory or tax authorities) which may materially and adversely affect our businesses and corporate structure.

We incur some of our expenses in foreign currencies and therefore we are exposed to foreign currency exchange rate fluctuations.

We incur some of our manufacturing, clinical, collaborative and consulting expenses in foreign currencies, primarily the U.S. dollar, the Euro and the British pound (“GBP”). We are therefore exposed to foreign currency rate fluctuations. Also, as we expand to other foreign jurisdictions there may be an increase in our foreign exchange exposure.

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We earn interest income on our excess cash reserves and are exposed to changes in interest rates.

We invest our excess cash reserves in investment vehicles that provide a rate of return with little risk to principal. As interest rates change the amount of interest income we earn will be directly impacted.

The Company may fail to achieve and maintain adequate internal control over financial reporting pursuant to the requirements of the Sarbanes-Oxley Act and equivalent Canadian legislation.

The Company documented and tested during its most recent fiscal year its internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act (“SOX”) and equivalent Canadian legislation. SOX requires an annual assessment by management of the effectiveness of the Company’s internal controls over financial reporting and an attestation report by the Company’s independent auditors addressing this assessment. The Company may fail to achieve and maintain the adequacy of its internal controls over financial reporting as such standards are modified, supplemented, or amended from time to time, and the Company may not be able to ensure that it can conclude, on an ongoing basis, that it has effective internal controls over financial reporting in accordance with Section 404 of SOX. The Company’s failure to satisfy the requirements of Section 404 of SOX on an ongoing, timely basis could result in the loss of investor confidence in the reliability of its financial statements, which in turn could harm the Company’s business and negatively impact the trading price of the common shares or the market value of its other securities. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm the Company’s operating results or cause it to fail to meet its reporting obligations. Future acquisitions of companies, if any, may provide the Company with challenges in implementing the required processes, procedures and controls in its acquired operations. No evaluation can provide complete assurance that the Company’s internal controls over financial reporting will detect or uncover all failures of persons within the Company to disclose material information otherwise required to be reported. The effectiveness of the Company’s processes, procedures and controls could also be limited by simple errors or faulty judgments. In addition, if the Company expands, the challenges involved in implementing appropriate internal controls over financial reporting will increase and will require that the Company continue to improve its internal controls over financial reporting.

Because the Company is a Canadian Company and the majority of its directors and officers are resident in Canada, it may be difficult for investors in the United States to enforce civil liabilities against the Company based solely upon the federal securities laws of the United States.

The Company is a Canadian company, with its principal place of business in Canada. A majority of the Company’s directors and officers are residents of Canada and a significant portion of the Company’s assets and the assets of a majority of the Company’s directors and officers are located outside the United States. Consequently, it may be difficult for U.S. investors to effect service of process within the United States upon the Company or its directors or officers or such experts who are not residents of the United States, or to realize in the United States upon judgments of courts of the United States predicated upon civil liabilities under the U.S. Securities Act of 1933, as amended. Investors should not assume that Canadian courts (1) would enforce judgments of U.S. courts obtained in actions against the Company or such directors, officers or experts predicated upon the civil liability provisions of the U.S. federal securities laws or the securities or “blue sky” laws of any state within the United States or (2) would enforce, in original actions, liabilities against the Company or such directors, officers or experts predicated upon the U.S. federal securities laws or any such state securities or “blue sky” laws. In addition, the protections afforded by Canadian securities laws may not be available to investors in the United States.

As a foreign private issuer, our shareholders may have less complete and timely data.



The Company is a “foreign private issuer” as defined in Rule 3b-4 under the United States Securities Exchange Act of 1934, as amended (the “U.S. Exchange Act”). Equity securities of the Company are accordingly exempt from Sections 14(a), 14(b), 14(c), 14(f) and 16 of the U.S. Exchange Act pursuant to Rule 3a12-3 of the U.S. Exchange Act. Therefore, the Company is not required to file a Schedule 14A proxy statement in relation to its annual meeting of shareholders. The submission of proxy and annual meeting of shareholder information on Form 6-K may result in shareholders having less complete and timely information in connection with shareholder actions. The exemption from Section 16 rules regarding reports of beneficial ownership and purchases and sales of common shares by insiders and restrictions on insider trading in our securities may result in shareholders having less data and there being fewer restrictions on insiders’ activities in our securities.

The Company is likely a "passive foreign investment company" which will likely have adverse U.S. federal income tax consequences for U.S. shareholders

U.S. shareholders of the Common Shares should be aware that the Company believes it was classified as a passive foreign investment

company ("PFIC") during the tax year ended December 31, 2011, and based on current business plans and financial expectations, the Company anticipates that it may qualify as a PFIC for subsequent taxable years. If the Company is a PFIC for any year during a U.S. shareholder's holding period, then such U.S. shareholder generally will be required to treat any gain realized upon a disposition of Common Shares, or any so-called "excess distribution" received on its common shares, as ordinary income, and to pay an interest charge on a portion of such gain or distributions, unless the shareholder makes a timely and effective "qualified electing fund" election ("QEF Election") or a "mark-to-market" election with respect to the Common Shares. A U.S. shareholder who makes a QEF Election generally must report on a current basis its share of the Company's net capital gain and ordinary earnings for any year in which the Company is a PFIC, whether or not the Company distributes any amounts to its shareholders. For each taxable year that the Company qualifies as a PFIC, the Company will make available to each U.S. Holder that has made a QEF Election, upon written request, a "PFIC Annual Information Statement" as described in Treasury Regulation Section 1.1295-1(g) (or any successor Treasury Regulation) and use commercially reasonable efforts to provide all additional information that such U.S. Holder is required to obtain in connection with maintaining such QEF Election with regard to the Company. A U.S. shareholder who makes the mark-to-market election generally must include as ordinary income each year the excess of the fair market value of the common shares over the taxpayer's basis therein. This paragraph is qualified in its entirety by the discussion below under the heading "Certain United States Federal Income Tax Considerations." Each U.S. shareholder should consult its own tax advisor regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership, and disposition of Common Shares.

Our share price may be highly volatile.

Market prices for securities of biotechnology companies generally are volatile. This increases the risk of securities litigation. Factors such as announcements (publicly made or at scientific conferences) of technological innovations, new commercial products, patents, the development of proprietary rights, results of clinical trials, regulatory actions, publications, quarterly financial results, our financial position, public concern over the safety of biotechnology, future sales of shares by us or our current shareholders and other factors could have a significant effect on the market price and volatility of the common shares.

Potential dilution of present and prospective shareholdings.

In order to finance future operations and development efforts, the Company may raise funds through the issue of common shares or the issue of securities convertible into common shares. The Company cannot predict the size of future issues of common shares or the issue of securities convertible into common shares or the effect, if any, that future issues and sales of the Company's common shares will have on the market price of its common shares. Any transaction involving the issue of previously authorized but unissued shares, or securities convertible into shares, would result in dilution, possibly substantial, to present and prospective holders of shares.

The Company does not intend to pay cash dividends in the foreseeable future.

The Company has not declared or paid any dividends since its incorporation. The Company intends to retain earnings, if any, to finance the growth and development of its business and does not intend to pay cash dividends on the common shares in the foreseeable future. Any return on an investment in the common shares will come from the appreciation, if any, in the value of the common shares. The payment of future cash dividends, if any, will be reviewed periodically by the board of directors and will depend upon, among other things, conditions then existing including earnings, financial condition and capital requirements, restrictions in financing agreements, business opportunities and conditions and other factors.

#### ITEM 4. INFORMATION ON THE COMPANY

#### A. History and Development of the Company

Oncolytics Biotech Inc. was formed under the Business Corporations Act (Alberta) on April 2, 1998 as 779738 Alberta Ltd. On April 8, 1998, we changed our name to Oncolytics Biotech Inc.

Our principal executive office is located at 210, 1167 Kensington Cres. NW, Calgary, Alberta, Canada, T2N 1X7, telephone (403) 670-7377. Our agent for service in the U.S. is CT Corporation, 111 Eighth Avenue, 13<sup>th</sup> Floor, New York, New York 10011.

A description of our principal capital expenditures and divestitures and a description of acquisitions of material assets can be found in our MD&A and in the notes to our financial statements included elsewhere in this annual report.

#### B. Business Overview

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Since our inception in April of 1998, Oncolytics Biotech Inc. has been a development stage company and we have focused our research and development efforts on the development of REOLYSIN<sup>®</sup>, our potential cancer therapeutic. We have not been profitable since our inception and expect to continue to incur substantial losses as we continue research and development efforts. We do not expect to generate significant revenues until, if and when, our cancer product becomes commercially viable.

#### Our Business

Our potential product for human use, REOLYSIN<sup>®</sup>, is developed from the reovirus. This virus has been demonstrated to replicate specifically in tumour cells bearing an activated Ras pathway. Activating mutations of Ras occur in approximately 30% of all human tumours directly, but considering its central role in signal transduction, activation of the Ras pathway has been shown to play a role in approximately two-thirds of all tumours.

The functionality of the product is based upon the finding that tumours bearing an activated Ras pathway are deficient in their ability to activate the anti-viral response mediated by the host cellular protein, PKR. Since PKR is responsible for preventing reovirus replication, tumour cells lacking the activity of PKR are susceptible to reovirus infections. As normal cells do not possess Ras activations, these cells are able to thwart reovirus infections by the activity of PKR. In a tumour cell with an activated Ras pathway, reovirus is able to freely replicate and hence kill the host tumour cell. The result of this replication is progeny viruses that are then free to infect surrounding cancer cells. This cycle of infection, replication and cell death is believed to be repeated until there are no longer any tumour cells carrying an activated Ras pathway available.

The following schematic illustrates the molecular basis of how the reovirus kills cancer cells.

## Scientific Background

The Ras protein is a key regulator of cell growth and differentiation. It transmits signals from the cell's surface, via growth factor receptors, to downstream elements, which are in turn relayed to the nucleus. This transmission of signals from the cell surface to the cell's nucleus is collectively referred to as "signal transduction." The transmission of these signals results in cell growth, division, and in some instances cellular differentiation. In normal cells, cell growth occurs only in the presence of factors stimulating the cells to grow. Mutations in Ras itself, or any of the elements along the Ras pathway, often lead to activation of the pathway in the absence of the appropriate growth stimuli, leading to the uncontrolled growth of these cells and ultimately to the development of a cancerous state. In fact, approximately 30% of all cancers are known to be due to mutations in Ras itself. The frequency of these Ras mutations, as well as their etiology in a given tumour is, however, tissue specific. Activating mutations in Ras are found in many types of human malignancies but are highly represented in pancreatic (90%), sporadic colorectal (50%), lung carcinomas (40%), and myeloid leukemia (30%). Because Ras is a regulator of key mitogenic signals, aberrant function of upstream elements such as receptor tyrosine kinases (RTKs) can also result in Ras activation in the absence of mutations in Ras itself. Indeed, over-expression of these RTKs such as HER2/neu/ErbB2 or the epidermal growth factor receptor is common in breast cancer (25-30%), and over-expression of the platelet-derived growth factor receptor ("PDGFR") is common in glioblastomas and gliomas, all of which are tumour types in which Ras mutations are relatively rare. Although activating mutations of Ras itself are thought to occur in only about 30% of all tumours, it is expected that approximately two-thirds of all tumours have activated Ras signaling pathways as a result of mutations in genes that lie upstream of Ras. With this in mind, Ras becomes a significant therapeutic target in oncology.

All available scientific evidence developed or reviewed by us to date supports the premise that the reovirus only actively infects and replicates in cells with an activated Ras pathway. This naturally occurring virus is believed to cause only mild infections of the respiratory and gastrointestinal tract and in general, reovirus infections in humans are asymptomatic and usually sub-clinical. Research has indicated this virus replicates in, and therefore kills, only cancer cells (i.e. cancer cells with an activated Ras pathway), but does not replicate in normal cells. It has been demonstrated that reovirus replication is restricted in "normal" cells due to the activation of the double stranded RNA-activated protein kinase ("PKR"). PKR is a crucial element in protecting cells from reovirus infection and is capable of blocking viral protein translation. Activated Ras (or an activated element of the Ras pathway) prevents PKR activation, and thus allows viral replication to ensue only in this subset of cancer cells. To prove that reovirus could be used as a potential cancer therapeutic, a number of animal models were developed. Experiments using this virus to treat mouse tumours, expanded animal models as well as human brain, breast, and prostate tumours implanted in immuno-compromised mice have yielded promising results. In animals where tumour regression was noted, a single injection of reovirus is often enough to cause complete tumour regression. More importantly, it was demonstrated that this treatment is effective in causing tumour regression in immune competent animals. We believe that the nature of this virus, combined with its selective replication makes it an attractive candidate as a cancer therapy.

We also believe that this research may have broad utility in the treatment of tumours with an activated Ras pathway as well as a potential use as an adjuvant therapy following surgical tumour resection or as an adjuvant therapy to conventional chemotherapeutic or radiation therapies.

## The Potential Cancer Product

Cancer is a group of related diseases characterized by the aberrant or uncontrolled growth of cells and the spread of these cells to other sites in the body. These cancer cells eventually accumulate and form tumours that can disrupt and impinge on normal tissue and organ function. In many instances, cells from these tumours can break away from the original tumour and travel through the body to form new tumours through a process referred to as metastasis.

Our cancer product is a potential therapeutic for tumours possessing an activated Ras pathway. In tumour cells with this type of activation, the virus is cytotoxic but may have no effect on the surrounding normal tissue. Activating mutations of Ras are believed to account for approximately 30% of all human tumours directly. It is also possible to activate Ras through mutation of proteins that control its activity rather than through direct mutations of Ras itself. This suggests that approximately two thirds of tumours may respond to this treatment.

#### Clinical Trial Program

We are directing a broad clinical trial program with the objective of developing REOLYSIN<sup>®</sup> as a human cancer therapeutic. The clinical program includes clinical trials which we sponsor directly along with Third Party Clinical Trials. Third Party Clinical Trials are clinical trials that are being sponsored by other institutions. As of the end of 2011, the U.S. National Cancer Institute (“NCI”), the University of Leeds and the Cancer Therapy & Research Center at the University of Texas Health Center in San Antonio (“CTRC”) were sponsoring part of our clinical trial program. Our clinical trial program has included human trials using

REOLYSIN® alone, and in combination with radiation and chemotherapy, and delivered via local administration and/or intravenous administration.

#### Clinical Trial Chart

The following chart shows our clinical trials along with the status for each as at December 31, 2011:

Trial number	Delivery Method	Trial Program and Cancer Indication	Location	Status
Pending (NCI Trial)	Intravenous Administration of REOLYSIN	Phase I Relapsed Multiple Myeloma	United States	US Announced
OSU-10045 (NCI Trial)	REOLYSIN® in Combination with Paclitaxel and Carboplatin	Phase II Metastatic Pancreatic Cancer	United States	US Ongoing
COG-ADV1014 (NCI / COG Trial)	Intravenous Administration of REOLYSIN® in Combination with Cyclophosphamide	Phase I Pediatric Patients with Relapsed or Refractory Solid Tumors	United States	US Ongoing
GOG-0186H (NCI / GOG Trial)	Intravenous Administration of REOLYSIN in Combination with Paclitaxel for Patients with Persistent or Recurrent Ovarian Cancer	Phase II ovarian cancer	United States	US Ongoing
REO 022	Intravenous administration in combination with FOLFIRI	Phase I colorectal cancer	United States	Ongoing
REO 021	Intravenous administration in combination with paclitaxel and carboplatin (sponsored by the CTRC)	Phase II squamous cell carcinoma lung cancer	United States	Ongoing
REO 020	Intravenous administration in combination with paclitaxel and carboplatin (sponsored by the CTRC)	Phase II metastatic melanoma	United States	Ongoing
REO 018	Intravenous administration in combination with paclitaxel and carboplatin	Phase III squamous cell carcinoma of the head and neck	12 countries including the United States, U.K., and Canada.	Ongoing
REO 017	Intravenous administration in combination with gemcitabine (sponsored by the CTRC)	Phase II advanced pancreatic cancer	United States	Ongoing
REO 016	Intravenous administration in combination with paclitaxel and carboplatin	Phase II non-small cell lung with K-RAS or EGFR-activated tumours	United States	Ongoing
REO 015	Intravenous administration in combination with paclitaxel and carboplatin	Phase II head and neck	United States	Ongoing
REO 014	Intravenous administration monotherapy	Phase II sarcoma	United States	Complete
REO 013	Intravenous administration monotherapy (sponsored by University of Leeds)	Translational metastatic colorectal	United Kingdom	Ongoing
NCI Trial	Intravenous administration monotherapy (NCI)	Phase II melanoma	United States	Ongoing
NCI Trial	Intravenous and intraperitoneal administration monotherapy (NCI)	Phase I/II ovarian	United States	Ongoing
REO 012				Ongoing

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	Intravenous administration in combination with cyclophosphamide	Phase I/II pancreatic, lung, ovarian	United Kingdom	
REO 011	Intravenous administration in combination with paclitaxel and carboplatin	Phase I/II melanoma, lung, ovarian	United Kingdom	Complete
REO 010	Intravenous administration in combination with docetaxel	Phase I/II bladder, prostate, lung, upper gastro-intestinal	United Kingdom	Complete
REO 009	Intravenous administration in combination with gemcitabine	Phase I/II pancreatic, lung, ovarian	United Kingdom	Complete
REO 008	Local therapy in combination with radiation	Phase II various metastatic tumours, including head & neck	United Kingdom	Complete



Trial number	Delivery Method	Trial Program and Cancer Indication	Location	Status
REO 007	Infusion monotherapy	Phase I/II recurrent malignant gliomas	United States	Complete
REO 006	Local therapy in combination with radiation	Phase I various metastatic tumours	United Kingdom	Complete
REO 005	Intravenous administration monotherapy	Phase I various metastatic tumours	United Kingdom	Complete
REO 004	Intravenous administration monotherapy	Phase I various metastatic tumours	United States	Complete
REO 003	Local monotherapy	Phase I recurrent malignant gliomas	Canada	Complete
REO 002	Local monotherapy	T2 prostate cancer	Canada	Complete
REO 001	Local monotherapy	Phase I trial for various subcutaneous tumours	Canada	Complete

#### Patents and Trade Secrets

The patent positions and proprietary rights of pharmaceutical and biotechnology firms, including us, are generally uncertain and involve complex legal and factual questions. We believe there will continue to be significant litigation in the industry regarding patent and other intellectual property rights.

Currently, we have over 319 issued patents including 45 issued U.S. patents. We also have numerous patent applications filed in the U.S., Canada, and other jurisdictions, but we cannot be certain whether any given patent application filed by us will result in the issuance of a patent or if any given patent issued to us will later be challenged and invalidated. Nor can we be certain whether any given patent that may be issued to us will provide any significant proprietary protection to our product and business.

Litigation or other proceedings may also be necessary to enforce or defend our proprietary rights and patents. To determine who was first to make an invention claimed in a United States patent application or patent and thus be entitled to a patent, the United States Patent and Trademark Office, or USPTO, can declare an interference proceeding. In Europe, patents can be revoked through opposition or nullity proceedings. In the United States patents may be revoked or invalidated in court actions or in re-examination proceedings in the USPTO. Such litigation or proceedings could result in substantial cost or distraction to us, or result in an adverse decision as to our or our licensors' patent applications and patents.

Our commercial success depends, in part, on not infringing the patents or proprietary rights of others and not breaching licenses granted that may be granted to us. Competitors may have filed patent applications and obtained patents and may in the future file patent applications and obtain patents relevant to our product and technologies. We are not aware of competing intellectual property relating to our REOLYSIN® project. While we currently believe that we have the necessary freedom to operate in these areas, there can be no assurance that others will not challenge our position in the future. Litigation to defend our position coul