ONCOLYTICS BIOTECH INC
Form 20-F
March 06, 2009
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended **December 31, 2008**

OR

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

For the transition period from _____ to _____

OR

o **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)

Doug Ball, info@oncolytics.ca, Suite 210, 1167 Kensington Crescent, N. W. Calgary, Alberta, T2N 1X7, (403) 670-7377

(Name, telephone, email, and address of Company Contact Person)

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

Indicate the number of outstanding shares of each of the Registrant's classes of capital of common stock as of December 31, 2008:
43,830,748 Common Shares

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

o Yes x 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.

o Yes x 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.

xYes o 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 o Accelerated filer x Non-accelerated filer o

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

U.S. GAAP o | International Reporting Standards as issued by the International Accounting Standards Board o | Other x

If "Other" has been checked in response to the previous questions, indicate by check mark which financial statement item the registrant has elected to follow.

o Item 17 x 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)

o Yes x No

ONCOLYTICS BIOTECH INC.

FORM 20-F

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this annual report 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 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 this annual report , 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. Investors should consult our quarterly and annual filings with 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.

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.

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				
	2008	**2007**	**2006**	**2005**	**2004**
Average for the period	0.9441	0.9348	0.8820	0.8259	0.7697
Low for the period	1.0289	1.0905	0.9099	0.8690	0.8493

For the Month of						
	February	**January**	**December**	**November**	**October**	**September**
High for the period	0.7758	0.7849	0.7711	0.7779	0.7726	0.9263
Low for the period	0.8202	0.8458	0.8358	0.8696	0.9426	0.9673

Exchange rates are based on the Bank of Canada nominal noon exchange rates. The nominal noon exchange rate on March 6, 2009 as reported by the Bank of Canada for the conversion of United States dollars into Canadian dollars was US$1.00 = Cdn$1.2863. 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 following table of selected financial data 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 22 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.

	2008	**2007**	**2006**	**2005**	**2004**
	$	**$**	**$**	**$**	**$**
Revenues	—	—	—	—	—
Net loss, Canadian GAAP[2]	17,550,204	15,950,426	14,628,291	13,256,271	13,640,338
Net loss, U.S. GAAP[2]	17,188,704	15,588,926	14,266,791	12,894,771	13,278,838
Basic and diluted loss per share, Canadian GAAP[2], [3], [4]	0.42	0.39	0.40	0.40	0.47
Basic and diluted loss per share, U.S. GAAP[2], [3], [4]	0.42	0.39	0.39	0.39	0.46
Total assets, Canadian GAAP [1], [3], [4]	13,987,195	26,297,567	29,389,636	42,449,038	36,117,793
Total assets, U.S. GAAP[1], [3], [4]	13,806,445	25,755,317	28,485,886	41,183,788	34,491,043
Shareholders' equity, Canadian GAAP[4]	9,453,084	23,476,340	26,773,217	40,756,556	35,168,536
Shareholders' equity, U.S. GAAP[4]	9,272,334	22,934,090	25,869,467	39,491,306	33,541,786
Cash dividends declared per share[5]	Nil	Nil	Nil	Nil	Nil
Weighted average number of common shares outstanding	41,369,515	40,428,825	36,346,266	32,804,540	29,028,391

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 2008.
2) Included in net loss and net loss per share is stock based compensation expense of $64,039 (2007 – $539,156; 2006 – $403,550; 2005 – $64,104).
3) We issued 2,650,000 commons shares for net cash proceeds of $3,421,309 (2007 – 4,660,000 common shares for net 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) On April 1, 2008, we early adopted the Canadian Institute of Chartered Accountants Handbook section 3064 *"Goodwill and Intangible Assets"*. Pursuant to the transitional provisions set out in Section 3064, we retroactively adopted this standard with restatement (see Note 3 of the December 31, 2008 audited consolidated financial statements).
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 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.

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, including withdrawal of the product from the market.

The U.S. 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, 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 thereunder 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 may be outside of our control. 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, 2008, we had an accumulated deficit of $102.6 million and we incurred net losses of $17.6 million, $16.0 million, and $14.6 million for the years ended December 31, 2008, 2007, and 2006, respectively. We anticipate that we will continue to incur significant losses during 2009 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.

Uncertainty exists regarding the reimbursement status of newly-approved pharmaceutical products and reimbursement may not be available for REOLYSIN®. 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® 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, 2008, we had cash and cash equivalents (including short-term investments) of $13.3 million and working capital of approximately $9.0 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, 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.

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.

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 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.

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.

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 DL Service, Inc. located at 1420 Fifth Avenue, Suite 3400, Seattle, Washington, 98101, telephone (206) 903-8800.

On July 1, 2008, we completed an internal reorganization to provide additional international flexibility and promote broadened opportunities for Oncolytics. Pursuant to the internal reorganization we transferred certain assets to our wholly-owned subsidiary, Oncolytics Biotech (Barbados) Inc. (“Oncolytics Barbados”), in consideration for additional shares in the capital of Oncolytics Barbados. The transferred assets consisted of: (a) the rights to certain regulatory submissions; (b) certain non-Canadian patents and patent applications; and (c) certain agreements to which we were a party, including, clinical research management agreements, clinical trial agreements, research agreements and manufacturing agreements. We also granted Oncolytics Barbados permission to use certain other intellectual property rights not transferred by us to Oncolytics Barbados. Concurrently with the asset transfer, the Corporation and Oncolytics Barbados entered into a trust agreement pursuant to which we agreed to hold legal title to the transferred assets with beneficial title remaining with Oncolytics Barbados.

As part of the internal reorganization, the Corporation and Oncolytics Barbados also entered into a research and development agreement on July 1, 2008 pursuant to which we agreed to provide certain services to Oncolytics Barbados, including: conducting research and development related to the transferred assets; coordinating clinical trials and the handling of data generated by such trials; pursuing regulatory approvals as required; coordinating the filing, prosecution and maintenance of patent applications and patents; and coordinating the development and implementation of manufacturing processes.

In December 2009, we incorporated a Delaware company, Oncolytics Biotech (U.S.) Inc. As at December 31, 2008, there was no ongoing activity in this subsidiary.

On March 2, 2009 we entered into an agreement to acquire an inactive private company ("PrivateCo"), pursuant to a plan of arrangement under the Business Corporations Act (Alberta) (the "Arrangement"). PrivateCo does not actively carry on any business operations, has accumulated tax losses from its previous development business, and is expected to have approximately $2.3 million in net cash available at the closing of the transaction.

Under the terms of the Arrangement, we will issue common shares of Oncolytics at an exchange ratio calculated based upon an agreed premium to PrivateCo's net cash per share at closing and using an ascribed price per common share of Oncolytics of $1.69 (which is based on the 20 day volume weighted average trading price of Oncolytics shares on the Toronto Stock Exchange up to and including March 2, 2009). Completion of this transaction is subject to a number of conditions including receipt of all necessary shareholder, court and regulatory approvals. The acquisition is expected to close in April 2009.

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

B. Business Overview

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®, 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®, 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® as a human cancer therapeutic. The clinical program includes clinical trials which we sponsor directly along with clinical trials that are being sponsored by the U.S. National Cancer Institute ("NCI"). Our clinical trial program includes 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 the clinical trials that we have sponsored:

Trial number	Delivery Method	Trial Program and Cancer Indication	Location	Status
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	Approved to Commence
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	Ongoing

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Trial number	Delivery Method	Trial Program and Cancer Indication	Location	Status
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	Approved to Commence
REO 012	Intravenous administration in combination with cyclophosphamide	Phase I/II pancreatic, lung, ovarian	United Kingdom	Ongoing
REO 011	Intravenous administration in combination with paclitaxel and carboplatin	Phase I/II melanoma, lung, ovarian	United Kingdom	Ongoing
REO 010	Intravenous administration in combination with docetaxel	Phase I/II bladder, prostate, lung, upper gastro-intestinal	United Kingdom	Ongoing
REO 009	Intravenous administration in combination with gemcitabine	Phase I/II pancreatic, lung, ovarian	United Kingdom	Ongoing
REO 008	Local therapy in combination with radiation	Phase II various metastatic tumours, including head & neck	United Kingdom	Ongoing
REO 007	Infusion monotherapy	Phase I/II recurrent malignant gliomas	United States	Ongoing
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 200 patents including 31 U.S. patents. We had over 190 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. We are not currently involved in any interference proceedings, re-examination proceedings, opposition or nullity proceedings or any court actions concerning our patent applications and patents. We may be involved in such proceedings in the future.

Our commercial success depends, in part, on not infringing the patents or proprietary rights of others and not breaching licenses 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 could be costly and time consuming. We also cannot be certain that we will be successful. We may be required to obtain a license from the prevailing party in order to continue the portion of our business that relates to the proceeding. We may also be required to obtain licenses to other third-party technologies necessary in order to market our products. Such licenses may not be available to us on acceptable terms or on any terms and we may have to discontinue that portion of our business. Any failure to license any technologies required to commercialize our technologies or products at reasonable cost may have a material adverse effect on our business, results of operations, financial condition, cash flow and future prospects. We are not currently involved in any litigation concerning our competitors' patent applications and patents. We may be involved in such litigation in the future.

We also rely on unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our rights to our unpatented trade secrets.

We require our employees and consultants to execute confidentiality agreements upon the commencement of employment and consulting relationships with us. These agreements provide that all confidential information developed by or made known to an individual during the course of the employment or consulting relationship generally must be kept confidential. In the case of employees, the agreements provide that all inventions conceived by the individual, while employed by us, relating to our business are our exclusive property. While we have implemented reasonable business measurements to protect confidential information, these agreements may not provide meaningful protection for our trade secrets in the event of unauthorized use or disclosure of such information.

Business Strategy

Our business strategy is to develop and market REOLYSIN® in an effective and timely manner, and access additional technologies at a time and in a manner that we believe is best for our development. We intend to achieve our business strategy by focusing on these key areas:

- Develop REOLYSIN® by continuing to progress the product through our clinical trial program assessing the safety and efficacy in human subjects;
- Establish collaborations with experts to assist us with scientific and clinical developments of this new potential pharmaceutical product;

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- Implement strategic alliances with selected pharmaceutical and biotechnology companies and selected laboratories, at a time and in a manner where such alliances may complement and expand our research and development efforts on the product and provide sales and marketing capabilities;
- Utilize our broadening patent base and collaborator network as a mechanism to meet our strategic objectives; and
- Develop relationships with companies that could be instrumental in assisting us to access other innovative therapeutics.

Our business strategy is based on attaining a number of commercial objectives, which, in turn, are supported by a number of product development goals. Our new product development presently being conducted is primarily of a research and development nature. In the context of this Annual Information Form, statements of our "belief" are based primarily upon our results derived to date from our research and development program with animals, and early stage human trials, and upon which we believe that we have a reasonable scientific basis to expect the particular results to occur. It is not possible to predict, based upon studies in animals, or early stage human trials, whether a new therapeutic will ultimately prove to be safe and effective in humans. There are no assurances that the particular result expected by us will occur.

At this time we do not intend to become a fully integrated pharmaceutical company with substantial in-house research and development, marketing and distribution or manufacturing capabilities. We are pursuing a strategy of establishing relationships with larger companies as strategic partners. We intend to partner or joint venture with larger pharmaceutical companies that have existing and relevant marketing capability for our products. It is anticipated that future clinical development into large international or pivotal trials would generally occur in conjunction with a strategic partner or partners, who would contribute expertise and financial assistance. In exchange for certain product rights and commitments to market our products, the strategic partners would be expected to share in gross proceeds from the sale of our product or products and potentially share in various market or manufacturing opportunities. The proceeds generated from partnering or joint venturing projects are expected to be distributed on the basis of relative risk taken and resources contributed by each party to the partnership or joint venture.

Regulatory Requirements

The development of new pharmaceuticals is strongly influenced by a country's regulatory environment. The drug approval process in Canada is regulated by Health Canada. The primary regulatory body in the United States is the FDA and in the UK is the MHRA. Similar processes are conducted in other countries by equivalent regulatory bodies. Regulations in each jurisdiction require the licensing of manufacturing facilities and mandate strict research and product testing standards. Companies must establish the safety and efficacy of their products, comply with current Good Manufacturing Practices and submit marketing materials before being allowed to market pharmaceutical products. While we plan to pursue or support the pursuit of the approval of our product, success in acquiring regulatory approval for any product is not assured.

In order to market our pharmaceutical product in Canada, the United States, Europe and other jurisdictions, we must successfully meet the requirements of those jurisdictions. The requirements of the Appropriate Regulatory Authority will generally include the following stages as part of the regulatory process:

- ***Pre-Pharmacological Studies***- Pre-Pharmacological studies involve extensive testing on laboratory animals to determine if a potential therapeutic product has utility in an *in vivo* disease model and has any adverse toxicology in a disease model.
- ***Investigational New Drug Application*** - An Investigational New Drug ("IND") Submission, or the equivalent, must be submitted to the appropriate regulatory authority prior to conducting Pharmacological Studies.
- ***Pharmacological Studies*** (or Phase I Clinical Trials) - Pharmacological studies are designed to assess the potential harmful or other side effects that an individual receiving the therapeutic compound may

experience. These studies, usually short in duration, are often conducted with healthy volunteers or actual patients and use up to the maximum expected therapeutic dose.

- ***Therapeutic Studies*** (or Phase II and III Clinical Trials) - Therapeutic studies are designed primarily to determine the appropriate manner for administering a drug to produce a preventive action or a significant beneficial effect against a disease. These studies are conducted using actual patients with the condition that the therapeutic is designed to remedy.
- Prior to initiating these studies, the organization sponsoring the program is required to satisfy a number of requirements via the submission of documentation to support the approval for a clinical trial.
- ***New Drug Submission*** - After all three phases of a clinical trial have been completed, the results are submitted with the original IND Submission to the appropriate regulatory authority for marketing approval. Once marketing approval is granted, the product is approved for commercial sales.

Marketing Approvals

The results of the preclinical and clinical testing, together with manufacturing and controls information, are submitted to regulatory agencies in order to obtain approval to commence commercial sales. In responding to such an application, regulatory agencies may grant marketing approval, request additional information or further research, or deny the application if they determine that the application does not satisfy their regulatory approval criteria. Approval for a pharmaceutical or biologic product may not be granted on a timely basis, if at all, or if granted may not cover all the clinical indications for which approval is sought, or may contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use.

Satisfaction of pre-market approval requirements for new drugs and biologics typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or targeted disease. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials or with prior versions of products does not assure success in later stage clinical trials. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Post-Marketing Regulations

Once approved, regulatory agencies may withdraw the product approval if compliance with pre- and/or post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, they may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of an approved product, and may limit further marketing of the product based on the results of these post-market studies. The FDA and other foreign regulatory agencies have broad post-market regulatory and enforcement powers, including the ability to levy fines and penalties, suspend or delay issuance of approvals, seize or recall products, or withdraw approvals.

Manufacturing Regulations

We use contract toll manufacturers to produce REOLYSIN®. Our toll manufacturers are subject to periodic inspection by the FDA, the United States Drug Enforcement Administration, or DEA, and other domestic and foreign authorities where applicable, and must comply with cGMP regulations. Manufacturers of biologics also must comply with general biological product standards. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, or mandatory or voluntary recall of a product. Adverse experiences with the product must be reported to the FDA and foreign agencies and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Advertising and Promotion Regulations

With respect to both pre- and post-market product advertising and promotion, the FDA and similar foreign agencies impose a number of complex regulations on entities that advertise and promote pharmaceuticals and biologics,

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which include, among other things, standards and regulations relating to direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. These agencies have very broad enforcement authority and failure to abide by these regulations can result in penalties including the issuance of a warning letter directing the entity to correct deviations from requisite standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA or relevant foreign agencies, and foreign, state and federal civil and criminal investigations and prosecutions.

Other Government Regulations

We are subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the government has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us.

Market and Competition

According to estimates for 2008 from the American Cancer Society, 1.4 million Americans are expected to be diagnosed with cancer in the year, and 565,650 Americans are forecast to die of cancer. In the United States cancer accounts for 25% of all deaths, second only to heart disease. In the United States, the relative lifetime risk of a male developing cancer is 1 in 2, while for women, this risk is 1 in 3.

The costs of this disease state are also significant. In the United States, the National Institute of Health estimates that the overall annual costs for cancer treatment are $206.3 billion. Of this figure, $78.2 billion can be attributed to direct patient costs.

It has been estimated that approximately 30% of all tumours are a result of activating mutations of Ras itself. Since Ras can be activated by mechanisms other than direct mutations it is believed that the number of tumours with activated Ras (either through direct activating mutation or mutation or over-expression of elements upstream of Ras) is approximately two thirds.

We face substantial competition in the development of products for cancer and other diseases. This competition from other manufacturers of the same types of products and from manufacturers of different types of products designed for the same uses is expected to continue in both U.S. and international markets. Oncolytic virus therapies, our primary focus area, is rapidly evolving areas in the biotechnology industry and are expected to undergo many changes in the coming years as a result of technological advances. We are currently aware of a number of groups that are developing oncolytic virus therapies including early-stage and established biotechnology companies, pharmaceutical companies, academic institutions, government agencies and research institutions. We face competition from these groups in areas such as recruiting employees, acquiring technologies that might enhance our ability to commercialize products, establishing relationships with certain research and academic institutions, enrolling patients in clinical trials and seeking program partnerships and collaborations with larger pharmaceutical companies. It is possible that our competitors could achieve earlier market commercialization, could have superior patent protection, or could have safer, more effective or more cost-effective products. These factors could render our potential products less competitive, which could adversely affect our business.

Product Marketing Strategy

The markets for the cancer product being developed by us may be large and could require substantial sales and marketing capability. Before or upon successful completion of the development of a cancer product, we intend to enter into one or more strategic partnerships or other collaborative arrangements with a pharmaceutical company or other company with marketing and distribution expertise to address this need. If necessary, we will establish arrangements with various partners for different geographical areas or specific applications at various times in the development process. Our management and consultants have relevant experience with the partnering process.

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Seasonality of Business

Our results of operations have not been materially impacted by seasonality.

C. Organizational Structure

On December 31, 2008, we had two wholly-owned subsidiaries; Oncolytics Biotech (Barbados) Inc., a Barbados Company, and Oncolytics Biotech (US) Inc., a Delaware corporation.

D. Property, Plants and Equipment

We currently lease our head office in Calgary, Alberta, Canada. We do not own or lease any other office space, manufacturing facilities or equipment and do not have any current material plans to construct or acquire any facilities.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion contains forward-looking statements, including our belief as to the potential of REOLYSIN®, a therapeutic reovirus, as a cancer therapeutic and our expectations as to the success of our research and development and manufacturing programs in 2009 and beyond, future financial position, business strategy and plans for future operations, and statements that are not historical facts, involve known and unknown risks and uncertainties, which could cause our actual results to differ materially from those in the forward-looking statements. See *"Cautionary Note Regarding Forward-Looking Statements"*.

With respect to the forward-looking statements made within this MD&A, we have made numerous assumptions regarding among other things: our ability to obtain financing to fund our development program, our ability to receive regulatory approval to commence enrollment in our clinical trial program, the final results of our co-therapy clinical trials, our ability to maintain our supply of REOLYSIN® and future expense levels being within our current expectations. Investors are cautioned against placing undue reliance on forward-looking statements. We do not undertake to update these forward-looking statements except as required by applicable law.

A. OPERATING RESULTS

REOLYSIN(r) DEVELOPMENT UPDATE FOR 2008

Oncolytics Biotech Inc. is a Development Stage Company

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®, 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.

We have been developing our product REOLYSIN® as a possible cancer therapy since our inception in 1998. Our goal each year is to advance REOLYSIN® through the various steps and stages of development required for potential pharmaceutical products. In order to achieve this goal, we believe that we have to actively manage the development of our clinical trial program, our pre-clinical and collaborative programs, our manufacturing process and REOLYSIN® supply, and our intellectual property.

Clinical Trial Program

We began 2008 with eight active clinical trials of which seven were being conducted by us and one was being sponsored by the U.S. National Cancer Institute (the "NCI"). During the year, we received approval to commence

another three clinical trials and the NCI received approval to commence one additional clinical trial study. We announced positive clinical trial results from three of our co-therapy clinical trials. We ended 2008 with 12 clinical trials, either underway or approved to commence, two of which are sponsored by the NCI, and we announced that we will be pursuing a Phase II/III, randomized trial using the combination of REOLYSIN® with paclitaxel and carboplatin in patients with head and neck cancers.

Clinical Trial – 2008 Results

U.K. Phase I/II Combination REOLYSIN® and Paclitaxel/Carboplatin Clinical Trial

In 2008 we announced positive interim clinical trial results from our U.K. co-therapy trial with paclitaxel and carboplatin and completed patient enrollment in this trial. The interim results were presented as an abstract entitled "Phase I Trial of Oncolytic Reovirus (REOLYSIN®) in Combination with Carboplatin/Paclitaxel in Patients with Advanced Solid Cancers" in the November/December issue of the Journal of Immunotherapy, the official journal of the International Society for Biological Therapy of Cancer (iSBTc). The results in this abstract were further updated with a poster presentation that occurred during the iSBTc annual meeting in November.

The results of the fourteen patients treated as reported by the principal investigator were:

Primary Tumour	**REOLYSIN Dose $TCID_{50}$**	**Cycles**	**Best Response**
Phase I patients			
Melanoma	$3x10^9$	2	PD
Squamous cell carcinoma (SCC) head & neck	$3x10^9$	8	Clinical CR, SD per CT scan
Peritoneal	$3x10^9$	3	PD
Melanoma (eye)	$1x10^{10}$	2	PD
Head & neck	$1x10^{10}$	8	PR
Nasopharynx	$1x10^{10}$	8	PR
Endometrial	$3x10^{10}$	8	SD
SCC nasopharynx	$3x10^{10}$	1	PD
Head & neck (laryngeal carcinoma)	$3x10^{10}$	2	SD
Phase II patients			
Nasopharynx	$3x10^{10}$	8*	SD
Nasopharynx with liver mets	$3x10^{10}$	7*	PR
SCC nasolabial fold	$3x10^{10}$	5*	SD
SCC nasopharynx	$3x10^{10}$	4*	PR
SCC nasopharynx	$3x10^{10}$	2*	PD

*still on study. CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease

U.K. Phase I/II Combination REOLYSIN® and Docetaxel Clinical Trial

In 2008, we announced positive interim clinical trial results from our U.K. co-therapy trial with Docetaxel and completed patient enrollment in this trial. The results were presented as an abstract entitled "A Phase I Study to Evaluate Systemic Wild-Type Reovirus (REOLYSIN®) in Combination with Docetaxel in Patients with Advanced Malignancies" in the November/December issue of the Journal of Immunotherapy. The principal investigator for the trial is Professor Hardev Pandha of the Royal Surrey County Hospital, U.K. The results of this abstract were further updated at the iSBTc annual meeting. The results of the fourteen patients treated as reported by the principal investigator were:

Primary Tumour	**REOLYSIN Dose**	**Cycles**	**Best Response**
	$TCID_{50}$		
Breast	$1x10^{10}$	8	PR
			CR in liver

Primary Tumour	REOLYSIN Dose	Cycles	Best Response
	$TCID_{50}$		
Gastric	$3x10^{10}$	8	PR
Mesothelioma	$1x10^{10}$	6	32% reduction in lymph nodes Minor response
Prostate	$3x10^{9}$	6	23% reduction in lymph nodes SD on scans
Squamous Cell Carcinoma	$3x10^{9}$	3	30% reduction in PSA Minor response
Head and Neck			26% reduction in lymph node
Unknown	$3x10^{9}$	6	SD
Pancreas	$3x10^{10}$	6*	SD
Prostate	$3x10^{10}$	5*	SD
Prostate	$3x10^{10}$	5	SD
Melanoma	$1x10^{10}$	4	SD
Pancreas	$3x10^{10}$	2	SD, but progressed clinically

*patients still on study. CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease

The researchers concluded that REOLYSIN® can be safely combined with docetaxel, that there was objective radiological evidence of anticancer activity and that Phase II studies with this combination are justified. Any significant toxicities observed were consistent with those expected with docetaxel alone.

U.S. Phase II Sarcoma Clinical Trial

At the beginning of 2008, we announced that we had met the initial criteria to proceed to full enrolment in our U.S. Phase II clinical trial to evaluate the intravenous administration of REOLYSIN® in patients with various sarcomas that have metastasized to the lung.

In order to proceed to full enrolment of 52 patients, we had to demonstrate that at least one patient in the first 38 patients treated experienced a complete or partial response, or stable disease for greater than six months. The third patient treated in this study demonstrated to have stable disease by RECIST criteria for more than six months as measured by CT scan. A PET scan taken at the same time showed that any residual mass was metabolically inert.

Later in June 2008, during the American Society of Clinical Oncology (“ASCO”) annual meeting, we announced further interim results in a presentation, entitled “A Phase II Study of Intravenous REOLYSIN (Wild-type Reovirus) in the Treatment of Patients with Bone and Soft Tissue Sarcomas Metastatic to the Lung”. The presentation was delivered by Dr. Monica Mita, the study principal investigator and her team at the Institute of Drug Development (IDD), the Cancer Therapy and Research Center at the University of Texas Health Science Center, (UTHSC), San Antonio, Texas.

The interim results presented, demonstrated that the treatment had been well tolerated, with 8 of 16 evaluable patients experiencing stable disease for periods ranging from two to more than twelve, 28-day cycles.

In December 2008, we determined that we had exceeded the primary statistical endpoint in this clinical trial. To meet this primary statistical endpoint, at least three out of 52 patients had to experience stabilization of disease or better for more than six months. Of the 33 evaluable patients treated as of the end of 2008, five experienced stable disease for periods greater than six months, including one patient who has maintained stable disease for more than 16 months. An additional 10 patients have experienced stable disease for periods ranging from three to six cycles (cycle = 28 days). At this time, twelve patients were continuing on study, including the five patients who had been stable for more than six months.

Tumour Type	**Months on Study**	**Best Response**
Synovial sarcoma	16*	SD
Ewing's sarcoma	9*	SD
Osteosarcoma	9*	SD (tumour resection after cycle 4)
Chordoma	6*	SD
Unspecified Spindle Cell	6*	SD

*patients still on study SD = stable disease

Clinical Trials – Approved to Commence in 2008

U.S. Phase II Combination REOLYSIN® Paclitaxel and Carboplatin Clinical Trial for Non-Small Cell Lung Cancer

In 2008, following a U.S. Food and Drug Administration ("FDA") review, we initiated a U.S. Phase II clinical trial using intravenous administration of REOLYSIN® in combination with paclitaxel and carboplatin in patients with non-small cell lung cancer ("NSCLC") with K-RAS or EGFR-activated tumours.

This trial is a single arm, single -stage, open-label, Phase II study of REOLYSIN® given intravenously with paclitaxel and carboplatin every 3 weeks. Patients will receive four to six cycles of paclitaxel and carboplatin in conjunction with REOLYSIN®, at which time REOLYSIN® may be continued as a monotherapy. It is anticipated that up to 36 patients will be treated in this trial. Eligible patients include those with metastatic or recurrent NSCLC with K-RAS or EGFR-activated tumours, who have not received chemotherapy treatment for their metastatic or recurrent disease. Patients must have demonstrated mutations in K-RAS or EGFR, or EGFR gene amplification in their tumours (metastatic or primary) in order to qualify for the trial.

The primary objectives of this trial are to determine the objective response rate of REOLYSIN® in combination with paclitaxel and carboplatin in patients with metastatic or recurrent NSCLC with K-RAS or EGFR-activated tumours, and to measure progression-free survival at 6 months. The secondary objectives are to determine the median duration of progression-free survival and the median to one year survival of patients, and to evaluate the safety and tolerability of REOLYSIN® in combination with paclitaxel and carboplatin in this patient population.

Clinical Trials – NCI

NCI Sponsored Phase I/II Ovarian Cancer Clinical Trial

In 2008, the NCI commenced enrollment in a Phase I/II ovarian cancer trial. This Phase I/II clinical trial is for patients with metastatic ovarian, peritoneal or fallopian tube cancers using concurrent systemic and intraperitoneal administration of REOLYSIN®. This trial is being carried out under our Clinical Trials Agreement with the NCI requiring us to provide clinical supplies of REOLYSIN®. It is initially being carried out at The Ohio State University Comprehensive Cancer Center, is expected to enroll up to 70 patients with metastatic ovarian, peritoneal or fallopian tube cancers. These cancer indications were selected after comprehensive preclinical studies carried out by the NCI indicated the reovirus can kill ovarian cancer cells.

NCI Sponsored Phase II Metastatic Melanoma Clinical Trial

In 2008, the NCI began enrolment in a Phase II clinical trial for patients with metastatic melanoma using systemic administration of REOLYSIN®. The trial is being carried out by the Mayo Phase 2 Consortium under our Clinical Trials Agreement with the NCI requiring us to provide clinical supplies of REOLYSIN®. The Principal Investigator is Dr. Evanthia Galanis of the Mayo Clinic Cancer Center.

The primary objectives of the study are to assess the antitumour effects of REOLYSIN® in patients with metastatic malignant melanoma, as well as the safety profile of REOLYSIN®. Secondary objectives include assessment of progression free survival and overall survival. Patients will receive systemic administration of REOLYSIN® at a dose of $3x10^{10}$ $TCID_{50}$ per day on days 1-5 of each 28 day cycle, and patients may receive up to 12 cycles of treatment. The trial is expected to enroll up to 47 patients with metastatic melanoma.

Pre-Clinical and Collaborative Program

Publications

During 2008, the following articles were published:

Title	Senior Author	Publication	Description/Conclusion
Cyclophosphamide Facilitates Antitumor Efficacy against Subcutaneous Tumors following Intravenous Delivery of Reovirus	Dr. Richard Vile	Clinical Cancer Research (online issue January 1, 2008)	After testing various doses and dosing regimens of reovirus and cyclophosphamide in mice, a metronomic dosing regimen was developed that resulted in increased survival, high levels of reovirus recovered from regressing tumours, levels of neutralizing antibodies that were protective, and only very mild toxicities. The data support investigation in human clinical trials of the use of cyclophosphamide prior to systemic reovirus administration to modulate, but not ablate, the immune system.
Enhanced In vitro and In vivo Cytotoxicity of Combined Reovirus and Radiotherapy	Dr. Kevin Harrington	Clinical Cancer Research (online issue February 1, 2008)	The effect of different schedules of reovirus and radiotherapy on viral replication and cytotoxicity was tested *in vitro* and the combination was assessed in three tumour models *in vivo*. The results demonstrated that combining reovirus and radiotherapy significantly increased cancer cell killing both *in vitro* and *in vivo*, particularly in cell lines with moderate susceptibility to reovirus alone.
Characterization of the Adaptive and Innate Immune Response to Intravenous Oncolytic Reovirus (Dearing Type 3) during a Phase I Clinical Trial	Dr. Kevin Harrington	Gene Therapy (online issue March 6, 2008)	The results suggest that reovirus may stimulate the immune system to mount a dynamic immune response to the presence of virus, increasing the potential to significantly enhance the efficacy of oncolytic virotherapy. About a third of those patients also showed increases in NK (natural killer) cells following therapy. The data support the development of interventions aimed at blunting the patient's immune response, although preclinical data also suggest that maintaining a baseline level is necessary to restrict systemic spread and toxicity of the virus.
Inflammatory Tumour Cell Killing by Oncolytic Reovirus for the Treatment of Melanoma	Prof. Alan Melcher et al.	Gene Therapy (online issue April 10, 2008)	The investigators showed that reovirus effectively kills and replicates in both human melanoma cell lines and freshly resected tumour. They demonstrated that reovirus melanoma killing is more potent than, and distinct from, chemotherapy or radiotherapy-induced cell death. They concluded that reovirus is suitable for clinical testing in melanoma.
Reovirus Activates Human Dendritic Cells to Promote Innate Antitumor Immunity	Prof. Alan Melcher et al.	Journal of Immunology (online issue May 1, 2008)	The researchers studied the ability of reovirus to activate human dendritic cells ("DC"), key regulators of both innate and adaptive immune

responses. The data demonstrated that reovirus directly activates human DC, which in turn stimulate innate killing of cancer cells by natural killer ("NK") and T cells,

Title	Senior Author	Publication	Description/Conclusion
			suggesting a novel potential role for T cells in oncolytic virus-induced local tumour cell death. Combined with the virus's ability to directly kill cancer cells, the researchers concluded that reovirus recognition by DC may enhance the efficacy of reovirus as a therapeutic agent.

Presentations

During 2008, the following presentations were made:

Title	Presenter	Location	Description/Conclusion
			The poster covered preclinical work using reovirus in combination with radiation in mice implanted with pediatric rhabdomyosarcoma and Ewing's sarcoma tumours. The results demonstrated that the combination of reovirus and radiation significantly enhanced efficacy compared to either treatment alone in terms of tumour regression and event-free survival.
Targeting Multiple Myeloma with Oncolytic Viral Therapy	Dr. Chandini Thirukkumaran	AACR	The presentation covered preclinical work using reovirus as a purging agent during autologous (harvested from the patient themselves) hematopoietic stem cell transplants for multiple myeloma. The results demonstrated that up to 70% of multiple myeloma cell lines tested showed reovirus sensitivity and reovirus induced cell death mediated through apoptosis. The investigators concluded that this preclinical data supports initiating a Phase I purging trial using reovirus against multiple myeloma.
Synergistic Anti-Tumour Activity of Oncolytic Reovirus and Docetaxel in a PC-3 Prostate Cancer Mouse Model	Prof. Hardev Pandha	iSBTc Annual Meeting in San Diego	The presentation covered preclinical research, which demonstrated that combining reovirus and docetaxel treatment resulted in markedly reduced tumour growth compared to single agent treatments.
Systemic Administration of Reolysin Inhibits Growth of Human Sarcoma Xenografts	Dr. Anders Kolb	Connective Tissue Oncology Society ("CTOS") meeting in	Mice were engrafted with a variety of sarcoma cell lines including rhabdomyosarcoma, Ewing's sarcoma, synovial sarcoma and

Alone and in Combination with Cisplatin and Radiation	London	osteosarcoma, then treated with REOLYSIN® or REOLYSIN® in combination with either cisplatin or radiation. The researchers concluded that in all tumour lines evaluated, REOLYSIN® exhibits significant antitumour activity, including a complete response in a rhabdomyosarcoma line. The combination of

Title	Presenter	Location	Description/Conclusion
			REOLYSIN® and radiation is effective in inhibiting the growth of rhabdomyosarcoma and Ewing's sarcoma xenografts, and the combination of REOLYSIN® and cisplatin is effective in Ewing's sarcoma, osteosarcoma and synovial sarcoma xenografts.
In Vivo Efficacy and Replication Dynamics of Intravenously Administered Oncolytic Reovirus in Nude Mice Bearing Human Melanoma Xenografts	Dr. Shizuko Sei et al	EORTC-AACR-NCI Symposium on Molecular Targets and Cancer Therapeutics held in Geneva	Mice bearing human melanoma tumours each received a single injection of reovirus at various dose levels, administered intravenously. Dose-dependent tumour growth delay was observed in the treated animals, with the effect most pronounced for the first seven days. Reovirus was demonstrated to be in all biopsied tumours and the level consistently increased from day 2 through day 7 in all dose groups. The investigators concluded that a single IV administration of reovirus led to substantial tumour growth delay in melanoma-bearing nude mice, and the extent of acute phase reovirus replication in tumour tissues appeared to predict the subsequent tumour response. This proof-of-principle study demonstrates that systemically administered reovirus can reach and replicate in distant tumour tissues, resulting in virus-induced oncolysis.
Synergistic Anti-Tumour Activity of Oncolytic Reovirus and Cisplatin in a B16.F10 Mouse Melanoma Model	Prof. Hardev Pandha	EORTC-AACR-NCI Symposium on Molecular Targets and Cancer Therapeutics held in Geneva	In the study, the researchers examined the *in vitro* and *in vivo* oncolytic activity of reovirus in combination with cisplatin against a mouse melanoma cell line. The researchers demonstrated that the combined therapy results in significantly increased cell death *in vitro* compared to either agent alone. In the mouse model, combined therapy suppressed tumour growth and significantly prolonged median survival time. The researchers concluded that the addition of chemotherapeutic agents can significantly enhance the anti-tumour efficacy of reovirus therapy and justify formal clinical evaluation.

Manufacturing and Process Development

In 2008, we completed the technology transfer of our 40-litre production process to our manufacturer in the U.S. and commenced production at the 40-litre scale under current Good Manufacturing Practices ("cGMP") conditions for use in our clinical trials. These 40-litre production runs are expected to provide us with sufficient product to supply the remainder of our existing clinical trial program.

Our process development activity in 2008 mainly focused on scale up from 40-litre to 100-litre production runs. We successfully completed this scale up work in the fourth quarter of 2008 allowing us to manufacture at a 100-litre

scale under cGMP with the potential to produce more than one million doses per year for intravenous use. In addition to these scale up studies we also continued work on lyophilization and process validation.

Intellectual Property

In 2008, five U.S. patents were issued. We have been issued over 200 patents including 31 U.S. and nine Canadian patents as well as issuances in other jurisdictions. We also have over 180 patent applications filed in the U.S., Canada and other jurisdictions.

Financing Activity

In 2008, pursuant to a public offering under our Canadian base shelf prospectus and a U.S. registration statement on Form F-10, we issued 2,650,000 units for net cash proceeds of $3,421,309. Each unit consisted of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to acquire one common share upon payment of $1.80 until December 5, 2011, subject to acceleration of the expiry date under certain circumstances. The net proceeds from this offering will be used for our clinical trial program manufacturing activities in support of the clinical trial program and for general corporate purposes.

Financial Impact

We estimated at the beginning of 2008 that our average monthly cash usage would be approximately $1,660,000 for total cash usage of $19,920,000 in 2008. In the third quarter of 2008, we updated our estimate of average monthly cash usage for 2008 between $1,400,000 to $1,500,000 per month for total cash usage of $16,800,000 to $18,000,000 for the year. Our cash usage for the year ended December 31, 2008 was $15,288,632 from operating activities which includes our intellectual property expenditures which is lower than our expected monthly average. A further $111,577 was expended on property and equipment. Our net loss for the year ending December 31, 2008 was $17,550,204.

Cash Resources