

# Oncolytics Biotech® Inc. Announces 2011 Year End Results

CALGARY, March 15, 2012 /PRNewswire/ - Oncolytics Biotech Inc. (TSX:ONC, NASDAQ:ONCY) ("Oncolytics" or the "Company") today announced its financial results and operational highlights for the year ended December 31, 2011.

"In the last year we made substantial progress as we announced positive clinical trial results and started clinical trials in additional cancer indications while maintaining the strength of our balance sheet," said Dr. Brad Thompson, President and CEO of Oncolytics. "Our primary focus in the near term remains completing enrollment in the first stage of our Phase III study in head and neck cancers with the support of an increasing number of enrolling centres in Europe and North America."

## **Selected Highlights**

Since January 1, 2011, the Company has made a number of significant announcements:

#### **Clinical Trial Results**

- Presented interim data from a Phase II clinical trial using intravenous administration of REOLYSIN<sup>®</sup> in combination with gemcitabine (Gemzal<sup>®</sup>) in patients with advanced pancreatic cancer (REO 017) indicating that the clinical study had successfully reached its primary endpoint, and that the drug combination was active. Eight patients of 13 evaluable patients in the study had stable disease (SD) for 12 weeks or longer, for a clinical benefit rate (complete response (CR) + partial response (PR) + SD) of 62%. An additional patient had an unconfirmed PR of less than six weeks. Seventeen evaluable patients with pancreatic cancer were expected to be treated in the first stage and if three or more patients received clinical benefit, the study would then proceed to the next stage. This endpoint was met after six evaluable patients were enrolled;
- Presented positive results from a Phase II clinical trial (REO 015) using intravenous administration of REOLYSIN in combination with paclitaxel and carboplatin in patients with advanced head and neck cancers at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Of the 13 patients evaluable for response, four had PRs, for an objective response rate of 31%. Six patients had SD or better for 12 weeks or longer for a disease control rate (SD or better) of 46%. Two of the four patients with PRs and both patients with SD had received prior treatment with taxanes;
- The presentation of interim preliminary results from a 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 *Kras* or EGFR-activated

tumours at the International Association for the Study of Lung Cancer World Conference on Lung Cancer. As of the presentation date, response evaluation in 21 patients showed six PR (28.6%), 13 SD (61.9%) and two progressive disease (PD) (9.5%), translating into a clinical benefit rate (complete response (CR) + PR + SD) of 90.5% and a response rate (CR + PR) of 28.6%;

Interim data from a U.K. translational clinical trial (REO 013) investigating intravenous
administration of REOLYSIN in patients with metastatic colorectal cancer prior to
surgical resection of liver metastases. On initial histological analysis of the 10 treated
patients, there was evidence of selective delivery of virus to tumour versus normal liver
and viral replication in the majority (seven) of patients;

### **Ongoing Clinical Program**

- Entry into an agreement whereby the NCIC Clinical Trials Group (CTG) at Queen's University in Kingston, Ontario, will sponsor and conduct a randomized Phase II study of REOLYSIN in patients with recurrent or metastatic castration resistant prostate cancer enrolling up to 80 patients;
- Agreement with the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, U.S. National Cancer Institute (NCI), which is part of the National Institutes of Health, to sponsor a Phase I study of REOLYSIN alone in patients with relapsed multiple myeloma;
- The opening of enrollment in a U.S. Phase 1 study of REOLYSIN in combination with FOLFIRI (Folinic Acid (leucovorin) + Fluorouracil (5-FU) + Irinotecan) in patients with oxaliplatin refractory/intolerant *Kras* mutant colorectal cancer (REO 022);
- Start of enrollment in a 2-Arm randomized Phase II study of carboplatin, paclitaxel plus REOLYSIN versus carboplatin and paclitaxel alone in the first line treatment of patients with recurrent or metastatic pancreatic cancer sponsored by the NCI;
- Completion of enrollment in a U.S. Phase II clinical trial using intravenous administration of REOLYSIN in combination with paclitaxel and carboplatin in patients with advanced head and neck cancers (REO 015);

#### Manufacturing

- SAFC<sup>®</sup>, a Division of Sigma-Aldrich Corporation, commenced validation activities designed to demonstrate the manufacturing process for the commercial production of REOLYSIN is robust and reproducible;
- A commercial supply agreement with SAFC for the commercial manufacture of REOLYSIN. Under the terms of the agreement, SAFC will perform process validation of the product, will continue to supply clinical requirements and will supply commercial material upon approval of the product;

## **Preclinical Program**

• The posting of a study in the online version of Molecular Therapy, a publication of The

American Society of Gene and Cell Therapy, investigating the timing of chemotherapy delivery that optimizes the efficacy of systemic REOLYSIN. The paper, authored by Kottke et al., was entitled "Precise Scheduling of Chemotherapy Primes VEGF-producing Tumors for Successful Systemic Oncolytic Virotherapy." It describes when best to administer taxanes with reovirus to optimize viral delivery to the tumor mass. The researchers demonstrated that this drug combination yielded superior results to either treatment alone. They were able to reproducibly cure nearly half of the treated animals by employing this optimized schedule of paclitaxel/REOLYSIN;

#### **Financial**

- Closed bought deal financing, that had been increased to \$18.5 million from \$15 million, for gross proceeds of \$21.3 million following the full exercise of the overallotment option by the syndicate of underwriters;
- Pursuant to the acceleration of the expiry date of those warrants issued on November 23, 2009, the Company received proceeds of approximately US\$6.8 million resulting from the exercise of 1,943,000 warrants;
- The exercise of 1,322,750 warrants, issued in connection with the financing that closed on November 8, 2010, providing the Company with proceeds of approximately \$8.2 million:

## Corporate

- The appointment of Gerard Kennealey, MD as Senior Vice President of Clinical Development and Chief Medical Officer (CMO). Dr. Kennealey most recently held the position of Vice President of Scientific Affairs at Cephalon Inc.; and
- The appointment of George M. Gill, MD as Senior Vice President of Regulatory Affairs and Chief Safety Officer. Dr. Gill has been an officer of Oncolytics since 2002.

# ONCOLYTICS BIOTECH INC. CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

|  | December 31,<br>2011<br>\$ | December 31,<br>2010<br>\$ | January 1,<br>2010<br>\$ |
|--|----------------------------|----------------------------|--------------------------|
| Assets                                   | •                          | •                          | •                        |
| Current assets                           |                            |                            |                          |
| Cash and cash equivalents                | 32,918,751                 | 39,296,682                 | 32,448,939               |
| Short-term investments                   | 1,936,787                  | 3,609,246                  | 1,679,937                |
| Accounts receivable                      | 55,392                     | 284,988                    | 64,787                   |
| Prepaid expenses                         | 721,576                    | 278,934                    | 507,408                  |
| Total current assets                     | 35,632,506                 | 43,469,850                 | 34,701,071               |
| Non-current assets                       |                            |                            |                          |
| Property and equipment                   | 392,111                    | 226,911                    | 208,320                  |
| Long term investment                     | _                          | _                          | 684,000                  |
| Total non-current assets                 | 392,111                    | 226,911                    | 892,320                  |
| Asset held for sale                      | _                          | 735,681                    | _                        |
| Total assets                             | 36,024,617                 | 44,432,442                 | 35,593,391               |
| Liabilities And Shareholders' Equity     |                            |                            |                          |
| Current Liabilities                      |                            |                            |                          |
| Accounts payable and accrued liabilities | 6,504,238                  | 2,500,682                  | 4,226,933                |
| Warrant liability                        | _                          | 5,536,800                  | 1,023,051                |
| Total current liabilities                | 6,504,238                  | 8,037,482                  | 5,249,984                |
| Shareholders' equity                     |                            |                            |                          |
| Share capital                            |                            |                            |                          |
| Authorized: unlimited<br>Issued:         |                            |                            |                          |
| December 31, 2011 - 71,251,335           |                            |                            |                          |
| December 31, 2010 - 67,958,302           |                            |                            |                          |
| January 1, 2010 - 61,549,969             | 177,282,566                | 155,439,610                | 131,908,274              |
| Warrants                                 | 2,653,627                  | 4,108,652                  | 2,437,460                |
| Contributed surplus                      | 21,142,519                 | 19,399,489                 | 13,734,743               |
| Accumulated other comprehensive loss     | (117,501)                  | (156,660)                  |                          |
| Accumulated deficit                      | (171,440,832)              | (142,396,131)              | (117,737,070)            |
| Total shareholders' equity               | 29,520,379                 | 36,394,960                 | 30,343,407               |
| Total liabilities and equity             | 36,024,617                 | 44,432,442                 | 35,593,391               |

# ONCOLYTICS BIOTECH INC. CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

|  | 2011         | 2010         |
|--|--------------|--------------|
| For the years ending December 31,                        | \$           | \$           |
|  |              |              |
| Expenses   |              |              |
| Research and development                                 | 23,386,685   | 13,882,565   |
| Operating  | 5,334,582    | 6,003,870    |
| Loss before the following                                | (28,721,267) | (19,886,435) |
| Write down of asset available for sale                   | (735,681)    | _            |
| Change in fair value of warrant liability                | 36,000       | (4,841,949)  |
| Interest   | 416,247      | 76,934       |
| Loss before income taxes                                 | (29,004,701) | (24,651,450) |
| Income tax expense                                       | (40,000)     | (7,611)      |
| Net loss   | (29,044,701) | (24,659,061) |
|  |              | ,            |
| Other comprehensive gain (loss) - translation adjustment | 39,159       | (156,660)    |
|  |              |              |
| Net comprehensive loss                                   | (29,005,542) | (24,815,721) |
| Basic and diluted loss per common share                  | (0.41)       | (0.39)       |
| ·  | , ,          | ,            |
| Weighted average number of shares (basic and diluted)    | 70,911,526   | 62,475,403   |

# ONCOLYTICS BIOTECH INC. CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

|   | Share Capital | Warrants<br>\$ | Contributed<br>Surplus<br>\$ | Accumulated<br>Other<br>Comprehensive<br>Income | Accumulated<br>Deficit<br>\$ | Total<br>\$  |
|---|---------------|----------------|------------------------------|---|------------------------------|--------------|
| As at January 1, 2010                   | 131,908,274   | 2,437,460      | 13,734,743                   | _   | (117,737,070)                | 30,343,407   |
| Net loss and comprehensive loss         | _             | _              | _                            | (156,660)                                       | (24,659,061)                 | (24,815,721) |
| Issue of common shares, public offering | 22,639,719    | 4,120,201      | _                            | _   | _                            | 26,759,920   |
| Exercise of warrants                    | 787,508       | (11,009)       | _                            | _   | _                            | 776,499      |
| Exercise of stock options               | 104,109       | _              | (24,295)                     | _   | _                            | 79,814       |
| Expired warrants                        | _             | (2,438,000)    | 2,438,000                    | _   | _                            | _            |
| Share based compensation                | _             | _              | 3,251,041                    | _   | _                            | 3,251,041    |
| As at December 31, 2010                 | 155,439,610   | 4,108,652      | 19,399,489                   | (156,660)                                       | (142,396,131)                | 36,394,960   |
| Net loss and comprehensive income       | _             | _              | _                            | 39,159  | (29,044,701)                 | (29,005,542) |
| Exercise of warrants                    | 21,487,080    | (1,455,025)    | _                            | _   | _                            | 20,032,055   |
| Exercise of stock options               | 355,876       | _              | (62,473)                     | _   | _                            | 293,403      |
| Share based compensation                | _             | _              | 1,805,503                    | _   | _                            | 1,805,503    |
| As at December 31, 2011                 | 177,282,566   | 2,653,627      | 21,142,519                   | (117,501)                                       | (171,440,832)                | 29,520,379   |

## ONCOLYTICS BIOTECH INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

| For the years ending December 31,  | 2011<br>\$   | 2010<br>\$  |
|--|--|---|
| Operating Activities   |  |   |
| Net loss for the year  | (29,044,701)   | (24,659,061)  |
| Amortization - property and equipment  | 92,590   | 63,156  |
| Share based compensation   | 1,805,503  | 3,251,041   |
| Change in fair value of warrant liability  | (36,000)   | 4,841,949   |
| Write down of asset available for sale   | 735,681  | _   |
| Unrealized foreign exchange loss   | 115,234  | 343,821   |
| Net change in non-cash working capital   | 3,790,510  | (1,717,978)   |
| Cash used in operating activities  | (22,541,183)   | (17,877,072)  |
| Investing Activities Acquisition of property and equipment Acquisition of investment Redemption (purchase) of short-term investments Cash provided by (used in) investing activities   | (257,790)<br>—<br>1,672,459<br>1,414,669   | (81,846)<br>(51,681)<br>(1,929,309)<br>(2,062,836)  |
| Financing Activities   |  |   |
| Proceeds from exercise of stock options and warrants Proceeds from public offering Cash provided by financing activities Increase (decrease) in cash Cash and cash equivalents, beginning of year Impact of foreign exchange on cash and cash equivalents Cash and cash equivalents, end of year | 14,824,658<br>—<br>14,824,658<br>(6,301,856)<br>39,296,682<br>(76,075)<br>32,918,751 | 528,211<br>26,759,921<br>27,288,132<br>7,348,224<br>32,448,939<br>(500,481)<br>39,296,682 |

To view the Company's Fiscal 2011 Consolidated Financial Statements, related Notes to Consolidated Financial Statements, and Management's Discussion and Analysis, please see the Company's quarterly filings which will be available on <a href="https://www.sedar.com">www.sedar.com</a> and on <a href="https://www.sedar.com">www.oncolyticsbiotech.com</a>.

#### **About Oncolytics Biotech Inc.**

Oncolytics is a Calgary-based biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. Oncolytics' clinical program includes a variety of human trials including a Phase 3 trial in head and neck cancers using REOLYSIN, its proprietary formulation of the human reovirus. For further information about Oncolytics, please visit: www.oncolyticsbiotech.com.

This press release contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company's belief as to the potential of REOLYSIN as a cancer therapeutic; the Company's expectations as to the success of its research and development programs in 2012 and beyond, the Company's planned operations, the value of the additional patents and intellectual property; the Company's expectations related to the applications of the patented technology; the Company's expectations as to adequacy of its existing capital resources; the design, timing, success of planned clinical trial programs; and other statements related to anticipated developments in the Company's business and technologies involve known and unknown risks and uncertainties, which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks

and uncertainties include, among others, the availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN as a cancer treatment, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN, uncertainties related to the research and development of pharmaceuticals, uncertainties related to the regulatory process and general changes to the economic environment. Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements, except as required by applicable laws.

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