

March 13, 2014



# Oncolytics Biotech® Inc. Announces 2013 Year End Results

CALGARY, March 13, 2014 /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, 2014.

"In 2013, we reported data from a number of clinical studies, which included our first data correlating specific biomarkers with survival in NSCLC lung cancer patients and culminated with the reporting of our first randomized data in head and neck cancer," said Dr. Brad Thompson, President and CEO of Oncolytics. "Our randomized clinical program continues to move ahead with six sponsored studies currently enrolling patients in a range of indications. Each of these studies will advance in parallel with our ongoing head and neck program which we are currently in the process of designing a follow-on registration study for discussion with regulators."

## **Selected Highlights**

Since January 1, 2013, specific highlights announced by the Company include:

### **Clinical Trial Results**

- Top-line data for the endpoints in a double blinded, randomized clinical study examining REOLYSIN® in combination with carboplatin and paclitaxel in patients with second-line platinum-refractory, taxane-naïve head and neck cancers (REO 018). An analysis was performed on an intent-to-treat basis of 118 patients with loco-regional head and neck cancer, with or without metastases. Patients in the control arm were treated with carboplatin and paclitaxel, while patients in the test arm were treated with carboplatin, paclitaxel and REOLYSIN. The analysis showed a median progression free survival (PFS) of 94 days (13.4 weeks) in the test arm (n=62), versus 50 days (7.1 weeks) in the control arm (n=56). The test arm maintained a PFS benefit over the control arm through five cycles of therapy. An analysis of 88 loco-regional patients that did not receive additional therapy following discontinuation of study treatment showed a median overall survival (OS) of 150 days (21.4 weeks) in the test arm (n=50), versus 115 days (16.4 weeks) in the control arm (n=38). REOLYSIN was deemed safe and well-tolerated by patients. The side effects experienced by patients in the test arm of the study were consistent with expectations based on outcomes of earlier clinical studies using REOLYSIN. Patients on the test arm of the study experienced a higher incidence of flu-like symptoms consistent with treatment with a virus, most commonly mild fever, chills, nausea and diarrhea, on both a per-patient and a per-cycle basis. Fewer patients required dose reductions of paclitaxel due to neuropathy or neurotoxicity on the test arm than the control arm (zero in the test arm versus six in the control arm; p=0.028). On this basis, the Company intends to explore the potential

chemoprotective and neuroprotective properties of REOLYSIN in future clinical studies;

- Positive final results from a U.S. Phase 2 study examining the use of REOLYSIN in combination with carboplatin and paclitaxel in patients with stage IV non-small cell lung cancer (NSCLC) with *Kras* or EGFR-activated tumors (REO 016). Response evaluation for 36 evaluable patients showed 11 partial responses (PR) (30%) (EGFR amplified, five; BRAF two; *Kras*, three; EGFR mutated, one), 21 stable disease (SD), and four progressive disease (PD). The data also correlated a number of molecular abnormalities with best response, PFS and one-year survival. Current data in these patients demonstrates that 20 of 36 evaluable patients (56%) survived a year or more. There were 13 patients with only EGFR mutations or amplifications, of whom nine (69.2%) survived a year or longer. Four of four (100%) patients with BRAF and EGFR amplification survived a year or longer;
- Final tumor response and PFS data from a U.S. Phase 2 clinical trial in patients with squamous cell carcinoma of the lung (SCCLC) using intravenous administration of REOLYSIN in combination with carboplatin and paclitaxel (REO 021). Of the 25 evaluable patients who had more than one cycle of therapy, 23 (92%) exhibited overall tumor shrinkage. When evaluated for best response, which is the best percentage response recorded on study compared to baseline, 10 patients (40%) had PR, while a further 14 (56%) showed SD, and one (4%), had PD. Using RECIST criteria to evaluate best overall response, 10 patients (40%) had PRs, 12 (48%) showed SD and three (12%), had PD. 31.8% of patients with sufficient follow up had a PFS greater than six months;
- Reaching the stage 1 endpoint in a U.S. Phase 2 clinical trial in patients with metastatic melanoma (REO 020) after only 14 patients were enrolled. The primary objective of this Phase 2 trial was to assess the antitumor effect of the treatment regimen in the study population in terms of objective response rates. The secondary objectives were to assess progression-free survival and overall survival for the treatment regimen; the disease control rate (complete response (CR) plus PR plus SD) and duration, and to assess the safety and tolerability of the treatment regimen in the study population. Three of the 14 patients exhibited a PR, and an additional seven patients had SD for a disease control rate of 71.5%; and
- Positive preliminary results from a Phase 1 study examining the intravenous administration of REOLYSIN in combination with FOLFIRI in patients with metastatic colorectal cancer (REO 022) in a poster presentation at the ASCO Gastrointestinal Cancers Symposium. Of the 18 patients evaluable for response there was one PR and nine had SD. The combined overall PFS of FOLFIRI-naïve and FOLFIRI-failed patients was 7.4 months. The authors concluded that the combination of REOLYSIN and FOLFIRI was safe and well tolerated and resulted in disease control in the majority of evaluable patients, including patients that had previously progressed on Irinotecan.

## Financial

- At December 31, 2013 the Company reported \$27.2 million in cash, cash equivalents and short-term investments; and

- Subsequent to year end, entry into a share purchase agreement with Lincoln Park Capital Fund, LLC that will provide an initial investment in Oncolytics of US\$1.0 million and make available additional periodic investments of up to US\$25.0 million over a 30-month term.

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

<i>as at</i>	December 31, 2013 \$	December 31, 2012 \$
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	25,220,328	19,323,541
Short-term investments	2,001,644	1,969,228
Accounts receivable	105,853	44,979
Prepaid expenses	361,743	331,094
<b>Total current assets</b>	<b>27,689,568</b>	<b>21,668,842</b>
<b>Non-current assets</b>		
Property and equipment	532,459	409,248
<b>Total non-current assets</b>	<b>532,459</b>	<b>409,248</b>
<b>Total assets</b>	<b>28,222,027</b>	<b>22,078,090</b>
<b>Liabilities And Shareholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable and accrued liabilities	6,008,661	7,291,310
<b>Total current liabilities</b>	<b>6,008,661</b>	<b>7,291,310</b>
<b>Shareholders' equity</b>		
Share capital		
Authorized: unlimited		
Issued: December 31, 2013 -		
84,803,818		
December 31, 2012 - 76,710,285	228,612,564	198,155,091
Warrants	376,892	376,892
Contributed surplus	24,491,212	24,126,265
Accumulated other comprehensive loss	79,698	(57,115)

Accumulated deficit	<b>(231,347,000)</b>	(207,814,353)
<b>Total shareholders' equity</b>	<b>22,213,366</b>	14,786,780
<b>Total liabilities and equity</b>	<b>28,222,027</b>	22,078,090

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

For the years ending December 31,	2013 \$	2012 \$
<b>Expenses</b>		
Research and development	<b>18,506,064</b>	31,402,625
Operating	<b>5,392,660</b>	5,285,425
<b>Loss before the following</b>	<b>(23,898,724)</b>	(36,688,050)
Write down of asset available for sale	—	—
Change in fair value of warrant liability	—	—
Interest	<b>371,485</b>	345,003
<b>Loss before income taxes</b>	<b>(23,527,239)</b>	(36,343,047)
Income tax expense	<b>(5,408)</b>	(30,474)
<b>Net loss</b>	<b>(23,532,647)</b>	(36,373,521)
<b>Other comprehensive income items that may be reclassified to net loss</b>		
Translation adjustment	<b>136,813</b>	60,386
<b>Net comprehensive loss</b>	<b>(23,395,834)</b>	(36,313,135)
<b>Basic and diluted loss per common share</b>	<b>(0.28)</b>	(0.48)
<b>Weighted average number of shares (basic and diluted)</b>	<b>83,530,981</b>	76,102,062

**ONCOLYTICS BIOTECH INC.  
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

	Share Capital \$	Warrants \$	Contributed Surplus \$	Accumulated Other Comprehensive Income \$	Accumulate Deficit \$
As at December 31, 2010	155,439,610	4,108,652	19,399,489	(156,660)	(142,396,13
Net loss and comprehensive income	—	—	—	39,159	(29,044,70
Exercise of warrants	21,487,080	(1,455,025)	—	—	-
Exercise of stock options	355,876	—	(62,473)	—	-
Share based compensation	—	—	1,805,503	—	-
As at December 31, 2011	177,282,566	2,653,627	21,142,519	(117,501)	(171,440,83
Net loss and comprehensive income	—	—	—	60,386	(36,373,52
Issued, pursuant to a bought deal financing	19,386,903	376,892	—	—	-
Expiry of warrants	—	(2,653,627)	2,653,627	—	-
Exercise of stock options	1,485,622	—	(400,632)	—	-
Share based compensation	—	—	730,751	—	-
As at December 31, 2012	198,155,091	376,892	24,126,265	(57,115)	(207,814,35
Net loss and comprehensive income	—	—	—	136,813	(23,532,64
Issued, pursuant to a bought deal financing	30,218,796	—	—	—	-

Expiry of warrants	—	—	—	—	—
Exercise of stock options	238,677	—	(59,437)	—	—
Share based compensation	—	—	424,384	—	—
<b>As at December 31, 2013</b>	<b>228,612,564</b>	<b>376,892</b>	<b>24,491,212</b>	<b>79,698</b>	<b>(231,347,001)</b>

**ONCOLYTICS BIOTECH INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS**

For the years ending December 31,	2013 \$	2012 \$	2011 \$
<b>Operating Activities</b>			
Net loss for the year	(23,532,647)	(36,373,521)	(29,044,701)
Amortization - property and equipment	131,623	109,275	92,590
Share based compensation	424,384	730,751	1,805,503
Change in fair value of warrant liability	—	—	(36,000)
Write down of asset available for sale	—	—	735,681
Unrealized foreign exchange loss	(89,721)	89,890	115,234
Net change in non-cash working capital	(1,374,172)	1,187,967	3,790,510
	<b>(24,440,533)</b>	<b>(34,255,638)</b>	<b>(22,541,183)</b>
<b>Cash used in operating activities</b>			
<b>Investing Activities</b>			
Acquisition of property and equipment	(254,834)	(126,412)	(257,790)
Redemption (purchase) of short-term investments	(32,416)	(32,441)	1,672,459
<b>Cash provided by (used in) investing activities</b>	<b>(287,250)</b>	<b>(158,853)</b>	<b>1,414,669</b>
<b>Financing Activities</b>			
Proceeds from exercise of stock options and warrants	179,240	1,084,990	14,824,658
Proceeds from public offering	30,218,796	19,763,795	—
<b>Cash provided by financing activities</b>	<b>30,398,036</b>	<b>20,848,785</b>	<b>14,824,658</b>
<b>Increase (decrease) in cash</b>	<b>5,670,253</b>	<b>(13,565,706)</b>	<b>(6,301,856)</b>
Cash and cash equivalents, beginning of year	19,323,541	32,918,751	39,296,682

Impact of foreign exchange on cash and cash equivalents	226,534	(29,504)	(76,075)
<b>Cash and cash equivalents, end of year</b>	<b>25,220,328</b>	19,323,541	32,918,751

To view the Company's Fiscal 2013 Consolidated Financial Statements, related Notes to Consolidated Financial Statements, and Management's Discussion and Analysis, please see the Company's annual filings which will be available on [www.sedar.com](http://www.sedar.com) and on [www.oncolyticsbiotech.com/for-investors/financials](http://www.oncolyticsbiotech.com/for-investors/financials).

### **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 III 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](http://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 2014 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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