

March 11, 2016



# Oncolytics Biotech(R) Inc. Announces 2015 Year End Results

CALGARY, March 11, 2016 /PRNewswire/ - Oncolytics Biotech<sup>®</sup> Inc. (TSX: ONC) (OTCQX: ONCYF) (FRA: ONY) ("Oncolytics" or the "Company") today announced its financial results and operational highlights for the year ended December 31, 2015.

"In 2015 we continued to advance our clinical program, reporting survival data from single arm Phase 2 studies in non-small cell lung and pancreatic cancers, as well as early data from a pilot study in multiple myeloma," said Dr. Brad Thompson, President and CEO of Oncolytics. "During the year we began combination therapy studies with REOLYSIN<sup>®</sup> and agents that modulate the immune system. Enrollment in a GM-CSF and REOLYSIN<sup>®</sup> combination therapy study in pediatric patients with gliomas began, and we recently announced our first study looking at REOLYSIN<sup>®</sup> in combination with an immunotherapeutic checkpoint inhibitor in pancreatic cancer."

## **Selected Highlights**

Since January 1, 2015, selected highlights announced by the Company include:

### **Clinical Program**

- Treatment of the first patients in a Phase Ib study of pembrolizumab (KEYTRUDA<sup>®</sup>) in combination with REOLYSIN<sup>®</sup> and chemotherapy in patients with advanced pancreatic adenocarcinoma, the Company's first trial examining REOLYSIN<sup>®</sup> in combination with a checkpoint inhibitor;
- Start of enrollment in a Phase Ib study of REOLYSIN<sup>®</sup> combined with standard doses of bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma (REO 019);
- A poster presentation at the 57<sup>th</sup> American Society of Hematology titled "REOLYSIN<sup>®</sup> Combined with Carfilzomib for Treatment of Relapsed Multiple Myeloma Patients," which disclosed updated findings (originally presented at the 15<sup>th</sup> International Myeloma Workshop) from a pilot study (NCI-9603) in patients with relapsed or refractory multiple myeloma treated using the combination of carfilzomib and REOLYSIN<sup>®</sup>. These findings included that all seven patients treated at the full clinical dose had a clinical response, as well as significant increases in the production of caspase-3 ( $p=0.005$ ) and upregulation of PD-L1 ( $p=0.005$ );
- An oral presentation at the International Association for the Study of Lung Cancer (IASLC) 16<sup>th</sup> World Conference on Lung Cancer titled "Oncolytic Reovirus in Combination with Paclitaxel/Carboplatin in NSCLC Patients with Ras Activated Malignancies, Long Term Results," covering updated results, including one- and two-year survival data (57% and 30%, respectively), from the Company's REO 016 Phase 2 study in Non-Small Cell Lung Cancer (NSCLC);
- Presentation of final data from a single arm clinical study examining the use of REOLYSIN<sup>®</sup> in combination with gemcitabine in patients with advanced pancreatic cancer (REO 017), which showed an increase in median overall survival, as well as an approximate two-fold increase in one-year survival rates, and a five-fold increase in two-year survival rates when compared to

- gemcitabine therapy alone as seen in historical data;
- Completion of enrollment in three randomized Phase 2 studies sponsored and conducted by the NCIC Clinical Trials Group; IND 211 is a study of REOLYSIN<sup>®</sup> in combination with chemotherapy in patients with previously treated advanced or metastatic non-small cell lung cancer; IND 210 is a study of REOLYSIN<sup>®</sup> in patients with advanced or metastatic colorectal cancer; and IND 209 is a study of REOLYSIN<sup>®</sup> in combination with chemotherapy in patients with recurrent or metastatic castration resistant prostate cancer;
  - An update on the planned registration program for REOLYSIN<sup>®</sup> including an initial focus on two indications: the neoadjuvant treatment of muscle-invasive bladder cancer and the treatment of glioblastoma;
  - Activation of an Investigational New Drug Application containing the protocol titled "MC1472: Phase 1 Study of Replication Competent Reovirus (REOLYSIN<sup>®</sup>) in Combination with GM-CSF in Pediatric Patients with Relapsed or Refractory Brain Tumors";
  - Presentation of data showing up-regulation of PD-1 and PD-L1 from a single arm clinical study examining the use of REOLYSIN<sup>®</sup> in patients with primary glioblastomas or brain metastases (REO 013b) at the Royal Society of Medicine's Immuno-oncology: Using the Body's Own Weapons Conference, held in London, UK;

## **Regulatory**

- Granting of Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for REOLYSIN<sup>®</sup> in the treatment of pancreatic, gastric, ovarian, primary peritoneal, and fallopian tube cancers, as well as malignant gliomas;
- Granting of Orphan Drug Designation by the European Medicines Agency for REOLYSIN<sup>®</sup> in the treatment of ovarian and pancreatic cancers;

## **Basic Research**

- Presentation of preclinical data at the 9<sup>th</sup> International Conference on Oncolytic Virus Therapeutics in Boston, MA, including findings around REOLYSIN<sup>®</sup>'s mechanism of action and its potential in new indications including chronic lymphocytic leukemia;
- Presentation of clinical and preclinical data at the 2015 Immune Checkpoint Inhibitors Meeting in Boston, MA, including content showing the combination of REOLYSIN<sup>®</sup>, GM-CSF, anti-PD-1 and anti-CTLA-4 improved survival in immune competent mice versus REOLYSIN<sup>®</sup> and GM-CSF alone, and REOLYSIN<sup>®</sup> and GM-CSF plus either one of the checkpoint inhibitors alone;
- A series of presentations made by the Company's research collaborators at the American Association for Cancer Research Annual Meeting held in Philadelphia, PA covering preclinical research in a range of indications, with a variety of treatment combinations including REOLYSIN<sup>®</sup>;

## **Financial**

- At December 31, 2015 the Company reported \$26.1 million in cash, cash equivalents and short-term investments. At March 10, 2016, the Company had approximately \$23.6 million in cash, cash equivalents and short-term investments, which is expected to provide sufficient funds to support several small early-stage immunotherapy combination studies as well as both a run-in and a registration study in muscle-invasive bladder cancer; and
- Subsequent to year-end, entry into an "at-the-market" equity distribution agreement with Canaccord Genuity Corp. permitting Oncolytics at its sole discretion, from time to time and until March 16, 2018, to sell common shares having an aggregate offering value of up to \$4.6 million.

ONCOLYTICS BIOTECH INC.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

As at December 31,	2015	2014
	\$	\$
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	24,016,275	14,152,825
Short-term investments	2,060,977	2,031,685
Accounts receivable	340,059	191,751
Prepaid expenses	506,669	291,553
<b>Total current assets</b>	<b>26,923,980</b>	<b>16,667,814</b>
<b>Non-current assets</b>		
Property and equipment	459,818	525,376
<b>Total non-current assets</b>	<b>459,818</b>	<b>525,376</b>
<b>Total assets</b>	<b>27,383,798</b>	<b>17,193,190</b>
<b>Liabilities And Shareholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable and accrued liabilities	2,709,492	3,373,997
<b>Total current liabilities</b>	<b>2,709,492</b>	<b>3,373,997</b>
<b>Shareholders' equity</b>		
Share capital		
Authorized: unlimited		
Issued:		
December 31, 2015 - 118,151,622		
December 31, 2014 - 93,512,494	261,324,692	237,657,056
Contributed surplus	26,277,966	25,848,429
Accumulated other comprehensive income	760,978	280,043
Accumulated deficit	(263,689,330)	(249,966,335)
<b>Total shareholders' equity</b>	<b>24,674,306</b>	<b>13,819,193</b>
<b>Total liabilities and equity</b>	<b>27,383,798</b>	<b>17,193,190</b>

ONCOLYTICS BIOTECH INC.

CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

For the years ending December 31,	2015	2014	2013
	\$	\$	\$

<b>Expenses</b>			
Research and development	8,601,864	13,824,252	18,506,064
Operating	5,315,837	4,998,694	5,392,660
<b>Loss before the following</b>	<b>(13,917,701)</b>	<b>(18,822,946)</b>	<b>(23,898,724)</b>
Interest	197,859	210,390	371,485
<b>Loss before income taxes</b>	<b>(13,719,842)</b>	<b>(18,612,556)</b>	<b>(23,527,239)</b>
Income tax (expense) recovery	(3,153)	(6,779)	(5,408)
<b>Net loss</b>	<b>(13,722,995)</b>	<b>(18,619,335)</b>	<b>(23,532,647)</b>
<b>Other comprehensive income items that may be reclassified to net loss</b>			
Translation adjustment	480,935	200,345	136,813
<b>Net comprehensive loss</b>	<b>(13,242,060)</b>	<b>(18,418,990)</b>	<b>(23,395,834)</b>
<b>Basic and diluted loss per common share</b>	<b>(0.12)</b>	<b>(0.21)</b>	<b>(0.28)</b>
<b>Weighted average number of shares (basic and diluted)</b>	<b>112,613,845</b>	<b>87,869,149</b>	<b>83,530,981</b>

**ONCOLYTICS BIOTECH INC.**

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

	Share	Capital Warrants	Contributed Surplus	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	\$	\$	\$	\$	\$	\$
<b>As at December 31, 2012</b>	198,155,091	376,892	24,126,265	(57,115)	(207,814,353)	14,786,780
Net loss and other comprehensive income	—	—	—	136,813	(23,532,647)	(23,395,834)
Issued, pursuant to a bought deal financing	30,218,796	—	—	—	—	30,218,796
Exercise of stock options	238,677	—	(59,437)	—	—	179,240
Share based compensation	—	—	424,384	—	—	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>(231,347,000)</b>	<b>22,213,366</b>

Net loss and other comprehensive income	—	—	—	200,345	(18,619,335)	(18,418,990)
Issued, pursuant to Share Purchase Agreement	7,830,409	—	—	—	—	7,830,409
Issued, pursuant to "At the Market" Agreement	1,214,083	—	—	—	—	1,214,083
Expired warrants	—	(376,892)	376,892	—	—	—
Share based compensation	—	—	980,325	—	—	980,325
<b>As at December 31, 2014</b>	<b>237,657,056</b>	<b>—</b>	<b>25,848,429</b>	<b>280,043</b>	<b>(249,966,335)</b>	<b>13,819,193</b>
Net loss and other comprehensive income	—	—	—	480,935	(13,722,995)	(13,242,060)
Issued, pursuant to Share Purchase Agreement	4,305,396	—	—	—	—	4,305,396
Issued, pursuant to "At the Market" Agreement	19,362,240	—	—	—	—	19,362,240
Share based compensation	—	—	429,537	—	—	429,537
<b>As at December 31, 2015</b>	<b>261,324,692</b>	<b>—</b>	<b>26,277,966</b>	<b>760,978</b>	<b>(263,689,330)</b>	<b>24,674,306</b>

**ONCOLYTICS BIOTECH INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

For the years ending December 31,	<b>2015</b>	<b>2014</b>	<b>2013</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>

## Operating Activities

Net loss for the year	(13,722,995)	(18,619,335)	(23,532,647)
Amortization - property and equipment	180,411	163,501	131,623
Share based compensation	429,537	980,325	424,384
Unrealized foreign exchange (gain) loss	(816,319)	242,542	(89,721)
Net change in non-cash working capital	(1,105,464)	(2,443,988)	(1,374,172)
<b>Cash used in operating activities</b>	<b>(15,034,830)</b>	<b>(19,676,955)</b>	<b>(24,440,533)</b>

## Investing Activities

Acquisition of property and equipment	(108,268)	(152,750)	(254,834)
Redemption (purchase) of short-term investments	(29,292)	(30,041)	(32,416)
<b>Cash used in investing activities</b>	<b>(137,560)</b>	<b>(182,791)</b>	<b>(287,250)</b>

## Financing Activities

Proceeds from exercise of stock options and warrants	—	—	179,240
Proceeds from Share Purchase Agreement	4,305,396	7,830,409	—
Proceeds from "At the Market" equity distribution agreement	19,362,240	1,214,083	—
Proceeds from public offering	—	—	30,218,796
<b>Cash provided by financing activities</b>	<b>23,667,636</b>	<b>9,044,492</b>	<b>30,398,036</b>
<b>(Decrease) increase in cash</b>	<b>8,495,246</b>	<b>(10,815,254)</b>	<b>5,670,253</b>
Cash and cash equivalents, beginning of year	14,152,825	25,220,328	19,323,541
Impact of foreign exchange on cash and cash equivalents	1,368,204	(252,249)	226,534
<b>Cash and cash equivalents, end of year</b>	<b>24,016,275</b>	<b>14,152,825</b>	<b>25,220,328</b>

To view the Company's Fiscal 2015 Consolidated Financial Statements, related Notes to the Consolidated Financial Statements, and Management's Discussion and Analysis, please see the Company's annual filings, which will be available under the Company's profile at [www.sedar.com](http://www.sedar.com) and on Oncolytics' website at <http://www.oncolyticsbiotech.com/investor-centre/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 later-stage, randomized human trials in various indications using REOLYSIN<sup>®</sup>, 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<sup>®</sup> as a cancer therapeutic; the Company's expectations as to the success of its research and development programs in 2016 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.*

SOURCE Oncolytics Biotech Inc.