March 9, 2018



# Oncolytics Biotech(R) Inc. Announces 2017 Year-End Results

CALGARY, AB and SAN DIEGO, CA -- (Marketwired) -- 03/09/18 -- Oncolytics Biotech<sup>®</sup> Inc. (TSX: ONC)(OTCQX: ONCYF), currently developing REOLYSIN<sup>®</sup> (pelareorep), an intravenously delivered immuno-oncolytic virus creating an inflamed phenotype, today announced its financial results and operational highlights for the year ended December 31, 2017. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"We view 2017 as a pivotal year for Oncolytics and one that positions us for a productive year ahead," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. "Our IND 213 study in metastatic breast cancer, or mBC, generated compelling results and marked the first time that an oncolytic virus has demonstrated a statistically significant median overall survival advantage in a randomized clinical study. We received supportive regulatory feedback on our proposed registrational study design for pelareorep in HR-positive. HER2negative breast cancer, the major genetic subgroup of mBC, from both the United States Food and Drug Administration and the European Medicines Agency. Looking forward, we are excited to initiate a phase 3 mBC registrational study later this year and also expand our development with highly focused phase 2 studies designed to further establish pelareorep as an immunotherapy and deliver near term clinical data. We plan to initiate three cost-effective, partner-sponsored phase 2 studies. These would include a basket study to generate efficacy data on pelareorep in combination with high profile checkpoint inhibitors in patients having specific genetic mutations across cancer types, and part two a trial using pelareorep in combination with pembrolizumab (KEYTRUDA<sup>®</sup>) in patients with relapsed metastatic adenocarcinoma of the pancreas. We are also planning to initiate a window of opportunity study using pelareorep and the standard of care in a neoadjuvant setting for treatment naïve mBC patients, potentially broadening pelareorep's treatment applicability to include first line treatment."

## Selected Highlights

Since January 1, 2017, selected highlights announced by the Company include:

## **Clinical Updates**

- Presented findings from IND 213, an open-label, randomized, phase 2 study of intravenously-administered pelareorep given in combination with paclitaxel versus paclitaxel alone in patients with advanced or metastatic breast cancer (mBC) at the American Association for Cancer Research meeting in April 2017. Results showed a statistically significant improvement in median overall survival (OS) from 10.4 months in the control arm to 17.4 months in the test arm.
- Presented additional clinical data from IND 213 at the European Society for Medical Oncology (ESMO) 2017 Congress that demonstrated a doubling of overall survival

benefit for patients with HR double-positive, HER2-negative mBC when treated with pelareorep/paclitaxel combination treatment versus paclitaxel alone.

 Announced a favorable End-of-Phase 2 meeting with the FDA for pelareorep in combination with paclitaxel, for the treatment of hormone receptor positive, HER2 receptor negative (HR+/HER2-) mBC patients. The agency's guidance proposed a single, 400 patient registration study to support a future Biologics License Application submission in the U.S.

-- Subsequently, increased to 450 patients to ensure the completion of the study with the planned evaluable population

- Received a Final Advice Letter from the EMA suggesting that a single phase 3 study may be acceptable to form the basis of a Marketing Authorization Application (MAA) in Europe.
- Announced the launch of MUK eleven, a phase 1b trial studying pelareorep in combination with Celgene's Imnovid<sup>®</sup> (pomalidomide) and Revlimid<sup>®</sup> (lenalidomide), as a rescue treatment in relapsing myeloma patients. Oncolytics treated the first patient in this trial in September 2017.
- Presented the largest ever safety database for an oncolytic virus at the ESMO 2017 Congress that demonstrated pelareorep is safe and well tolerated when administered in combination with paclitaxel plus/minus carboplatin.
- Announced that the FDA granted Fast Track designation for pelareorep for the treatment of mBC, based on the data from IND 213. However, our request for breakthrough therapy designation (BTD) in mBC was not approved at this time based on certain data requirements. The FDA provided guidance that the Company may reapply for BTD once additional supportive information is available.

# Corporate Updates

- Entered into a USD \$86.6 million regional licensing agreement with Adlai Nortye for pelareorep covering China, Hong Kong, Macau, Singapore, South Korea and Taiwan. Under the terms of the agreement, Oncolytics is eligible to receive upfront, licensing fee and milestone payments of USD \$21.2 million to support our phase 3 registration study and is eligible to receive up to an additional USD \$65.4 million upon achievement of clinical, regulatory and commercialization milestones.
- Received shareholder approval for the consolidation of the Company's common shares, which enables Oncolytics to meet requirements for listing on the NASDAQ Capital Market.
- Closed an underwritten public share offering of 16,445,000 units at a purchase price of \$0.70 for gross proceeds of approximately \$11.5 million (\$10.6 million net).
- Established a Scientific Advisory Board focused on pelareorep's registration study in mBC.
- Appointed Oncolytics co-founder and long-serving senior executive Matt Coffey PhD, MBA, as President and CEO.
- Appointed Andrew de Guttadauro as President of its US subsidiary, Oncolytics Biotech (U.S.) Inc. and Head of Global Business Development.

# Anticipated Milestones

• Initiate a phase 3 registration study of pelareorep in combination with paclitaxel, for the treatment HR+/HER2- mBC patients in Q3 2018.

- Initiate a phase 2 partner-sponsored window of opportunity study of pelareorep in combination with standard of care therapy in the neoadjuvant setting in mBC in H2 2018.
- Initiate a phase 2 partner-sponsored basket study to generate important biomarker and efficacy data of pelareorep in combination with checkpoint inhibitors in H2 2018.
- Initiate part two of a phase 2 North-West University/Merck sponsored trial of pelareorep in combination with pembrolizumab (KEYTRUDA<sup>®</sup>) in patients with relapsed metastatic adenocarcinoma of the pancreas.
- Re-list on the NASDAQ in 2Q 2018.

## 2017 Year-End Financial Results

• At December 31, 2017, the Company reported \$11.8 million in cash, cash equivalents and short-term investments.

As at December 31,	2017 \$	2016 \$	
Assets	Ψ	Ψ	
Current assets			
Cash and cash equivalents	11,836,119	12,034,282	
Short-term investments		2,088,800	
Contract receivable	4,767,100	-	
Other receivables	37,726	54,406	
Prepaid expenses	1,176,063	260,841	
Total current assets	17,817,008	14,438,329	
Non-current assets			
Property and equipment	333,441	319,955	
Total non-current assets	333,441	319,955	
Total assets	18,150,449	14,758,284	
Liabilities And Shareholders' Equity			
Current Liabilities			
Accounts payable and accrued liabilities	3,684,023	4,068,664	
Contract liability	1,545,645	-	
Total current liabilities	5,229,668	4,068,664	
Non-current liabilities			
Contract liability	4,636,935	-	
Total non-current liabilities	4,636,935	-	
Total liabilities	9,866,603	4,068,664	
Shareholders' equity			
Share capital			
Authorized: unlimited			
Issued:			
December 31, 2017 - 141,805,722			
December 31, 2016 - 121,258,222	271,710,138	262,321,825	
Warrants	3,617,900		
Contributed surplus	27,028,238	26,643,044	
Accumulated other comprehensive income	373,730	554,060	
Accumulated deficit	(294,446,160)	(278,829,309)	
Total shareholders' equity	8,283,846	10,689,620	
Total liabilities and equity	18,150,449	14,758,284	

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

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

For the years ending December 31,	2017 \$	2016 \$	2015 \$	
Expenses				
Research and development	9,392,623	9,770,007	8,601,864	
Operating	6,212,831	5,524,500	5,315,837	
Loss before the following	(15,605,454)	(15,294,507)	(13,917,701)	
Interest	130,101	163,902	197,859	
Loss before income taxes	(15,475,353)	(15,130,605)	(13,719,842)	
Income tax expense	(141,498)	(9,374)	(3,153)	
Net loss	(15,616,851)	(15,139,979)	(13,722,995)	
Other comprehensive (loss) income items that may be reclassified to net loss			( · · · )	
Translation adjustment	(180,330)	(206,918)	480,935	
Net comprehensive loss	(15,797,181)	(15,346,897)	(13,242,060)	
Basic and diluted loss per common share	(0.12)	(0.13)	(0.12)	
Weighted average number of shares (basic and diluted)	132,395,752	119,880,200	112,613,845	

CO	ONCOLYTICS BIOTECH INC. ONSOLIDATED STATEMENTS OF CHANGES IN EQUITY Accumulated Other					
	Share Capital \$	Warrants \$	Contributed Surplus \$	Comprehensive Income \$	Accumulated Deficit \$	Total \$
As at December 31, 2014	237,657,056	-	25,848,429	280,043	(249,966,335)	13,819,193
Net loss and other comprehensive income	-	-	-	480,935	(13,722,995)	(13,242,060)
Issued pursuant to Share Purchase Agreement Issued pursuant to "At the Market"	4,371,687	-	-	-	-	4,371,687
Agreement	20,049,693	-	-	-	-	20,049,693
Share based compensation	-	-	429,537	-	-	429,537
Share issue costs	(753,744)	-	-	-	-	(753,744)
As at December 31, 2015	261,324,692	-	26,277,966	760,978	(263,689,330)	24,674,306
Net loss and other comprehensive loss Issued pursuant to incentive share	-	-	-	(206,918)	(15,139,979)	(15,346,897)
award plan Issue pursuant to "At the Market"	41,000	-	(41,000)	-	-	-
Agreement	1,456,296	-	-	-	-	1,456,296
Share based compensation	-	-	406,078	-	-	406,078
Share issue costs	(500,163)	-	-	-	-	(500,163)
As at December 31, 2016	262,321,825	-	26,643,044	554,060	(278,829,309)	10,689,620
Net loss and other comprehensive loss	-	-	-	(180,330)	(15,616,851)	(15,797,181)
Issued pursuant to stock option plan Issued pursuant to "At the Market"	536,949	-	(193,509)	-	-	343,440
Agreement	2,348,821	-	-	-	-	2,348,821
Issued pursuant to public offering	7,893,600	3,617,900	-	-	-	11,511,500
Share based compensation	-	-	578,703	-	-	578,703
Share issue costs	(1,391,057)	-	-	-	-	(1,391,057)
As at December 31, 2017	271,710,138	3,617,900	27,028,238	373,730	(294,446,160)	8,283,846

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

	2017	2016	2015	
For the years ending December 31,	\$	\$	\$	
Operating Activities				
Net loss for the year	(15,616,851)	(15,139,979)	(13,722,995)	
Amortization - property and equipment	90,768	162,233	180,411	
Share based compensation	578,703	406,078	429,537	
Unrealized foreign exchange gain	(124,793)	(139,810)	(816,319)	
Net change in non-cash working capital	180,855	2,233,865	(1,105,464)	
Cash used in operating activities	(14,891,318)	(12,477,613)	(15,034,830)	
Investing Activities	· · ·	· · ·	· · ·	
Acquisition of property and equipment	(105,765)	(23,527)	(108,268)	
Redemption (purchase) of short-term investments	2,088,800	(27,823)	(29,292)	
Cash provided by (used in) investing activities	1,983,035	(51,350)	(137,560)	
Financing Activities		· · ·		
Proceeds from Share Purchase Agreement	-	-	4,305,396	
Proceeds from "At the Market" equity distribution agreement	2,103,166	956,133	19,362,240	
Proceeds from public offering	10,366,098	-	-	
Proceeds from exercise of stock options	343,440	-	-	
Cash provided by financing activities	12,812,704	956,133	23,667,636	
(Decrease) increase in cash	(95,579)	(11,572,830)	8,495,246	
Cash and cash equivalents, beginning of year	12,034,282	24,016,275	14,152,825	
Impact of foreign exchange on cash and cash equivalents	(102,584)	(409,163)	1,368,204	
Cash and cash equivalents, end of year	11,836,119	12,034,282	24,016,275	

To view the Company's Fiscal 2017 year end 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 <u>www.sedar.com</u> and on Oncolytics' investor relations website at <u>https://ir.oncolyticsbiotech.com/reports</u>.

## About Oncolytics Biotech Inc.

Oncolytics is a biotechnology company developing REOLYSIN, also known as pelareorep, an intravenously delivered immuno-oncolytic virus. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype - turning "cold" tumors "hot" - through innate and adaptive immune responses to treat a variety of cancers. Oncolytics' clinical development program emphasizes three pillars: chemotherapy combinations to trigger selective tumor lysis; immuno-therapy combinations to produce adaptive immune responses; and immune modulator (IMiD) combinations to facilitate innate immune responses. Oncolytics is currently planning its first registration study in metastatic breast cancer, as well as studies in combination with checkpoint inhibitors and targeted and IMiD therapies in solid and hematological malignancies. For further information, 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 and forward-looking information under applicable Canadian securities laws (such forward-looking statements and forward-looking information are collectively referred to herein as "forward-looking statements"). Forwardlooking statements, including the Company's belief as to the potential and mode of action of REOLYSIN, also known as pelareorep, as a cancer therapeutic; 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 pelareorep as a cancer treatment, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize pelareorep, 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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