

May 8, 2020



# Oncolytics Biotech® Reports 2020 First Quarter Financial Results and Operational Highlights

SAN DIEGO and CALGARY, Alberta, May 8, 2020 /PRNewswire/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus, today announced its financial results and operational highlights for the quarter ended March 31, 2020. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"With the rapid global spread of COVID-19 in the first quarter of 2020, the operational environment has become challenging. Despite these challenges, we have successfully progressed our clinical objectives," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech Inc. "The first part of 2020 saw positive clinical updates not only in our breast cancer program but also in pancreatic, colorectal, and multiple myeloma. Through our collaborations with academia, the National Cancer Institute, and industry partners, including Roche, Pfizer, and Merck, we have been able to demonstrate that pelareorep is a potent stimulator of both the innate and adaptive immune response across a spectrum of malignancies. These collaborations dramatically expanded our understanding of how pelareorep mobilizes the immune system to combat these malignancies, and we have characterized new biomarkers to more readily identify patients who are most likely to derive benefit from our agent. These new teachings significantly de-risk our clinical program as we move towards a registration study in metastatic breast cancer while pursuing new emerging clinical signals for pelareorep. Looking beyond the first quarter, the COVID-19 pandemic may affect the timelines of our clinical programs. At this point, we are not able to quantify to what extent our programs may be impacted, but we will provide additional guidance as to any such impact as it becomes known to us."

"We have strengthened our balance sheet significantly with a cash balance in excess of \$30.0 million at the end of the first quarter. The Company raised \$18.4 million in financing during the three months ended March 30, 2020. This funding extends our financial runway into the second half of 2021," said Kirk Look, Chief Financial Officer of Oncolytics Biotech. "Importantly, we expect to accomplish multiple data catalysts and operational milestones during this time."

## **First Quarter Highlights**

### ***Clinical & Scientific Highlights***

#### Favourable Safety Committee Assessment for AWARE-1

During the quarter, Oncolytics received a favourable assessment from the Safety Committee

following review of data from the AWARE-1 early-stage breast cancer study. Patients receiving pelareorep and Tecentriq<sup>®</sup> demonstrated productive and tumor cell-specific pelareorep replication along with the creation of a pro-inflammatory effect in the tumor microenvironment. No negative effects to healthy tissue were noted.

### Statistically Significant CEACAM6 Biomarker Data

Statistically significant data identifying CEACAM6 as a prospective biomarker for pelareorep in the treatment of pancreatic cancer was presented at the 2020 Gastrointestinal Cancers Symposium sponsored by ASCO in San Francisco. Low levels of the gene CEACAM6 were associated with prolonged progression free survival increasing over 80%, from 5.72 months on the control arm to 10.32 months (p=0.05) on the test arm.

### Publication in Molecular Cancer Therapeutics

During the quarter, *Molecular Cancer Therapeutics* published a paper highlighting positive clinical data from a phase 1 colorectal cancer study combining FOLFIRI, bevacizumab and pelareorep in colorectal cancer patients. The data demonstrated this combination triggered a robust adaptive immune response highlighted by a unique pattern of dendritic cell maturation followed by CD8 T cell activation observed after every dose of pelareorep. Among 30 evaluable patients, 20% of patients had a partial response, and 73.3% had stable disease, for a clinical benefit rate of 93.3%.

### Key Opinion Leader Call

A Key Opinion Leader call was held featuring Dr. Craig Hofmeister of Winship Cancer Institute at Emory University and Dr. Flavia Pichiorri of the Judy and Bernard Briskin Center for Multiple Myeloma at the City of Hope. Data deliberated on the call demonstrated that carfilzomib promotes pelareorep infection by suppressing the innate antiviral response and suggested that the combination does not interfere with T cell activation. Further, it was noted that pelareorep infection, not proteasome inhibition, upregulated PD-L1 expression on myeloma cells, and the adaptive immune system can then assist in clearing infected tumor cells.

### ***Milestones & News Flow***

- AWARE-1 breast cancer study - interim biomarker data (ESMO Breast Cancer): Q2 2020
- Multiple myeloma study (NCI-9603) - interim data (ASCO)\*: Q2 2020
- Phase 2 second-line pancreatic cancer study – interim data (ASCO)\*: Q2 2020
  - Phase 2 second-line pancreatic cancer study - final data\*: Q4 2020
  - Multiple myeloma study (Opdivo<sup>®</sup> combination) - interim data (ASH)\*: Q4 2020

### ***Anticipated Milestones & News Flow***

While we are making every effort to maintain the timing of our future milestones, the full impact of the pandemic is currently unknown. Patient safety is our foremost concern, and we will provide updates as they become known.

- Initiate phase 2 BRACELET-1 study in HR+ / HER2- mBC
- AWARE-1 breast cancer study - final biomarker data
- Phase 2 BRACELET-1 metastatic breast cancer study - interim safety update
- Complete enrollment in BRACELET-1 metastatic breast cancer study
- Phase 2 BRACELET-1 metastatic breast cancer study - final data

\*Guidance provided by clinical investigators

### ***Financial Highlights***

- As at March 31, 2020, the Company reported \$30.6 million in cash and cash equivalents. The Company raised \$18.4 million during the first quarter through option and warrants exercises and issuing common stock through our ATM facility.
- Operating expense for the first quarter of 2020 was \$3.0 million, compared to \$1.8 million in the first quarter of 2019.
- R&D expense for the first quarter of 2020 was \$2.5 million, compared to \$3.1 million in the first quarter of 2019.
- Net cash used in operating activities for the first quarter of 2020 was \$4.0 million, compared to \$3.4 million for the first quarter of 2019.
- The net income for the first quarter of 2020 was \$0.4 million, compared to a net loss of \$4.9 million in the first quarter of 2019. The basic earnings and diluted loss per share were \$0.01 and \$0.04, respectively, in the first quarter of 2020, compared to a basic and diluted loss per share of \$0.27 in the first quarter of 2019. The diluted loss per share in the first quarter of 2020 was due to the warrant derivative. The net income for the first quarter of 2020 reflected a \$4.2 million non-cash gain in fair value of warrant derivative, compared to nil in the first quarter of 2019. The warrants issued in connection with our August 2019 public offering are required to be treated as a financial instrument and are revalued at each exercise date and reporting period. Gains and losses resulting from the revaluation are non-cash, do not impact our cash flow and are recorded as a change in fair value of warrant derivative. In addition, the net income for the first quarter of 2020 reflected a \$1.7 million foreign exchange gain, compared to a \$0.1 million foreign exchange loss in the first quarter of 2019. The foreign exchange gain and loss incurred was primarily due to unrealized translation gain and loss on U.S. dollar denominated cash balances.

### **Subsequent to Quarter End**

#### ***Financial Highlights***

- As at May 5, 2020, the Company had approximately \$31.6 million in cash and cash equivalents, an unlimited number of authorized common shares with 39,289,208 common shares issued and outstanding, 16,443,500 warrants (exercisable into 1,730,894 common shares) issued in 2017 with a \$9.025 strike price, 478,938 warrants issued in 2019 with a US\$0.90 strike price and 2,465,550 options and share units.

### **About Pelareorep**

Pelareorep is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class intravenously delivered immuno-oncolytic dsRNA virus in development for the treatment of

solid tumors and hematological malignancies. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype through innate and adaptive immune responses to treat a variety of cancers and has been demonstrated to be able to escape neutralizing antibodies found in patients.

## **About Oncolytics Biotech Inc.**

Oncolytics is a biotechnology company developing 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.

Pelareorep has demonstrated synergies with immune checkpoint inhibitors and may also be synergistic with other approved immuno-oncology agents. Oncolytics is currently conducting and planning additional studies in combination with checkpoint inhibitors and targeted therapies in solid and hematological malignancies, as it prepares for a phase 3 registration study in metastatic breast cancer. For further information, please visit:

[www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com).

## **Forward Looking Statements**

*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"). Forward-looking statements, including the Company's belief as to the potential and mode of action of pelareorep as a cancer therapeutic; the Company's plans to move towards a registration study in metastatic breast cancer while pursuing additional clinical signals for pelareorep; the Company's anticipated milestones and news flow, including the Company's expectations regarding the accomplishment of multiple data catalysts and operational milestones and the timing thereof the Company's anticipated financial runway; 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. In particular, we may be impacted by business interruptions resulting from COVID-19 coronavirus, including operating, manufacturing supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). It is unknown whether and how the Company may be affected if the COVID-19 pandemic persists for an extended period of time. We may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business, operating results and financial condition. 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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