

August 4, 2020



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

**Expanded clinical studies to amass clinical proof that pelareorep significantly boosts the effectiveness of high-profile checkpoint inhibitors in breast cancer, multiple myeloma and other cancers**

**Reported a clinical biomarker to identify cancer patients most likely to respond to pelareorep**

**Demonstrated clinically that pelareorep reverses the immunosuppressive microenvironments of tumors**

**Management hosting a conference call and webcast today at 4:30 pm ET**

SAN DIEGO and CALGARY, Alberta, Aug. 4, 2020 /PRNewswire/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced its financial results and operational highlights for the quarter ended June 30, 2020. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"I'm thrilled with the progress made by Oncolytics last quarter, as we achieved numerous value-creating clinical milestones despite the unpredictable challenges presented by COVID-19," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech Inc. "Importantly, we collected critical mechanistic, biomarker, and proof of concept data that advanced our lead breast cancer program. We initiated dosing in our phase 2 BRACELET-1 trial and are enrolling patients in our AWARE-1 study following an expansion in the number of study sites. I am particularly pleased with recent AWARE-1 data presented at the European Society for Medical Oncology (ESMO) Breast Cancer Meeting, which confirm pelareorep's mechanism of action and highlight its potential to synergistically combine with checkpoint

inhibitors and increase the number of patients responding to such therapies. Notably, these data provide strong support for the anticipated success of our BRACELET-1 trial and our recently announced phase 2 IRENE trial, which aims to demonstrate the applicability of pelareorep to an additional disease subtype by evaluating the safety and efficacy of pelareorep-anti-PD-1 combination treatment in triple-negative breast cancer patients."

Dr. Coffey continued, "Alongside the progress made in breast cancer, we also advanced our hematological and gastrointestinal cancer programs. Clinical proof-of-concept data presented at the American Society of Clinical Oncology (ASCO) meeting showed that pelareorep-carfilzomib combination therapy led to a compelling association between clinical and anti-tumor inflammatory response in multiple myeloma patients. When considered with earlier data, these results support our ongoing multiple myeloma trial investigating pelareorep-carfilzomib-checkpoint inhibitor combination therapy. Further, we announced encouraging clinical results in second-line pancreatic cancer patients demonstrating pelareorep-induced expansion and creation of T cell clones in the peripheral blood. Taken together, these compelling data demonstrate the significant progress made last quarter to deepen Oncolytics' pipeline as we target the broad commercial opportunity offered by pelareorep's continued development."

## **Second Quarter Highlights**

### **Clinical Highlights**

#### ***Presented Clinical Findings of Pelareorep-Induced Immune Responses in Multiple Breast Cancer Subtypes***

Newly announced AWARE-1 data presented at the ESMO Breast Cancer Meeting showed that systemic pelareorep administration increased tumor PD-L1 expression, infiltration of tumor immune lymphocytes, and CeTIL (a measurement of tumor-associated cellularity and tumor-infiltrating lymphocytes). These data demonstrate that pelareorep induces adaptive as well as innate immune responses and support the observed survival benefit in a previous randomized phase 2 study of pelareorep in metastatic breast cancer patients. Data also showed that changes in the tumor microenvironment and CeTIL (which is associated with favorable clinical response) correlated with peripheral T cell clonality, supporting its potential as a biomarker of pelareorep response that may aid in future registrational trial study design and patient selection.

#### ***Key Opinion Leader Call Highlighting Compelling AWARE-1 Data***

The call featured Dr. Aleix Prat, M.D., Ph.D., Head of Medical Oncology at the Hospital Clínic of Barcelona, Associate Professor of the University of Barcelona, Head of the Translational Genomics and Targeted Therapeutics in Solid Tumors Group at August Pi i Sunyer Biomedical Research Institute (IDIBAPS), Chair of SOLTI and lead translational investigator of the AWARE-1 study. On the call, Dr. Prat highlighted how AWARE-1 data showing a pelareorep-induced increase in tumor PD-L1 expression demonstrate the synergistic potential between pelareorep and checkpoint inhibitor therapies. Dr. Prat also noted how such data addresses a critical unmet need, as many patients are ineligible for (and fail to respond to) checkpoint inhibitor-based therapies due to an immunosuppressive tumor microenvironment and low PD-L1 expression.

### ***Initiation of Dosing in Phase 2 BRACELET-1 Study***

Oncolytics advanced its lead breast cancer program with the dosing of the first patient in BRACELET-1, a randomized phase 2 study being conducted under a co-development agreement with Merck KGaA (Darmstadt, Germany) and Pfizer. BRACELET-1 is designed to generate mechanistic data supporting the results of a prior successful phase 2 trial that showed a near doubling of overall survival with pelareorep treatment and to evaluate the ability of pelareorep-induced immune responses to enhance anti-PD-L1 therapy. Importantly, the study also seeks to validate peripheral T cell clonality as a biomarker of pelareorep response in HR+/HER2- metastatic breast cancer, which may aid in future registrational trial study design and patient selection.

### ***Announced Investigator Sponsored Phase 2 Trial in Triple-Negative Breast Cancer (TNBC)***

The newly announced multi-center study represents an expansion of Oncolytics' lead breast cancer program into a new disease subtype. The trial, known as IRENE, will investigate the use of pelareorep in combination with Incyte's anti-PD-1 checkpoint inhibitor retifanlimab (INCMGA00012) in patients with unresectable locally advanced or metastatic TNBC. In addition to investigating the safety and efficacy of pelareorep-anti-PD-1 combination treatment in TNBC patients, the study will also evaluate changes in PD-L1 expression and correlations between treatment outcomes and peripheral T cell clonality.

### ***Presented New Clinical Proof-of-Concept Data at the ASCO Virtual Meeting***

The recently announced phase 1b data showed that pelareorep when combined with carfilzomib, activated a profound inflammatory response accompanied by a 50% overall response rate and an 83% clinical benefit rate in patients with challenging to treat carfilzomib-refractory multiple myeloma. The data also showed the first reported incidence of cytokine stimulation associated with tumor response in multiple myeloma, highlighting the ability of pelareorep to induce robust immune cell activation and tumor lysis. Taken together with earlier data from the trial demonstrating pelareorep-induced upregulation of PD-L1 expression, the recently announced results support the success of Oncolytics' ongoing trial investigating pelareorep-carfilzomib-checkpoint inhibitor combination therapy for the treatment of multiple myeloma.

### ***Reported Encouraging Clinical Results in Second-line Pancreatic Cancer Patients***

An abstract published as part of the 2020 ASCO Annual Meeting showed that pelareorep-pembrolizumab combination therapy was well tolerated and resulted in tumor-specific replication, a high degree of T cell repertoire turnover, and the creation of new T cell clones in the peripheral blood of second-line pancreatic cancer patients. Oncolytics plans to publish detailed translational and biomarker data from the study in the first half of 2021.

### ***Upcoming & Anticipated Milestones***

- Dosing of the first patient in phase 2 IRENE study in TNBC: H2 2020
- Announcement of final data from Phase 2 NU 18101 second line pancreatic cancer study\*: H1 2021

Oncolytics expects to provide updates on the timing of the following milestones over the coming months:

- Announcement of interim data from Phase 1 WINSHIP 4398-18 multiple myeloma study
- Interim safety update for phase 2 BRACELET-1 metastatic breast cancer study
- Final biomarker data for AWARE-1 breast cancer study
- Complete enrollment in phase 2 BRACELET-1 metastatic breast cancer study
- Final data for phase 2 BRACELET-1 metastatic breast cancer study

*\*Guidance provided by clinical investigators*

## **Corporate Highlights**

### ***Established New At-The-Market (ATM) Facility***

The ATM provides Oncolytics with the option to efficiently approach financial markets as needed to support ongoing business development activities and clinical trials while bolstering management's ability to negotiate potential business development agreements from a position of financial strength. The company has no obligation to sell any shares pursuant to the ATM.

## **Update on COVID-19**

### ***Company Continues to Efficiently Execute Business Continuity Plan***

Oncolytics has developed a robust business continuity plan to ensure the safety of patients, employees, and investigators, as well as the productivity of our clinical programs. We expect that the continued execution of this plan will allow the Company to build on the positive momentum of last quarter, despite any COVID-19-related challenges that may arise. Moving forward, we will remain in contact with relevant stakeholders and will keep the market apprised of any new information that may impact clinical timelines.

## **Subsequent to Quarter End**

### ***Appointed Thomas C. Heineman, M.D., Ph.D., as Global Head of Clinical Development and Operations***

On August 1, 2020, Oncolytics appointed Thomas C. Heineman, M.D., Ph.D., as the Company's Global Head of Clinical Development and Operations. Dr. Heineman has extensive experience leading clinical development at biotech companies, most recently serving as Senior Vice President and Head of Clinical Development at Denovo Biopharma. Prior to his time at Denovo, Dr. Heineman served as Vice President and Head of Clinical Development at Genocera Biosciences and Halozyme Therapeutics, where he was also the Head of Translational Medicine. Dr. Heineman's experience further extends into big pharma and academia, as he has previously held roles as Senior Director, Global Clinical Research and Development at GlaxoSmithKline and as an Associate Professor at the Saint Louis University School of Medicine. At Oncolytics, Dr. Heineman will be taking over the responsibilities of former Chief Medical Officer Dr. Rita Laeufle, who is no longer with the Company.

## Financial Highlights

- As of June 30, 2020, the Company reported \$29.9 million in cash and cash equivalents. The Company raised \$6.4 million during the second quarter through the issuing of common stock through our ATM facility.
- Operating expense for the second quarter of 2020 was \$3.0 million, compared to \$1.8 million in the second quarter of 2019.
- R&D expense for the second quarter of 2020 was \$2.5 million, compared to \$3.4 million in the second quarter of 2019.
- Net cash used in operating activities for the second quarter of 2020 was \$6.3 million, compared to \$4.7 million for the second quarter of 2019.
- The net loss for the second quarter of 2020 was \$6.8 million, compared to a net loss of \$5.3 million in the second quarter of 2019. The basic and diluted loss per share was \$0.17 in the second quarter of 2020, compared to a basic and diluted loss per share of \$0.26 in the second quarter of 2019.

## Webcast and Conference Call

Management will host a conference call for Analysts and Institutional Investors at 4:30 pm ET, today, August 4, 2020. To access the call please dial (866)-269-4261 (United States) or (323)-347-3612 (international) and provide the Conference ID 2366778. A live webcast of the call will also be available on the Investor Relations page of Oncolytics' website ([LINK](#)) and will be archived for three months.

## About BRACELET-1

The BRACELET-1 (**BR**east **cAn**CEr with the Oncolytic Reovirus **PeL**areor**Ep** in Combina**T**ion with anti- PD-L1 and Paclitaxel) study is an open-label, phase 2, randomized study in patients with HR+/HER2-, endocrine-refractory metastatic breast cancer being conducted under a co-development agreement with [Merck KGaA](#), Darmstadt, Germany and Pfizer. [PRECOG LLC](#), a leading cancer research network, is managing the study. The study will take place at 20 trial sites and enroll 45 patients randomized into three cohorts. A three patient safety run-in will be conducted with patients receiving pelareorep, paclitaxel, and avelumab prior to randomization. The three cohorts will be treated as follows:

- Cohort 1 (n=15): paclitaxel
- Cohort 2 (n=15): paclitaxel + pelareorep
- Cohort 3 (n=18): paclitaxel + pelareorep + avelumab (Bavencio<sup>®</sup>)

Patients in cohort 1 will receive paclitaxel on days 1, 8, and 15 of a 28-day cycle. Patients in cohort 2 will receive the same paclitaxel regimen as cohort 1, plus pelareorep on days 1, 2, 8, 9, 15 and 16 of the 28-day cycle. Patients in cohort 3 will receive the same combination and dosing regimen as cohort 2, plus avelumab on days 3 and 17 of the 28-day cycle. The primary endpoint of the study is overall response rate. Exploratory endpoints include peripheral and tumor T cell clonality, inflammatory markers, and safety and tolerability assessments.

For more information about the BRACELET-1 study, refer to [clinicaltrials.gov](http://clinicaltrials.gov) ([NCT04215146](#)).

## About AWARE-1

AWARE-1 is an open label window-of-opportunity study in early-stage breast cancer enrolling 38 patients into five cohorts:

- Cohort 1 (n=10), HR+ / HER2- (pelareorep + letrozole)
- Cohort 2 (n=10), HR+ / HER2- (pelareorep + letrozole + atezolizumab (Tecentriq®))
- Cohort 3 (n=6), TNBC (pelareorep + atezolizumab)
- Cohort 4 (n=6), HR+ / HER2+ (pelareorep + trastuzumab + atezolizumab)
- Cohort 5 (n=6), HR- / HER2+ (pelareorep + trastuzumab + atezolizumab)

The study combines pelareorep with the standard of care according to breast cancer subtype and atezolizumab. Patients are biopsied on day one followed immediately by treatment, then again on day three, and a final biopsy after three weeks, on the day of their mastectomy. Data generated from this study is intended to confirm that the virus is acting as a novel immunotherapy and to provide comprehensive biomarker data by breast cancer subtype. The primary endpoint of the study is overall CeITIL (a measurement of cellularity and tumor-infiltrating lymphocytes). Secondary endpoints for the study include CeITIL by breast cancer subtype, safety and tumor, and blood-based biomarkers.

For more information about the AWARE-1 study, refer to [clinicaltrials.gov NCT04102618](https://clinicaltrials.gov/NCT04102618)).

## About IRENE

The IRENE (INCMGA00012 and the oncolytic virus pelareorep in metastatic triple-negative breast cancer) study is a single-arm, open-label, phase 2 study evaluating the combination of pelareorep and INCMGA00012 for the treatment of unresectable locally advanced or metastatic triple-negative breast cancer. The study will enroll 25 patients and will be conducted at the [Rutgers Cancer Institute of New Jersey](#) and [The Ohio State University Comprehensive Cancer Center](#).

Study participants will receive pelareorep intravenously on days 1, 2, 15, and 16 of 28-day treatment cycles. INCMGA00012 will be administered on day 3 of each cycle, with treatment cycles continuing until disease progression is observed. The co-primary endpoints of the study are safety and objective response rate. Secondary endpoints include progression free survival, overall survival, and duration of response. Exploratory endpoints include peripheral T cell clonality and pre- vs. post-treatment change in tumor PD-L1 expression.

For more information on the IRENE study, refer to [clinicaltrials.gov NCT04445844](https://clinicaltrials.gov/NCT04445844)).

## About Breast Cancer

Breast cancer is the most common cancer in women worldwide, with over two million new cases diagnosed in 2018, representing about 25 percent of all cancers in women. Incidence rates vary widely across the world, from 27 per 100,000 in Middle Africa and Eastern Asia to 85 per 100,000 in Northern America. It is the fifth most common cause of death from cancer in women globally, with an estimated 522,000 deaths.

Breast cancer starts when cells in the breast begin to grow out of control. These cells usually form a tumor that can often be seen on an x-ray or felt as a lump. The malignant tumor

(cancer) is getting worse when the cells grow into (invade) surrounding tissues or spread (metastasize) to distant areas of the body.

## **About Pelareorep**

Pelareorep is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class intravenously delivered immuno-oncolytic virus 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).

*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 design, aims and timing of our various clinical studies; enrollment in our AWARE-1 study; the anticipated success of our BRACELET-1 study; our ongoing multiple myeloma trial investigating pelareorep-carfilzomib-checkpoint inhibitor combination therapy; our plans to publish detailed translational and biomarker data from the study in the first half of 2021; our expectations regarding the announcement of interim data from Phase 1 WINSHIP 4398-18 multiple myeloma study, interim safety update for phase 2 BRACELET-1 metastatic breast cancer study, final biomarker data for AWARE-1 breast cancer study, complete enrollment in phase 2 BRACELET-1 metastatic breast cancer study, and final data for phase 2 BRACELET-1 metastatic breast cancer study; our continuity plan to ensure the safety of patients, employees, and investigators, as well as the productivity of our clinical 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 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.*

<b>Company Contact</b>	<b>Investor Relations for Oncolytics</b>
Kirk Look	Timothy McCarthy
Chief Financial Officer	LifeSci Advisors
+1-403-670-7658	+1-212-915-2564
KLook@oncolytics.ca	<a href="mailto:tim@lifesciadvisors.com">tim@lifesciadvisors.com</a>

Logo - [https://mma.prnewswire.com/media/1064079/Oncolytics\\_Logo.jpg](https://mma.prnewswire.com/media/1064079/Oncolytics_Logo.jpg)

 View original content: <http://www.prnewswire.com/news-releases/oncolytics-biotech-reports-2020-second-quarter-financial-results-and-operational-highlights-301106010.html>

SOURCE Oncolytics Biotech® Inc.