

August 14, 2023



# Oncolytics Biotech® Reports Second Quarter 2023 Financial Results and Operational Highlights

*Phase 2 data from randomized BRACELET-1 trial in HR+/HER2- metastatic breast cancer showed a near tripling of confirmed ORR, >50% improvement in PFS, and 71% reduction in risk of disease progression*

*Pelareorep selected for inclusion in the Precision Promise<sup>SM</sup> phase 3 platform trial in pancreatic cancer, designed to accelerate registration path and reduce by ~50% phase 3 costs compared to traditional trial*

*\$24.4 million in cash, cash equivalents and marketable securities as of June 30, 2023 provides projected runway into H2 2024*

*Strengthened financial position with a successful US\$15 million public offering on August 8, 2023*

*Management hosting conference call and webcast today at 8:30 a.m. ET*

SAN DIEGO and CALGARY, AB, Aug. 14, 2023 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced recent operational highlights and financial results for the second quarter ended June 30, 2023. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"Our core programs in pancreatic and breast cancer are both progressing rapidly towards registrational studies on the back of the impressive clinical data showing the potential of pelareorep as a backbone immunotherapy," said Dr. Matt Coffey, President and Chief Executive Officer. "Data reported at the American Society of Clinical Oncology (ASCO) Annual Meeting from our BRACELET-1 randomized phase 2 trial demonstrated robust improvements in objective response rate (ORR) and progression-free survival (PFS) with a hazard ratio of 0.29 (95% CI: 0.09, 0.98). This has unlocked the potential for including PFS

as a dual endpoint in our registrational trial, which could considerably reduce the time to a pivotal readout. At the same time, pelareorep was selected for inclusion in the ongoing Precision Promise pancreatic cancer platform trial. Precision Promise, created by the Pancreatic Cancer Action Network, provides us with the opportunity to reduce the time and costs needed for a potential approval, and we are honored to have been selected for participation in this novel and exclusive trial."

## **Second Quarter and Subsequent Highlights**

### **Breast Cancer Program**

#### ***BRACELET-1 data demonstrated a >50% improvement in progression-free survival and a nearly three-fold increase in confirmed overall response rate***

An oral presentation at the ASCO Annual Meeting featured results from a randomized trial of pelareorep in HR+/HER2- metastatic breast cancer. As of a March 3, 2023 cut-off date, BRACELET-1 data in the paclitaxel plus pelareorep cohort showed median PFS of 9.5 months, compared to 6.3 months in the paclitaxel monotherapy cohort. This resulted in a hazard ratio of 0.29 (95% CI: 0.09, 0.98), indicating the pelareorep-paclitaxel combination reduced the risk of disease progression by 71%. Confirmed ORR in these cohorts was 37.5% for paclitaxel plus pelareorep and 13.3% for paclitaxel. Overall survival data continues to mature as several patients are still on study. With these data, the HR+/HER2- metastatic breast cancer program is now phase 3-ready, and, with two randomized phase 2 trials showing meaningful benefits to patients, the focus is now on progressing to a registrational trial evaluating pelareorep-paclitaxel compared to paclitaxel alone.

Oncolytics hosted a key opinion leader (KOL) webinar on June 5, 2023 where breast cancer experts and the management team discussed recent data from the BRACELET-1 study. A link to the replay is available by [clicking here](#).

### **Pancreatic Cancer Program**

#### ***Pelareorep selected for inclusion in Precision Promise Pivotal Phase 3 Platform Trial***

Pelareorep has been selected for inclusion as a new investigational treatment in Precision Promise. Created by the Pancreatic Cancer Action Network (PanCAN), Precision Promise is an innovative adaptive phase 3 clinical trial designed to streamline registration pathways for promising pancreatic cancer therapies. Inclusion is expected to accelerate the registrational pathway and reduce by half the phase 3 costs compared to a traditional trial. The study is designed to evaluate pelareorep in combination with a checkpoint inhibitor and the chemotherapeutic agents gemcitabine and nab-paclitaxel in comparison to gemcitabine and nab-paclitaxel standard of care therapy. This clinical study is expected to support the approval of the pelareorep combination therapy as a treatment for first-line metastatic pancreatic ductal adenocarcinoma.

### **Additional Immunotherapeutic Opportunity**

#### ***Preclinical pelareorep-chimeric antigen receptor (CAR) T cell therapy combination program***

A poster presentation at ASCO showed preclinical results of pelareorep synergistically

enhancing CAR T cell therapy efficacy in murine solid tumor models ([link](#) to the poster). The results suggest pelareorep could substantially expand the commercial potential of CAR T cell therapy beyond hematologic malignancies to include solid tumors, which represent the vast majority of cancer cases. Oncolytics is currently advancing preclinical research collaborations evaluating pelareorep-CAR T cell combination therapies.

## Financial Highlights

- As of June 30, 2023, the Company reported \$24.4 million in cash, cash equivalents, and marketable securities, then successfully closed a US\$15 million public offering on August 8, 2023. On a pro forma basis, including the estimated US\$13.6 million in net proceeds from the public offering, the Company's cash, cash equivalents and marketable securities would have been approximately \$42.7 million.
- The net loss for the second quarter of 2023 was \$7.4 million, compared to a net loss of \$5.1 million for the second quarter of 2022. The basic and diluted loss per share was \$0.12 in the second quarter of 2023, compared to a basic and diluted loss per share of \$0.09 in the second quarter of 2022.
- Net cash used in operating activities for the six months ended June 30, 2023 was \$16.3 million, compared to \$13.2 million for the six months ended June 30, 2022. The change reflected higher net operating activities and non-cash working capital changes.
- General and administrative expenses for the second quarter of 2023 were \$3.5 million, compared to \$2.8 million for the second quarter of 2022. The increase was primarily due to higher investor relations activities and annual general meeting of shareholders costs.
- Research and development expenses for the second quarter of 2023 were \$3.7 million, compared to \$3.2 million for the second quarter of 2022. The increase was primarily due to higher manufacturing expenses associated with an engineering production run along with process and analytical development activities and higher personnel-related expenses. The increase was partly offset by lower BRACELET-1 study costs.

## Anticipated Milestones and Catalysts

- Updated GOBLET study data in advanced/metastatic pancreatic ductal adenocarcinoma (PDAC): H2 2023
- Update on GOBLET study's metastatic colorectal and anal cancer cohorts: H2 2023
- Guidance on both the HR+/HER2- metastatic breast cancer and advanced/metastatic PDAC registration paths: H2 2023
- BRACELET-1 phase 2 metastatic breast cancer study overall survival data

## Webcast and Conference Call

Management will host a conference call for analysts and investors at 8:30 a.m. ET today, August 14, 2023. To access the call, please dial (888) 664-6383 (North America) or (416) 764-8650 (International) and, if needed, provide confirmation number 5411-4798. To join the conference call without operator assistance, please [click here](#). A live webcast of the call will also be available by [clicking here](#) or on the Investor Relations page of Oncolytics' website ([LINK](#)) and will be archived for three months. A dial-in replay will be available for one week and can be accessed by dialing (888) 390-0541 (North America) or (416) 764-8677 (International) and using replay code: 114-798#.

**ONCOLYTICS BIOTECH INC.****CONDENSED INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION****(unaudited)**

(in thousands of Canadian dollars, except share amounts)

As at	June 30, 2023	December 31, 2022
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 17,520	\$ 11,666
Marketable securities	6,831	20,472
Other receivables	559	521
Prepaid expenses	6,085	3,025
<b>Total current assets</b>	<b>30,995</b>	<b>35,684</b>
Property and equipment	318	356
Right-of-use assets	426	296
Prepaid expenses	227	998
<b>Total assets</b>	<b>\$ 31,966</b>	<b>\$ 37,334</b>
<b>Liabilities and Shareholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 2,365	\$ 3,650
Lease liabilities	133	216
Warrant derivative	153	79
<b>Total current liabilities</b>	<b>2,651</b>	<b>3,945</b>
Contract liability	6,730	6,730
Lease liabilities	346	157
<b>Total liabilities</b>	<b>9,727</b>	<b>10,832</b>
Commitments and contingencies		
<b>Shareholders' equity</b>		
Share capital		
Authorized: unlimited		
Issued: June 30, 2023 – 65,701,797		
December 31, 2022 – 61,327,914	413,424	404,040
Contributed surplus	40,390	40,051
Accumulated other comprehensive income	554	662
Accumulated deficit	(432,129)	(418,251)
<b>Total shareholders' equity</b>	<b>22,239</b>	<b>26,502</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 31,966</b>	<b>\$ 37,334</b>

**ONCOLYTICS BIOTECH INC.****CONDENSED INTERIM CONSOLIDATED STATEMENTS OF LOSS AND  
COMPREHENSIVE LOSS****(unaudited)**

(in thousands of Canadian dollars, except share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
<b>Expenses</b>				
Research and development	\$ 3,701	\$ 3,204	\$ 7,240	\$ 6,912
General and administrative	3,459	2,842	6,654	5,444
<b>Loss before the following</b>	<b>(7,160)</b>	<b>(6,046)</b>	<b>(13,894)</b>	<b>(12,356)</b>
Change in fair value of warrant derivative	(107)	39	(76)	26
Foreign exchange (loss) gain	(394)	888	(393)	414
Interest income, net	267	49	532	68
<b>Loss before income taxes</b>	<b>(7,394)</b>	<b>(5,070)</b>	<b>(13,831)</b>	<b>(11,848)</b>
Income tax expense	(47)	(25)	(47)	(25)
<b>Net loss</b>	<b>(7,441)</b>	<b>(5,095)</b>	<b>(13,878)</b>	<b>(11,873)</b>
<b>Other comprehensive (loss) income items that may be reclassified to net loss</b>				
Translation adjustment	(105)	113	(108)	65
<b>Net comprehensive loss</b>	<b>(7,546)</b>	<b>(4,982)</b>	<b>(13,986)</b>	<b>(11,808)</b>
	\$	\$	\$	\$
<b>Basic and diluted loss per common share</b>	<b>(0.12)</b>	<b>(0.09)</b>	<b>(0.22)</b>	<b>(0.21)</b>
<b>Weighted average number of shares (basic and diluted)</b>	<b>64,467,908</b>	<b>57,669,167</b>	<b>63,412,091</b>	<b>57,125,833</b>

## ONCOLYTICS BIOTECH INC.

### CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(unaudited)

(in thousands of Canadian dollars)

	Share Capital	Warrants	Contributed Surplus	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
As at December 31, 2021	\$ 391,348	\$ 3,618	\$ 34,161	\$ 388	\$ (393,416)	\$ 36,099
Net loss and other comprehensive loss	—	—	—	65	(11,873)	(11,808)
Issued pursuant to stock option plan	20	—	(8)	—	—	12
Issued pursuant to incentive share award plan	98	—	(98)	—	—	—
Expiry of equity warrant agreement	—	(3,618)	3,618	—	—	—
Issued pursuant to "At the Market" Agreement	5,819	—	—	—	—	5,819
Share issue costs	(478)	—	—	—	—	(478)
Share-based compensation expense	—	—	1,129	—	—	1,129
<b>As at June 30, 2022</b>	<b>\$ 396,807</b>	<b>\$ —</b>	<b>\$ 38,802</b>	<b>\$ 453</b>	<b>\$ (405,289)</b>	<b>\$ 30,773</b>
As at December 31, 2022	\$ 404,040	\$ —	\$ 40,051	\$ 662	\$ (418,251)	\$ 26,502
Net loss and other comprehensive loss	—	—	—	(108)	(13,878)	(13,986)
Issued pursuant to stock option plan	563	—	(220)	—	—	343
Issued pursuant to "At the Market" Agreement	9,128	—	—	—	—	9,128
Share issue costs	(307)	—	—	—	—	(307)
Share-based compensation expense	—	—	559	—	—	559
<b>As at June 30, 2023</b>	<b>\$ 413,424</b>	<b>\$ —</b>	<b>\$ 40,390</b>	<b>\$ 554</b>	<b>\$ (432,129)</b>	<b>\$ 22,239</b>

## ONCOLYTICS BIOTECH INC.

### CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands of Canadian dollars)

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Operating Activities</b>		
Net loss for the period	\$ (13,878)	\$ (11,873)
Depreciation - property and equipment	42	48
Depreciation - right-of-use-assets	151	148
Share-based compensation expense	559	1,129
Interest (income) expense, net	(21)	45
Unrealized foreign exchange loss (gain)	213	(376)
Change in fair value of warrant derivative	76	(26)
Net change in non-cash working capital	(3,436)	(2,264)
<b>Cash used in operating activities</b>	<b>(16,294)</b>	<b>(13,169)</b>
<b>Investing Activities</b>		
Acquisition of property and equipment	(5)	(47)
Maturities of marketable securities	13,464	—
<b>Cash provided by (used in) investing activities</b>	<b>13,459</b>	<b>(47)</b>
<b>Financing Activities</b>		
Proceeds from exercise of stock options	343	12
Proceeds from "At the Market" equity distribution agreement	8,821	5,341
Payment of lease liabilities	(201)	(183)
<b>Cash provided by financing activities</b>	<b>8,963</b>	<b>5,170</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>6,128</b>	<b>(8,046)</b>
Cash and cash equivalents, beginning of period	11,666	41,262
Impact of foreign exchange on cash and cash equivalents	(274)	473
<b>Cash and cash equivalents, end of period</b>	<b>\$ 17,520</b>	<b>\$ 33,689</b>

## About the Pancreatic Cancer Action Network

The Pancreatic Cancer Action Network (PanCAN) leads the way in accelerating critical progress for pancreatic cancer patients. PanCAN takes bold action by funding life-saving research, providing personalized patient services and creating a community of supporters and volunteers who will stop at nothing to create a world in which all pancreatic cancer patients will thrive. For 18 years in a row, PanCAN has earned a Four-Star Rating from Charity Navigator – the highest rating an organization can receive. This rating designates PanCAN as an official "Give with Confidence" charity, indicating strong financial health, ongoing accountability and transparency.

## About Oncolytics Biotech Inc.

Oncolytics is a biotechnology company developing pelareorep, an intravenously delivered immunotherapeutic agent. This compound induces anti-cancer immune responses 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 multiple approved oncology treatments. Oncolytics is currently conducting and planning combination clinical trials with pelareorep in solid and hematological malignancies as it advances towards registrational studies in metastatic breast cancer and pancreatic 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 contained in this press release include statements regarding Oncolytics' belief as to the potential and benefits of pelareorep as a cancer therapeutic; our belief that our core programs in pancreatic and breast cancer are both progressing rapidly towards registrational studies; our belief that recent data has unlocked the potential for including PFS as a dual endpoint in our registrational trial, which could considerably reduce the time to a pivotal readout; our plans and expectations regarding the inclusion of pelareorep in the Precision Promise pancreatic cancer platform trial; our anticipated milestones and catalysts; our plans to advance towards a registrational study in metastatic breast cancer and pancreatic cancer; our belief that our combined cash resources provide a runway into H2 2024; and other statements related to anticipated developments in Oncolytics' business and technologies. In any forward-looking statement in which Oncolytics expresses an expectation or belief as to future results, such expectations or beliefs are expressed in good faith and are believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will be achieved. Such forward-looking statements involve known and unknown risks and uncertainties, which could cause Oncolytics' 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, Oncolytics' 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 Oncolytics 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 Oncolytics' 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 any obligation to update these forward-looking statements, except as required by applicable laws.


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