

Oncolytics Biotech® Reports First Quarter 2023 Financial Results and Operational Highlights

Randomized phase 2 data from BRACELET-1 trial in HR+/HER2- metastatic breast cancer to be shared in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting

Guidance on the registration paths for pelareorep in HR+/HER2- metastatic breast and firstline pancreatic cancer expected in H2 2023

\$29.7 million in cash, cash equivalents, and marketable securities as of March 31, 2023 provides projected cash runway for at least 12 months

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

SAN DIEGO, Calif. and CALGARY, AB, May 5, 2023 /CNW/ -- Oncolytics Biotech[®] Inc. (NASDAQ: ONCY) (TSX: ONC) today announced recent operational highlights and financial results for the first quarter ended March 31, 2023. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"Our core programs in breast and pancreatic cancer are moving towards registrational studies with compelling clinical data and important milestones expected this year," said Dr. Matt Coffey, President and Chief Executive Officer. "The first of these milestones will come later this month when we report data from BRACELET-1, a randomized phase 2 trial expected to inform the design of a subsequent pivotal registrational study in HR+/HER2-metastatic breast cancer. Stakeholders across the breast cancer community have demonstrated a keen interest in this readout, which will add to a dataset that already includes statistically significant phase 2 results showing pelareorep's ability to drive a robust overall survival benefit in this indication. Notably, the BRACELET-1 abstract was selected for an oral presentation at the upcoming ASCO meeting, providing a highly prestigious venue to discuss the results with potential partners and the clinical community."

Dr. Coffey continued, "Looking into the second half of 2023, we expect to report updated results from GOBLET's first-line pancreatic cancer cohort and provide guidance on the optimal registration paths for our breast and pancreatic cancer programs. With these programs both targeting large markets with significant clinical unmet needs and supported by robust clinical proof-of-concept data, we believe confirming their paths towards approval will represent important value-creating events and substantially de-risk and maintain pelareorep's development pathway."

First Quarter and Subsequent Highlights

Breast Cancer Program

BRACELET-1 data to be shared in an oral presentation at the ASCO Annual Meeting

BRACELET-1 is designed to confirm and expand upon Oncolytics' prior positive clinical results for pelareorep in HR+/HER2- metastatic breast cancer and inform the design of a subsequent registrational study. These prior data include phase 1 results demonstrating pelareorep's single-agent activity, as well as randomized phase 2 data that showed a statistically significant near doubling of median overall survival in patients treated with pelareorep combined with paclitaxel compared to those treated with paclitaxel monotherapy. Additionally, data from early-stage HR+/HER2- breast cancer patients demonstrated pelareorep's ability to stimulate anti-tumor immunity, remodel tumor microenvironments, and potentially improve patient prognosis by decreasing the risk of cancer recurrence score.

BRACELET-1 includes cohorts evaluating paclitaxel monotherapy, paclitaxel plus pelareorep, and paclitaxel plus pelareorep in combination with avelumab in HR+/HER2-metastatic breast cancer. The trial was designed to enroll a total of 48 patients and is not powered to detect statistical significance. An abstract corresponding to the upcoming oral presentation will be published by ASCO on May 25, 2023, at 5:00 p.m. ET. The oral presentation will take place on June 3, 2023, during a session being held from 2:15 p.m. – 3:45 p.m. ET.

Additional Immunotherapeutic Opportunity

Upcoming ASCO poster on preclinical pelareorep-chimeric antigen receptor (CAR) T cell therapy combination program

The poster, titled "Efficacy of function-enhanced, re-activatable, dual-specific CAR T cells pre-loaded with oncolytic virus for immunotherapy of high-grade glioma," will be presented in Poster Hall A from 2:15 p.m. – 5:15 p.m. ET on June 3, 2023. The corresponding abstract will be published prior to the ASCO meeting, on May 25, 2023, at 5:00 p.m. ET.

The data to be presented at the ASCO meeting follow preclinical results published in *Science Translational Medicine (STM)*, which showed pelareorep synergistically enhancing the efficacy of CAR T cell therapy in murine solid tumor models (<u>link</u> to PR, <u>link</u> to the paper). Oncolytics is currently advancing preclinical research collaborations evaluating pelareorep-CAR T cell combination therapies, one of which has generated results with a potential partner's own CAR T constructs that are in-line with those published in the *STM* publication.

Key Opinion Leader Webinar

Oncolytics will host a key opinion leader (KOL) webinar on June 5, 2023 at 8 a.m. ET, where KOLs and the Oncolytics management team will discuss recent data from the BRACELET-1 study. A live question and answer session will follow the formal presentation.

To register for the webinar, please click<u>here</u>.

Financial Highlights

- As of March 31, 2023, the Company reported \$29.7 million in cash, cash equivalents, and marketable securities.
- The net loss for the first quarter of 2023 was \$6.4 million, compared to a net loss of \$6.8 million for the first quarter of 2022. The basic and diluted loss per share was \$0.10 in the first quarter of 2023, compared to a basic and diluted loss per share of \$0.12 in the first quarter of 2022.
- Net cash used in operating activities for the three months ended March 31, 2023 was \$7.8 million, compared to \$6.3 million for the three months ended March 31, 2022. The change reflected higher net operating activities and non-cash working capital changes.
- General and administrative expenses for the first quarter of 2023 were \$3.2 million, compared to \$2.6 million for the first quarter of 2022. The increase was mainly due to increased investor relations activities, partly offset by lower share-based compensation expense.
- Research and development expenses for the first quarter of 2023 were \$3.5 million, compared to \$3.7 million for the first quarter of 2022. The decrease was primarily due to lower BRACELET-1 study costs and share-based compensation expense, partly offset by increased manufacturing expenses associated with a process development production run and higher personnel-related expenses.

2023 Anticipated Milestones and Catalysts

- Overall response rate and progression-free survival data from phase 2 BRACELET-1 metastatic breast cancer study: Q2 2023
- Preclinical data from the combination of pelareorep and CAR T cell therapy: Q2 2023
- Updated data in advanced/metastatic pancreatic ductal adenocarcinoma (PDAC) from the GOBLET study: H2 2023
- Update on the metastatic colorectal and anal cancer cohorts from the GOBLET study: H2 2023
- Guidance for the registration paths for HR+/HER2- metastatic breast cancer and advanced/metastatic PDAC: H2 2023

Webcast and Conference Call

Management will host a conference call for analysts and investors at 8:30 a.m. ET today, May 5, 2023. To access the call, please dial (888) 664-6383 (North America) or (416) 764-8650 (International) and, if needed, provide confirmation number 3550-3191. To join the conference call without operator assistance, please <u>click here</u>. A live webcast of the call will also be available by <u>clicking here</u> or on the Investor Relations page of Oncolytics' website (<u>LINK</u>) 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: 503-191#.

ONCOLYTICS BIOTECH INC.

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(unaudited)

(in thousands of Canadian dollars, except share amounts)

As at	March 31, 2023		December 31, 2022	
Assets	2023		LULL	
Current assets				
Cash and cash equivalents	\$	15,872	\$	11,666
Marketable securities	• 13,798		¥ 20,472	11,000
Other receivables	730		521	
Prepaid expenses	3,861		3,025	
Total current assets	34,261		35,684	
Property and equipment	339		356	
Right-of-use assets	501		296	
Prepaid expenses	227		998	
Total assets	\$	35,328	\$	37,334
Liabilities and Shareholders' Equity				
Current liabilities				
	\$		\$	
Accounts payable and accrued liabilities	2,232		3,650	
Lease liabilities	189		216	
Warrant derivative	48		79	
Total current liabilities	2,469		3,945	
Contract liability	6,730		6,730	
Lease liabilities	378		157	
Total liabilities	9,577		10,832	
Commitments and contingencies				
Shareholders' equity				
Share capital				
Authorized: unlimited				
Issued: March 31, 2023 – 63,990,950	400 440		404 040	
December 31, 2022 – 61,327,914	409,412		404,040	
Contributed surplus	40,368		40,051 662	
Accumulated other comprehensive income Accumulated deficit) \		1
	(424,688)	(418,251)
Total shareholders' equity	25,751 ¢	25 220	26,502 \$	37,334
Total liabilities and shareholders' equity	\$	35,328	ψ	57,334

ONCOLYTICS BIOTECH INC.

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands of Canadian dollars, except share amounts)

For the three months ended March 31,	2023		2022	
Expenses				
Research and development	\$	3,539	\$	3,708
General and administrative	3,195		2,602	
Loss before the following	(6,734)		(6,310)	
Change in fair value of warrant derivative	31		(13)	
Foreign exchange gain (loss)	1		(474)	
Interest income, net	265		18	
Net loss	(6,437)		(6,779)	
Other comprehensive loss items that may be reclassified to net loss				
Translation adjustment	(3)		(47)	
Net comprehensive loss	\$	(6,440)	\$	(6,826)
Basic and diluted loss per common share	\$	(0.10)	\$	(0.12)
Weighted average number of shares (basic and diluted)	62,344,544		56,576,462	

ONCOLYTICS BIOTECH INC.

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(unaudited)

(in thousands of Canadian dollars)

	Share Capital	Warrants	Contributed Surplus		ated Other ensive 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	—	—		(47)		(6,779)	(6,826)
Issued pursuant to stock option							
plan (notes 6, 7)	19	_	(7)	—		—	12
Issued pursuant to incentive share							
award plan (notes 6, 7)	46	—	(46)			—	—
Issued pursuant to "At the Market"							
Agreement (note 6)	5,267	—				—	5,267
Share issue costs (note 6)	(176)	—				—	(176)
Share-based compensation							
expense (note 7)	—	—	639	—		—	639
	\$	\$	\$			\$	\$
As at March 31, 2022	396,504	3,618	34,747	\$	341	(400,195)	35,015
	\$	\$	\$			\$	\$
As at December 31, 2022	404,040	÷ —	40,051	\$	662	(418,251)	26,502
Net loss and other comprehensive	,		,	Ŧ		(,,	
loss	_	_	_	(3)		(6,437)	(6,440)
Issued pursuant to "At the Market"				(-)		(-,)	(-,)
Agreement (note 6)	5,552	_	_			_	5,552
Share issue costs (note 6)	(180)	_		_		_	(180)
Share-based compensation	(,						()
expense (note 7)	_	_	317	_		_	317
• • • •	\$	\$	\$			\$	\$
As at March 31, 2023	409,412	—	40,368	\$	659	(424,688)	25,751
	-	:	=				

ONCOLYTICS BIOTECH INC.

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands of Canadian dollars)

For the three months ended March 31,	2023		2022	
Operating Activities				
Net loss for the period	\$	(6,437)	\$	(6,779)
Depreciation - property and equipment	21		24	
Depreciation - right-of-use-assets	76		74	
Share-based compensation expense	317		639	
Interest (income) expense, net	(96)		24	
Unrealized foreign exchange (gain) loss	(124)		410	
Change in fair value of warrant derivative	(31)		13	
Change in non-cash working capital	(1,555)		(657)	
Cash used in operating activities	(7,829)		(6,252)	
Investing Activities				
Acquisition of property and equipment	(5)		(36)	
Maturities of marketable securities	6,674		_	
Cash provided by (used in) investing activities	6,669		(36)	
Financing Activities				
Proceeds from exercise of stock options	_		12	
Proceeds from "At the Market" equity distribution				
agreement	5,372		5,091	
Payment of lease liabilities	(101)		(89)	
Cash provided by financing activities	5,271		5,014	
Increase (decrease) in cash and cash equivalents	4,111		(1,274)	
Cash and cash equivalents, beginning of period	11,666		41,262	
Impact of foreign exchange on cash and cash equivalents	95		(505)	
Cash and cash equivalents, end of period	\$	15,872	\$	39,483

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 immune checkpoint inhibitors and may also be synergistic with other approved oncology treatments. Oncolytics is currently conducting and planning clinical trials evaluating pelareorep in combination with checkpoint inhibitors and targeted therapies in solid and hematological malignancies as it advances towards registration studies in metastatic breast cancer and pancreatic cancer. For further information, please visit: <u>www.oncolyticsbiotech.com</u>.

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 2023 milestones and catalysts and the anticipated timing thereof and expected benefits therefrom, including the release of data in relation to our BRACELET-1 study in Q2 2023, our study on the combination of pelareorep and CAR T cell therapy in Q2 2023; our GOBLET study in H2 2023 and the release of guidance for the registration paths for HR+/HER2- metastatic breast cancer and advanced/metastatic PDAC in H2 2023; our plans to advance towards a registration study in metastatic breast cancer and pancreatic cancer; 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 or anticipated milestones and catalysts, 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. Additionally, general market conditions resulting from high inflation, high interest rates, the Russia-Ukraine conflict, bank failures, general market uncertainty, and other macroeconomic factors, as well as market conditions affecting companies in the life sciences industry in general, may make it difficult to obtain financing from the capital markets on attractive terms or at all. 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 forwardlooking statements, except as required by applicable laws.

Logo: https://mma.prnewswire.com/media/1808285/4021219/Oncolytics_Biotech_Grey.jpg

	Investor Relations for
Company Contact	Oncolytics
Jon Patton	Timothy McCarthy
Director of IR & Communication	LifeSci Advisors
+1-858-886-7813	+1-917-679-9282
jpatton@oncolytics.ca	tim@lifesciadvisors.com

C View original content to download multimedia<u>https://www.prnewswire.com/news-</u> releases/oncolytics-biotech-reports-first-quarter-2023-financial-results-and-operationalhighlights-301816734.html

SOURCE Oncolytics Biotech® Inc.