

August 11, 2022



Oncolytics Biotech® Reports Second Quarter 2022 Financial Results and Recent Operational Highlights

Phase 2 BRACELET-1 trial fully enrolled and advancing towards a randomized data readout that is expected to inform the design of a registrational study in HR+/HER2- breast cancer

Achieved success criteria for efficacy in Stage 1 of the GOBLET trial's pancreatic cancer cohort with partial responses in all phase 1b patients

Clinical biomarker data show pelareorep remodeling tumor microenvironments to improve prognosis and decrease the risk of recurrence in HR+/HER2- breast cancer patients

\$33.7 million in cash and cash equivalents provides projected runway into the second half of 2023 and through key clinical readouts in breast and pancreatic cancer

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

SAN DIEGO and CALGARY, AB, Aug. 11, 2022 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced recent operational highlights and financial results for the second quarter ended June 30, 2022. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"Recent clinical data in breast and pancreatic cancer highlight pelareorep's multifaceted mechanism of action and the broad therapeutic benefits it confers," said Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech Inc. "Results from AWARE-1 showed pelareorep activating cancer-killing T cells and modifying HR+/HER2- breast tumor microenvironments in ways that improve patient prognosis and long-term outlook. In the GOBLET trial's pancreatic cancer cohort, we were thrilled to see objective responses in all phase 1b patients, suggesting pelareorep's clinically demonstrated synergy with checkpoint inhibition in breast cancer extends into additional difficult-to-treat indications. Together, these findings further position pelareorep as an immune platform molecule that can enhance the efficacy of a variety of drug classes to improve treatment paradigms across a range of

indications."

Dr. Coffey continued, "As we move forward, we are focused internally on pursuing strong signals of efficacy observed with pelareorep in breast and pancreatic cancer. With BRACELET-1 now fully enrolled, we are on a clear path towards a randomized phase 2 readout that is expected to validate prior positive survival data and catalyze our advancement into a registrational breast cancer study. If GOBLET's initial results continue to show similar indications of efficacy, we will work to move expeditiously towards a late-stage pancreatic cancer trial that will de-risk our pipeline and provide additional opportunities to create stakeholder value. Alongside these internal programs, we continue to leverage preclinical data demonstrating pelareorep's synergy with CAR T cells against solid tumors to advance business development efforts. We are fortunate to be supported in these various endeavors by a suite of top-flight biopharma collaborators, which allows us to execute on our objectives with a capital-efficient approach."

Second Quarter and Subsequent Highlights

Breast Cancer Program

Completed enrollment in phase 2 BRACELET-1 trial

BRACELET-1 is a randomized phase 2 trial in HR+/HER2- metastatic breast cancer that is being conducted under a co-development agreement with Pfizer Inc. and Merck KGaA (Darmstadt, Germany). Data from the trial represent the final confirmatory component of a data package Oncolytics intends to share with regulators to align on the best design for a registrational study. This package will also include the results of IND-213, a prior randomized phase 2 study in HR+/HER2- breast cancer that showed a statistically significant near doubling of median overall survival when pelareorep was combined with paclitaxel.

Following the completion of BRACELET-1's 16-week patient monitoring period and database lock, Oncolytics will provide Pfizer and Merck KGaA with a study report. Delivery of the report will trigger a contractually-obligated 90-day exclusivity period during which the data cannot be publicly disclosed. Based on the expected timing of these steps, Oncolytics anticipates the public disclosure of BRACELET-1's data to occur at a major oncology meeting in the first half of 2023. The change in the expected timing of the trial's first data announcement will allow Oncolytics and its partners and collaborators to showcase not only top-line data on overall response rate, but also mature progression-free survival data, evolving overall survival data, and translational data. Oncolytics believes presenting this dataset as a whole will aid in its efforts to advance pelareorep towards registration as efficiently as possible. Oncolytics remains engaged with regulators and partners as it plans its registration program.

Biomarker data from AWARE-1 show pelareorep remodeling tumor microenvironments to improve prognosis and decrease the risk of recurrence in HR+/HER2- breast cancer patients

A poster presentation at the European Society for Medical Oncology (ESMO) Breast Cancer Meeting featured data from AWARE-1's first two cohorts, which evaluated changes in HR+/HER2- breast tumor microenvironments (TMEs) following treatment with pelareorep

and letrozole without (cohort 1) or with (cohort 2) Roche's anti-PD-L1 checkpoint inhibitor atezolizumab. These data showed the prognosis of patients improving and their risk of cancer recurrence decreasing following treatment, as assessed by the well-validated PAM50 gene expression assay ([link](#) to PR, [link](#) to poster). All evaluable patients had a 'low' Risk of Recurrence Score after treatment compared to only 55% at baseline. Statistically significant increases in markers of tumor cell death and T cell activation were also observed. Together, these data further demonstrate pelareorep's ability to activate the immune system and remodel TMEs in ways that improve the long-term outlook of cancer patients. Oncolytics anticipates presenting final AWARE-1 data in the fourth quarter of 2022.

Gastrointestinal Cancer Program

Achieved success criteria for efficacy in Stage 1 of the GOBLET trial's pancreatic cancer cohort with partial responses in all phase 1b patients

Initial clinical data from the phase 1/2 GOBLET study's pancreatic cancer cohort were featured in a poster at the ESMO World Congress on Gastrointestinal Cancer 2022 ([link](#) to PR, [link](#) to poster). These data revealed a strong efficacy signal with all phase 1b patients (n = 3) achieving a partial response following treatment with pelareorep in combination with atezolizumab and the chemotherapeutic agents gemcitabine and nab-paclitaxel. With these responses, the pancreatic cancer cohort has achieved the pre-specified success criteria for Stage 1. An independent safety review identified no safety concerns associated with the study treatment and recommended the study continue as planned. Collectively, these data suggest pelareorep synergizes with atezolizumab in pancreatic cancer and strongly support its continued evaluation in this highly challenging and prevalent indication. Oncolytics plans to report additional efficacy data on all evaluable patients in Stage 1 of GOBLET's pancreatic cancer cohort at a major medical meeting in late 2022.

Additional Immunotherapeutic Opportunity

Science Translational Medicine paper provides external validation for the synergistic efficacy of pelareorep combined with chimeric antigen receptor (CAR) T cell therapy in murine solid tumor models

While long-term cures have been achieved with CAR T cell therapies in hematologic malignancies¹, their efficacy against solid tumors has generally been poor. This severely limits the therapeutic and commercial potential of these therapies, as solid tumors represent the vast majority of cancer cases. A peer-reviewed preclinical study published in *Science Translational Medicine* suggests that pelareorep has the potential to realize the value of CAR T cells by enabling their success against solid tumors. In murine models of brain and skin cancer, loading CAR T cells with pelareorep led to statistically significant survival benefits compared to treatment with CAR T therapy alone ([link](#) to PR, [link](#) to the paper). The efficacy of pelareorep-loaded CAR T cells was augmented when mice received a subsequent intravenous dose (boost) of pelareorep, with results showing tumor cures in >80% of treated mice in each model. These impressive results were linked to the ability of pelareorep-loaded CAR T cells to overcome the three most significant barriers to effective CAR T therapy by dramatically increasing CAR T cell persistence, reversing immunosuppressive TMEs, and reducing antigen escape. Pelareorep's ability to reduce antigen escape was due to the generation of dual-specific CAR T cells that targeted both tumor-derived and pelareorep proteins within the tumor. These immunotherapeutic effects

position pelareorep to substantially expand the commercial potential presented by CAR T cell therapies since solid tumors offer a significant and unaddressed opportunity.

Corporate Updates

Elected James T. Parsons to the Board of Directors

Mr. Parsons has over twenty years of executive experience in the life sciences industry and served as Chief Financial Officer (CFO) of the immuno-oncology company Trillium Therapeutics Inc. through its acquisition by Pfizer for an aggregate purchase price of approximately US\$2.2 billion.

Financial Highlights

- As of June 30, 2022, the Company reported \$33.7 million in cash and cash equivalents.
- Operating expense for the second quarter of 2022 was \$2.8 million, compared to \$3.5 million for the second quarter of 2021.
- R&D expense for the second quarter of 2022 was \$3.2 million, compared to \$3.2 million for the second quarter of 2021.
- The net loss for the second quarter of 2022 was \$5.1 million, compared to a net loss of \$7.2 million in the second quarter of 2021. The basic and diluted loss per share was \$0.09 in the second quarter of 2022, compared to a basic and diluted loss per share of \$0.13 in the second quarter of 2021.
- Net cash used in operating activities for the second quarter of 2022 was \$6.9 million, compared to \$6.8 million in the second quarter of 2021.

Anticipated Milestones and Catalysts

- Additional efficacy data on all evaluable patients in Stage 1 of the phase 1/2 GOBLET study's pancreatic cohort: Q4 2022
- Final AWARE-1 study data: Q4 2022
- Clinical data from Adlai Nortye's bridging trial in HR+/HER2- metastatic breast cancer patients: Q4 2022
- Overall response rate, progression-free survival, and evolving overall survival data from phase 2 BRACELET-1 metastatic breast cancer study: H1 2023

Webcast and Conference Call

Management will host a conference call for analysts and institutional investors at 8:30 a.m. ET today, August 11, 2022. To access the call, please dial (888) 220-8474 (North America) or (647) 484-0475 (International) and, if needed, provide confirmation number 8806-576. 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) 203-1112 (North America) or (647) 436-0148 (International) and using replay code: 8806-576#.

ONCOLYTICS BIOTECH INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
(unaudited)
(in Canadian dollars, except share amounts)

As at	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 33,689,255	\$ 41,262,044
Other receivables	355,606	866,055
Prepaid expenses	5,362,596	2,775,800
Total current assets	39,407,457	44,903,899
Property and equipment	392,116	392,041
Right-of-use assets	439,754	584,251
Total assets	\$ 40,239,327	\$ 45,880,191
Liabilities And Shareholders' Equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 2,182,323	\$ 1,987,870
Other liabilities	—	352,279
Lease liabilities	330,351	293,672
Warrant derivative	31,356	56,017
Total current liabilities	2,544,030	2,689,838
Contract liability	6,730,287	6,730,287
Lease liabilities	192,092	361,081
Total liabilities	9,466,409	9,781,206
Commitments and contingencies		
Shareholders' equity		
Share capital		
Authorized: unlimited		
Issued: June 30, 2022 – 57,867,367		
December 31, 2021 – 55,043,789	396,806,726	391,348,183
Warrants	—	3,617,570
Contributed surplus	38,801,890	34,161,103
Accumulated other comprehensive income	453,241	387,738
Accumulated deficit	(405,288,939)	(393,415,609)
Total shareholders' equity	30,772,918	36,098,985
Total liabilities and shareholders' equity	\$ 40,239,327	\$ 45,880,191

ONCOLYTICS BIOTECH INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF LOSS AND
COMPREHENSIVE LOSS
(unaudited)
(in Canadian dollars, except share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Expenses				
Research and development	\$ 3,203,972	\$ 3,203,181	\$ 6,911,968	\$ 5,962,195
Operating	2,842,156	3,520,986	5,444,246	6,662,876
Loss before the following	(6,046,128)	(6,724,167)	(12,356,214)	(12,625,071)
Change in fair value of warrant derivative	39,005	80,159	25,986	(84,621)
Foreign exchange gain (loss)	888,074	(631,352)	413,954	(1,021,906)
Interest income, net	49,063	29,224	67,767	50,717
Loss before income taxes	(5,069,986)	(7,246,136)	(11,848,507)	(13,680,881)
Income tax expense	(24,823)	—	(24,823)	—
Net loss	(5,094,809)	(7,246,136)	(11,873,330)	(13,680,881)
Other comprehensive income (loss) items that may be reclassified to net loss				
Translation adjustment	112,513	(48,370)	65,503	(88,682)
Net comprehensive loss	\$ (4,982,296)	\$ (7,294,506)	\$ (11,807,827)	\$ (13,769,563)
Basic and diluted loss per common share	\$ (0.09)	\$ (0.13)	\$ (0.21)	\$ (0.26)
Weighted average number of shares (basic and diluted)	57,669,167	54,325,212	57,125,833	52,008,768

ONCOLYTICS BIOTECH INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(unaudited)
(in Canadian dollars)

	Share Capital	Warrants	Contributed Surplus	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	\$	\$	\$	\$	\$	\$
As at December 31, 2020	356,824,172	3,617,570	31,022,356	400,225	(367,111,330)	24,752,993
Net loss and other comprehensive loss	—	—	—	(88,682)	(13,680,881)	(13,769,563)
Issued pursuant to stock option plan	313,867	—	(117,751)	—	—	196,116
Issued pursuant to incentive share award plan	370,117	—	(370,117)	—	—	—
Issued pursuant to "At the Market" Agreement	34,168,071	—	—	—	—	34,168,071
Issued pursuant to warrant derivative exercised	686,616	—	—	—	—	686,616
Share-based compensation	—	—	1,690,318	—	—	1,690,318
Share issue costs	(1,237,848)	—	—	—	—	(1,237,848)
As at June 30, 2021	391,124,995	3,617,570	32,224,806	311,543	(380,792,211)	46,486,703
As at December 31, 2021	391,348,183	3,617,570	34,161,103	387,738	(393,415,609)	36,098,985
Net loss and other comprehensive income	—	—	—	65,503	(11,873,330)	(11,807,827)
Issued pursuant to stock option plan	19,570	—	(7,487)	—	—	12,083
Issued pursuant to incentive share award plan	98,388	—	(98,388)	—	—	—
Expiry of equity warrant agreement	—	(3,617,570)	3,617,570	—	—	—
Issued pursuant to "At the Market" Agreement	5,819,149	—	—	—	—	5,819,149
Share-based compensation	—	—	1,129,092	—	—	1,129,092
Share issue costs	(478,564)	—	—	—	—	(478,564)
As at June 30, 2022	396,806,726	—	38,801,890	453,241	(405,288,939)	30,772,918

ONCOLYTICS BIOTECH INC.
CONDENSED INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in Canadian dollars)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating Activities				
Net loss for the period	\$ (5,094,809)	\$ (7,246,136)	\$ (11,873,330)	\$ (13,680,881)
Depreciation - property and equipment	23,647	75,340	47,599	95,890
Depreciation - right-of-use-assets	73,960	88,493	147,572	174,677
Share-based compensation	490,111	1,032,242	1,129,092	1,690,318
Interest expense on lease liabilities	21,327	24,450	45,101	38,259
Unrealized foreign exchange (gain) loss	(785,135)	713,763	(375,272)	1,233,131
Change in fair value of warrant derivative	(39,005)	(80,159)	(25,986)	84,621
Net change in non-cash working capital	(1,607,305)	(1,404,875)	(2,264,110)	(2,001,354)
Cash used in operating activities	(6,917,209)	(6,796,882)	(13,169,334)	(12,365,339)
Investing Activities				
Acquisition of property and equipment	(11,645)	(6,598)	(47,166)	(6,598)
Cash used in investing activities	(11,645)	(6,598)	(47,166)	(6,598)
Financing Activities				
Proceeds from exercise of stock options	—	6,766	12,083	196,116
Proceeds from exercise of warrant derivative	—	—	—	230,946
Proceeds from "At the Market" equity distribution agreement	249,937	8,072,561	5,340,585	32,930,223
Payment of lease liabilities	(93,668)	(98,555)	(182,504)	(210,228)
Cash provided by financing activities	156,269	7,980,772	5,170,164	33,147,057
(Decrease) increase in cash	(6,772,585)	1,177,292	(8,046,336)	20,775,120
Cash and cash equivalents, beginning of period	39,483,022	50,362,162	41,262,044	31,219,574
Impact of foreign exchange on cash and cash equivalents	978,818	(740,022)	473,547	(1,195,262)
Cash and cash equivalents, end of period	\$ 33,689,255	\$ 50,799,432	\$ 33,689,255	\$ 50,799,432

References

1. Melenhorst, J.J., Chen, G.M., Wang, M. *et al.* Decade-long leukaemia remissions with persistence of CD4⁺ CAR T cells. *Nature* (2022). <https://doi.org/10.1038/s41586-021-04390-6>

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 a registration study in metastatic breast cancer.

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"). 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; Oncolytics' expectations as to the purpose, design, outcomes and benefits of its current or pending clinical trials involving pelareorep; our belief that our recent clinical data further positions

pelareorep as an immune platform molecule that can enhance the efficacy of a variety of drug classes to improve treatment paradigms across a range of indications; our internal focus on pursuing strong signals of efficacy observed with pelareorep in breast and pancreatic cancer; our belief that we are on a clear path towards a randomized phase 2 readout that is expected to validate prior positive survival data and catalyze our advancement into a registrational breast cancer study; our plans in the event that GOBLET's initial results continue to show indications of efficacy, including moving expeditiously towards a late-stage pancreatic cancer trial that will de-risk our pipeline and provide additional opportunities to create stakeholder value; our plans to continue to leverage preclinical data demonstrating pelareorep's synergy with CAR T cells against solid tumors to advance business development efforts; our plans to report additional data from GOBLET's pancreatic cancer cohort at a major medical meeting in late 2022; our expectation that pelareorep could substantially expand the commercial potential presented by CAR T cell therapies; 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.


Company Contact

Jon Patton
Director of IR & Communication
+1-858-886-7813
jpatton@oncolytics.ca

**Investor Relations for
Oncolytics**

Timothy McCarthy
LifeSci Advisors
+1-917-679-9282
tim@lifesciadvisors.com

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

 View original content to download multimedia <https://www.prnewswire.com/news-releases/oncolytics-biotech-reports-second-quarter-2022-financial-results-and-recent-operational-highlights-301604104.html>

SOURCE Oncolytics Biotech® Inc.