

November 7, 2022



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

*Clinical interim data reported earlier today from GOBLET trial's pancreatic cancer cohort show an objective response rate (ORR) nearly triple the average ORR seen in relevant historical control trials*

*Pipeline now provides multiple registration opportunities in breast and pancreatic cancer*

*\$32.4 million in cash and cash equivalents as of September 30, 2022 provides projected runway through key milestones to the end of 2023*

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

SAN DIEGO and CALGARY, AB, Nov. 7, 2022 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced recent operational highlights and financial results for the third quarter ended September 30, 2022. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"Our continued progress in breast cancer and the highly-promising pancreatic cancer data we reported earlier today have pelareorep moving confidently towards pivotal trials in both of these indications for which new treatment options are needed," said Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech Inc. "In breast cancer, we remain on track to report an expansive dataset from our randomized BRACELET-1 trial in the first half of next year. This phase 2 trial was carefully designed to validate the statistically significant survival benefit provided by pelareorep in a prior phase 2 study, and its results are expected to inform the optimal design of a subsequent registrational trial. In pancreatic cancer, we plan to discuss our new data with regulators to enable the program's expeditious advancement into a pivotal study. With these core programs each representing a potential registration opportunity and distinct avenue for value creation, we believe we are entering a new phase in Oncolytics' evolution."

## **Third Quarter and Subsequent Highlights**

### **Pancreatic Cancer Program**

#### ***Reported interim data showing a 70% ORR in phase 1/2 GOBLET trial's pancreatic cancer cohort***

An abstract published as part of the SITC Meeting, and highlighted in a separate [press release](#) issued earlier today, features data from the phase 1/2 GOBLET trial's cohort in first-line advanced/metastatic pancreatic ductal adenocarcinoma, one of the most difficult-to-treat human cancers. As of the abstract's data cutoff date (July 28, 2022), seven of ten evaluable patients had achieved a partial response following treatment with pelareorep in combination with atezolizumab and the chemotherapeutic agents gemcitabine and nab-paclitaxel. An additional two patients achieved stable disease, leading to an ORR and clinical benefit rate of 70% and 90%, respectively. The 70% ORR reported as of the cutoff date is nearly triple the average ORR of approximately 25% reported in historical control trials evaluating the combination of gemcitabine and nab-paclitaxel in pancreatic cancer<sup>1-4</sup>. Together with data from prior clinical studies, these results suggest pelareorep synergizes with checkpoint inhibition and chemotherapy in pancreatic cancer and support Oncolytics' plan to advance into a registrational pancreatic cancer study pending discussions with regulatory authorities.

### **Breast Cancer Program**

#### ***New AWARE-1 data further demonstrate pelareorep's immune-mediated mechanism of action***

An abstract published earlier today as part of the Society for Immunotherapy of Cancer (SITC) 37<sup>th</sup> Annual Meeting features new data on the twenty HR+/HER2- breast cancer patients comprising the first two cohorts of the AWARE-1 study. Patients in these cohorts were treated with pelareorep and letrozole without (cohort 1) or with (cohort 2) Roche's anti-PD-L1 checkpoint inhibitor atezolizumab. Flow cytometry analyses of blood samples from these patients showed a statistically significant increase in anti-cancer NK cells on day 21 post-treatment in cohort 2 compared to cohort 1. In addition, cohort 2 patients showed higher levels of HLA-DR expression (a marker of T cell activation) in anti-cancer CD8+ T cells, and better maintained low levels of T cell exhaustion markers on day 21 compared to cohort 1 patients. Together with prior clinical data, these results further demonstrate pelareorep's immunologic mechanism of action and its potential to synergistically combine with a variety of drug classes.

### **Corporate Updates**

#### ***Elected Jonathan Rigby to the Board of Directors***

Mr. Rigby has over thirty years of pharmaceutical and biotechnology industry experience. He is currently the Group Chief Executive Officer of Revolo Biotherapeutics and previously co-founded Zogenix, Inc., a CNS-focused specialty pharmaceutical company that was acquired by UCB earlier this year in a transaction valued at up to approximately U.S. \$1.9 billion.

### **Financial Highlights**

- As of September 30, 2022, the Company reported \$32.4 million in cash and cash equivalents.
- General and administrative expenses for the third quarter of 2022 were \$2.4 million, compared to \$2.9 million for the third quarter of 2021.
- Research and development expenses for the third quarter of 2022 were \$3.7 million, compared to \$3.3 million for the third quarter of 2021.
- The net loss for the third quarter of 2022 was \$4.4 million, compared to a net loss of \$4.9 million in the third quarter of 2021. The basic and diluted loss per share was \$0.08 in the third quarter of 2022, compared to a basic and diluted loss per share of \$0.09 in the third quarter of 2021.
- Net cash used in operating activities for the nine months ended September 30, 2022 was \$17.4 million, compared to \$16.1 million for the nine months ended September 30, 2021.

### **Anticipated Milestones and Catalysts**

- 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

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

(in Canadian dollars, except share amounts)

As at	September 30, 2022	December 31, 2021
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 32,362,063	\$ 41,262,044
Other receivables	496,855	866,055
Prepaid expenses	5,346,353	2,775,800
<b>Total current assets</b>	<b>38,205,271</b>	44,903,899
Property and equipment	379,700	392,041
Right-of-use assets	374,006	584,251
<b>Total assets</b>	<b>\$ 38,958,977</b>	<b>\$ 45,880,191</b>
<b>Liabilities and Shareholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 3,321,251	\$ 1,987,870
Other liabilities	—	352,279
Lease liabilities	294,864	293,672
Warrant derivative	50,030	56,017
<b>Total current liabilities</b>	<b>3,666,145</b>	2,689,838
Contract liability	6,730,287	6,730,287
Lease liabilities	165,918	361,081
<b>Total liabilities</b>	<b>10,562,350</b>	9,781,206
Commitments and contingencies		
<b>Shareholders' equity</b>		
Share capital		
Authorized: unlimited		
Issued: September 30, 2022 – 58,706,442		
December 31, 2021 – 55,043,789	398,068,304	391,348,183
Warrants	—	3,617,570
Contributed surplus	39,301,814	34,161,103
Accumulated other comprehensive income	722,631	387,738
Accumulated deficit	(409,696,122)	(393,415,609)
<b>Total shareholders' equity</b>	<b>28,396,627</b>	36,098,985
<b>Total liabilities and shareholders' equity</b>	<b>\$ 38,958,977</b>	<b>\$ 45,880,191</b>

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

(in Canadian dollars, except share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
<b>Expenses</b>				
			\$	
Research and development	\$ 3,678,496	\$ 3,278,705	10,590,464	\$ 9,240,900
General and administrative	2,381,413	2,876,312	7,825,659	9,539,188
<b>Loss before the following</b>	<b>(6,059,909)</b>	<b>(6,155,017)</b>	<b>(18,416,123)</b>	<b>(18,780,088)</b>
Change in fair value of warrant derivative	(16,677)	52,216	9,309	(32,405)
Foreign exchange gain	1,525,514	1,212,070	1,939,468	190,164
Interest income, net	146,487	25,740	214,254	76,457
<b>Loss before income taxes</b>	<b>(4,404,585)</b>	<b>(4,864,991)</b>	<b>(16,253,092)</b>	<b>(18,545,872)</b>
Income tax expense	(2,598)	(7,151)	(27,421)	(7,151)
<b>Net loss</b>	<b>(4,407,183)</b>	<b>(4,872,142)</b>	<b>(16,280,513)</b>	<b>(18,553,023)</b>
<b>Other comprehensive income items that may be reclassified to net loss</b>				
Translation adjustment	269,390	94,907	334,893	6,225
			\$	
<b>Net comprehensive loss</b>	<b>\$ (4,137,793)</b>	<b>\$ (4,777,235)</b>	<b>(15,945,620)</b>	<b>\$ (18,546,798)</b>
	\$	\$	\$	\$
<b>Basic and diluted loss per common share</b>	<b>(0.08)</b>	<b>(0.09)</b>	<b>(0.28)</b>	<b>(0.35)</b>
<b>Weighted average number of shares (basic and diluted)</b>	<b>58,325,075</b>	<b>54,960,650</b>	<b>57,529,973</b>	<b>53,003,541</b>

**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	—	—	—	6,225	(18,553,023)	(18,546,798)
Issued pursuant to stock option plan	321,697	—	(120,747)	—	—	200,950
Issued pursuant to incentive share award plan	413,282	—	(413,282)	—	—	—
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	—	—	2,697,238	—	—	2,697,238
Share issue costs	(1,247,078)	—	—	—	—	(1,247,078)
	\$	\$	\$	\$	\$	\$
<b>As at September 30, 2021</b>	<b>391,166,760</b>	<b>3,617,570</b>	<b>33,185,565</b>	<b>\$ 406,450</b>	<b>(385,664,353)</b>	<b>42,711,992</b>
	\$	\$	\$	\$	\$	\$
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	—	—	—	334,893	(16,280,513)	(15,945,620)
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	7,159,552	—	—	—	—	7,159,552
Share-based compensation	—	—	1,629,016	—	—	1,629,016
Share issue costs	(557,389)	—	—	—	—	(557,389)
	\$	\$	\$	\$	\$	\$
<b>As at September 30, 2022</b>	<b>398,068,304</b>	<b>—</b>	<b>39,301,814</b>	<b>\$ 722,631</b>	<b>(409,696,122)</b>	<b>28,396,627</b>

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

	<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>Operating Activities</b>		
Net loss for the period	\$ (16,280,513)	\$ (18,553,023)
Depreciation - property and equipment	70,588	106,979
Depreciation - right-of-use-assets	222,401	248,111
Share-based compensation	1,629,016	2,697,238
Interest expense on lease liabilities	63,959	65,848
Unrealized foreign exchange (gain) loss	(1,663,988)	79,925
Change in fair value of warrant derivative	(9,309)	32,405
Net change in non-cash working capital	(1,448,590)	(775,818)
<b>Cash used in operating activities</b>	<b>(17,416,436)</b>	<b>(16,098,335)</b>
<b>Investing Activities</b>		
Acquisition of property and equipment	(55,740)	(211,236)
<b>Cash used in investing activities</b>	<b>(55,740)</b>	<b>(211,236)</b>
<b>Financing Activities</b>		
Proceeds from exercise of stock options	12,083	200,950
Proceeds from exercise of warrant derivative	—	230,946
Proceeds from "At the Market" equity distribution agreement	6,602,163	32,920,993
Payment of lease liabilities	(279,405)	(285,502)
<b>Cash provided by financing activities</b>	<b>6,334,841</b>	<b>33,067,387</b>
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(11,137,335)</b>	<b>16,757,816</b>
Cash and cash equivalents, beginning of period	41,262,044	31,219,574
Impact of foreign exchange on cash and cash equivalents	2,237,354	109,979
<b>Cash and cash equivalents, end of period</b>	<b>\$ 32,362,063</b>	<b>\$ 48,087,369</b>

## Webcast and Conference Call

Management will host a conference call for analysts and institutional investors at 8:30 a.m. ET today, November 7, 2022. To access the call, please dial (888) 664-6383 (North America) or (416) 764-8650 (International) and, if needed, provide confirmation number 4240-6541. 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: 406-541#.

## References

1. Von Hoff D et al. N Engl J Med 2013; 369:1691-1703 DOI: 10.1056/NEJMoa1304369
2. O'Reilly et al. Eur J Cancer. 2020 June; 132: 112–121. DOI:10.1016/j.ejca.2020.03.005
3. Karasic et al. JAMA Oncol. 2019 Jul 1; 5(7):993-998. DOI: 10.1001/jamaoncol.2019.0684
4. Tempero et al. Ann Oncol. 2021 May; 32(5):600-608. DOI: 10.1016/j.annonc.2021.01.070

## 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: [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, mode of action, and benefits of pelareorep as a cancer therapeutic; our belief that pelareorep is moving confidently towards pivotal trials in both breast cancer and pancreatic cancer; our belief that we remain on track to report additional data from our BRACELET-1 study and the anticipated timing thereof and our expectations related thereto; our plans to discuss our new data with regulators and the rationale therefor; our upcoming milestones and catalysts, including, the release of additional data from our AWARE-1 and BRACELET-1 studies and clinical data from Adlai Nortye's bridging trial, in each case the anticipated timing thereof, 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, 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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