

March 3, 2023



# Oncolytics Biotech® Reports Fourth Quarter and Full Year 2022 Financial Results and Operational Highlights

*Pancreatic cancer program advancing towards registration path supported by phase 1/2 GOBLET data showing a confirmed complete response and 69% objective response rate in advanced/metastatic patients*

*Phase 2 BRACELET-1 trial in HR+/HER2- metastatic breast cancer on track for a randomized data readout in Q2 2023 that will inform the design of a pivotal trial*

*Registration opportunities in breast and pancreatic cancer are supported by FDA Fast Track designations*

*\$32.1 million in cash, cash equivalents and marketable securities as of December 31, 2022 provides projected runway through BRACELET-1's upcoming readout and into 2024*

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

SAN DIEGO and CALGARY, Alberta, March 3, 2023 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced recent operational highlights and financial results for the fourth quarter and full year ended December 31, 2022. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"This is a truly exciting time for Oncolytics, as our progress last year provides pelareorep with clear and substantially de-risked paths to registrational studies in both breast and pancreatic cancer," said Dr. Matt Coffey, President and Chief Executive Officer. "Our partner Adlai Nortye recently confirmed pelareorep's ability to combine with paclitaxel and generate sustained clinical responses in HR+/HER2- metastatic breast cancer, which we believe bodes well for BRACELET-1's anticipated readout next quarter. With this readout, we aim to showcase a randomized dataset that shows one or both of the trial's pelareorep-based treatment regimens numerically outperforming the paclitaxel monotherapy arm on key

metrics such as overall response rate and progression-free survival. We believe this result would represent a key inflection point, as it would confirm our breast cancer program's prior statistically significant results, accelerate its advancement into a registrational trial, and bolster our business development prospects."

Dr. Coffey continued, "In pancreatic cancer, interim results from pelareorep's GOBLET trial showed an objective response rate that was nearly three times greater than those recorded in historical control trials. These data supported a subsequent Fast Track designation from the FDA, which will be incredibly valuable as we work with the agency and other key stakeholders to identify the optimal path to registration. GOBLET's data also transformed our pancreatic cancer program into our pipeline's second core pillar, thereby adding an important value driver that strengthens our foundation for sustained growth."

## **Fourth Quarter Highlights**

### **Pancreatic Cancer Program**

#### ***Reported a 69% ORR and confirmed complete response in phase 1/2 GOBLET trial's pancreatic cancer cohort***

A poster presented at the Society for Immunotherapy of Cancer (SITC) 37<sup>th</sup> Annual Meeting featured data from the phase 1/2 GOBLET trial's cohort in first-line advanced/metastatic pancreatic ductal adenocarcinoma (PDAC) ([link](#) to PR, [link](#) to poster). Thirteen patients were evaluable for efficacy as of the poster's cut-off date (October 12, 2022), with one achieving a confirmed complete response and eight achieving a partial response (PR) following treatment with the combination of pelareorep, Roche's anti-PD-L1 checkpoint inhibitor atezolizumab, and the chemotherapeutic agents gemcitabine and nab-paclitaxel. The 69% objective response rate (ORR) reported in the SITC poster is nearly triple the average ORR of ~25% achieved in historical control trials of gemcitabine plus nab-paclitaxel<sup>1-4</sup>, suggesting that pelareorep can synergize with checkpoint inhibition and chemotherapy to improve the standard-of-care in PDAC. Based upon these results and favorable safety data from GOBLET's pancreatic cancer cohort, Oncolytics will continue to engage with regulators to determine the optimal and most expeditious registration-enabling pathway.

#### ***Received FDA Fast Track designation for the treatment of advanced/metastatic PDAC***

Following the announcement of interim data from GOBLET's pancreatic cancer cohort, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to pelareorep in combination with atezolizumab, gemcitabine, and nab-paclitaxel for the treatment of advanced/metastatic PDAC ([link](#) to PR). With this designation, Oncolytics' pancreatic cancer program may be eligible for more frequent meetings and communications with the FDA to review development plans and discuss the data needed to support approval. Furthermore, programs that receive Fast Track designation may be eligible for Accelerated Approval and Priority Review in certain situations.

### **Breast Cancer Program**

#### ***Interim results from Adlai Nortye's bridging trial further demonstrate the anti-cancer activity of pelareorep plus paclitaxel in HR+/HER2- metastatic breast cancer***

Oncolytics' Chinese development partner, Adlai Nortye, presented interim results from its single-arm bridging trial of pelareorep-paclitaxel combination therapy in HR+/HER2-metastatic breast cancer at the San Antonio Breast Cancer Symposium ([link to PR](#), [link to poster](#)). Fourteen patients were evaluable for efficacy as of the trial's data cutoff date (September 26, 2022), with thirteen achieving disease control (PR or stable disease), twelve achieving tumor shrinkage from baseline, and seven achieving a PR. One patient achieved a PR at week 8, maintained the PR, and remained on study at week 48, providing evidence of the durable clinical benefit from pelareorep-paclitaxel combination therapy. Safety data showed that the studied combination was well tolerated, with no dose-limiting toxicities or serious adverse events reported. These results are expected to accelerate pelareorep's development in China by allowing Adlai Nortye's future regulatory submissions to include data from Oncolytics' North American metastatic breast cancer trials, IND-213 and BRACELET-1.

IND-213 was a randomized phase 2 trial that showed a statistically significant near doubling of median overall survival in HR+/HER2- breast cancer patients treated with pelareorep plus paclitaxel compared to those treated with paclitaxel alone. BRACELET-1 is a randomized phase 2 trial in HR+/HER2- metastatic breast cancer with cohorts evaluating: (1) paclitaxel alone; (2) paclitaxel plus pelareorep; and (3) paclitaxel plus pelareorep in combination with the checkpoint inhibitor avelumab. Oncolytics expects to announce overall response rate and progression-free survival data from BRACELET-1 at a major medical meeting in the second quarter of 2023.

## Financial Highlights

- As of December 31, 2022, the Company reported \$32.1 million in cash, cash equivalents and marketable securities.
- The net loss for the fourth quarter of 2022 was \$8.6 million, compared to a net loss of \$7.8 million in the fourth quarter of 2021. The basic and diluted loss per share was \$0.14 in the fourth quarter of 2022, compared to a basic and diluted loss per share of \$0.14 in the fourth quarter of 2021. The net loss for the full year 2022 was \$24.8 million, compared to a net loss of \$26.3 million for the full year 2021. The basic and diluted loss per share was \$0.43 for the full year 2022, compared to a basic and diluted loss per share of \$0.49 for the full year 2021.
- Net cash used in operating activities was \$23.4 million for the full year 2022, compared to \$22.4 million for the full year 2021.
- General and administrative expenses for the fourth quarter of 2022 were \$3.7 million and \$11.5 million for the full year 2022, compared to \$3.8 million for the fourth quarter of 2021 and \$13.3 million for the full year 2021. The quarter-over-quarter decrease was largely due to lower share-based compensation expense, partly offset by higher office expenses. The year-over-year decrease was primarily due to lower public company-related costs.
- Research and development expenses for the fourth quarter of 2022 were \$4.8 million and \$15.4 million for the full year 2022, compared to \$3.7 million for the fourth quarter of 2021 and \$12.9 million for the full year 2021. The increases were primarily due to higher clinical trial costs and personnel-related expenses associated with our clinical development program.

## 2023 Anticipated Milestones and Catalysts

- Overall response rate, progression-free survival, and evolving overall survival data from phase 2 BRACELET-1 metastatic breast cancer study: Q2 2023
- Preclinical data from the combination of pelareorep and CAR T therapy: Q2 2023
- Updated advanced/metastatic PDAC data from the GOBLET study: H2 2023
- Updates on the metastatic colorectal and advanced anal 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, March 3, 2023. To access the call, please dial (888) 664-6383 (North America) or (416) 764-8650 and, if needed, provide confirmation number 4947-4770. 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: 474-770#.

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**  
(in thousands of Canadian dollars, except share amounts)

<b>As at December 31,</b>	<b>2022</b>	<b>2021</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 11,666	\$ 41,262
Marketable securities	20,472	—
Other receivables	521	866
Prepaid expenses	3,025	2,776
<b>Total current assets</b>	<b>35,684</b>	<b>44,904</b>
Property and equipment	356	392
Right-of-use assets	296	584
Prepaid expenses	998	—
<b>Total assets</b>	<b>\$ 37,334</b>	<b>\$ 45,880</b>
<b>Liabilities And Shareholders' Equity</b>		
<b>Current liabilities</b>		
	\$	\$
Accounts payable and accrued liabilities	3,650	1,988
Other liabilities	—	352
Lease liabilities	216	294
Warrant derivative	79	56
<b>Total current liabilities</b>	<b>3,945</b>	<b>2,690</b>
Contract liability	6,730	6,730
Lease liabilities	157	361
<b>Total liabilities</b>	<b>10,832</b>	<b>9,781</b>
Commitments and contingencies		
<b>Shareholders' equity</b>		
Share capital		
Authorized: unlimited		
Issued: December 31, 2022 – 61,327,914		
December 31, 2021 – 55,043,789	404,040	391,348
Warrants	—	3,618
Contributed surplus	40,051	34,161
Accumulated other comprehensive income	662	388
Accumulated deficit	(418,251)	(393,416)
<b>Total shareholders' equity</b>	<b>26,502</b>	<b>36,099</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 37,334</b>	<b>\$ 45,880</b>

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS**  
(in thousands of Canadian dollars, except share amounts)

For the years ended December 31,	2022	2021	2020
<b>Expenses</b>			
Research and development	\$ 15,432	\$ 12,920	\$ 12,945
General and administrative	11,492	13,315	12,514
<b>Loss before the following</b>	<b>(26,924)</b>	<b>(26,235)</b>	<b>(25,459)</b>
Change in fair value of warrant derivative	(20)	17	3,492
Foreign exchange gain (loss)	1,665	(136)	(659)
Interest income, net	528	99	121
<b>Loss before income taxes</b>	<b>(24,751)</b>	<b>(26,255)</b>	<b>(22,505)</b>
Income tax expense	(84)	(49)	—
<b>Net loss</b>	<b>(24,835)</b>	<b>(26,304)</b>	<b>(22,505)</b>
<b>Other comprehensive income (loss) items that may be reclassified to net loss</b>			
Translation adjustment	274	(12)	(64)
<b>Net comprehensive loss</b>	<b>\$ (24,561)</b>	<b>\$ (26,316)</b>	<b>\$ (22,569)</b>
<b>Basic and diluted loss per common share</b>	<b>\$ (0.43)</b>	<b>\$ (0.49)</b>	<b>\$ (0.56)</b>
<b>Weighted average number of shares (basic and diluted)</b>	<b>58,029,745</b>	<b>53,513,225</b>	<b>40,338,789</b>

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**  
(in thousands of Canadian dollars)

	Share Capital	Warrants	Contributed Surplus	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	\$	\$	\$	\$	\$	\$
As at December 31, 2019	311,078	3,618	29,339	464	(344,607)	(108)
Net loss and other comprehensive loss	—	—	—	(64)	(22,505)	(22,569)
Issued pursuant to stock option plan	385	—	(144)	—	—	241
Issued pursuant to incentive share award plan	732	—	(732)	—	—	—
Issued pursuant to "At the Market" Agreement	40,038	—	—	—	—	40,038
Issued pursuant to warrant derivative exercised	6,333	—	—	—	—	6,333
Share-based compensation expense	—	—	2,559	—	—	2,559
Share issue costs	(1,742)	—	—	—	—	(1,742)
	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>
As at December 31, 2020	356,824	3,618	31,022	400	(367,112)	24,752
Net loss and other comprehensive loss	—	—	—	(12)	(26,304)	(26,316)
Issued pursuant to stock option plan	381	—	(143)	—	—	238
Issued pursuant to incentive share award plan	544	—	(544)	—	—	—
Issued pursuant to "At the Market" Agreement	34,168	—	—	—	—	34,168
Issued pursuant to warrant derivative exercised	687	—	—	—	—	687
Share-based compensation expense	—	—	3,826	—	—	3,826
Share issue costs	(1,256)	—	—	—	—	(1,256)
	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>
As at December 31, 2021	391,348	3,618	34,161	388	(393,416)	36,099
Net loss and other comprehensive income	—	—	—	274	(24,835)	(24,561)
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	13,338	—	—	—	—	13,338
Share-based compensation expense	—	—	2,378	—	—	2,378
Share issue costs	(764)	—	—	—	—	(764)
	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>	<u>\$</u>
<b>As at December 31, 2022</b>	<b>404,040</b>	<b>—</b>	<b>40,051</b>	<b>662</b>	<b>(418,251)</b>	<b>26,502</b>

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands of Canadian dollars)

<b>For the years ended December 31,</b>	<b>2022</b>	<b>2021</b>	<b>2020</b>
<b>Operating Activities</b>			
Net loss for the year	\$ (24,835)	\$ (26,304)	\$ (22,505)
Depreciation - property and equipment	93	130	89
Depreciation - right-of-use assets	299	322	357
Share-based compensation expense	2,378	3,826	2,559
Interest (income) expense, net	(76)	92	69
Unrealized foreign exchange (gain) loss	(1,625)	426	645
Change in fair value of warrant derivative	20	(17)	(3,492)
Net change in non-cash working capital	391	(908)	210
<b>Cash used in operating activities</b>	<b>(23,355)</b>	<b>(22,433)</b>	<b>(22,068)</b>
<b>Investing Activities</b>			
Acquisition of marketable securities	(20,348)	—	—
Acquisition of property and equipment	(55)	(286)	(29)
<b>Cash used in investing activities</b>	<b>(20,403)</b>	<b>(286)</b>	<b>(29)</b>
<b>Financing Activities</b>			
Proceeds from exercise of stock options	12	238	241
Proceeds from exercise of warrants	—	231	1,697
Proceeds from "At the Market" equity distribution agreement	12,574	32,912	38,296
Payment of lease liabilities	(381)	(366)	(461)
<b>Cash provided by financing activities</b>	<b>12,205</b>	<b>33,015</b>	<b>39,773</b>
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(31,553)</b>	<b>10,296</b>	<b>17,676</b>
Cash and cash equivalents, beginning of year	41,262	31,220	14,148
Impact of foreign exchange on cash and cash equivalents	1,957	(254)	(604)
<b>Cash and cash equivalents, end of year</b>	<b>\$ 11,666</b>	<b>\$ 41,262</b>	<b>\$ 31,220</b>

## 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 and benefits of pelareorep as a cancer therapeutic; the anticipated timing of upcoming data from our clinical trials and the potential benefit of such data in relation to our plans for registrational studies and business development opportunities; our plans to continue to engage with regulators; the anticipated benefits of FDA Fast Track designation; our anticipated milestones and catalysts; our plans to advance towards registration studies 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.*

### **Company Contact**

Jon Patton  
Director of IR & Communication  
+1-858-886-7813  
[jpatton@oncolytics.ca](mailto:jpatton@oncolytics.ca)

### **Investor Relations for Oncolytics**

Timothy McCarthy  
LifeSci Advisors  
+1-917-679-9282  
[tim@lifesciadvisors.com](mailto:tim@lifesciadvisors.com)

Logo - [https://mma.prnewswire.com/media/1762876/Oncolytics\\_Biotech\\_New\\_Logo.jpg](https://mma.prnewswire.com/media/1762876/Oncolytics_Biotech_New_Logo.jpg)

View original content to download multimedia <https://www.prnewswire.com/news-releases/oncolytics-biotech-reports-fourth-quarter-and-full-year-2022-financial-results-and-operational-highlights-301761958.html>

SOURCE Oncolytics Biotech® Inc.