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Oncolytics Biotech Inc. (ONCY-NASDAQ)

ONCY: FDA Provides Alignment on Registrational Pathway for Pelareorep in CRC

Based on our probability-adjusted DCF model that takes into account potential future revenues for pelareorep in SCAC, mCRC, and mPDAC, ONCY is valued at $6.00 per share. This model is highly dependent upon the continued clinical success of pelareorep and will be adjusted accordingly based on future results.

Current Price (08/27/26)	$0.86
Valuation	**$6.00**

OUTLOOK

On August 18, 2026, Oncolytics Biotech, Inc. (ONCY) provided a regulatory update on REO 033, the ongoing randomized controlled trial evaluating pelareorep in combination with FOLFIRI and bevacizumab for the second-line treatment of patient with RAS-mutated, MSS-stable metastatic colorectal cancer. The company received written feedback from U.S. FDA on the potential for the ongoing Part A of REO 033 to support expansion into a pivotal Part B that represents alignment with the agency on key aspects of the trial design, including the potential for an accelerated approval pathway based on objective response rate and the use of progression-free survival as the basis for full approval. The company anticipates all sites to be activated by the end of August 2026, with initial results possible by the end of 2026 or 1Q27.

SUMMARY DATA

52-Week High	**$1.42**
52-Week Low	**$0.75**
One-Year Return (%)	**-19.28**
Beta	**1.13**
Average Daily Volume (sh)	**673,489**
Shares Outstanding (mil)	**128**
Market Capitalization ($mil)	**$109**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2026 Estimate	**-3.0**
P/E using 2027 Estimate	**-4.0**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2026	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2027					0.0 E
2028					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	-$0.08 A	-$0.07 A	-$0.14 A	-$0.04 A	-$0.30 A
2026	-$0.08 A	-$0.08 A	-$0.06 E	-$0.06 E	-$0.27 E
2027					-$0.23 E
2028					-$0.21 E

WHAT'S NEW

Business Update

Alignment Reached with FDA on Potential Registrational Pathway in CRC

On August 18, 2026, Oncolytics Biotech, Inc. (ONCY) announced it had received written feedback from the FDA regarding the potential expansion of the ongoing REO 033 trial into a pivotal Part B study. REO 033 is a randomized study evaluating pelareorep in combination with folinic acid, fluorouracil, and irinotecan (FOLFIRI) and bevacizumab for the second-line treatment of patients with RAS-mutant, microsatellite stable (MSS) metastatic colorectal cancer (CRC). Pelareorep is a systemically delivered oncolytic virus designed to selectively replicate in cancer cells and enhance anti-tumor immunity.

The company had specifically sought confirmation that the existing randomized Part A design could support a pivotal expansion, as well as regulatory guidance on the potential use of objective response rate (ORR) to support accelerated approval and progression-free survival (PFS) to support full approval. The FDA's written feedback was sufficiently supportive that Oncolytics elected to forego a planned Type D meeting and instead intends to pursue an 'End-of-Phase' meeting to finalize key elements of the registration program.

Importantly, management indicated that its discussions with the FDA also addressed the ability to incorporate blinding and blinded, centralized tumor-response adjudication into Part B while preserving the overall REO 033 framework. The company now expects the eventual Part B sample size and statistical plan to be determined based in part on the initial efficacy data generated in Part A, with final agreement on these elements to be reached with the FDA. The ongoing Part A is enrolling 60 patients and was specifically designed to generate the clinical data needed to inform a potential pivotal expansion.

The company is therefore prioritizing rapid completion of Part A, with management expecting all trial sites to be activated by the end of August 2026 and initial tumor response data potentially available in 1Q27. Following supportive interim Part A data, Oncolytics plans to move quickly into Part B start-up activities, potentially allowing the existing randomized study to transition directly into a pivotal trial rather than requiring a separate registrational study. The FDA feedback supports a potentially efficient approval strategy in which ORR could support accelerated approval while PFS would provide the basis for full approval.

Fast Track Designation for Pelareorep in Second-Line and Later Anal Cancer

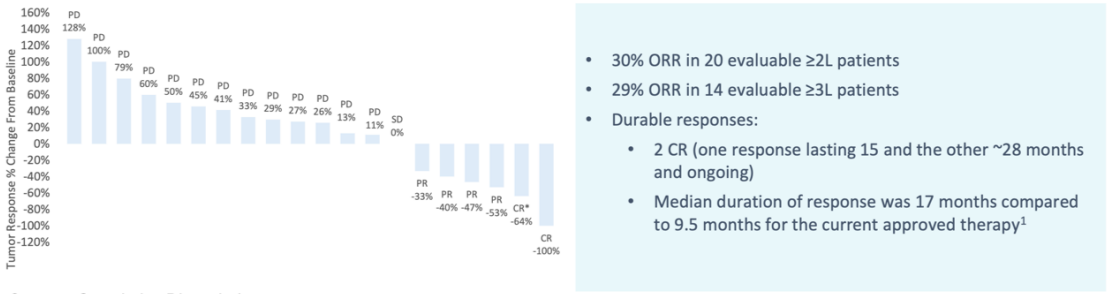
In July 2026, Oncolytics announced that the U.S. FDA has granted Fast Track designation to pelareorep in combination with checkpoint inhibitor for the treatment of patients with inoperable, locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) who have progressed on or were intolerant to one or more prior lines of therapy.

Fast Track designation allows for more frequent interactions with the FDA during development, a rolling review of a Biologics License Application (BLA), and eligibility for Priority Review. The program is intended to facilitate the development and expedite the review of treatments for serious diseases with significant unmet medical needs.

Earlier this year, Oncolytics announced it had reach alignment with the FDA on a pivotal study for pelareorep in unresectable metastatic SCAC, which is expected to be a single, randomized controlled clinical trial with the ability to seek both accelerated approval and full approval at different points in the trial.

Pelareorep has been evaluated in SCAC in the GOBLET study, an ongoing multi-cohort clinical trial investigating pelareorep in combination with checkpoint inhibition and chemotherapy, as appropriate, across gastrointestinal malignancies (NCT07280377). In Cohort 4, pelareorep was combined with the PD-L1 inhibitor atezolizumab in patients with second-line or later SCAC, representing a heavily pretreated population with limited therapeutic options. Updated data from this cohort demonstrated evidence of clinical activity, including a 30% overall response rate and a median 17-month duration of response.

Notably, the pattern of response observed in GOBLET Cohort 4 is consistent with pelareorep's proposed mechanism as an immune primer. Treatment was associated with tumor shrinkage across multiple patients, including both partial responses and prolonged stable disease, suggesting that the combination of pelareorep and checkpoint inhibition may overcome resistance mechanisms that limit the efficacy of PD-1/PD-L1 blockade alone. While cross-trial comparisons should be interpreted cautiously, the observed activity compares favorably to historical benchmarks for checkpoint inhibitor monotherapy in this setting, where response rates are generally low and disease control is limited.



Source: Oncolytics Biotech, Inc.

Financial Update

On August 12, 2026, Oncolytics filed form 10-Q with financial results for the second quarter of 2026. As expected, the company did not report any revenues in the second quarter of 2026. R&D expenses in the second quarter of 2026 were $4.3 million compared to $1.9 million in the second quarter of 2025. The increase was primarily due to increased personnel-related expenses and clinical trial costs. G&A expenses in the second quarter of 2026 were $5.1 million compared to $2.7 million in the second quarter of 2025. The increase was primarily due to increased public company-related expenses and personnel-related expenses.

As of June 30, 2026, Oncolytics had approximately $4.1 million in cash and cash equivalents. Subsequent to the end of the quarter, the company sold approximately 2.3 million common shares pursuant to an Open Market Sale Agreement signed in April 2026 with Jefferies LLC for net proceeds of approximately $1.8. As of August 10, 2026, Oncolytics had approximately 127.5 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 156.4 million.

Conclusion

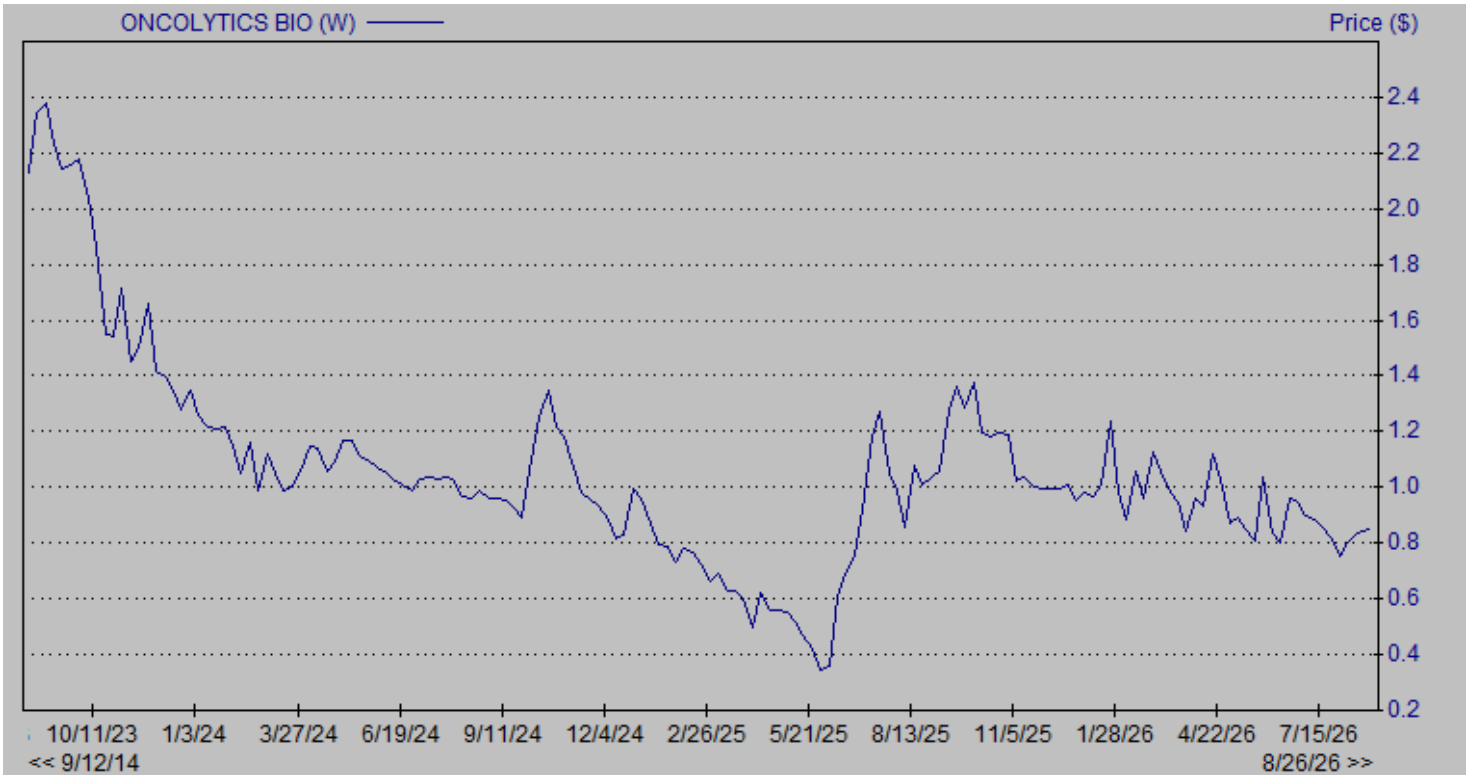
Now that the company has reached alignment with the FDA regarding the REO 033 trial, we look forward to additional updates regarding patient enrollment and the potential for initial data in 1Q27. Fast Track designation for pelareorep in SCAC is further validation of the company's technology and we look forward to additional updates on that program as the year progresses. With no changes to our model, our valuation remains at $6 per share.

PROJECTED FINANCIALS

Oncolytics Biotech, Inc.	2025 A	1Q A	2Q A	3Q E	4Q E	2026 E	2027 E	2028 E
SCAC	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
mCRC	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
mPDAC	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Grants & Collaborative Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Research & Development	$13.3	$4.6	$4.3	$3.6	$3.8	$16.2	$17.0	$20.0
General & Administrative	$15.4	$4.7	$5.1	$4.0	$4.0	$17.8	$17.0	$18.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($28.7)	($9.3)	($9.4)	($7.6)	($7.8)	($34.1)	($34.0)	($38.0)
Non-Operating Expenses (Net)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$1.0
Pre-Tax Income	($28.7)	($9.2)	($9.3)	($7.6)	($7.8)	($34.0)	($34.0)	($37.0)
Income Taxes Paid	($0.1)	$0.0	($0.1)	$0.0	$0.0	($0.1)	$0.0	$1.0
Net Income	**($28.8)**	**($9.2)**	**($9.4)**	**($7.6)**	**($7.8)**	**($34.1)**	**($34.0)**	**($36.0)**
Translation Adjustments	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Total Comprehensive Gain/Loss	**($28.90)**	**($9.24)**	**($9.44)**	**($7.60)**	**($7.80)**	**($34.08)**	**($34.00)**	**($35.00)**
Net Loss per Share	**($0.30)**	**($0.08)**	**($0.08)**	**($0.06)**	**($0.06)**	**($0.27)**	**($0.23)**	**($0.21)**
Basic Shares Outstanding	95.9	112.3	119.7	126.0	140.0	124.5	150.0	175.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



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