Zacks Small-Cap Research
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Oncolytics Biotech Inc. (ONCY-NASDAQ)

ONCY: Seeking Registration Pathway for Part B of REO 033 Trial

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 (07/16/26)	$0.90
Valuation	**$6.00**

OUTLOOK

On July 13, 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 has activated nearly half of the planned clinical sites, with the remaining sites expected to be activated by the end of August 2026. In the first half of August 2026, Oncolytics plans to conduct a Type D meeting with the FDA to discuss the potential addition of Part B to REO 033. The company is seeking FDA alignment on a registration-directed expansion of the study that could potentially support accelerated and/or full approval while preserving the core elements of the existing trial. We anticipate an update following FDA feedback that should provide greater clarity regarding trial size, endpoint strategy, and approval pathway.

SUMMARY DATA

52-Week High	**$1.42**
52-Week Low	**$0.77**
One-Year Return (%)	**-27.68**
Beta	**1.09**
Average Daily Volume (sh)	**1,333,874**
Shares Outstanding (mil)	**119**
Market Capitalization ($mil)	**$108**
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	**-3.7**
P/E using 2027 Estimate	**-4.8**

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 E	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	-$0.06 E	-$0.06 E	-$0.06 E	-$0.24 E
2027					-$0.23 E
2028					-$0.21 E

WHAT'S NEW

Business Update

Seeking Alignment on Turning REO 033 Into a Registration-Directed Trial

On July 13, 2026, Oncolytics Biotech, Inc. (ONCY) provided a regulatory update for REO 033, an ongoing randomized study evaluating pelareorep, the company's lead development product, 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 (mCRC). Pelareorep is a systemically delivered oncolytic virus designed to selectively replicate in cancer cells and enhance anti-tumor immunity

Oncolytics intends to leverage the existing clinical infrastructure for the multi-part REO 033 study to potentially accelerate development of pelareorep. The company expects approximately half of planned clinical sites to be activated by the end of July 2026, with remaining sites to be activated by the end of August 2026. We anticipate Part A of the study, which is planned to enroll 60 patients, could achieve accelerated enrollment during the second half of 2026, with Oncolytics reporting that more than 20 patients having already been pre-identified at participating trial sites.

The company will be conducting a Type D meeting with the FDA to discuss the addition of Part B to the REO 033 study. Part B is expected to be a larger randomized cohort intended to potentially support registration while preserving the core elements of the ongoing study. Key areas for regulatory alignment include trial size, endpoint strategy, statistical considerations, and the appropriate approval pathway.

Alignment with the FDA could enable Oncolytics to expand the existing randomized study into a registration-directed program rather than initiating a separate Phase 3 trial, potentially reducing timelines for pelareorep in second-line RAS-mutant MSS mCRC. The FDA has up to 30 days to provide feedback following the meeting, and we anticipate additional clarity from the company following receipt of the formal meeting minutes.

The REO 033 study builds upon results generated in the prior REO 022, for which Oncolytics recently provided updated durability data. Those results demonstrated a 19.5-month median duration of response in second-line RAS-mutant MSS mCRC patients, in addition to previously reported median overall survival (OS) of 27.0 months. These results compare favorably to established benchmarks for FOLFIRI plus bevacizumab in the second-line setting. Across prospective trials and real-world studies, objective response rates for FOLFIRI-based regimens in previously treated mCRC are typically in the range of ~6–11%, with median PFS of approximately 5–7 months and median OS of approximately 11–13 months (Bennouna *et al.*, 2013; Iwamoto *et al.*, 2015). While cross-trial comparisons should be interpreted with caution, the magnitude of improvement observed with pelareorep, particularly in a molecularly defined, poor-prognosis RAS-mutant population, suggests the potential for meaningful clinical benefit beyond cytotoxic therapy alone.

Conclusion

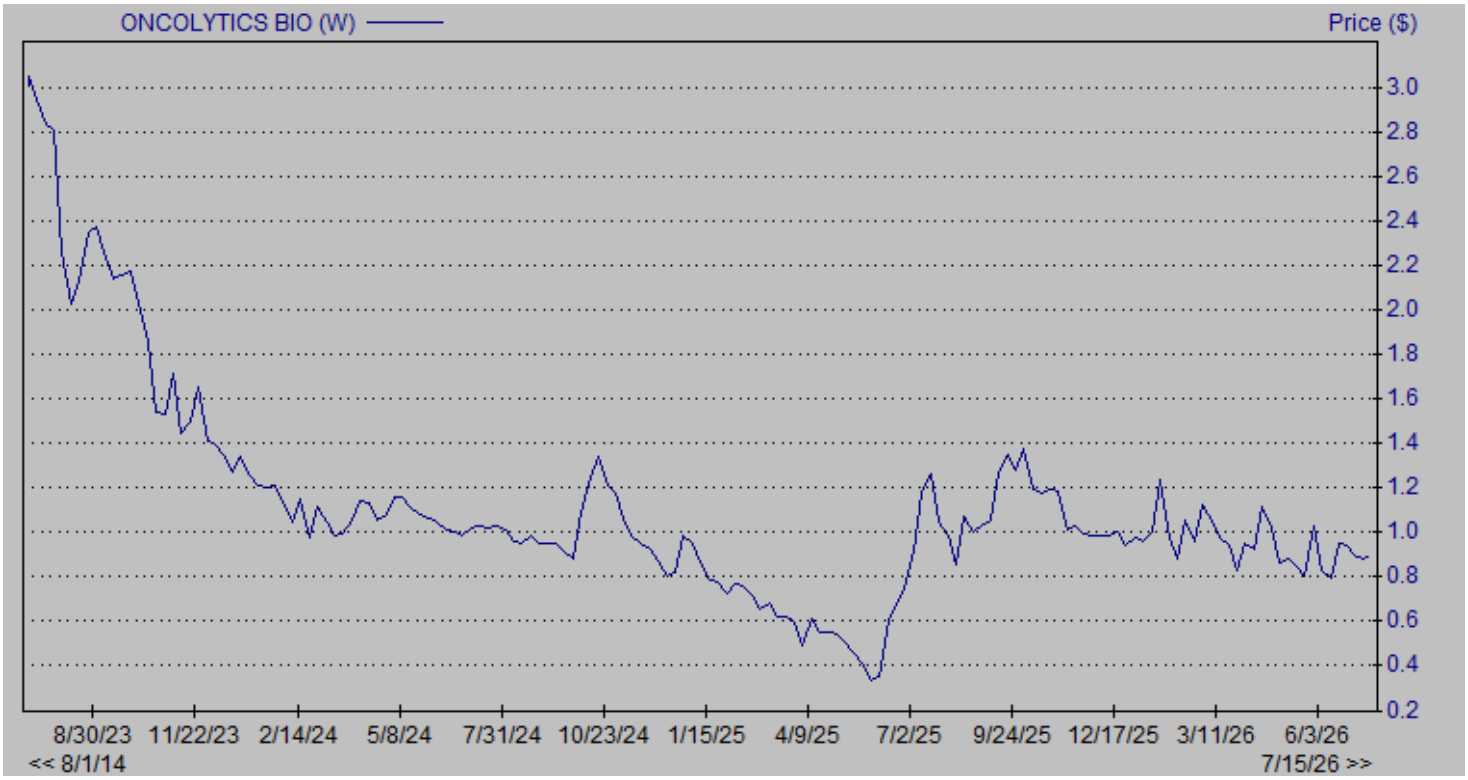
We view the upcoming Type D meeting with the FDA regarding the potential expansion of REO 033 into a registration-directed study as an important inflection point for Oncolytics. FDA feedback will be critical in determining the trial design, endpoint strategy, and regulatory pathway required to support potential registration. Importantly, a successful regulatory alignment could allow Oncolytics to leverage an ongoing randomized trial rather than restart development with a de novo pivotal study, potentially preserving time and capital. We look forward to an update from the company following the receipt of the meeting minutes. With no changes to our model, our valuation remains at $6 per share.

PROJECTED FINANCIALS

Oncolytics Biotech, Inc.	2025 A	1Q A	2Q E	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	$3.4	$3.6	$3.8	$15.4	$17.0	$20.0
General & Administrative	$15.4	$4.7	$4.0	$4.0	$4.0	$16.7	$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)	($7.4)	($7.6)	($7.8)	($32.1)	($34.0)	($38.0)
Non-Operating Expenses (Net)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Pre-Tax Income	($28.7)	($9.2)	($7.4)	($7.6)	($7.8)	($32.0)	($34.0)	($37.0)
Income Taxes Paid	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Net Income	**($28.8)**	**($9.2)**	**($7.4)**	**($7.6)**	**($7.8)**	**($32.0)**	**($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)**	**($7.40)**	**($7.60)**	**($7.80)**	**($32.04)**	**($34.00)**	**($35.00)**
Net Loss per Share	**($0.30)**	**($0.08)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.26)**	**($0.23)**	**($0.21)**
Basic Shares Outstanding	95.9	112.3	120.0	130.0	140.0	125.6	150.0	175.0

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

HISTORICAL STOCK PRICE



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