

## Cardiff Oncology

Jan 28, 2026

### Phase 2 Data Announced With Management Changes

Healthcare

**CRDF**

NCM

Rating

**Outperform**

Unchanged

Current Price

**\$2.00**

Target Price

**\$12.00**

Market Capitalization

**134.72m**

Shares Outstanding

**67.36m**

Float

**62.17m**

Institutional Holdings

**34%**

12-Month Low/High

**\$1.85/\$4.99**

Average 90-Day Volume

**1130000**

Fiscal Year End

**2025-12-31**

**Cardiff Made Two Significant Announcements.** New data from the Phase 2 CRDF-004 trial testing onvansertib as a first line treatment for metastatic colorectal cancer was announced as expected. Patients in the high-dose onvansertib group showed a large benefit in overall response rates (ORR) and progression free survival (PFS). Separately, the CEO and CFO have left the company. Board Member Dr. Mani Mohindru was named Interim CEO.

**Phase 2 Trial Design.** As discussed in our January 5 report, CDRF-004 is a Phase 2 dose-finding trial testing two doses of onvansertib in combination with two standard-of-care (SOC) regimens against the standard of care regimens alone. It enrolled 110 patients with RAS-mutated metastatic colorectal cancer, mCRC. Its primary endpoint is objective response rate (ORR). Secondary endpoints include progression-free survival (PFS), duration of response (DOR) and safety. These endpoints were selected to guide the design of Phase 3.

**Phase 2 Results Show Improvement Over Standard Of Care.** The confirmed Overall Response Rate (ORR) was 72.2% (n=18) for the 30 mg dose compared with 43.2% (n=37) for the combined standard-of-care groups. This touched statistical significance (p<0.051) with a small number of patients. Median Progression Free Survival (PFS) has not been reached for the two onvansertib groups, but the lower end of the confidence interval of 9.72 months for the 30 mg group and exceeds the lower limit the combined SOC groups (9.43, upper limit of 15.44 months) with a median of 10.97 months. The full analysis is expected later in 2026.

**Management Changes.** On a conference call discussing the two news events, Interim CEO Mani Mohindru stated that the company now needs FDA regulatory and marketing experience. CEO Dr. Mark Erlander and CFO James Levine have resigned from the company. A search for a permanent Chief Executive Officer and Chief Financial Officer is underway.

**Conclusion.** We see the CDRF-004 data as a positive result, with additional data expected to be presented at a medical meeting during 1H26. The company intends to confer with the FDA on the design of Phase 3, expected to start later in 2026. The timing of the CEO and CFO departures, in our opinion, created uncertainty and lead to sharp sell-off in the stock despite these results. We are reiterating our Outperform rating and \$12 price target.

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#### Revenues (\$ MIL)

Period	2024A	2025A	2026A
Q1	0.205A	0.109A	0.110E
Q2	0.163A	0.121A	0.110E
Q3	0.165A	0.120A	0.115E
Q4	0.150A	0.085E	0.085E
	0.683A	0.420AE	0.245E

#### EPS (\$)

Period	2024A	2025E	2026E
Q1	(0.22)	(0.20)A	(0.19)E
Q2	(0.26)	(0.21)A	(0.20)E
Q3	(0.25)	(0.18A	(0.21)E
Q4	(0.25)	(0.19)E	(0.22)E
	(0.99)	(8.26)E	(0.82)E

**Summary — Cardiff Oncology Made Two Significant Announcements**

Cardiff Oncology announced new data from the Phase 2 CRDF-004 trial testing onvansertib as a first-line treatment for metastatic colorectal cancer. The trial tests two doses onvansertib in combination with two standard-of-care chemotherapy against standard-of-care alone (SOC). The results as of the January 22, 2026 evaluation date show a substantial improvement in overall response rates (ORR of 72.2%) for the 30mg high-dose group compared with the SOC controls (43.2%). Median Progression Free Survival (PFS) has not been reached for the high dose group, and the lower limit of the confidence interval was 9.72 months. Median survival for the SOC was 10.97 months, with a confidence interval (9.43 to 15.44 months). These SOC results are consistent with published studies, supporting the trial design assumptions.

Based on these data, the company plans to discuss its plans for a Phase 3 that would test the 30 mg dose of onvansertib in combination with a standard of care regimen as a first line treatment, similar to one of the high-dose arms of Phase 2. This is consistent with our expectations and would begin later in 2026.

Separately, the company announced that CEO Dr. Mark Erlander and CFO, James Levine have resigned. Dr. Mani Mohindru, a member of Cardiff Oncology’s Board of Directors was named Interim Chief Executive Officer. Ms. Brigitte Lindsay has been promoted to Chief Financial Office from Senior Vice President of Finance. On a conference call discussing the two news events, the Interim CEO stated that the company has advanced and now needs FDA regulatory and marketing experience. A search for a permanent Chief Executive Officer and Chief Financial Officer is underway.

**Phase 2 Results Show Improvement Over Standard Of Care.** CDRF-004 is a Phase 2 dose-finding trial designed to test two dose levels of onvansertib in combination with standard of care regimens. It enrolled 110 patients with RAS-mutated metastatic colorectal cancer (mCRC), with the four onvansertib combination arms compared to the two standard of care (SOC) regimens alone. The objective of the trial was to determine efficacy, safety, and optimal dosing for a Phase 3 trial.

Patients received onvansertib with FOLFIRI and bevacizumab or FOLFOX with bevacizumab as a first-line treatment, while the control groups received either FOLFIRI or FOLFOX with bevacizumab. The primary endpoint is objective response rate (ORR), and the secondary endpoints include progression-free survival (PFS), duration of response (DOR), pharmacokinetics, safety, and tolerability.

**Exhibit 1. Design of the Phase 2 CRDF-004 Trial.** Patients were randomized into one of four treatment groups receiving onvansertib in combination with either FOLIRI with bevacizumab or FOLFOX with bevacizumab. The control groups received FOLIRI with bevacizumab alone or FOLFOX with bevacizumab alone.

**ENROLLMENT CRITERIA**

First-line mCRC  
 KRAS+/NRAS+  
 Unresectable  
 No prior bev

**R**  
 ITT=110

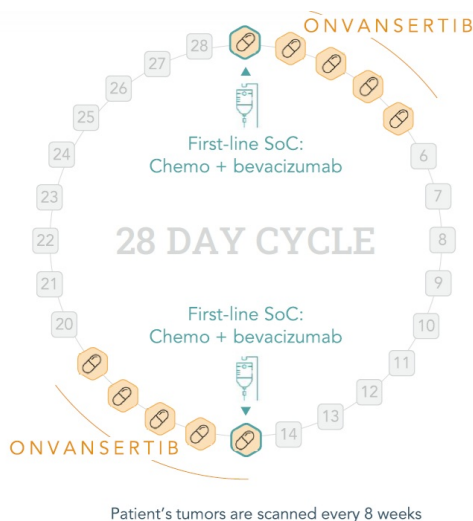
**6 RANDOMIZATION ARMS**

- SoC alone
  1. FOLFIRI/bev
  2. FOLFOX/bev
- Onv 20mg +
  3. FOLFIRI/bev
  4. FOLFOX/bev
- Onv 30mg +
  5. FOLFIRI/bev
  6. FOLFOX/bev

**ENDPOINTS\***

- Primary: ORR
- Secondary: DoR and PFS

\* Assessed by blinded independent central review (BICR)



**Trial Results.** The confirmed Overall Response Rate (ORR) was 72.2% (n=18) for the 30 mg dose compared with 43.2% (n=37) for the combined standard-of-care groups. This endpoint reached statistical significance ( $p < 0.051$ ) even with a small number of patients. The trial is still ongoing, with a final analysis expected later in 2026.

Median Progression Free Survival (PFS) has not been reached for the two onvansertib groups, but the lower end of the confidence interval of 9.72 months for the 30 mg group and exceeds the lower limit the combined SOC groups (9.43, upper limit of 15.44 months) with a median of 10.97 months.

**Exhibit 2. ORR and PFS Data From CRDF-004.** Results from the patients evaluated by January 22, 2026 show substantial benefit over the SOC control group. Hazard ratios (HR, probability of an event happening) also showed a reduction for the onvansertib treatment groups.

Topline Results in intent-to-treat (ITT) population, data cut-off as of January 22, 2026

Parameter	SoC <sup>c</sup> (FOLFIRI/bev+FOLFOX/bev) (n=37)	FOLFIRI/bev (n=19)	Onv 20 mg +FOLFIRI/bev (n=18)	Onv 30 mg +FOLFIRI/bev (n=18)
<b>Objective Response Rate (per BICR)<sup>a</sup></b>				
Confirmed Responders	16	8	8	13
Confirmed ORR (%)	43.2	42.1	44.4	72.2 p-value = 0.051 <sup>f</sup> (vs SoC)
<b>Progression Free Survival<sup>b</sup></b>				
Median PFS (months, 95% CI)	10.97 (9.43-15.44)	10.97 (7.52-NR)	NR (7.49-NR)	NR (9.72-NR)
PFS HR (vs FOLFIRI/bev)			0.56 (0.18-1.73) <sup>d</sup>	0.38 (0.12-1.17) <sup>d</sup>
PFS HR (vs SoC)			0.57 (0.21-1.58) <sup>e</sup>	0.37 (0.13-1.02) <sup>e</sup> p-value = 0.048 <sup>g</sup> (vs SoC)
PFS Rate at 6 months (95% CI)	88.8 (77.4-100)	79.5 (61.1-100)	88.1 (73.9-100)	94.1 (83.6-100)

Bev=bevacizumab; BICR=Blinded Independent Central Review; CI=confidence interval; HR=hazard ratio; NR=not reached; Onv=onvansertib; ORR=objective response rate; PFS=progression-free survival; SoC=standard of care.

<sup>a</sup>ORR is confirmed responses

<sup>b</sup>Progressive disease events were based on combined BICR and Investigator assessments due to very small number of events in BICR assessment. The earliest reported date was used for a conservative estimate.

<sup>c</sup>SoC is the combination of the FOLFIRI/bev and FOLFOX/bev arms

<sup>d</sup>PFS HR is the comparison of the onvansertib arm to FOLFIRI/bev

<sup>e</sup>PFS HR is the comparison of the onvansertib arm to SoC

<sup>f</sup>Fisher's exact test

<sup>g</sup>Log-rank test

Source: Cardiff Oncology, Inc.

**Data Will Be Used To Design The Phase 3 Registration Trial.** Based on these data, we expect the Phase 3 trial to enroll patients with RAS-mutated mCRC, testing onvansertib in combination with FOLFIRI/bevacizumab as first-line treatment. This Phase 3 design would be to be similar to the 30 mg dosage arm in CDRF-004. We expect the comparator to be the SOC arm with either FOLFIRI/bevacizumab or FOLFOX/bevacizumab.

**Conclusion.** We see the CDRF-004 data as a positive result, with additional data expected to be presented at a medical meeting during 1H26. The company intends to meet with the FDA for guidance on the design of Phase 3, expected to start later in 2026. The timing of the CEO and CFO departures, in our opinion, created uncertainty and lead to sharp sell-off in the stock despite these strong results. We are reiterating our Outperform rating and \$12 price target.

## Company Profile

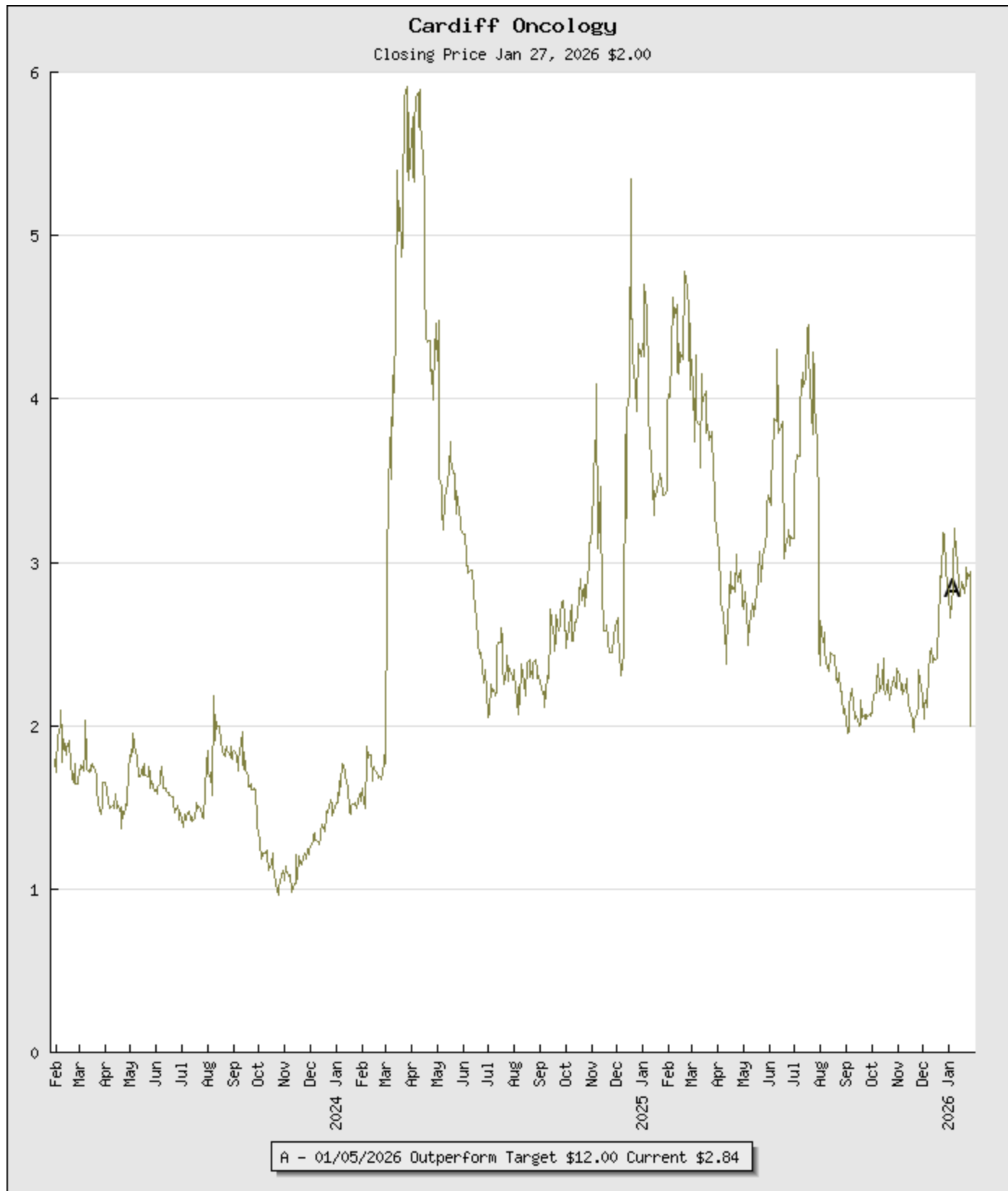
Cardiff Oncology, Inc. is a clinical stage biotechnology company focused on the development of new therapeutics for hematology and oncology. The company's clinical programs evaluating onvansertib (PLK1 inhibitor) include 2 trial in KRAS-mutant colorectal cancer.

## Fundamental Analysis – 4.0/5.0 Checks

In our assessment, we give Cardiff Oncology 4.0 checks out of 5.0, which falls within our “Above Average” range. The company has a unique drug in mid-stage development that can address cancers that resist treatment with standard of care drugs. We see a significant commercial opportunity for a potential KRAS inhibitor such as onvansertib.

## Valuation Summary

We base our valuation intended to be conservative and based on the first full year of onvansertib sales, FY2030. We discount our 2030 revenue estimate of \$661.5 million by 50% to allow for clinical and regulatory risk. We value the stock based on FY2030 EPS of \$2.30 per share. This estimate is discounted at 30% per year to allow for risk, and assigned a multiple of 15X for a price target of \$12 per share.



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Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

### Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

### The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or underserved needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

### Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

### Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

### Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclicalities, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

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Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

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Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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Outperform: potential return is >15% above the current price	84%	14%
Market Perform: potential return is -15% to 15% of the current price	16%	6%
Underperform: potential return is >15% below the current price	0%	0%

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