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## OncoMed Pharmaceuticals, Inc. (OMED)

## Overweight

AACR-NCI-EORTC Summary: Solid Data, Little Stock Impact; Reiterate Overweight

#### CONCLUSION

We attended the AACR-NCI-EORTC meeting in Boston where OncoMed reported positive Phase Ib data on demcizumab in 1st-line Non-Small Cell Lung Cancer (NSCLC) and pancreatic cancer. Demcizumab was active in both indications and OncoMed will begin Phase II trials in 2014. Importantly, OncoMed's cardiac risk mitigation program has been effective with no CV tox and efficacy maintained in patients on truncated demcizumab dosing. The company also reported encouraging Phase I data on anti-Notch1 antibody. OncoMed is the leading Cancer Stem Cell (CSC) play with 5 antibodies in the clinic and partnerships with GlaxoSmithKline and Bayer. We reiterate our Overweight rating and \$30 price target.

- Demcizumab Appears Active. At the AACR-NCI-EORTC meeting in Boston, OncoMed reported positive Phase Ib data in 1st-line NSCLC and pancreatic cancer. The NSCLC dose-escalation trial of 2.5mg/kg, 5mg/kg and 7.5mg/kg demcizumab + Alimta + carboplatin showed 9 (39%) PRs, 11 (48%) stable disease and only 3 (13%) progressive disease. Median PFS was 126 days on 2.5mg/kg and 160 days on 5mg/kg including 3 patients with PFS of >480 days. The on-going pancreatic cancer trial evaluated patients at 2.5mg/kg and 5mg/kg demcizumab + gemcitabine with 4 (25%) PRs, 7 (44%) stable disease for an impressive disease control rate (DCR) of 69%. Estimated median progression free survival (PFS) of 5mg/kg demcizumab + gemcitabine was 176 days. The pancreatic cancer study will enroll patients to demcizumab + gemcitabine + Abraxane with data potentially at ASCO-GI in January. OncoMed will initiate Phase II trials in both indications in 2014.
- Risk Mitigation Program Effective. Due to early signs of cardiopulmonary toxicity with demcizumab, OncoMed instituted a risk mitigation program including BNP monitoring, echocardiograms as well as hypertensive medication and truncated demcizumab dosing if necessary. Importantly, of the 7 NSCLC and 3 pancreatic patients who received truncated dosing, none had CV tox and 3 had PRs and there were 4 patients with stable disease including durable responses.
- First-in-Man Data on 2 Antibodies. OncoMed also presented first-in-man data on OMP-52M51 (Notch1) showing single agent activity in metastatic colorectal and HER2-negative breast cancer patients. Dose escalation continues of OMP-52M51 in an expansion cohort of patients with tumors that have Notch1 activation. OMP-54F28 (Fxd8-Fc) has shown on-target Wnt pathway knock-down. OncoMed and Bayer will initiate 3 Phase Ib studies in 2014. We believe these trials will serve to further validate OncoMed's early clinical pipeline.

### RISKS TO ACHIEVEMENT OF PRICE TARGET

Cancer is a competitive space. Demcizumab or OncoMed's other antibodies may fail in the clinic. OncoMed may not sign new partnerships and will likely require future cash.

## **COMPANY DESCRIPTION**

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	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
YEAR	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2012A	_	_	_	_	24.7	17.0X	–	_	_	_	(1.00)	NM
2013E	2.9A	2.9A	12.9	25.9	44.7	9.4x	(o.39)A	(o.41)A	(0.02)	0.41	(0.40)	NM
2014E	3.9	28.9	3.9	21.9	58.7	7.2X	(0.36)	0.47	(0.42)	0.18	(0.13)	NM

2013 qtrly EPS does not add to annual b/c of IPO

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#### PRICE: US\$15.12 TARGET: US\$30.00

Proj EV of \$684 million + \$164 million mid'14E cash

#### Edward A. Tenthoff

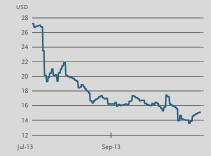
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Changes	Previous	Current
Rating	_	Overweight
Price Tgt	_	US\$30.00
FY13E Rev (mil)	_	US\$44.7
FY14E Rev (mil)	_	US\$58.7
FY13E EPS	_	US\$(0.40)
FY14E EPS	_	US\$(0.13)
52-Week High / Low	US\$31.0	oo / US\$13.51

Shares Out (mil) 27.8 Incl. shares issued in IPO + over allotment

Market Cap. (mil) US\$420.3 Avg Daily Vol (000) 221 Book Value/Share NA Net Cash Per Share US\$5.39 Debt to Total Capital 0% Div (ann) NA Fiscal Year End Dec Pro forma cash following IPO

#### Price Performance - 1 Year



Source: Bloomberg

## **NOVEL CANCER STEM CELL PLAY**

OncoMed is developing therapeutic antibodies that target critical pathways relied upon by cancer stem cells (CSCs). While perhaps not the most precise term, CSCs were so named due to their ability to self-renew and differentiate; similar characteristics that define stem cells in healthy tissue. The easiest way to think of CSCs are as the seed cells that enable a tumor to regrow after initial response to chemo, radiation or targeted therapy. These relapsed or refractory cancers rely on different pathways in order to survive and proliferate, and are often more aggressive than the initial malignancy. It is for this reason that a patient's response subsequent lines of therapy are shorter in duration, representing a huge unmet medical need for advanced and metastatic cancer patients.

OncoMed was founded on a proprietary approach to identify and isolate CSCs. The company wisely focused on understanding the biological pathways that enable these CDCs to proliferate and differentiate. Based on this early start, we now view OncoMed as the dominant CSC play with industry leading discovery efforts, intellectual property and partnerships. This work has yielded a rich pipeline with 5 first-in-class cancer antibodies in the clinic plus another 2 proprietary INDs planned for 2014. Importantly, OncoMed is led by a strong senior management and scientific team.

The company's lead wholly-owned antibody is demcizumab, which targets Delta-Like Ligand 4 (DLL4). DLL4 is a member of the Notch signaling pathway and was originally part of the GlaxoSmithKline (GSK) alliance. GSK did not exercise its option on demcizumab due to cardiopulmonary toxicity. OncoMed has instituted a cardiac risk mitigation plan including BNP monitoring, echocardiograms, as well as hypertensive medication and truncated demcizumab dosing if necessary. Data at the AACR-NCI-EORTC meeting showed that the CRM plan is working with demcizumab showing robust and durable activity, even in patients with shortened dosing. OncoMed intends to initiate the Phase II trials in Non-Small Cell Lung cancer (NSCLC) with Alimta and carboplatin and in pancreatic cancer with Abraxane and gemcitabine early next year. OncoMed is also conducting a Phase Ib study of demcizumab in ovarian cancer with paclitaxel.

In 2007, OncoMed signed an alliance with GSK to develop antibodies targeting the Notch pathway. OncoMed received \$35 million upfront and is eligible for up to \$1.4 billion in milestones and double-digit royalties. The lead antibody under the partnerships is OMP-59R5, which targets Notch 2 and 3. The partners reported encouraging Phase I data at the EORTC meeting last fall and have now embarked upon 2 Phase Ib/II trials of OMP-59R5: the ALPINE trial in pancreatic cancer and the PINNACLE trial in small cell lung cancer. The partners are also conducting 2 Phase I studies in hematologic and solid tumors on OMP-52M51, which targets Notch 1. First-in-man data on OMP-52M51 at the AACR-NCI-EORTC meeting showed single-agent activity in metastatic colorectal and HER2-negative breast cancer patients. Dose escalation continues of OMP-52M51 in an expansion cohort of patients with tumors that have Notch1 activation.

In 2010, OncoMed signed an alliance with Bayer to develop antibodies targeting the Wnt pathway. OncoMed received \$40 million upfront plus \$40 million in milestone for 2 IND filings. OncoMed is eligible for milestones of up to \$387.5 million for each antibody and \$112 million for any small molecule drugs plus double-digit royalties. OncoMed reported Phase I data on the lead antibody, vantictumab, at ASCO and encouraging first-in-man data on OMP-54F28 at the AACR-NCI-EORTC meeting. We expect Bayer will initiate a series of 3 Phase Ib combination trials of both antibodies next year.

Beyond this rich clinical pipeline, we expect OncoMed to file Investigational New Drug (IND) applications on 2 additional wholly-owned antibodies in 2014. Building on its experience with demcizumab, OncoMed is progressing a bi-specific antibody that targets DLL4 and VEGF towards the clinic next year. OncoMed has also identified RSPO-LGR as an emerging CSC pathway and intends to file an IND on novel antibody in early 2014.

### **Upcoming Events**

- Begin 3 Phase Ib combination trials of vantictumab this year and next
- Begin 3 Phase Ib combination trials of OMP-54F28 in early 2014
- Report Phase Ib data on Demcizumab + Abraxane + gemcitabine at ASCO-GI in San Francisco in January 2014
- Report data from the ALPINE trial of OMP-59R5 in pancreatic cancer at ASCO-GI in San Francisco in January 2014
- File an IND on wholly-owned bi-specific antibody targeting DLL4 and VEGF in 2014
- File an IND on novel RSPO-LGR antibody in 2014
- BIG ASCO meeting with meaningful updates on OncoMed's cancer antibodies in June
- GSK could opt-in on both OMP-59R5 and OMP-52M51 next year, triggering milestones of up to \$43 million in 2014
- OncoMed could sign new CSC antibody partnerships

## INVESTMENT RECOMMENDATION

We reiterate our Overweight rating of OncoMed and \$30 price target based on a projected enterprise value of \$684 million plus \$164 million mid'14E net cash. We value whollyowned demcizumab at \$266 million by applying an industry standard 5x multiple to 2020 U.S. NSCLC and pancreatic cancer sales of \$1.13 billion, discounted back at 60% annually to mid'14. This discount rate is high, however we believe captures the safety and clinical risks associated with demcizumab and could come down with positive clinical data. We presently value OMP-59R5 (partnered with GSK) at \$168 million by applying a 5x multiple to OncoMed's royalties on 2021 U.S. sales in pancreatic and small cell cancer of \$544 million, discounted back at 45% annually to mid'14. We view this discount rate as appropriate for this Phase Ib/II antibody having reported early signs of activity. We add \$250 million for the rest of OncoMed's wholly-owned and partnered cancer antibody pipeline, which we will adjust based on +/- clinical results. To this we add mid'14 net cash of \$164 million, which assumes several milestone payments over the next 12 months. Any delay or failure to achieve these milestones would lower our \$30 target. OncoMed has no meaningful long-term debt.

## DEMCIZUMAB (ANTI-DELTA LIKE LIGAND 4 ANTIBODY)

The Delta-Like Ligand 4 (DLL4) contributes to Cancer Stem Cell self-renewal and vascular development. Demcizumab (OMP-21M18) is a humanized IgG2 antibody that blocks DLL4 in the Notch signaling pathway. In minimally passaged human tumor xenografts, demcizumab was observed to have activity against a variety of tumors including colorectal cancer, breast cancer, lung cancer, pancreatic cancer, melanoma and ovarian cancer. In several models using different chemotherapeutic agents, chemotherapy alone was shown to decrease tumor volume; however, this was accompanied by an increased frequency of CSCs in the residual tumors. In contrast, when demcizumab was used alone a decreased frequency of CSCs was observed, with the greatest reduction in CSCs observed when demcizumab was combined with chemotherapy.

In 2011 demcizumab was evaluated as a single agent in Phase I trials in advanced solid tumors. 55 patients were treated in the trial which showed stable disease in a variety of solid tumors including refractory NSCLC, colorectal cancer, head and neck cancer, sarcoma, melanoma, and renal cell carcinoma, among others. 17/55 patients (31%) had a disease control rate of at least three months on the trial. At the highest dose cohort (10mg/kg/week) a disease control rate of 64% was observed out of 25 evaluable patients.

That said, on the data cut-off date of January 19, 2012, the toxicity profile of demcizumab showed that continuous dosing resulted in hypertension and rare cardiovascular toxicity. The hypertension was generally manageable and seen  $1/3^{\rm rd}$  of the patients. Other treatment related adverse events included fatigue, anemia, diarrhea, headache, nausea, hypoalbuminemia and blood pressure increases. 3 patients had Grade 3 congestive heart failure, 1 had Grade 4 congestive heart failure, and 1 had right ventricular failure, all of which were considered treatment related and resulted in demcizumab being put on partial clinical hold, which was lifted in December 2012.

OncoMed subsequently created a risk mitigation (CRM) plan to enhance the therapeutic index of demcizumab and mediated this toxicity by employing an intermittent dosing schedule in the on-going Phase Ib combination trials, and has instituted B-type natriuretic peptide (BNP) cardiac monitoring, echocardiograms and intervention with ACE inhibitors. Three new cases of pulmonary hypertension and heart failure (no deaths) have occurred under these protocols in patients who have been dosed demcizumab for >125 days and the company is exploring truncated dosing. The company has therefore added new cohorts to these trials to evaluate more limited duration of treatment.

Demcizumab is presently in 3 Phase Ib combination trials with Carboplatin + Alimta in advanced non-small cell lung cancer (NSCLC), and with gemcitabine and abraxane in pancreatic cancer and with paclitaxel in ovarian cancer.

OncoMed reported updated Phase Ib data from the first-line NSCLC trial at the AACR-NCI-EORTC meeting in Boston in October. The dose-escalation trial evaluated patients at 2.5mg/kg, 5mg/kg and 7.5mg/kg demcizumab + Alimta + carboplatin. Of 23 evaluable patients, there were 9 (39%) PRs, 11 (48%) stable disease and only 3 (13%) progressive disease. Median progression free survival (PFS) was 126 days on 2.5mg/kg and 160 days on 5mg/kg including 3 patients with PFS of >480 days. Seven patients were not yet evaluable. Importantly, the CRM appears to be working. Of the 7 (23%) patients who had elevations in BNP and received truncated demcizumab dosing (63 days), none had CV tox and there were 1 (14%) PR and 3 (43%) stable disease including durable responses

OncoMed also reported Phase Ib data in 1st-line pancreatic cancer at the AACR-NCI-EORTC meeting. The on-going dose-escalation trial has evaluated patients at 2.5mg/kg and 5mg/kg demcizumab + gemcitabine. Of 16 evaluable patients, there were 4 (25%) PRs and 7 (44%) patients with stable disease for an impressive disease control rate (DCR) of 69%. Estimated median progression free survival (PFS) of 5mg/kg demcizumab + gemcitabine was 176 days. Of the 3 patients on 5mg/kg demcizumab who received truncated dosing (70 days), none had CV tox. Moreover, all 3 responded including 2 PRs and one stable disease with durable responses of >200 days. Five patients (31%) progressed and 8 were not yet evaluable. The study will continue to enroll patients to demcizumab + gemcitabine + Abraxane with data likely at the ASCO-GI meeting in January in San Francisco.

We are encouraged by these Phase Ib results and expect OncoMed to initiate Phase II trials in both NSCLC and pancreatic cancer in 2014. In addition, OncoMed has initiated a Phase Ib/II study of demcizumab in platinum-resistant ovarian cancer, fallopian tube cancer or primary peritoneal cancer. Following a Phase Ib dose-escalation portion to determine MTD of demcizumab in combination with paclitaxel, the company will initiate a Phase II portion with PFS and ORR as the primary endpoints overall survival as a key secondary endpoint. The trial is being conducted at the MD Anderson Cancer Center and will be in part funded by a National Cancer Institute SPORE Grant.

## **NOTCH PATHWAY ANTIBODIES**

In 2007, OncoMed signed an alliance with GSK to develop antibodies targeting the Notch pathway. OncoMed received \$35 million upfront and is eligible for up to \$1.4 billion in milestones and double-digit royalties. GSK retains an option to exclusively license OMP-59R5 through the end of Phase II trials and an early option through the end of Phase I or a standard option through the end of Phase II on OMP-52M51. We presently anticipate GSK will exercise its options on both programs triggering up to \$43 million milestone in 2014.

OMP-52M51

OMP-52M51 is a humanized monoclonal antibody that targets the Notch1 receptor. OncoMed is conducting 2 Phase Ia studies of OMP-52M51 in hematologic and solid tumors. First-in-man data on OMP-52M51 at the AACR-NCI-EORTC meeting showed single-agent stable disease in metastatic colorectal and HER2-negative breast cancer patients. Most common treatment-related AEs have been diarrhea (64%), nausea (27%), fatigue (18%) and rash (18%) including three Grade 3 toxicities: 1 hypertension, 1 diarrhea and 1 fatigue DLT at 2.5mg/kg. Dose escalation continues of OMP-52M51 in an expansion cohort of patients with tumors that have Notch1 activation.

We expect OncoMed will report first-in-man data the Phase I hematologic cancer study in 2014. We presently anticipate that GSK will also exercise its option on OMP-52M51 after completion of Phase I trials next year triggering an additional \$18 million milestone to OncoMed.

## WNT PATHWAY ANTIBODIES

In 2010, OncoMed signed an alliance with Bayer to develop drugs targeting the Wnt pathway. OncoMed received \$40 million upfront, \$40 million for two IND filings and is eligible for significant milestones on any antibody or small molecule drugs developed plus double-digit royalties. Bayer retains an option to exclusively license either vantictumab or OMP-54F28 at any point through completion of Phase I trials. OncoMed and Bayer are also working on a third bi-specific antibody targeting the Wnt pathway that could enter the clinic in 2014 or 2015.

#### OMP-52M51

OMP -54F28 is OncoMed's second Wnt pathway modulator that binds to Wnt ligands rather than the Frizzled receptors distinguishing it from vantictumab. OMP-54F28 is a fusion protein that contains part of the Fzd8 receptor fused to a human Immunoglobulin Fc domain. OMP-54F28 has shown evidence of strong anti-tumor activity and reduction of CSC numbers in multiple preclinical solid tumors models including pancreatic, breast, hepatocellular, ovarian and colorectal cancers.

OncoMed reported first-in-man OMP-54F28 data at the AACR-NCI-EORTC meeting in October. A total of 18 advanced solid tumor patients have been administered 0.5, 1, 2.5, 5, 10 and 15 mg/kg OMP-54F28 every 3 weeks (q3W) with dosing on-going at the 15mg/kg cohort and potential to escalate to 20mg/kg. As of the cut-off date of August 30th, most common Grade 1/2 treatment-related AEs have been decreased appetite (28%), muscle spasm (28%), nausea (22%), altered taste (22%), fatigue (22%), hypocalcemia (16%), diarrhea (11%), peripheral edema (11%), hypophosphatemia (11%), pruritus (11%) and vomiting (11%). One case of Grade 3 anemia was observed. OMP-54F28 had a less pronounced effect on markers of bone metabolism than vantictumab. OMP-54F28 appears to have decreased expression of the Wnt pathway and showed intriguing activity in 2 Desmoid tumors, 1 RCC and 1 pancreatic cancer patient. We anticipate OncoMed will begin 3 Phase Ib combination trials in 2014.

#### INVESTMENT RISKS

Risks associated with OncoMed are typical with all cancer drug discovery/development companies including clinical, regulatory and commercial. Cancer is a competitive field and cancer stem cells represent a novel therapeutic approach with no approved drugs. Cardiovascular toxicity observed with demcizumab could result in the drug not gaining approval. Even if approved, demcizumab utilization may be limited and thus not achieve our sales projections. Other of OncoMed's antibodies may fail in the clinic. OncoMed may be unable to file new INDs. The company's partnerships with GSK and Bayer may falter, resulting in lower milestone payments or royalties than forecast. OncoMed may be unable to attract new partners. OncoMed may need to invest more than projected to develop its drugs and will likely need to raise additional capital in the future. The company could face future unforeseen litigation.

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## OncoMed Pharmaceuticals, Inc. Quarterly Earnings Estimates

(\$ in thousands, except per share data)

9/3/13

	<u>2012A</u>	1QA	2QA	3QE	4QE	2013E	1QE	2QE	3QE	4QE	2014E
Revenues:											
Collaborative R&D	\$24,659	\$2,932	\$2,932	\$12,932	\$25,932	\$44,726	\$3,932	\$28,932	\$3,932	\$21,932	\$58,726
<u>Grants</u>	<u>22</u>	<u>0</u>									
Total Revenues	\$24,681	\$2,932	\$2,932	\$12,932	\$25,932	\$44,726	\$3,932	\$28,932	\$3,932	\$21,932	\$58,726
Operating Expenses:											
Research and Development	\$39,893	\$9,576	\$10,475	\$11,000	\$12,000	\$43,051	\$12,000	\$13,000	\$13,500	\$14,000	\$52,500
General and Administrative	<u>7,157</u>	<u>1,985</u>	<u>1,952</u>	<u>2,500</u>	<u>2,500</u>	<u>8,937</u>	<u>2,250</u>	<u>2,500</u>	<u>2,500</u>	<u>2,750</u>	<u>10,000</u>
Total Operating Expenses	\$47,050	\$11,561	\$12,427	\$13,500	\$14,500	\$51,988	\$14,250	\$15,500	\$16,000	\$16,750	\$62,500
Operating Loss	(\$22,369)	(\$8,630)	(\$9,495)	(\$569)	\$11,432	(\$7,262)	(\$10,319)	\$13,432	(\$12,069)	\$5,182	(\$3,774)
Operating Margin	NM	NM	NM	NM	44.1%	NM	NM	46.4%	NM	23.6%	NM
Other Income/(Expense):											
Interest and Other Income	\$140	\$31	(\$149)	\$65	\$55	\$2	\$45	\$35	\$25	\$15	\$120
Interest Expense	<u>(6)</u>	<u>0</u>									
Total Other Income/(Expense)	\$134	\$31	(\$149)	\$65	\$55	\$2	\$45	\$35	\$25	\$15	\$120
Pretax Loss	(\$22,235)	(\$8,598)	(\$9,644)	(\$504)	\$11,487	(\$7,259)	(\$10,274)	\$13,467	(\$12,044)	\$5,197	(\$3,654)
Pretax Margin	NM	NM	NM	NM	44.3%	NM	NM	46.5%	NM	23.7%	NM
Income Tax/(Benefit)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Tax Rate	NM										
Net Loss	(\$22,235)	(\$8,598)	(\$9,644)	(\$504)	\$11,487	(\$7,259)	(\$10,274)	\$13,467	(\$12,044)	\$5,197	(\$3,654)
Pretax Margin	NM	NM	NM	NM	44.3%	NM	NM	46.5%	NM	23.7%	NM
Net Loss per Share	(\$1.00)	(\$0.39)	(\$0.41)	(\$0.02)	\$0.41	(\$0.40)	(\$0.36)	\$0.47	(\$0.42)	\$0.18	(\$0.13)
Shares Outstanding	22,224	22,265	23,763	27,800	28,000	25,457	28,250	28,500	28,750	29,000	28,625

Source: Company reports and Piper Jaffray & Co. analysis.

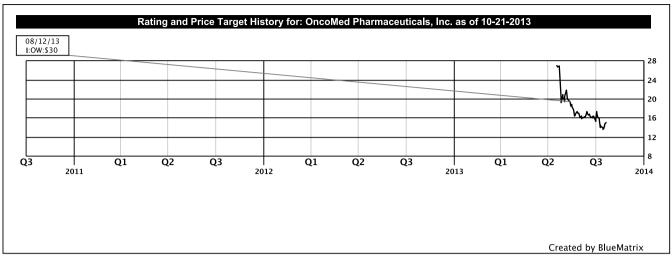
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OncoMed Pharmaceuticals, Inc.

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Legend:

I: Initiating Coverage

R: Resuming Coverage

T: Transferring Coverage

D: Discontinuing Coverage

S: Suspending Coverage

OW: Overweight

N: Neutral

UW: Underweight NA: Not Available UR: Under Review

Distribution of Ratings/IB Services Piper Jaffray								
			IB Serv.	IB Serv./Past 12 Mos.				
Rating	Count	Percent	Count	Percent				
BUY [OW]	336	56.66	72	21.43				
HOLD [N]	231	38.95	14	6.06				
SELL [UW]	26	4.38	0	0.00				

Note: Distribution of Ratings/IB Services shows the number of companies currently in each rating category from which Piper Jaffray and its affiliates received compensation for investment banking services within the past 12 months. FINRA rules require disclosure of which ratings most closely correspond with "buy," "hold," and "sell" recommendations. Piper Jaffray ratings are not the equivalent of buy, hold or sell, but instead represent recommended relative weightings. Nevertheless, Overweight corresponds most closely with buy, Neutral with hold and Underweight with sell. See Stock Rating definitions below.

## Analyst Certification — Edward A. Tenthoff, Sr Research Analyst

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- Overweight (OW): Anticipated to outperform relative to the median of the group of stocks covered by the analyst.
- Neutral (N): Anticipated to perform in line relative to the median of the group of stocks covered by the analyst.
- Underweight (UW): Anticipated to underperform relative to the median of the group of stocks covered by the analyst.

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