Zacks Small-Cap Research

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Celator Pharma (CPXX-NASDAQ)

CPXX: DSMB recommends Phase III to continue, top line data expected to be available in 2Q15, new financing boosts balance sheet, New Applications revealed– Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	04/15/2014
Current Price (02/23/15)	$2.80
12-Month Target Price	**$7.00**

OUTLOOK

Celator is a late stage drug development company with a focus on cancer. The Company has a pipeline based on its unique proprietary CombiPlex platform technology and liposomal/nanoparticle delivery system.

Its lead candidate CPX-351 is a combination of cytarabine and daunorubicin co-encapsulated in a synergistic ratio. CPX-351is in an ongoing Phase III trial and top line data will be available in 2Q15.

Fundamentals of Celator are strong and we are optimistic about the prospect of the company. We rate the shares of the company Outperform.

SUMMARY DATA

52-Week High	**$3.49**
52-Week Low	**$1.70**
One-Year Return (%)	**-19.08**
Beta	**-4.61**
Average Daily Volume (sh)	**238,500**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$94**
Short Interest Ratio (days)	**0.24**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**N/A**
Industry	**Pharmaceutical**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2014	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2015					0.00 E
2016					0.00 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.71 A	-$0.18 A	-$0.14 A	-$0.13 A	-$0.95 A
2014	-$0.16 A	-$0.18 A	-$0.21 A	-$0.15 E	-$0.70 E
2015					-$0.39 E
2016					-$0.49 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

- **DSMB recommends Phase III of CPX-351 to continue,**
- **Top line data for Phase III CPX-351 expected in 2Q15, overall survival data in 1Q16;**
- **Interim Data of Phase II CPX-351 Presented at ASH Meeting**
- **New financing boosts balance sheet;**
- **PKPD study initiated to support NDA filing of CPX-351;**
- **Preclinical data support ongoing Phase I trial of CPX-351 in pediatric patients with ALL;**
- **Valuation attractive;**

The DSMB Recommends Phase III to Continue

On Dec. 1, 2014, Celator announced that the independent Data and Safety Monitoring Board (DSMB) for the Company's Phase III clinical study of CPX-351 has completed a **second planned safety review** and recommended that the study continue as planned without any modifications.

The DSMB decision was based on the safety analysis of the first 225 randomized patients, out of a total of 309 patients who were enrolled in the study. The DSMB will conduct an additional review after all patients become evaluable for safety review.

Celator's lead clinical program **CPX-351** is a 5:1 synergistic ratio of cytarabine:daunorubicin, co-encapsulated in a nano-scale liposome, based on Celator's **CombiPlex** technology platform.

In December 2012, Celator initiated a **pivotal Phase III study** of CPX-351 in partnership with the Leukemia & Lymphoma Society® (LLS). This is a multicenter, randomized, open-label Phase III study of CPX-351 versus the current standard of care, conventional cytarabine and daunorubicin therapy (7+3) in patients with untreated high-risk (secondary) acute myeloid leukemia **(sAML).** Patients were randomized to receive CPX-351 (100u/m^2; Days 1, 3, 5) or conventional 7+3 chemotherapy. The primary efficacy endpoint of the study is overall survival. Secondary endpoints include complete response (CR+CRi) rate, duration of remission, 30- and 60-day mortality, event-free survival, aplasia rate, and rate of stem cell transplant.

In December 2013, the independent Data and Safety Monitoring Board (DSMB) reviewed the first 75 patients and recommended the study continue as planned without any modifications.

The DSMB decision is in line with our expectations. It's not a surprise to us because CPX-351 already demonstrated excellent safety profile in previous clinical studies.

We Look Forward to the Release of Efficacy Data

In October, 2014, Celator completed the targeted enrollment of 300 patients.

The Company is on track to announce remission rate data, a secondary endpoint in **2Q15**. Overall survival data is expected to be available in **1Q16** with the NDA anticipated to be filed in the **2H16**. We estimate CPX-351 to be approved in late 2017 or early 2018 by the FDA.

Celator is also conducting a **Phase II** pharmacokinetic and pharmacodynamics **(PK/PD)** study evaluating the effects of CPX-351 on cardiac repolarization in adult patients with acute hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS). This study will also include patients with moderate baseline hepatic and renal impairment, extending the range of safety and pharmacokinetic observations to this important group of patients.

This PK/PD study is an open-label, single-arm, thorough PK/PD assessment, which will support the NDA filing for CPX-351.

The FDA granted **Fast Track designation** for CPX-351for the treatment of elderly patients with secondary AML. If approved, CPX-351 may ultimately replace 7+3 on the basis of improved efficacy and acceptable safety.

New Financing Boosts Balance Sheet

On Oct. 28, 2014, Celator completed an underwritten public offering of 7,602,823 shares of common stock and warrants to purchase up to 760,282 shares of its common stock, including the exercise in full of the underwriters' over-allotment option to purchase up to an additional 991,673 units.

The financing is offered in units. One unit consists of one share of common stock and a warrant to purchase 0.10 of a share of common stock at a price of $1.95 per unit. The shares of common stock and the warrants are immediately separable and will be issued separately. The warrants will be exercisable upon issuance at an exercise price of $3.58 per whole share and will have a term of five years. The net proceeds to Celator, after underwriting discounts and commissions and estimated offering expenses, were approximately $13.5 million.

We welcome the new financing which has a favorable term. The Company priced the shares at $1.95 per share which is 13% higher than its previous closing market price of $1.72. This new financing immediately boosted the balance sheet of the Company.

In May, 2014, Celator entered into a loan agreement with **Hercules Technology Growth Capital** (HTGC), a specialty finance company that provides customized debt financing to companies in life sciences and technology-related markets. Hercules will provide Celator with access to a term loan of **up to $15 million.**

The first $10 million of the term loan was funded at closing, and is repayable in installments over forty-two months, including an initial interest-only period of twelve months after closing. The interest-only period is extendable to October 2015, contingent upon completion of certain related development milestones. Pursuant to the loan and security agreement, Celator issued Hercules a warrant to purchase 158,006 shares of the Company's common stock at an exercise price of $2.67 per share. The remaining $5 million of the term loan can be drawn down at Celator's option at any time between December 15, 2014 and March 31, 2015. If Celator draws down the remaining $5 million of the term loan, the warrant will become exercisable for an additional 52,669 shares of the Company's common stock.

Also in Jan, 2015, CPXX received approximately $1,937,000 from the sale of its net operating losses under the New Jersey Technology Business Tax Certificate Transfer Program for the year 2014.

As of September 30, 2014, Celator held cash and cash equivalents of $20.2 million. With the proceeds from the new financing, the Company should have cash of approximate $28 million at the end of 2014. Current cash balance, coupled with projected cash flows, will allow the Company to carry its operations into the **2nd half of 2016**.

Interim Data of Phase II CPX-351 Presented at ASH Meeting

In December, 2014, CPXX presented interim clinical data from an ongoing investigator-initiated study of CPX-351 in adults with untreated high-risk myelodysplastic syndrome (MDS) and AML at high risk of treatment-related mortality at the ASH meeting.

In this study, patients were randomized to receive lower doses of CPX-351 at either 32 or 64 units/m^2 by 90-minute infusion on days 1, 3, and 5.

The 32 unit/m^2 dose level continues to enroll and now has 15 patients. The historical rate of 30-day mortality for patients eligible for the study is reported to be 31%. The 64 unit/m^2 dose level observed a similar rate of 30-day mortality and is thought to be unlikely to reduce the rate further. Objective responses have been observed at both dose levels.

Patients who historically were considered 'unfit' to receive intensive chemotherapy are typically at high risk for treatment-related mortality or therapeutic resistance, but there is no agreed upon approach to define these patients. This study is the first of a series of studies that will attempt to define the "unfit" population and how best to use CPX-351 in patients who may not be able to tolerate the dose and schedule used in more intensive treatment regimens.

CPXX Initiates PK/PD Clinical Study of CPX-351 to Support NDA Filing

On August 19, 2014, CPXX announced that the first patient has been enrolled in a **Phase II** pharmacokinetic and pharmacodynamics (PK/PD) study evaluating the effects of CPX-351 (cytarabine:daunorubicin) Liposome Injection on cardiac repolarization in adult patients with acute hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), and myelodysplastic syndrome (MDS). This study will also include patients with moderate baseline hepatic and renal impairment, extending the range of safety and pharmacokinetic observations to this important group of patients.

This Phase II PK/PD study is an open-label, single-arm, thorough PK/PD assessment. The study will

- measure the effects of CPX-351 on cardiac repolarization following the first induction cycle of CPX-351;
- assess the impact of moderate hepatic impairment on cytarabine and daunorubicin pharmacokinetics;
- assess the impact of moderate renal impairment on cytarabine and daunorubicin pharmacokinetics.

According to the protocol, the study is expected to enroll 36 patients. Each patient will receive a first induction of CPX-351 on days 1, 3 and 5 and, if necessary, a second induction for patients with reduced leukemia/MDS burden not yet achieving a leukemia/MDS-free state. Responding patients are eligible for up to four consolidation courses. Analysis of treatment impact on cardiac electrophysiology, as measured by the QTc interval, and PK assessments will be performed only following the first induction course.

This Phase II study is being conducted to support the NDA for CPX-351.

Preclinical Data for CPX-351 Support Ongoing Pediatric Phase I Trial

On September 15, 2014, CPXX announced the publication of **preclinical data** in Pediatric Blood & Cancer. The title of the publication is "Efficacy of CPX-351, (Cytarabine:Daunorubicin) Liposome Injection, Against Acute Lymphoblastic Leukemia Xenograft Models of the Pediatric Preclinical Testing Program."

The efficacy of CPX-351 was studied against a panel of aggressive and chemoresistant childhood ALL **xenograft models**. The results show that CPX-351 administered at 5 units/kg demonstrated potent anti-leukemic activity in vivo and was highly efficacious against all xenograft models tested, inducing complete responses in four B-lineage xenografts and a partial response in one T-lineage xenograft. The dose used provided clinically relevant plasma drug exposure and correlated to the pharmacokinetic properties observed in patients with AML.

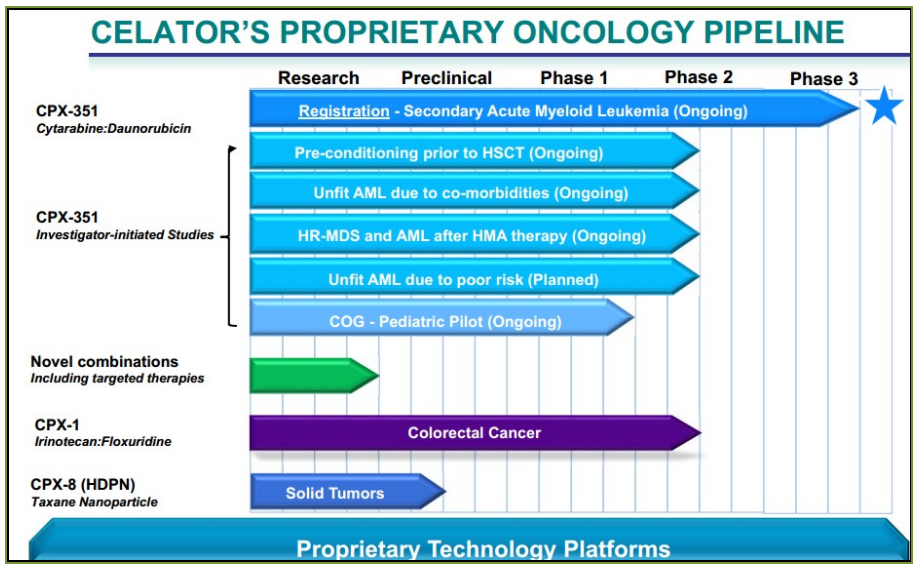
The preclinical data further demonstrated the potential of CPX-351 in hematological malignancies and support its ongoing **Phase I** clinical testing in pediatric patients with ALL.

CPX-351 to be Explored in Additional Patient Populations

In addition to the Phase III study of CPX-351 for sAML, Celator is also studying CPX-351 in **other patient populations**. Parallel development in **other AML patient populations** and other **hematologic malignancies** is underway, which include:

- A **Phase II** study in high-risk myelodysplastic syndromes (MDS) and AML patients at increased risk of treatment-related mortality is ongoing at Fred Hutchinson Cancer Research Center.
- Another ongoing **Phase II** study of AML and high-risk MDS patients who have relapsed or are refractory to prior hypomethylating agents is conducted at Stanford University.
- A **Phase I/II** study of CPX-351 as a pre-conditioning regimen prior to hematopoietic stem cell transplantation (HSCT) in AML and high-risk MDS patients is conducted at Cornell University.
- Ongoing **Phase I/II** study in pediatric, adolescent and young adult patients with relapsed or refractory hematologic malignancies (COG Pilot Study) at Cincinnati Children's Hospital.
- Planned **Phase II** study to initiate in 2014 of newly diagnosed AML patients at high risk for induction mortality at MD Anderson Cancer Center.

The development of CPX-351 in other patient populations will help establish the utility of the drug. The differentiation strategy being pursued is for CPX-351 to replace the standard of care, the 7+3 regimen, in AML. There has been interest among hematologists in extending the use of CPX-351 to other hematologic malignancies such as myelodysplastic syndrome and acute lymphoblastic leukemia based on data obtained in Celator's clinical studies as well as in preclinical studies.

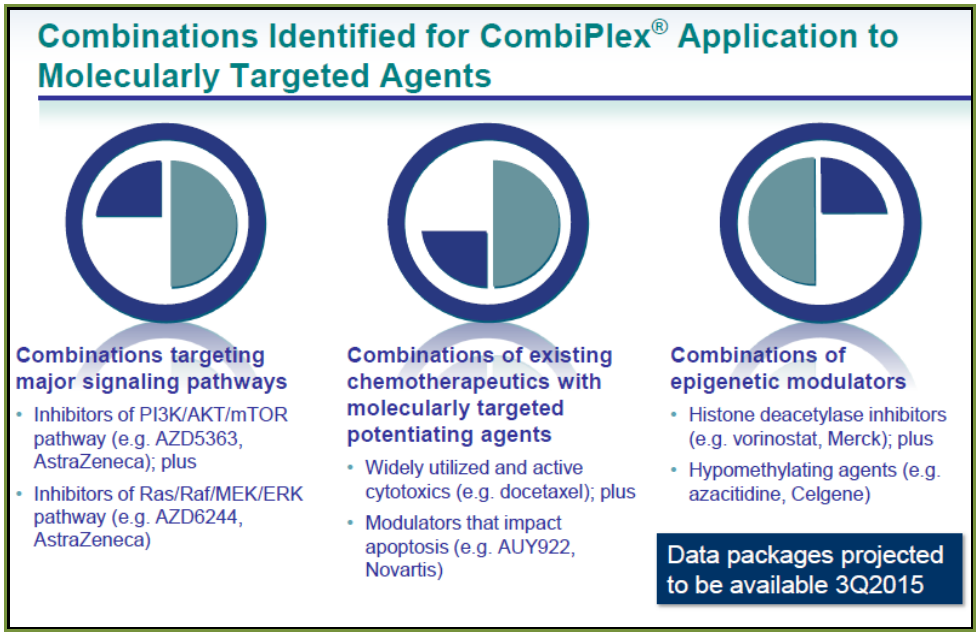


New Applications Announced for CombiPlex Platform for Targeted Therapies

At the Analyst Day meeting, Celator also announced plans to widen its application to include **molecularly targeted therapies** from its CombiPlex platform. Data from the new applications are expected by **3Q2015**. Three areas of applications have been identified:

- Combinations targeting major signaling pathways associated with major cancer indications:
  - Inhibitors of PI3K/AKT/mTOR pathway in combination with
  - Inhibitors of Ras/Raf/MEK/ERK pathway
- Combinations of existing chemotherapeutics with molecularly targeted agents:
  - Active cytotoxics such as taxanes in combination with
  - Cellular response modulators that control apoptosis
- Combinations of epigenetic modulators:

- o Histone deacetylase inhibitors in combination with
- o Hypomethylating agents



It's our belief that the new applications will generate promising new product candidates for internal as well as establish proof of principle to support potential research and development collaborations.

Valuation Attractive

We maintain an Outperform rating on Celator shares and reiterate our 12-month price target of $7.00.

Celator is a late stage specialty pharmaceutical company with a focus on cancer. The company has built a decent pipeline using its unique, proprietary **CombiPlex** platform technology and **liposome/nanoparticle** delivery system.

Celator's lead clinical program **CPX-351** is in a **Phase III** clinical trial and top line data will be available in 2Q15. CPX-351 targets **AML** patients. Completed Phase II studies demonstrated that CPX-351 was safe and well tolerated in AML patients and that the drug candidate achieved significant efficacy improvements over control in high-risk AML patient populations such as secondary AML and poor-risk first relapse patients. Based on the positive Phase II data, we believe CPX-351 has a high success rate in the ongoing Phase III study. We expect CPX-351 to be approved by the FDA in late 2017 and by the EMA in 2018.

Celator's second program is **CPX-1** for **CRC.** CPX-1 has completed a **Phase II** clinical trial for CRC. Other than CPX-351 and CPX-1, Celator has two preclinical programs: CPX-571 and CPX-8 for solid tumors.

In terms of valuation, we think Celator's shares are undervalued at current market price. Currently Celator shares are trading at about $2.80 per share, which represents a market cap of $95 million based on 34 million outstanding shares. This undervalues Celator based on its relatively strong fundamentals. According to our model, we expect CPX-351 to be approved in 2017 by the FDA and in 2018 by the EMA. We model Celator will become profitable (EPS of $0.03) in 2018 based on CPX-351 sales of $35 million. Sales of CPX-351 will accelerate in 2019 after the company gains marketing experience and further market penetration. If we use a P/E multiple of 350x, coupled with EPS of $0.62 in 2019, and discounted at 28% for 4 years, we come up with our price target of $7.00, which represents a market cap of $182 million.

But keep in mind the **risks**. Since Celator is still a clinical stage company, there are still **clinical** and **regulatory** hurdles for the company to overcome. Even when CPX-351 is approved, there are still **commercial risks** since CPX-351 will be the first commercial product for the company. In addition, general market condition will also have significant impact on the company's share price down the road. However, overall, we believe Celator is a name for investors with a long term investment horizon and high risk tolerance.

PROJECTED INCOME STATEMENT

	2012 (Dec)	2013A (Dec)	2014E (Dec)					2015E (Dec)	2016E (Dec)	2017E (Dec)	2018E (Dec)	2019E (Dec)
$ in million except per share data	FYA	FYA	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE	FYE
Product revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$3.50	$35.00	$75.00
Other revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$3.50**	**$35.00**	**$75.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	900.0%	114.3%
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.53	5.25	11.25
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$2.98**	**$29.75**	**$63.75**
Gross Margin	-	-	-	-	-	-	-	-	-	85.0%	85.0%	85.0%
R&D	$3.41	$8.86	$2.33	$2.80	$3.20	$4.25	$12.58	$7.50	$10.00	$13.50	$15.00	$17.50
% R&D	-	-	-	-	-	-	-	-	-	385.7%	42.9%	23.3%
SG&A	$4.10	$5.43	$1.89	$1.73	$1.87	$1.60	$7.09	$7.00	$8.50	$10.50	$12.50	$15.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.49	$0.32	$0.05	$0.05	$0.05	$0.05	$0.19	$0.20	$0.50	$0.50	$0.50	$0.00
Operating Income	**($8.0)**	**($14.6)**	**($4.3)**	**($4.6)**	**($5.1)**	**($5.9)**	**($19.9)**	**($14.7)**	**($19.0)**	**($21.5)**	**$1.8**	**$31.3**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	41.67%
Other Net	($4.3)	($7.6)	($0.0)	($0.2)	($0.4)	($0.2)	($0.8)	($0.8)	($0.8)	($0.5)	($0.1)	($0.1)
Pre-Tax Income	**($12.3)**	**($22.2)**	**($4.3)**	**($4.8)**	**($5.5)**	**($6.1)**	**($20.6)**	**($15.5)**	**($19.8)**	**($22.0)**	**$1.7**	**$31.2**
Income taxes(benefit)	($1.4)	($1.4)	$0.0	$0.0	$0.0	($1.1)	($1.1)	($1.0)	($1.0)	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($10.9)**	**($20.8)**	**($4.3)**	**($4.8)**	**($5.5)**	**($5.0)**	**($19.5)**	**($14.5)**	**($18.8)**	**($22.0)**	**$1.7**	**$31.2**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-			
Diluted Shares Out	12.4	22.0	26.0	26.1	26.1	33.0	27.8	37.0	38.5	45.0	48.5	50.0
Reported EPS	**($0.88)**	**($0.95)**	**($0.16)**	**($0.18)**	**($0.21)**	**($0.15)**	**($0.70)**	**($0.39)**	**($0.49)**	**($0.49)**	**$0.03**	**$0.62**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($10.9)**	**($20.8)**	**($4.3)**	**($4.8)**	**($5.5)**	**($5.0)**	**($19.5)**	**($14.5)**	**($18.8)**	**($22.0)**	**$1.7**	**$31.2**
Non GAAP EPS	**($0.88)**	**($0.95)**	**($0.16)**	**($0.18)**	**($0.21)**	**($0.15)**	**($0.70)**	**($0.39)**	**($0.49)**	**($0.49)**	**$0.03**	**$0.62**

Source: company filings and Zacks estimates

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.3%, Hold/Neutral- 78.4%, Sell/Underperform – 4.6%. Data is as of midnight on the business day immediately prior to this publication.