Zacks Small-Cap Research

May 11, 2015
Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Celator Pharma (CPXX-NASDAQ)

CPXX: Current cash can last into 2H2016, top line data expected to be available in 2Q15---Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	04/15/2014
Current Price (05/08/15)	$2.00
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 Buy.

SUMMARY DATA

52-Week High	**$3.12**
52-Week Low	**$1.70**
One-Year Return (%)	**-27.41**
Beta	**-3.51**
Average Daily Volume (sh)	**110,333**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$66**
Short Interest Ratio (days)	**0.67**
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)
2014	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2015	0.00 A	0.00 E	0.00 E	0.00 E	0.00 E
2016					0.00 E
2017					3.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.16 A	-$0.18 A	-$0.21 A	-$0.07 A	-$0.62 A
2015	-$0.14 A	-$0.13 E	-$0.11 E	-$0.10 E	-$0.47 E
2016					-$0.49 E
2017					-$0.49 E

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

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

- ***Update on 1Q15 Financials;***
- ***Remission rate data from Phase III CPX-351 expected by the end of 2Q15, overall survival data in 1Q16;***
- ***Promising data of CPX-351 in combination with Chk1 inhibitors presented at AACR;***
- ***Valuation attractive;***

CPXX's Current Cash Can Last into 2H2016

On May 7, Celator reported its financial and operational results for the first quarter ended March 31, 2015.

There was no revenue for the first quarter of 2015.

R&D expenses decreased to $2.7 million for 1Q15 from $3.0 million for the same period in 2014. The decrease was largely due to lower manufacturing costs and the elimination of costs associated with a metabolism study that began during the second half of 2013 for CPX-351 and ended in 2014. These decreases were offset by increases in outsourced clinical trial and regulatory activities related to CPX-351.

G&A expenses were $1.8 million for the first quarter of 2015, compared to $1.9 million for the same period in 2014. The decrease was primarily due to a decrease in professional fees and franchise taxes. These decreases were offset by increases in compensation and stock option expenses.

Net loss was $4.7 million ($0.14 per share) for the first quarter of 2015, compared to $4.3 million ($0.16 per share) for the same period in 2014.

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.

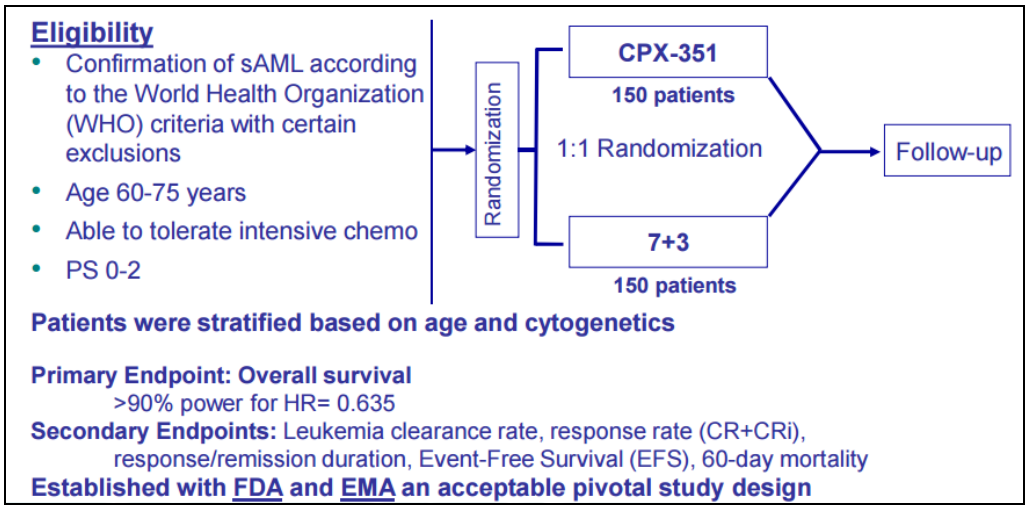
As of March 31, 2015, cash and cash equivalents were $32.9 million, compared to $32.4 million as of December 31, 2014. The net increase of $0.5 million was due to $5.0 million in proceeds from the final draw down of the Hercules Technology Growth Capital loan. This was offset by cash used in operating activities of approximately $4.5 million.

Current cash balance, coupled with projected cash flows, will allow the Company to carry its operations into the **2nd half of 2016**.

Initial Efficacy Data of Phase III CPX-351 Available by the end of 2Q15

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 October, 2014, Celator completed the targeted enrollment of 309 patients and the last patient has completed the treatment.

The Company is collecting data now and is on track to announce **remission rate data (CR/CRi)**, a secondary endpoint at **the end of 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.

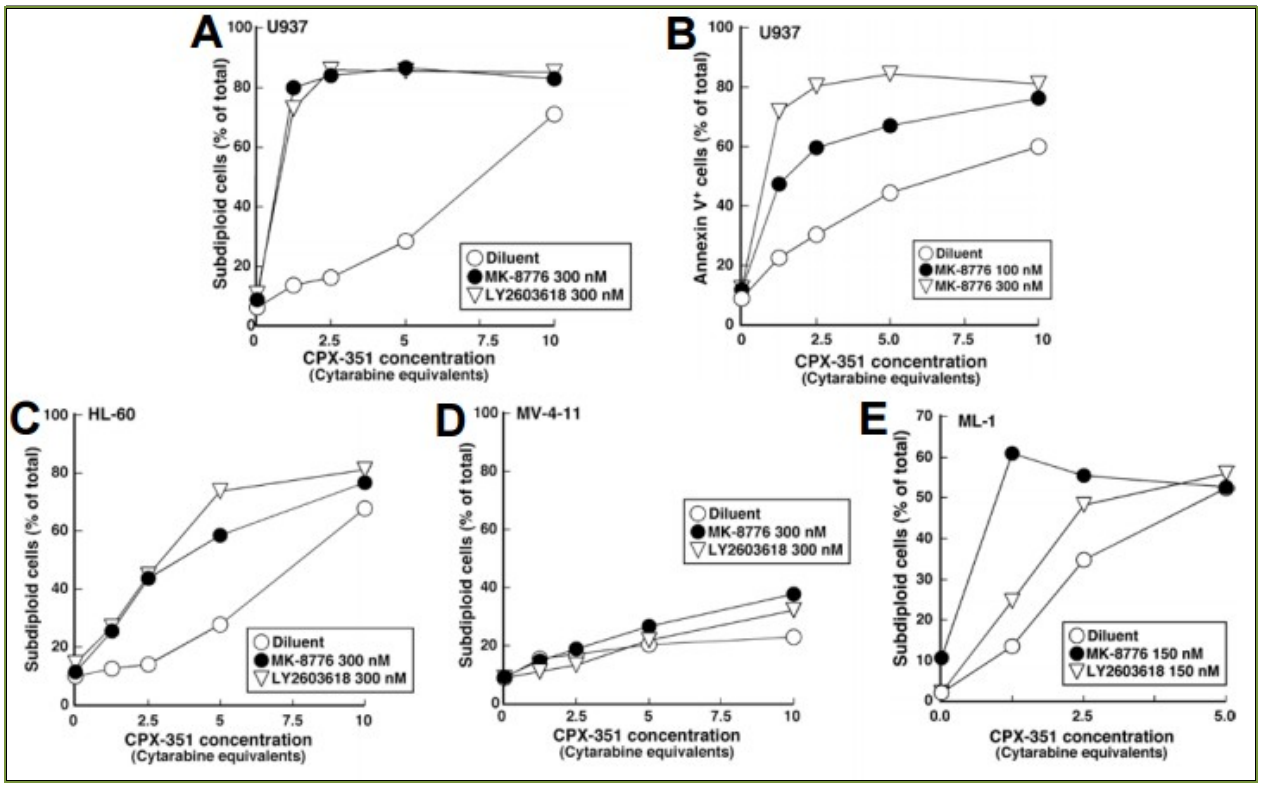
Combination of CPX-351 with Targeted Therapy Are Promising in Treating Cancers

In April at the American Association for Cancer Research (AACR) Annual Meeting, Celator presented promising new data from CPX-351 in combination with targeted therapy.

Human checkpoint kinase 1 **(Chk1)** is an essential kinase required to preserve genome stability, and has emerged as promising novel therapeutic target for cancer treatment. At the AACR meeting, Celator presented data evaluating CPX-351 alone and in combination with the Chk1 inhibitors MK-8776 and/or LY2603618 in AML cell lines and in clinical AML samples ex vivo.

Data demonstrated that CPX-351 in combination with MK-8776 or LY2603618 enhances cell death in different AML cell lines. The CPX-351/MK-8776 combination displayed enhanced antiproliferative effects against some clinical AML isolates ex vivo compared to CPX-351 alone.

These results show that Chk1 inhibition enhances the cytotoxicity of CPX-351 in AML cell lines and some clinical AML samples, offering the possibility that CPX-351 may be well suited for combining with such molecularly targeted agents.

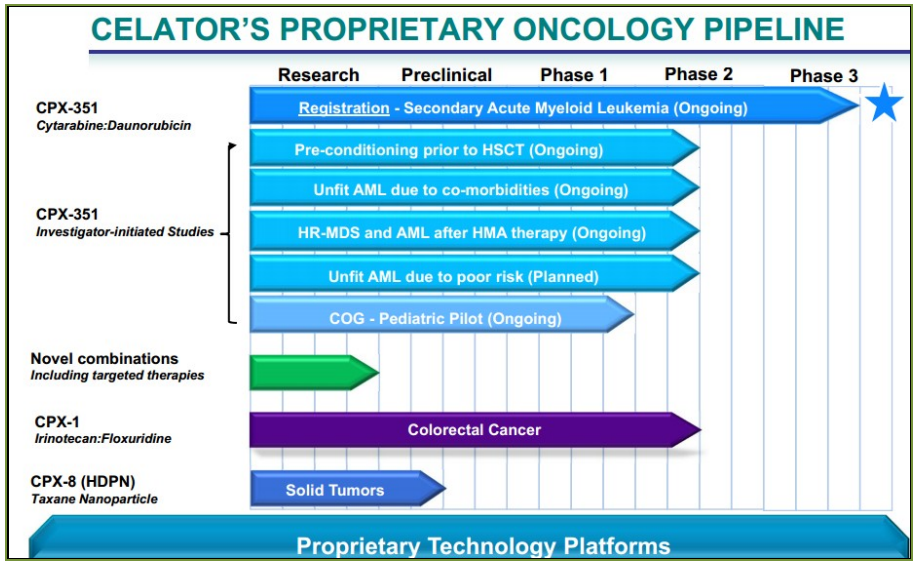


CPX-351 to be Explored in Additional Patient Populations

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 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.

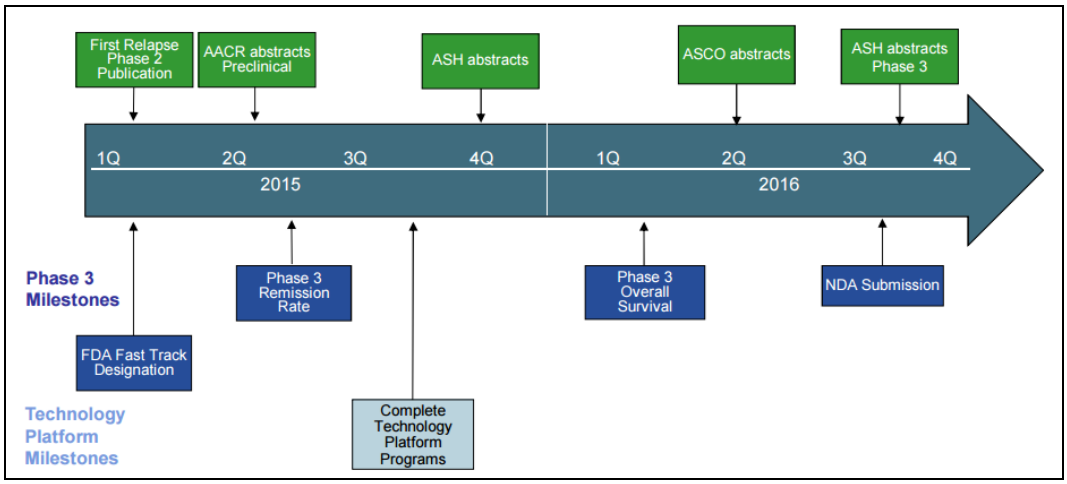


Valuation Attractive

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 June 2015, which is a major catalyst for Celator. 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 $2.00 per share, which represents a market cap of $68 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 30x, 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 $238 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. However, overall, we believe Celator is a name for investors with a long term investment horizon and high risk tolerance.

PROJECTED INCOME STATEMENT

	2014 (Dec)					2015E (Dec)					2016E (Dec)	2017E (Dec)	2018E (Dec)	2019E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4	FYA	Q1A	Q2E	Q3E	Q4E	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	$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	$0.00	$0.00
Total Revenues	**$0.00**	**$0.00**	**$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	0.00	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**	**$0.00**	**$0.00**	**$2.98**	**$29.75**	**$63.75**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	85.0%	85.0%	85.0%
R&D	$2.33	$2.80	$3.20	$2.02	$10.35	$2.57	$2.20	$1.85	$1.70	$8.32	$10.00	$13.50	$15.00	$17.50
% R&D	-	-	-	-	-	-	-	-	-	-	-	385.7%	42.9%	23.3%
SG&A	$1.89	$1.73	$1.87	$1.80	$7.29	$1.76	$1.95	$2.00	$2.20	$7.91	$8.50	$10.50	$12.50	$15.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$0.05	$0.05	$0.05	$0.13	$0.27	$0.05	$0.05	$0.05	$0.05	$0.20	$0.50	$0.50	$0.50	$0.00
Operating Income	**($4.3)**	**($4.6)**	**($5.1)**	**($3.9)**	**($17.9)**	**($4.4)**	**($4.2)**	**($3.9)**	**($4.0)**	**($16.4)**	**($19.0)**	**($21.5)**	**$1.8**	**$31.3**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	41.67%
Other Net	($0.0)	($0.2)	($0.4)	($0.3)	($0.9)	($0.3)	($0.2)	($0.2)	($0.2)	($0.9)	($0.8)	($0.5)	($0.1)	($0.1)
Pre-Tax Income	**($4.3)**	**($4.8)**	**($5.5)**	**($4.3)**	**($18.8)**	**($4.7)**	**($4.4)**	**($4.1)**	**($4.2)**	**($17.4)**	**($19.8)**	**($22.0)**	**$1.7**	**$31.2**
Income taxes(benefit)	$0.0	$0.0	$0.0	($1.9)	($1.9)	$0.0	$0.0	$0.0	$0.0	$0.0	($1.0)	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($4.3)**	**($4.8)**	**($5.5)**	**($2.4)**	**($16.9)**	**($4.7)**	**($4.4)**	**($4.1)**	**($4.2)**	**($17.4)**	**($18.8)**	**($22.0)**	**$1.7**	**$31.2**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-			
Diluted Shares Out	26.0	26.1	26.1	31.5	27.4	33.7	35.0	37.5	40.0	36.6	38.5	45.0	48.5	50.0
Reported EPS	**($0.16)**	**($0.18)**	**($0.21)**	**($0.07)**	**($0.62)**	**($0.14)**	**($0.13)**	**($0.11)**	**($0.10)**	**($0.47)**	**($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*	*$0.00*	*$0.00*
Non GAAP Net Income	**($4.3)**	**($4.8)**	**($5.5)**	**($2.4)**	**($16.9)**	**($4.7)**	**($4.4)**	**($4.1)**	**($4.2)**	**($17.4)**	**($18.8)**	**($22.0)**	**$1.7**	**$31.2**
Non GAAP EPS	**($0.16)**	**($0.18)**	**($0.21)**	**($0.07)**	**($0.62)**	**($0.14)**	**($0.13)**	**($0.11)**	**($0.10)**	**($0.47)**	**($0.49)**	**($0.49)**	**$0.03**	**$0.62**

Source: company filings and Zacks estimates

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Grant Zeng, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

© Copyright 2015, Zacks Investment Research. All Rights Reserved.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1104 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
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.