Zacks Small-Cap Research

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Celator Pharma (CPXX-NASDAQ)

CPXX: Positive top line data reported for Phase III CPX-351, overall survival expected for 1Q16 ---Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	04/15/2014
Current Price (06/23/15)	$2.24
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. The company just announced positive top line data from the Phase III trial.

Fundamentals of Celator remains 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**
52-Week High	**$3.12**
52-Week Low	**$1.70**
One-Year Return (%)	**-25.58**
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**

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WHAT'S NEW

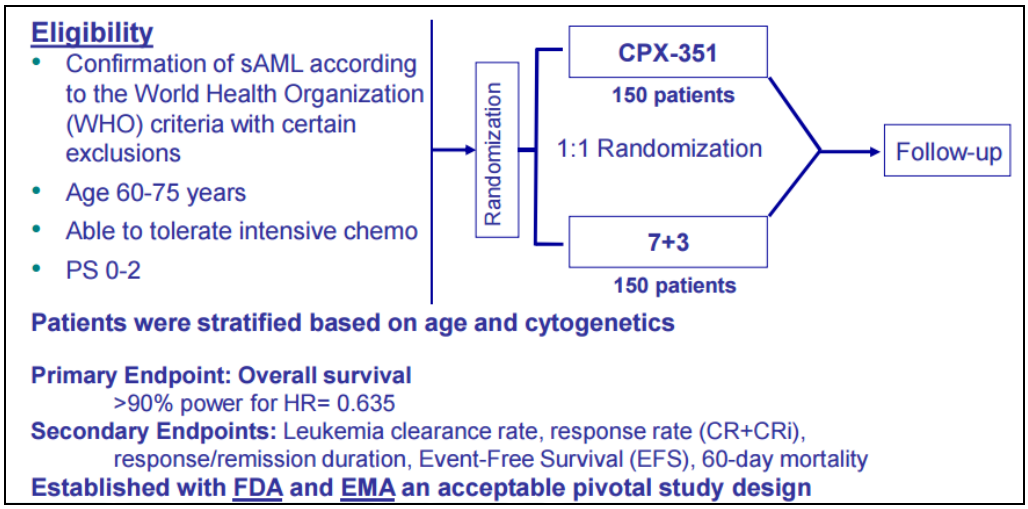
- ***Positive induction response rate announced, overall survival data in 1Q16;***
- ***CPXX completes enrollment of Phase II PKPD study;***
- ***CPXX expands clinical study of CPX-351 for MDS and AML;***
- ***Valuation attractive;***

CPXX Announces Positive Induction Response Results from Phase III Study of CPX-351

Background

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.

Positive Data Announced

Earlier today (June 24, 2015), Celator announced final **induction response rate** (complete remission plus complete remission with incomplete hematologic recovery, or CR+CRi) in the Phase III study comparing CPX-351 to the standard of care regimen 7+3.

The Phase III study evaluated 309 patients, aged 60-75 years, from 39 clinical centers in the U.S. and Canada, with untreated high-risk (secondary) AML. The induction response rate for CPX-351 is 47.7% vs. 33.3% for the 7+3 regimen, representing a relative improvement of 43.2%.

Data on overall survival, the primary endpoint, are expected in 1Q16.

In addition to induction response and overall survival, other important information, such as rate of morphologic leukemia-free state, best overall response, response duration, event-free survival, and early mortality, as well as pharmacoeconomic comparisons, will be assessed and available at the conclusion of the study.

Induction response rate is a key secondary endpoint in the Phase III study and has been an important surrogate of overall survival and clinical benefit in this patient population. These data validate the induction response rates observed in the Phase II study, which was associated with a marked improvement in overall survival.

We are pleased with the positive data from the Phase III trial. The 43% improvement in induction response rate for CPX-351 is promising since response rate in induction therapy for AML has historically served as a surrogate for overall survival. Based on the encouraging induction response rate, we believe there will be a high probability that the overall survival will also be positive.

CPXX Completes Enrollment in CPX-351 Phase II PKPD Study to Support NDA Submission

In early June, Celator completed the enrollment of its **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 Phase II is an open-label, single-arm PK/PD study for the thorough assessment of

- the effects of CPX-351 on cardiac repolarization following the first induction cycle of CPX-351;
- the correlation of changes in cardiac repolarization with plasma pharmacokinetic data for cytarabine and daunorubicin and their metabolites.

CPXX initiated the PK/PD study in August 2014 to support the NDA of CPX-351. Each patient received 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 disease-free state. Responding patients were eligible for up to four consolidation courses. Analysis of treatment impact on cardiac electrophysiology, as measured by the QTc interval, and PK assessments were performed following the first induction course.

The study enrolled total of **26 patients** with newly diagnosed de novo and high-risk (secondary) AML, relapsed/refractory AML and relapsed ALL. Fifteen of the 26 patients enrolled are evaluable for response at this time. Six of the 15 patients **(40%)** responded to CPX-351 (defined as CR-complete response or CRi-complete response with incomplete hematologic recovery) including 2 of 3 patients **(67%)** with high-risk (secondary) AML, the study population of the ongoing Phase III trial. Responses were also seen in patients with de novo AML, relapsed AML, and relapsed ALL.

The company expects to report top-line results from this PKPD study by **the end of the year**.

With the data available from the PKPD study by year end, CPXX is one step closer to submit a NDA for market approval. Specifically, we estimate CPXX will submit a NDA in the 2H16 and that CPX-351 will be approved in late 2017 or early 2018 by the FDA.

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.

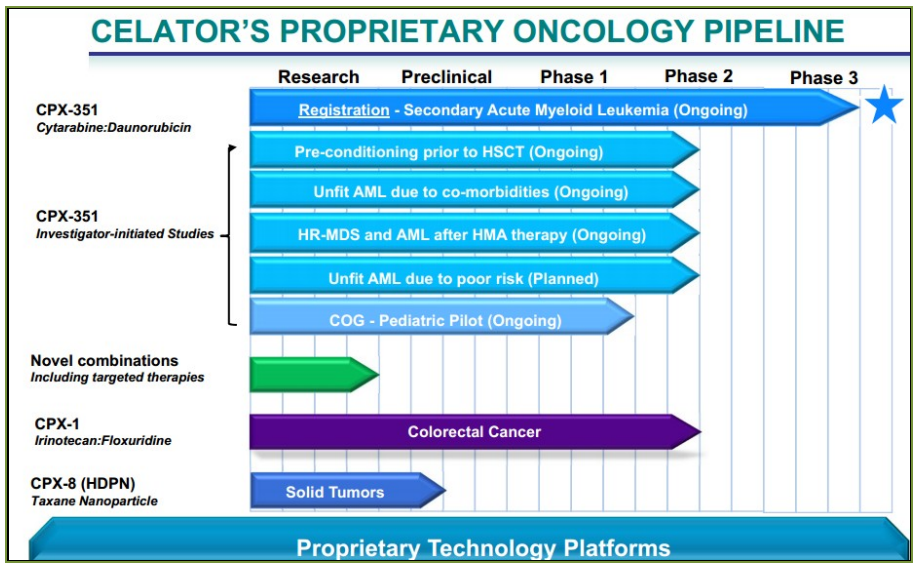
CPXX Expands Clinical Study in Patients with Untreated MDS or AML at High-Risk of Treatment-Related Mortality

Also in June 2015, CPXX announced the expansion of an investigator-initiated clinical study of its lead candidate **CPX-351** in patients with untreated high-risk myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML), at high risk of treatment-related mortality.

The expansion of the 32units/m^2 dose cohort is based on the encouraging efficacy and safety results observed so far. In order to expand the 32units/m^2 cohort, the protocol requires 5 or more complete responses and fewer than five deaths by day 28 in the first 20 patients. In this trial, CPX-351 resulted in 6 responses in the first 20 patients with 2 early treatment-related deaths by day 28.

CPX-351 surpassed both criteria and the number of patients in the cohort was increased from 20 to 30.

This investigator initiated trial and expansion represents the company's ongoing effort to expand the CPX-351's utility into additional cancer indications in addition to sAML. Data so far have demonstrated the advantages of CPX-351 over standard chemotherapy regimens in terms of safety and efficacy.

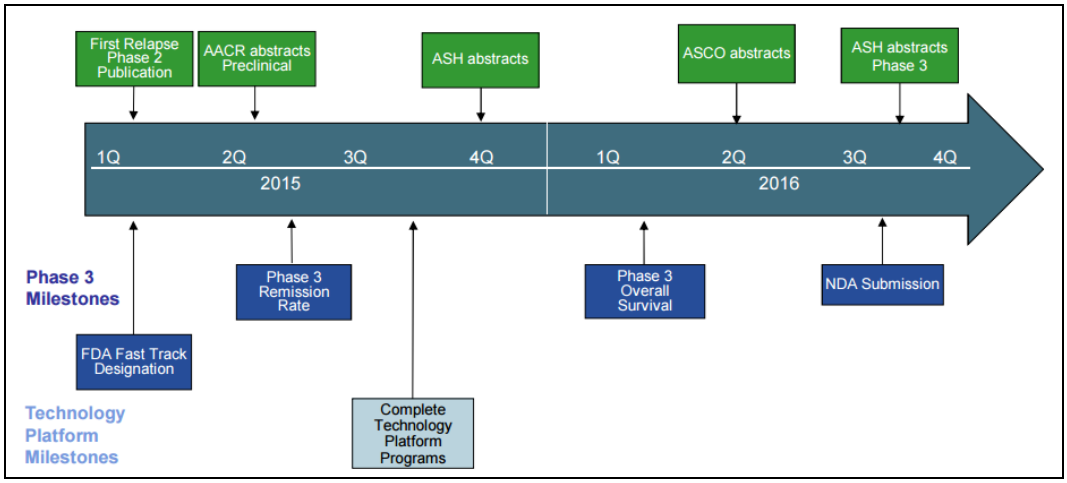


Valuation Attractive

We maintain our Buy 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.

We think the positive top line data from the company's lead Phase III clinical program **CPX-351** serves as a major catalyst for Celator now, while overall survival data will be a second major catalyst within one year. CPX-351 targets **AML** patients. Based on positive Phase II data and the encouraging top line 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 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. Our price target values CPXX at a market cap of $238 million, which we think is still conservative.

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

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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.