



### **RBC Capital Markets, LLC**

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All values in USD unless otherwise noted.

## FIRST GLANCE | COMMENT

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**Endocyte, Inc.** (NASDAQ: ECYT; 10.46)
Ongoing Doxil Shortage Poses Risk to ECYT Phase III
Timeline

# Outperform Speculative Risk

## **Impact**

Negative - Doxil remains in short supply and enrollment in the EC145 Phase III trial is taking a hit

## First Impression

Endocyte is unfortunately suffering collateral damage from a manufacturing problem of another company. The drug that it is using in both its control and experimental arm of the Phase III trial, Doxil, is being made available only to a limited number of patients and the timing of the return of supply remains uncertain. The shortage has nearly halted the enrollment of new patients into the Phase III. While ECYT could potentially make up some time through increased clinical sites, we believe that the current Phase III time line is at risk.

- Manufacturing problems. Janssen, a subsidiary of JNJ, sells Doxil, which is manufactured by Ben Venue Laboratories. We believe that quality control issues are likely the problem and Janssen has an ongoing program to ensure continued supply of drug to patients that are already on Doxil. New patients must apply through Janssen's access program. The latest update stated that there is a wait list and that not all patients on the wait list will get drug.
- Options for ECYT. According to ECYT, a small number of patients are still getting added to the trial at centers that have Doxil supply. ECYT is considering expanding the trial to additional sites to accelerate enrollment once supply comes on line. The other alternative for ECYT (a last resort) is to modify the design of the trial to allow taxol or topotecan rather than Doxil as the background chemotherapy, but that would require buy-in from FDA and would introduce significant clinical risk. The most likely scenario is the addition of new sites, and the resumption of enrollment later this year or early next.

Copies of the current and past "Dear Doctor" letters from Janssen are available via this link:

http://www.doxil.com/sites/default/files/popup\_09232011.html

# **Company Description**

Endocyte is a biopharmaceutical company developing targeted therapies for the treatment of cancer and other serious diseases. The company uses its proprietary technology to create novel small molecule drug conjugates (SMDCs) and companion imaging diagnostics. SMDCs actively target receptors that are over-expressed on diseased cells, relative to healthy cells, which enables the treatment of patients with highly active drugs at greater doses, delivered more frequently, and over longer periods of time than would be possible with the untargeted drug alone. The combination of an SMDC with its companion imaging diagnostic is designed to personalize the treatment of patients by delivering effective therapy, selectively to diseased cells, in patients most likely to benefit. The company's lead SMDC, EC145, targets the folate receptor, which is frequently over-expressed in some of the most prevalent, and difficult to treat solid tumor indications, including ovarian, non-small cell lung, breast, colorectal, kidney, endometrial, and other cancers.



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