Endocyte, Inc. (ECYT)

Sell-Off an Overreaction; We See a Short Delay to EMA Filing, Reiterate OUTPERFORM, Lowering Price Target to $16 on Just the 6-Month Push to EU Launch Timing

- **Endocyte updated the results of the Phase II PRECEDENT trial of EC145 in platinum-resistant ovarian cancer (PROC), announcing that while the independent review committee (IRC) confirmed the PFS advantage EC145 had strong folate receptor expressors over the control (Doxil-treated) arm, there was no overall survival benefit for EC145.** Recall that the investigator-assessed PFS advantage was statistically significant across groups from ITT to moderately folate receptor enhanced patients (FR+) and strong folate receptor expressors (FR++). While the benefit that the IRC determined in the FR+ and ITT groups was not statistically significant, the trends remained favorable to EC145.
- **We view the severe decline in ECYT shares to levels that imply nearly no technology value as a significant overreaction by the Street for three reasons: 1) the trial was not powered to determine survival, 2) the survival data are confounded in our opinion by imbalances in subsequent platinum treatment and 3) the survival curve of the control group appears to be anomalous.** Conversely, the Street appears to be completely ignoring the validation of PFS benefit for FR++ patients.
- **We now put the potential EU conditional launch at Q3:13 (from Q1:13), as the company revises its Phase III plans to include FR++ patients and alternative chemotherapy regimens.** While the Street is likely to assess a higher relative discount to the EMA path to conditional approval and the uncertain timeline with the need to re-work a confirmatory study design due to the Doxil shortage, we continue to expect EMA approval in 2013, roughly 18 months from now.
- **Reiterate OUTPERFORM rating, lowering price target to $16.** We arrive at our $16 PT by taking the sum of our value for US sales and EU royalties in 2015. We value US sales at $6 by applying a 6x multiple to our 2015 US sales estimate, discounted 35% annually and the EU opportunity at $10 a share, based upon a 15x multiple of 2015 estimated EU royalties, discounted 30% annually.
- Risks to our price target include 1) failure of EC145 for PROC in the clinic; and 2) failure to receive marketing approval in the US or EU.

FYE Dec	2010A	2011E			2012E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.0A	$0.0A		--	$0.0E		$1.1E
Q2 Jun	0.0A	0.0A		0.0A	0.0E		0.8E
Q3 Sep	0.0A	0.0A		0.0A	0.0E		1.1E
Q4 Dec	0.0A	0.0E		0.0E	0.0E		3.6E
Year*	**$0.0A**	**$0.0E**		**$0.0E**	**$0.0E**		**$6.6E**
Change	--	--			--		
	2010A	**2011E**			**2012E**		
EPS	**ACTUAL**	**CURR.**	**PREV.**	**CONS.**	**CURR.**	**PREV.**	**CONS.**
Q1 Mar	$0.00A	($0.43)A		--	($0.35)E	($0.37)E	($0.32)E
Q2 Jun	0.00A	(0.35)A		(0.35)A	(0.37)E	(0.39)E	(0.33)E
Q3 Sep	(1.10)A	(0.36)A		(0.36)A	(0.39)E	(0.37)E	(0.32)E
Q4 Dec	(0.22)A	(0.33)E	(0.36)E	(0.35)E	(0.40)E	(0.37)E	(0.26)E
Year*	**($1.32)A**	**($1.44)E**	**($1.47)E**	**($1.46)E**	**($1.50)E**		**($1.22)E**
P/E	--	--			--		
Change	93%	-9%			-4%		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

December 14, 2011

Price
$3.57

Rating
OUTPERFORM

12-Month Price Target
$16 **(from $20)**

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Company Information

Shares Outst (M)	35.7
Market Cap	$127.6
52-Wk Range	$3.48 - $14.80
Book Value/sh	$N/A
Cash/sh	$3.89
Enterprise Value (M)	$-3.9
LT Debt/Cap %	0
Cash Burn (M)	$53.6

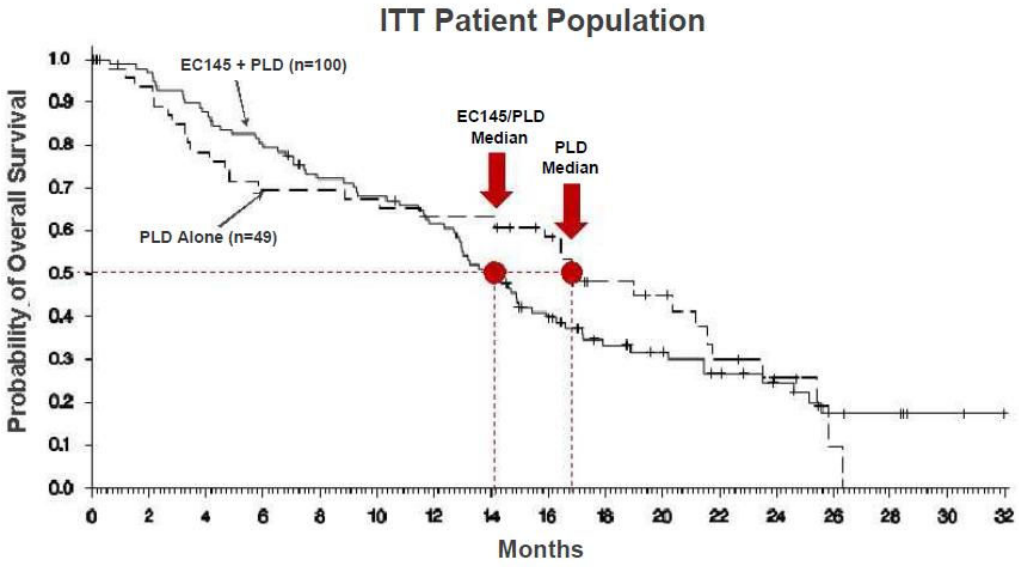
Company Description

Endocyte is developing novel small molecule drug conjugates and companion imaging prognostics. Their lead candidate, EC145, is in PIII trials in the PROC setting, targets cancers expressing the folate receptor that is also expressed on many solid tumors.

Source: Thomson Reuters

Survival data—anomalous control group appears to have confounded the survival data
The PRECEDENT trial was not powered for survival, and as such, interpretation of the survival results is inherently problematic. Historically, this patient population has had median overall survival ranging from 8.3-13.5 months, but the control group in this study had a median survival of 16.9 months, well above historical norms. Additionally, the actual survival curve for the control group is oddly shaped, and does not appear to fit the usual proportional hazard seen in cancer patients. Note the nearly flat survival curve in the PLD group from ~6 months to ~14 months. **Lastly it is well recognized in oncology that the opportunity for subsequent efficacious therapies will confound any potential survival signal and is the very reason that FDA and EMA have indicated a willingness to accept compelling PFS results as evidence of clinical benefit in this setting.**

Exhibit 1: PRECEDENT Survival Curve (ITT Population)



Source: Endocyte Inc

The control group had a significantly larger proportion of patients who had a >3 month platinum-free interval, and were disproportionately treated with platinum after progression.
Literature reports show that ovarian cancer patients who progress on platinum therapy, are treated with an alternative chemotherapy to progression, and then are re-treated with platinum agents do better in terms of response rates the longer it has been since the first platinum treatment (Michael Bookman, The Oncologist 1999; 4:87-94).

Exhibit 2: Response Rates in Ovarian Cancer Trials by Interval Between Platinum Therapy

Table 1. Response rates using interval from previous treatment to phase II treatment* in relapsed and recurrent ovarian cancer: analysis of five phase II clinical studies ($n = 92$) [5]

Treatment-free interval (months)	Number of patients	Number of responders (%)
0-6	50	5 (10%)
7-12	17	5 (29%)
13-18	8	5 (63%)
19->21	17	16 (94%)

*Phase II therapy included: platinum-based chemotherapy ($n = 13$), mitoxantrone ($n = 31$), bleomycin/mitomycin C ($n = 15$), and epirubicin/mitomycin ($n = 33$).

Adapted from [5]; used with permission.

Table 2. Response rate of patients with relapsed ovarian cancer to second-line platinum-based therapy based on platinum-free and treatment-free intervals ($n = 72$) [4]

	Total response (%)	Complete response (%)
Platinum-free interval		
5 to 12 months	6/22 (27%)	1/22 (5%)
13 to 24 months	6/18 (33%)	2/18 (11%)
>24 months	19/32 (59%)	7/32 (22%)
Treatment-free interval		
≤12 months	9/35 (26%)	2/35 (6%)
13 to 24 months	5/15 (33%)	1/15 (7%)
>24 months	17/22 (77%)	7/22 (32%)

Adapted from [4]; used with permission.

Source: Bookman, The Oncologist 1999; 4:87-94

We think that one explanation for the surprising survival rates of the control patients might be explainable by their longer platinum-free interval and subsequent treatment with platinum.

Exhibit 3: Imbalance in Platinum-Free Intervals and Subsequent Therapy in the PRECEDENT Trial

% of Patients	ITT		FR(++)	
	EC145/PLD	PLD	EC145/PLD	PLD
≥ 3 months platinum free interval*	**56%**	**76%**	**57%**	**73%**
Received post-study chemotherapy	70%	71%	65%	80%
Platinum	18%	33%	**17%**	**27%**
Topotecan	34%	31%	44%	33%
Gemcitabine	27%	37%	22%	33%
Paclitaxel/Docetaxel	24%	29%	30%	40%
Bevacizumab	18%	14%	22%	20%

*** Last platinum dose to progression**

Source: Endocyte, Inc

Indeed, when the company adjusted the analysis to include these prognostic factors (and others), the adjusted OS favors EC145, especially in the FR(++) group. Admittedly these analyses are problematic, but we do think in this instance that it should be considered as a valid reason for the surprising unadjusted OS data, especially in light of the apparent PFS advantage provided by EC145.

Exhibit 4: Adjusted Overall Survival Analysis

Population (events by arm)	N(1)	Overall Survival Hazard Ratio	
		Unadjusted Analysis	Adjusted Analysis (2)
ITT (events: 70/32)	149	1.099	0.928
FR(++) (events: 18/10)	38	**1.420**	**0.495**

Source: Endocyte, Inc

The potential Phase III program is coming into focus, with a likely stratification of patients based on platinum-free interval, a focus on FR(++) patients, and the use of a chemotherapy alternative to Doxil.
While the Phase III studies will likely begin later than our previously anticipated Q1:12 timing, we look toward a well-defined Phase III program guided by these results. We expect that focusing on FR(++) patients and including stratification according to platinum-free survival could yield significant clinical benefits.

We are adjusting our model and price target to account for this anticipated ~6 month clinical and EU regulatory delay.

Exhibit 5: Financial Model

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Gregory R. Wade, Ph.D.

12/13/2011

Endocyte Inc.

Annual Financial Results & Projections
($ in thousands except per share data)
Ticker: ECYT (Nasdaq)

	FY:10A	FY:11E	FY:12E	FY:13E	FY:14E	FY:15E
Revenue:						
Sales	0	0	0	0	12,862	137,433
License fee and other revenues	0	0	0	3,570	28,846	75,177
Contracts	0	0	0	0	0	0
Total Revenues	**$0**	**$0**	**$0**	**$3,570**	**$41,708**	**$212,610**
Cost and Expenses:						
Costs of goods sold	0	0	0	0	1,929	20,615
Research and Development	14,561	30,436	42,038	27,611	28,423	40,604
Sales, General and Administrative	6,039	10,133	12,831	16,242	19,084	19,859
Other	0	0	0	0	0	0
Total Costs and Expenses	**$20,600**	**$40,569**	**$54,869**	**$43,852**	**$49,436**	**$81,078**
Operating Income (loss)	(20,600)	(40,569)	(54,869)	(40,283)	(7,728)	131,533
Net Interest Income (Expense)	(1,059)	(1,130)	1,291	911	1,202	1,640
Other income / (Expense)	1,564	(18)	0	0	0	0
Income Before Income Taxes	(20,095)	(41,717)	(53,579)	(39,372)	(6,526)	133,173
Net Income	**($20,095)**	**($41,717)**	**($53,579)**	**($39,372)**	**($1,650)**	**$121,897**
GAAP Basic EPS with sFAS123	**(1.32)**	**(1.44)**	**(1.50)**	**(1.04)**	**(0.04)**	**3.04**
GAAP Diluted EPS with sFAS123	**(1.32)**	**(1.44)**	**(1.50)**	**(1.04)**	**(0.04)**	**3.04**
Weighted shares outstanding	15,220	28,938	35,801	37,882	39,951	40,051
Fully diluted shares outstanding	15,220	28,938	35,801	37,882	39,951	40,051
Cash Balance	16,873	126,931	73,352	108,009	104,015	221,230
Cash Burn	(7,036)	(41,717)	53,579	(39,372)	(1,650)	121,897

Analyst Certification
I, Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., Christopher N. Marai, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Company	Disclosure
Endocyte, Inc.	1,3,4,5,7

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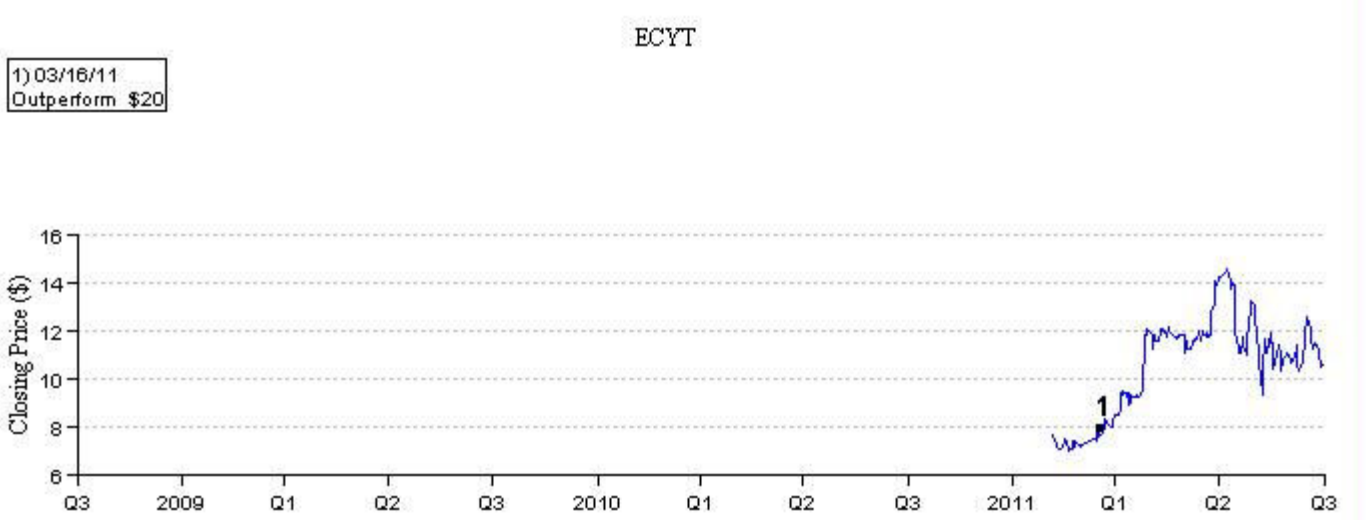

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