



RBC Capital Markets, LLC

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FY Dec	2010A	2011E	2012E	2013E
Rpt EPS - Basic	(21.77)	(1.43)	(1.33)	(0.90)
Revenue (MM)	0.0	0.0	0.0	22.5
P/Rpt EPS	NM	NM	NM	NM
Revenue (MM)	Q1	Q2	Q3	Q4
2010	0.0A	0.0A	0.0A	0.0A
2011	0.0A	0.0A	0.0A	0.0E
2012	0.0E	0.0E	0.0E	0.0E
Rpt EPS - Basic				
2010	(6.37)A	(5.79)A	(6.10)A	(3.57)A
2011	(0.43)A	(0.35)A	(0.36)A	(0.32)E
2012	(0.32)E	(0.33)E	(0.34)E	(0.34)E

All values in USD unless otherwise noted.

COMPANY UPDATE | COMMENT

FEBRUARY 28, 2012

Endocyte, Inc. (NASDAQ: ECYT)

Major Regulatory Updates to be Announced on Q4 Call

Outperform Speculative Risk

Price:	3.59	Price Target:	8.00
		Implied All-In Return:	123%
Shares O/S (MM):	35.6	Market Cap (MM):	128
Dividend:	0.00	Yield:	0.0%
Priced at market close February 28	2012 FT		

Event

ECYT expected to provide update on EU filing strategy and Phase III design changes on Q4 call.

Investment Opinion

ECYT announced plans to update investors on two key aspects of its regulatory strategy on its Q4 conference call in the second week of March: (1) an update on plans to file for early approval in the EU based on Phase II data, and (2) an update on the redesign of the Phase III registrational trial. Given the recent clinical and regulatory limbo following the updated Phase II data and ongoing Doxil shortage, the update could boost investor confidence for a stock that is already trading near cash.

- Plans for EU filing. ECYT's previous plans to file early in EU based on Phase II data were dependent on validation of the EC20 assay, independent review of the Phase II data, and contingent on an ongoing Phase III trial. Given the setback of the Doxil shortage, the filing has been delayed, and most investors have written off the potential for a near-term filing. We expect ECYT will provide guidance on its plans in early March and the upside/downside around this news event is favorable given the current low sentiment.
- Phase III amendment. ECYT has met with EU regulators and is meeting with FDA in early March to discuss plans to amend the Phase III by: (1) inclusion of only the FR++ patients, which would require fewer patients in the Phase III, and (2) use of previously purchased Doxil from Europe, newly imported liposomal doxorubicin (from another manufacturer), and/or a switch to taxol. Given the very robust result in FR++ patients and the validation of the EC20 diagnostic, we believe the first issue should be non-controvercial. The second issue is more difficult, but we suspect regulators will be flexible given the current shortage of Doxil.
- Sufficient cash position. ECYT reiterated that it has sufficient cash to complete the Phase III ovarian study (assuming amendment for 200 FR++ patients), complete the Phase IIb portion of the Phase IIb/III lung cancer trial, and file an IND for another drug candidate. A clearer regulatory path plus sufficient funds to generate key data in two indications, should drive shares higher.

Details

Favorable Risk Reward

ECYT is currently trading near its approximate year-end cash value of \$3.50/share. We believe the depressed stock price reflects high investor skepticism that EC145 will be approved in the EU based on the Phase II results or that ECYT will be successful in conducting its Phase III registrational trial. We believe at its current price there is very little downside from any real or perceived regulatory setback given the current low sentiment. However, if ECYT announces plans to file in the EU in 2012 based on recent regulatory interactions and after review of the available data, investor sentiment will likely shift as it did in 2011 when the EU filing strategy was first formally announced. At that time, ECYT shares surged 25% from \$9.50 to approximately \$12/share (vs. flat COMP).

Mapping the Path Forward and Evaluating the Points of Risk

The current Phase III design was to test EC145 + Doxil to Doxil alone in patients with platinum resistant ovarian cancer. The lack of availability of Doxil and the uncertain timeline for supply to become readily available has forced ECYT to look for alternative Phase III approaches. The question of efficacy in patients that are not high expressors of folate receptor is also driving change in the Phase III design to focus on the patients that screen FR(++) by the EC20 assay.

Proposed changes to the Phase III design:

- Potential switch from Doxil to Taxol in the treatment regimen. Taxol is a standard first and second line agent in ovarian cancer and its use in this treatment setting is non-controvercial as a control arm. It is also expected that the control arm with Taxol would behave similarly to Doxil. ECYT could also have chosen topotecan (another commonly used drug in ovarian cancer). However, the toxicity of topotecan makes it less preferred.
- Other options to replace Doxil. FDA recently permitted the importation of a similar liposomal doxorubicin product called Lipodox (not identical to Doxil) to temporarily fill the shortage caused by the lack of Doxil. It is possible that Endocyte could use Lipodox to run its Phase III trial, and not have to switch to another chemotherapy agent. However, this switch would also need to be sanctioned by regulators, as the final label would need to broadly cover the use in combination with liposomal doxorubicin (and not be limited to Lipodox).
- Focus on FR(++) patients. The validation of the EC20 assay and the continued strong benefit seen in this population provides the rationale for moving forward in this population which is most likely to derive benefit from EC145 treatment.
- Smaller trial size. By focusing on a population with a higher expected clinical benefit, the same statistical power can be achieved with a small number of patients. ECYT estimates that it can achieve the same statistical power with 200 patients as it did with the original 600 patient trial design.
- Safety assessment. Because EC145 has never been combined with Taxol in human trials, ECYT hopes to run a small dose escalation or de-escalation run in to assess the safety prior to initiating full enrollment in the trial. One strategy would be to start several patients at a lower dose of taxol, and if it is well tolerated, move to full dose taxol.

Regulatory and clinical timeline (as previously disclosed):

- ECYT expects to meet with FDA and EMA in Q1:12 to discuss proposed Phase III trial changes.
- Initiate redesigned Phase III trial in Q2:12 (ECYT also expects to start its Phase IIb trial in lung cancer in Q2)
- File for regulatory approval in EMA based on Phase II data in mid-2012. EU regulators wanted the Phase III up and running before considering a regulatory filing.
- An EU regulatory decision could come in 2013
- Data from Phase III could come in H1:14
- We assume EU launch in 2014 and US launch in 2015

Key risks

- Buy in from regulators. The timeline are clearly dependent on both US and EU regulators agreeing to the proposed Phase III trial changes. The issue of swapping out Taxol may be tricky, especially given the current lack of Phase I safety data. ECYT is proposing a run in period to evaluate safety, but either FDA or EMA may require a separate Phase I trial, which could substantially delay Phase III.
- Safety with taxol. ECYT's proposed timelines assume that there is no problem combining taxol with EC145. Both drugs target microtubules. While the preclinical data suggests the drugs can be easily combined, it is possible that even with the run in design proposed by ECYT that there could emerge a safety issue with this combination.
- Statistical assumptions. ECYT is basing its proposed clinical trial design on the assumption that EC145 will perform equally well with taxol as it did with Doxil in the Phase II. While this is supported by animal data, one of the major risk lowering features of ECYT was that the Phase III trial designed closely matched the Phase II design. That will no longer be the case, which raises clinical risk.



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• Regulatory risk in EU. ECYT has an accelerated approval strategy in EU based on its Phase II results. The new overall survival data may make those results less compelling to regulators. It is also not 100% clear that EU regulators will accept the proposed taxol study as a confirmatory study for the Phase II. We assume they will, but the risk for approval in EU has increased.

Valuation

Our \$8 target reflects a launch in the US in 2015 and EU in 2014. We assume a probability of success for EC145 of 50% for ovarian cancer and to 25% in NSCLC. Our high assumed clinical and regulatory risk reflect: 1) a potential change in protocol (to Taxol from Doxil), 2) efficacy measures that deteriorated upon an independent assessment, and 3) uncertainty around discussions with regulators in the US and EU.

Our sum-of-the parts DCF analysis of ~\$8/share includes EC145 for PROC (\$5.94/share) and NSCLC (\$2.81/share). The DCF of its financial assets including net cash and NOLs net of next 4 year burn is (\$0.71)/share. We assume that EC145's patent life extends through 2026.

Our P/E and company level DCF valuations model a success scenario (not probability adjusted) and arrive at a higher value in the mid-to-high teens. However, we do not expect any visibility on the likelihood of success over the next 12-months and expect ECYT shares to continue to trade on a probability adjusted basis vs. the upside scenarios.

Price Target Impediment

Our price target is dependent primarily on the regulatory and commercial success of EC145 in platinum resistant ovarian cancer as well as in non-small cell lung cancer. Any setbacks in clinical development, delay in launch, increased competition or other limitations to the market potential of EC145 could negatively impact our valuation. Upside could come from pricing, better than anticipated market penetration, new partnerships, clinical success of earlier-stage programs that are not included in our valuation and/or setbacks for potential competitors.

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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Endocyte

Revenue to Endocyte

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0.0

3.1

41.3

100.6

177.9

241.2

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Annual and Quarterly Income Statement															Adnan Bu	tt (415) 6	33-8588
(\$ in MM; except per share)	2010A	Q1:11A	Q2:11A	Q3:11A	Q4:11E	2011E	Q1:12E	Q2:12E	Q3:12E	Q4:12E	2012E	2013E	2014E	2015E	2016E	2017E	2018E
EC145																	
U.S. Sales - PROC											0.0	0.0	0.0	33.6	87.0	156.6	211.3
EU Royalty - PROC											0.0	0.0	3.1	7.8	13.6	21.4	29.9
EC145 - NSCLC											0.0	0.0	0.0	0.0	0.0	20.0	70.0
EC0225											0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Product Revenues							0.0	0.0	0.0	0.0	0.0	0.0	3.1	41.3	100.6	197.9	311.2
Collaboration revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	22.5	29.6	9.2	9.2	20.0	0.0
Total Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	22.5	32.7	50.5	109.7	217.9	311.2
COGS		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.4	8.7	17.7	28.1
Research and Development Expenses	14.6	4.4	7.7	8.9	8.5	29.6	8.7	8.9	9.1	9.3	36.0	40.0	46.0	55.0	55.0	60.0	65.0
Sales, General and Administrative Expenses	6.0	2.1	2.3	2.7	2.5	9.6	2.6	2.7	2.8	2.9	11.0	15.0	25.0	35.0	37.0	40.0	50.0
Total Costs and Expenses	20.6	6.5	10.1	11.6	11.0	39.2	11.3	11.6	11.9	12.2	47.0	55.0	71.0	93.4	100.7	117.7	143.1
Operating Income (Loss)	(20.6)	(6.5)	(10.1)	(11.6)	(11.0)	(39.2)	(11.3)	(11.6)	(11.9)	(12.2)	(47.0)	(32.5)	(38.3)	(42.9)	9.0	100.3	168.1
Other Income/(Expense), Net	0.5	(0.7)	(0.5)	(0.4)	(0.5)	(2.1)	(0.3)	(0.2)	(0.2)	(0.1)	(0.8)	(0.1)	0.3	0.3	0.3	0.3	0.3
Income (Loss) before Tax	(20.1)	(7.2)	(10.5)	(12.1)	(11.5)	(41.3)	(11.6)	(11.8)	(12.1)	(12.3)	(47.8)	(32.6)	(38.0)	(42.6)	9.3	100.6	168.3
Provision for Income Tax		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	8.4
Net Income (Loss) - GAAP	(20.1)	(7.2)	(10.5)	(12.1)	(11.5)	(41.3)	(11.6)	(11.8)	(12.1)	(12.3)	(47.8)	(32.6)	(38.0)	(42.6)	9.3	98.1	159.9
EPS, Basic (GAAP)	(\$21.77)	(\$0.43)	(\$0.35)	(\$0.36)	(\$0.32)	(\$1.43)	(\$0.32)	(\$0.33)	(\$0.34)	(\$0.34)	(\$1.33)	(\$0.90)	(\$0.91)	(\$1.01)	\$0.22	\$2.28	\$3.68
EPS, Diluted (GAAP)	(\$21.77)	(\$0.43)	(\$0.35)	(\$0.36)	(\$0.32)	(\$1.43)	(\$0.32)	(\$0.33)	(\$0.34)	(\$0.34)	(\$1.33)	(\$0.90)	(\$0.91)	(\$1.01)	\$0.21	\$2.17	\$3.50
Shares Outstanding, Basic	0.9	16.9	29.7	33.4	35.7	28.9	35.8	35.9	35.9	36.0	35.9	36.4	41.8	42.2	42.6	43.0	43.5
Shares Outstanding, Diluted	3.1	19.1	31.9	35.6	37.9	31.1	38.0	38.1	38.2	38.3	38.1	38.6	44.0	44.4	44.8	45.2	45.7
EC145 summary		- 4			-	_		A -	-	1	~+	2013E	2014E	2015E	2016E	2017E	2018E
US sales	$\kappa \rightarrow \epsilon$		_			\sim				-		0.0	0.0	33.6	87.0	156.6	211.3
EU sales											-	0.0	15.4	38.9	67.9	106.8	149.3
												0.0	15.4	72.4	154.9	263.4	360.6
Total sales												0.0	13.4	72.4	154.9	203.4	300.6

Expense analysis	2013E	2014E	2015E	2016E	2017E	2018E
Cost of goods (% of sales)		10%	10%	10%	10%	10%
R&D (% of revenues)		141%	109%	50%	28%	21%
SG&A (% of revenues)		77%	69%	34%	18%	16%
Operating Margin		-117%	-85%	8%	46%	54%

Source: Company reports and RBC Capital Markets estimates.

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HOLD[SP]	649	43.30	151	23.27				
SELL[U]	70	4.70	5	7.14				





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