Cerulean Pharma

BUY

CERU: NASDAQ: US\$3.46

Target: US\$11.00

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COMPANY STATISTICS:

Forecast Return:	217.9%
Market Cap (M):	US\$49
52-week Range:	3.35 - 8.06
Avg. Daily Vol. (000s):	25.4

EARNINGS SUMMARY:

FYE Dec		2013A	2014E	2015E		
Revenue (M):		0.0	0.0	0.0		
EPS:		(0.90)	(1.27)	(2.26)		
Revenue (M):	Q1	-	0.0A	0.0		
	Q2	-	0.0A	0.0		
	Q3	-	0.0	0.0		
	Q4	-	0.0	0.0		
Total		0.0	0.0	0.0		
EPS:	Q1	-	(0.17)A	(0.63)		
	Q2	-	(0.44)A	(0.53)		
	Q3	-	(0.30)	(0.57)		
	Q4	-	(0.36)	(0.53)		
Total		(0.90)	(1.27)	(2.26)		

SHARE PRICE PERFORMANCE:



COMPANY DESCRIPTION:

Cerulean is a development stage oncology company focused on developing novel cancer drugs using its tumor targeting platform. The company was founded in 2006 and is currently headquartered in Cambridge, MA.

All amounts in US\$ unless otherwise noted.

Life Sciences -- Biotechnology

KEY OVARIAN, RECTAL READOUTS BY YE14; WOULD SIGNIFICANTLY BOOST VALUE

Investment highlights

Avastin+CRLX101 ovarian readout YE14 could surprise on ORR CRLX101+Avastin could show a >20% response rate in relapsed ovarian cancer by YE14, which would boost share value and allow for a randomized study. CRLX101 showed PFS >6 months in n=7 / 19 patients in an earlier study, and 14% response rate. Combination with Avastin could significantly boost efficacy.

CRLX101 rectal readout YE14 could access large market

CRLX101 could access a large $\sim 35,000$ -patient neoadjuvant rectal cancer market with positive data, and preliminary results by YE14 could boost share value for the indication. CRLX101 is being tested in combination with chemoradiotherapy in neoadjuvant rectal cancer, where pCR rates are only $\sim 15\%$. Importantly, irinotecan is known to increase pCR to $\sim 25\%$, but is too toxic. Camptothecin, the active drug in CRLX101, is more potent than irinotecan and safer thus far in CRLX101.

Key randomized RCC study data YE15, enrollment initiated

Randomized data in Relapsed Renal Cell Carcinoma (RCC) should surface by YE14, including ORR and pCR, a key catalyst for shares. CRLX101+Avastin are being tested against standard of care in a n=110 patient study. Control arm PFS is expected to be ~2.5 months, and the study is powered to show a 2.3 mo or greater improvement.

Adjusting estimates, maintain BUY rating, \$11 price target

We are adjusting our EPS estimates based on lower spending in Q2/14. Our 2014 GAAP EPS estimate rises to (\$1.27) from (\$1.45).

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CATALYSTS

Figure 1: Cerulean expected catalysts								
Event	Timing	Drug	Description	Effect	Importance	Notes		
Data	4Q14	CRLX101	Phase 2 RCC		High	Single Arm Trial with Relapsed RCC patients, initial data at ASCO		
Data	4Q14	CRLX101	Phase 2 Ovarian	↑	High	Single Arm Trial with platinum resistant patients, initial data at ASCO		
Data	4Q14	CRLX101	Phase 1b Rectal	↑	Moderate	Maximum Tolerated Dose in neoadjuvant rectal cancer		
Data	1Q15	CRLX101	Phase 2 Rectal	↑	High	pCR data, single-arm trial		
Data	YE2014	CRLX101	Phase 2 Ovarian		High	ORR data single arm, platinum resistant ovarian cancer		
Data	1Q15	CRLX101	Phase 2 RCC	↑	High	Relapsed RCC, Final ORR, PFS Data, single-arm study		
Data	3Q15	CRLX101	Phase 2 Ovarian	↑	Critical	Final ORR, PFS Data, single- arm study		
Data	4Q15	CRLX101	Phase 2 Rectal	↑	Critical	pCR data, randomized, blinded data		
Data	4Q15	CRLX101	Phase 2 RCC	↑	Critical	ORR data, randomized, blinded data		
Data	4Q15	CRLX301	Phase 1	↑	Moderate	Maximum Tolerated Dose		

Source: Canaccord Genuity, Cerulean company reports



VALUATION

Figure 2: Cerulean	valuation				
	Peak Sales Yea	r	Current Value	Probability Adjustment	Value Per Share
Ovarian	\$333	2020	\$427	30%	\$7
RCC	\$136	2021	\$97	30%	\$2
Rectal	\$191	2021	\$163	30%	\$3
Total			\$687	30%	\$11
Risk Free Rate	2%				
Beta	1.3			Shares outstanding (M's)	19
Risk Premium	9%				
Discount Rate	14%				

Source: Canaccord Genuity, Inc.



Figure 3: Cerulean income sta	tement											
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(000's) [FY - JUN]	2013A	Mar-14A	Jun-14A	Sep-14E	Dec-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues	201074	mai 1474	ouii 1474	OCP 142	DC0 14E	20142	20102	20102	20112	20102	20102	20201
Rectal									-	_	24,257	123,603
RCC									-	-	19,397	65,914
Ovarian									-	55,214	182,988	332,844
Total									-	55,214	226,643	522,362
Income Statement	2013A	Mar-14A	Jun-14A	Sep-14E	Dec-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues												
Total Revenue	6	47	33						-	55,214	226,643	522,362
COGS									-	8,282	33,996	78,354
Gross Profit	6	47	33	-	-				-	46,932	192,646	444,007
Operating Expenses												
Research and development	9,700	1,495	2,648	3,648	4,648	12,439	46,667	49,000	51,450	54,023	48,620	48,620
General and administrative	6,166	1,510	2,029	2,500	2,700	8,739	13,200	14,520	15,972	24,972	33,972	42,972
Total Operating Expense	15,866	3,005	4,677	6,148	7,348	21,178	59,867	63,520	67,422	78,995	82,592	91,592
EBITDA												
Operating income	(15,860)	(2,958)	(4,644)	(6,148)	(7,348)	(21,098)	(59,867)	(63,520)	(67,422)	(32,062)	110,054	352,415
Investment income, net												
Interest Income	2	1	2									
Interest Expense	(1,487)	(461)	(268)	-	-	(729)	-	-	-	-	-	
Loss on extinguishment of debt			(2,493)									
Decrease in value of pref stock	202											
Pre-tax income (GAAP)	(17,143)	(3,418)	(7,403)	(6,148)	(7,348)	(24,317)	(59,867)	(63,520)	(67,422)	(32,062)	110,054	352,415
Pre-tax income (non-GAAP)												
Taxes (GAAP)	-	-	-	-	-	-	-	-	-	-	40,720	130,394
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Net Income (GAAP)	(17,143)	(3,418)	(7,403)	(6,148)	(7,348)	(24,317)	(59,867)	(63,520)	(67,422)	(32,062)	69,334	222,022
GAAP adjustments												
Adjusted Net Income	-											
GAAP EPS (diluted)	(\$0.90)	(\$0.17)	(\$0.44)	(\$0.30)	(\$0.36)	(\$1.27)	(\$2.26)	(\$1.82)	(\$1.64)	(\$0.72)	\$1.56	\$4.96
Basic shares outstanding		19	19	19	19	19	26	35	41	44	45	45
Diluted charge systematics		20	17	20	21	20	26	25	11	4.4	15	15

Source: Company reports, Canaccord Genuity estimates

Diluted shares outstanding



Investment risks

Cerluean's lead drug CRLX101 may fail in any or all three currently ongoing clinical programs, resulting in downside to our price target and the current stock price. In addition, clinical studies may be successful but not meet investor expectations, also resulting in downside to our price target and the stock price. Even assuming clinical success for CRLX101, FDA approval could require more clinical data than originally anticipated, resulting in delayed revenue timelines, potentially pressuring the share price. In addition, CRLX101 may be deemed efficacious, but could generate unexpected toxicity, resulting in reduced market share and lower revenues than expected, even if FDA approval is attained.

We view the use of CRLX101 in combination with Avastin for the treatment of ovarian cancer as potentially risky because Avastin has not been FDA approved for the treatment of ovarian cancer. While Avastin is approved in the EU for the treatment of ovarian cancer there have been issues with regards to safety in certain cancer indications, including ovarian. Specifically, adverse events and safety data may be skewed significantly higher as a result of the effects of Avastin, rather than from CRLX101. US studies of Avastin in ovarian cancer resulted in some bowel perforations and deaths, which might limit the overall safety profile for CRLX101+Avastin in platinum resistant ovarian cancer in the clinic, resulting in downside to our price target and the stock price.

Although data readouts are expected throughout 2014 and 2015, critical randomized data are unlikely to be available until 2H15, a timeline which may be too long for certain investors, creating potential downside pressure on the stock. In addition, if timelines for any data readouts during 2014 and 2015 are delayed, investors could become skeptical regarding the results, also creating downward pressure on the stock and potential downside to our price target.

The oncology space is highly competitive, and other companies could generate data potentially limiting the commercial opportunity for Cerulean, resulting in downside to our revenue estimates and price target. Specifically, although we view recent data from Merrimack as a positive, some investors may believe that the drug will compete directly with CRLX101, limiting upside for Cerulean. Also, other companies are developing "reformulated" chemotherapy drugs including Sorrento, Nektar, Celgene, and others. Specifically, Nektar is also developing a reformulated, long-acting PEGylated formulation of irinotecan, which investors may also view as a threat to CRLX101 market share going forward, pressuring the stock.



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Site Visit:

An analyst has not visited Cerulean Pharma's material operations.

Price Chart:*



Distribution of Ratings: Global Stock Ratings (as of 3 July 2014)

Coverage Universe					
Rating	#	%	IB Clients %		
Buy	602	61.2%	38.2%		
Speculative Buy	49	5.0%	55.1%		
Hold	290	29.5%	13.1%		
Sell	41	4.2%	7.3%		



984

100.0%

*Total includes stocks that are Under Review

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Company	Disclosure
Cerulean Pharma	1A, 2, 3, 5, 7

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