

**Annual EPS** 

**Today's Changes** 2014E (\$1.21) from \$(\$1.27)

### **Cerulean Pharma**

CERU: NASDAO: US\$5.93

**Target: US\$11.00** 

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#### **COMPANY STATISTICS:**

Forecast Return:	85.5%
Market Cap (M):	US\$85
52-week Range:	3.35 - 8.06
Avg. Daily Vol. (000s):	28.8

#### **EARNINGS SUMMARY:**

FYE Dec		2013A	2014E	2015E
Revenue (M):		0.0	0.0	0.0
EPS:		(0.90)	(1.21)	(2.26)
Revenue (M):	Q1		47.0A	0.0
	Q2		33.0A	0.0
	Q3		0.0A	0.0
	Q4		0.0	0.0
Total		0.0	0.0	0.0
EPS:	Q1		(0.17)A	(0.63)
	Q2	0.00	(0.44)A	(0.53)
	Q3	0.00	(0.28)A	(0.57)
	Q4	0.00	(0.32)	(0.53)
Total		(0.90)	(1.21)	(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

# INTERESTING RECTAL DATA, THREE DATA READOUTS AHEAD IN 1H15

#### **Investment highlights**

Early rectal data very encouraging, additional info early 2015 Cerulean announced one pCR and two patients with substantially reduced disease burden in the 12 mg/m2 dose cohort for CRLX-101+chemo radiotherapy in neoadjuvant rectal cancer. Importantly, combining with capecitabine+radiation did not show a safety signal at 12mg/m2 or 15 mg/m2. We expect positive date from n=10-12 patients in 1H15 to reach the ~30% pCR rate to advance to Phase 2.

#### Ovarian readout for go/no-go 1H15, could be gateway for Avastin

We are unclear whether Avastin will receive FDA approval for ovarian cancer, but believe CRLX-101+Avastin may provide better efficacy and enable broader Avastin usage. Importantly, Avastin is contra-indicated in  $3^{\rm rd}$  and  $4^{\rm th}$  line patients due to safety concerns. Interestingly, the safety profiles for CRLX-101 and Avastin do not overlap, suggesting low concern over toxicity for the combined regimen. We anticipate positive ORR data in early 2015 to meet the ~20% threshold to move into Phase 2.

#### Randomized Phase 2 CRLX-101 data in RCC 4Q15

Cerulean expects randomized Phase 2 data for CRLX-101+Avastin in 3<sup>rd</sup>/4<sup>th</sup>-line Renal Cell Carcinoma by YE15, a major catalyst for shares. Importantly, assuming positive PFS data, CRLX-101 might be combined with other VEGF agents in earlier lines of therapy, accessing a larger market.

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Figure :	1: C	erulea	ın Cata	lysts
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<b>Event</b> Data	Timing 1Q15	<b>Drug</b> CRLX101	<b>Description</b> Phase 2 Ov arian	Effect	Importance Critical	<b>Notes</b> Final ORR, PFS Data, single- arm study
Data	1Q15	CRLX101	Phase 2 Rectal	<b>↑</b>	Critical	pCR data, Single arm data
Data	2Q15	CRLX101	Phase 2 RCC	<b>↑</b>	High	Clinical data from the final 11 patients in relapsed RCC - ASCO
Data	4Q15	CRLX101	Phase 2 RCC	<b>↑</b>	Critical	ORR data, randomized, blinded data
Data	4Q15	CRLX301	Phase 1 data	<b>↑</b>	High	MTD and dose regimen

Source: Canaccord Genuity Estimates



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Figure 2: CERU Income st	atement											
(000's) [FY - DEC]	2013A	Mar-14A	Jun-14A	Sep-14A	Dec-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues												
Rectal									-	-	24,257	123,603
RCC									-	-	19,397	65,914
Ov arian									-	55,214	182,988	332,844
Total									-	55,214	226,643	522,362
Income Statement	2013A	Mar-14A	Jun-14A	Sep-14A	Dec-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues												
Total Revenue	6	47	33	_					_	55,214	226,643	522,362
COGS	ŭ	"								8,282	33,996	78,354
Gross Profit	6	47	33							46,932	192,646	444,007
GIOSS FIOIIL	0	41	33	-	-				-	40,532	192,040	444,007
Operating Expenses												
Research and development	9,700	1,495	2,648	2,928	3,928	10,999	46,667	49,000	51,450	54,023	48,620	48,620
General and administrative	6,166	1,510	2,029	2,441	2,700	8,680	13,200	14,520	15,972	24,972	33,972	42,972
Total Operating Expense	15,866	3,005	4,677	5,369	6,628	19,679	59,867	63,520	67,422	78,995	82,592	91,592
EBITDA												
Operating income	(15,860)	(2,958)	(4,644)	(5,369)	(6,628)	(19,599)	(59,867)	(63,520)	(67,422)	(32,062)	110,054	352,415
Investment income, net												
Interest Income	2	1	2	2								
	(1,487)	(461)	(268)	(191)		(920)						
Interest Expense	(1,407)	(401)		(191)	-	(920)	-	-	-	-	-	-
Loss on extinguishment of debt	000		(2,493)									
Decrease in value of pref stock	202	(0.440)	(7.400)	(5.550)	(0.000)	(00.007)	(50.007)	(00 500)	(07, 400)	(00.000)	440.054	050 445
Pre-tax income (GAAP)	(17, 143)	(3,418)	(7,403)	(5,558)	(6,628)	(23,007)	(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)	(5,558)	(6,628)	(23,007)	(59,867)	(63,520)	(67,422)	(32,062)	69,334	222,022
GAAP adjustments	(,)	(-, )	(.,)	(-,)	(5,525)	(==,===)	(,)	(,)	(,)	(,)	,	,
Adjusted Net Income	_											
GAAP EPS (diluted)	(\$0.90)	(\$0.17)	(\$0.44)	(\$0.28)	(\$0.32)	(\$1.21)	(\$2.26)	(\$1.82)	(\$1.64)	(\$0.72)	\$1.56	\$4.96
Basic shares outstanding	(1.1.17)	19	19	19	19	19	26	35	41	44	45	45
Diluted shares outstanding		20	17	20	21	19	26	35	41	44	45	45

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Figure 3: CERU Valuation

	Peak Sales	Year	Current Value	Probability Adjustment	Value Per Share
Ov arian	\$333	2020	\$419	30%	\$7
RCC	\$136	2021	\$95	30%	\$1
Rectal	\$191	2021	\$159	30%	\$3
Total			\$673	30%	\$11
Risk Free Rate	2%				
Beta	1.3			Shares outstanding (M's)	19
Risk Premium	9%				
Discount Rate	13.9%				

Source: Canaccord Genuity estimates



#### **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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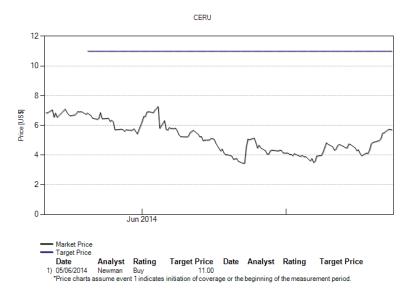
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**Site Visit:** 

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

#### **Price Chart:\***



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Coverage Universe						
Rating	#	%	%			
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Speculative Buy	53	5.1%	54.7%			
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	1041	100.0%				

<sup>\*</sup>Total includes stocks that are Under Review

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