# **US Equity Research**

15 December 2014

#### BUY

unchanged

#### PRICE TARGET US\$11.00

unchanged

Price (15-Dec) US\$5.98 Ticker CERU-NASDAQ

52-Week Range (US\$): 3.35 - 8.06
Avg Daily Vol (M) : 39.5
Shares Out. (M) : 20.1
Market Cap (US\$M): 120

FYE Dec	2013A	2014E	2015E
Sales (US\$M)	0.0	0.0	0.0
EPS Adj&Dil (US\$)	(0.90)	(1.21)	(2.26)

Quarterly Sales	Q1	Q2	Q3	Q4
2013A	0.0	0.0	0.0	0.0
2014E	0.0A↓	0.0A↓	0.0A	0.0
2015F	0.0	0.0	0.0	0.0

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2013A	0.00	0.00	0.00	0.00
2014E	(0.17)A	(0.44)A	(0.28)A	(0.32)
2015E	(0.63)	(0.53)	(0.57)	(0.53)



Cerulean is a development-stage oncology company developing novel cancer drugs using its tumor targeting platform.

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# **Company Update**

# CRLX101 completes Phase 1b/2 study enrollment in relapsed RCC, on track

# CRLX101 completes Phase 1b/2 study enrollment in relapsed RCC, on track; possible \$136M peak sales

Cerulean completed enrollment of its Phase 1b/2 study of CRLX101 + avastin in relapsed renal cell carcinoma (RCC) of 22 patients, which we believe is a positive as the drug is on track for data readout by end of 2015. We remind investors that prior proof of concept data in 11 patients demonstrated a ~27% overall response rate (ORR) in a single-arm relapsed/refractory RCC study, an improvement vs. Avastin monotherapy, suggesting strong efficacy for CRLX101. Historically, third-line patients that previously received a TKI have achieved RECIST partial response rates of 2-4% with a median PFS of 3.5 months, while CRLX101 achieved a near doubling PFS of ~7.6 months. Even moving to second-line, response rates are generally <10%. We expect positive results by YE15 to be a major catalyst for the stock.

#### Expect data for CRLX101 in rectal cancer by early 2015; encouraging early data

Early-look data in neoadjuvant rectal cancer showed one pathologic complete response (pCR) and two patients with substantially reduced disease burden with CRLX101 + chemoradiation, which we find interesting. Importantly, we believe the results will be positive since it is already known that other FDA-approved topoisomerase inhibitors, specifically irinotecan, demonstrates activity in this setting (irinotecan + Xeloda with radiotherapy demonstrated pCR of 21 – 37% in neoadjuvant rectal cancer). The trial is on track for data readout in 10-12 patients by H1/15, with anticipated  $\sim$ 30% pathologic complete response rate for trial advancement into Phase 2.

# Maintain BUY rating, \$11 PT

We maintain our BUY rating of CERU and an \$11PT. We believe the company is currently on track for data readout for CRLX101 in RCC by YE15, as well as data in rectal and ovarian cancer by early 2015.

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Figure 1: CERU Income statement

(000's) [FY - DEC]	2012A	1Q13A	2Q13A	3Q13A	4Q13A	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
Ovarian														-	55,214	182,988	332,844
Total														-	55,214	226,643	522,362
iotai														-	33,214	220,043	322,302
Income Statement						2013A	Mar-14A	Jun-14A	Sep-14A	Dec-14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues																	
Total Revenue	625					6	47	33	_					-	55,214	226,643	522,362
COGS	0													-	8,282	33,996	78,354
Gross Profit	625					6	47	33	-	-				-	46,932	192,646	444,007
Operating Expenses																	
Research and development	15,807					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	6,393					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	22,200					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	(21,575)					(15,860)	(2,958)	(4,644)	(5,369)	(6,628)	(19,599)	(59,867)	(63,520)	(67,422)	(32,062)	110,054	352,415
In a discretification and																	
Investment income, net							1	2	2								
Interest Income Interest Expense	(567)					(1,487)	(461)	(268)	(191)		(920)						
Loss on extinguishment of debt	(307)					(1,407)	(401)	(2,493)	(191)	-	(320)	-	-	-	-	-	-
Decrease in value of pref stock	39					202		(2,493)									
Pre-tax income (GAAP)	(526)					(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)	(320)					(17,145)	(3,410)	(1,400)	(0,000)	(0,020)	(23,007)	(55,007)	(00,020)	(01,422)	(32,002)	110,004	332,413
Tre-tax medite (non-daza)																	
Taxes (GAAP)						_	_	_	_	-		-	-	-	-	40,720	130,394
Tax rate (GAAP)						37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
,																	
Net Income (GAAP)	(22,101)					(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																	
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							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

Source: Company reports, Canaccord Genuity Estimates

Figure 2: 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 outs	standing (M's)	19
Risk Premium	9%			
Discount Rate	13.9%			

Source: Canaccord Genuity Estimates



# Appendix: Important Disclosures

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#### **Target Price / Valuation Methodology:**

Cerulean Pharma - CERU:

We have an \$11 price target based on a sum-of-the-parts probability-adjusted NPV analysis.

# Risks to achieving Target Price / Valuation:

Cerulean Pharma - CERU:

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.

# **Distribution of Ratings:**

Global Stock Ratings (as of 12/15/14)

Rating	Coverage	Coverage Universe				
	#	%	%			
Buy	702	65.42%	34.90%			
Hold	321	29.92%	14.95%			
Sell	50	4.66%	2.00%			
	1073*	100.0%				

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



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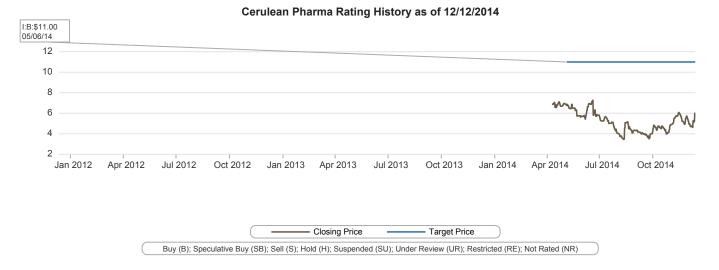
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