

US Equity Research

21 January 2015

BUY

unchanged

PRICE TARGET US\$11.00

unchanged

Price (20-Jan) US\$7.77

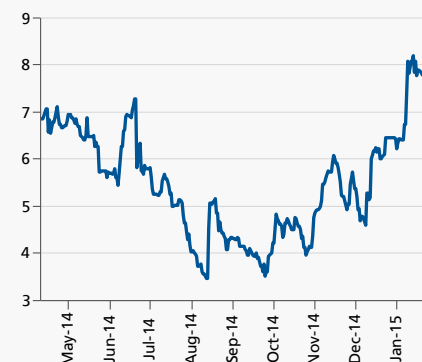
Ticker CERU-NASDAQ

52-Week Range (US\$): 3.35 - 8.25
 Avg Daily Vol (M) : 37.3
 Shares Out. (M) : 20.1
 Market Cap (US\$M): 156

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
2015E	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

Numerous meaningful data readouts in 2015

Expect positive CRLX101 data in neoadjuvant rectal cancer by March 2015

CERU will present data on 10 patients from its phase 1 study in neoadjuvant rectal cancer where CRLX101 is combined with chemoradiotherapy by end of March, which we believe will be positive since early response rates have already been seen. Importantly, no dose limiting toxicity (DLT) has been reported, which we find significant since the drug is to be combined with intense chemotherapy and radiation.

CRLX101 in ovarian cancer – data readout by March 2015

We expect data to be presented in 10 ovarian cancer patients by March 2015, where CRLX101 is combined with Avastin for relapsed platinum-resistant ovarian cancer in the second- and third-line setting. We believe the recent approval of Avastin in platinum-resistant ovarian cancer, based on a 3.4 month improvement in PFS vs. chemo alone, is a positive for CERU since recent preclinical data demonstrated that CRLX101 reduced the up-regulation of HIF-1 α by Avastin, which is believed to be a mechanism of resistance to anti-angiogenic therapy. Because this disease is extremely difficult to treat with a significant lack of effective therapy, we believe the bar for success is set low for the drug and positive response rates will be a catalyst for the stock.

CRLX101 in renal cell carcinoma - data readout by ASCO 2015

We expect response rate and safety data in a total of 22 patients to be presented by ASCO (June) and full data on ORR by YE15. We remind investors that prior proof of concept in 11 patients showed a ~27% ORR and a 7.6 mon PFS, which is significantly higher than other conventional third-line agents (Avastin, TKIs). We expect continued positive response data in the additional 11 patients to be a driver for our price target, although we would not expect to see PFS data until 2016.

CRLX301 in solid tumors - data readout by YE15

CERU plans to present data on the phase 1 portion of CRLX301 by YE15 in solid tumors, which fits well with the current pipeline. Unlike CRLX101, where the nanoparticle-drug conjugate (NDC) is with a camptotecin, CRLX301 uses docetaxel. We believe that positive data may add another potential drug candidate to the company, which we currently do not include into our valuation.

Low risk oncology play due to known activity for mechanism of action

We emphasize that the mechanism of CRLX101 de-risks the compound significantly. Camptothecin (topoisomerase inhibitors) is currently the backbone for many oncologic diseases. However, although efficacious, these drugs are limited by high toxicity, with the lesser potent irinotecan and topotecan only available to physicians. CRLX101 takes the most potent member of the class and incorporates the compound into a nanopharmaceutical to maximize the efficacy without increasing toxicity. Additionally, similar technologies involving drug conjugate chemotherapies have been validated by other companies, including NKTR and MACK, which we believe is positive for CERU.

Figure 1: CERU Catalysts

Event	Timing	Drug	Description	Effect	Importance	Notes
Data	1Q15 (March)	CRLX101	Phase 2 Ovarian (combo with avastin)	↑	Critical	Final ORR, PFS Data, single-arm study (n - 10 patients)
Data	1Q15 (March)	CRLX101	Phase 2 Rectal	↑	Critical	pCR data, Single arm data (n - 10 patients)
Data	2Q15	CRLX101	Phase 2 RCC	↑	High	Clinical data from final 22 patients in relapsed RCC - ASCO
Data	4Q15	CRLX101	Phase 2 RCC	↑	Critical	ORR data, randomized, blinded data
Data	4Q15	CRLX301	Phase 1 data	↑	High	MTD and dose regimen

Source: Canaccord Genuity estimates, Cerulean

Figure 2: Cerulean 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
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
Investment income, net																	
Interest Income	2					2	1	2	2								
Interest Expense	(567)					(1,487)	(461)	(268)	(191)	-	(920)	-	-	-	-	-	-
Loss on extinguishment of debt								(2,493)									
Decrease in value of pref stock	39					202											
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)																	
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: Canaccord Genuity estimates

Figure 3: CERU Valuation

	Peak Sales	Year	Current Value	Probability Adjustment	Value Per Share
Ovarian	\$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				
Risk Premium	9%				
Discount Rate	13.9%				
Shares outstanding (M's)					19

Source: Canaccord Genuity estimates

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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

Cerulean'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 01/21/15)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	635	58.74%	31.02%
Hold	348	32.19%	13.51%
Sell	50	4.63%	2.00%
Speculative Buy	48	4.44%	60.42%
	1081*	100.0%	

*Total includes stocks that are Under Review

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