Cerulean Pharma (CERU)

Q4:EPS, Positive Top-line Data from Ph I/II Trial of CRXL101 in Renal Cell Carcinoma and Further Clinical Updates, REITERATE OP and Raising PT to $16

- **CERU announced positive interim data from its Ph 1b/2 investigator-sponsored trial (IST) of CRLX101 in combination with Avastin in relapsed renal cell carcinoma (RCC).** As of the data cut-off, median progression-free survival (PFS) was 9.9 months, compared to a current standard of care (SOC) in this 3rd and 4th line setting of 3.5 months. In addition, the RECIST response rate was 23% vs. current SOC of 2-4%. The 22-patient study, being conducted at U Penn and Thomas Jefferson University Hospital, enrolled its last patient in December 2014, with seven remaining on trial. This data will be presented at the ASCO meeting (May 29-June 2), with final data submitted for publication in a peer-reviewed journal late this year.
- **These results bode well for CERU's ongoing company-sponsored randomized Phase II trial, which is evaluating CRLX101 in combination with Avastin in up to 110 patients (up to 90 with RCC), and which will likely serve as one of the two registration studies needed for NDA submission.** On the call, management indicated they expect enrollment to be completed in Q4:14, and top-line primary endpoint data and overall response rate data from this trial is expected in the second quarter of 2016.
- **CERU also announced interim data from two further ISTs.**
- **These studies continue to reaffirm the strong safety and tolerability profile of CRLX101, which may allow clinical investigation to expand into additional indications in the future.**
- **CERU reported a Q4:14 EPS of ($0.37), below our estimate of ($0.30), and a cash balance of $51.2M, in line with our estimate of $53M, enough to fund its current clinical studies through 2015.** This balance does not include $11M available to the company through a term-loan facility, entered into in Q1:15.
- **Reiterate OUTPERFORM rating and raising our price target to $16.** Our $16 price target is derived from applying a 6x multiple to estimated 2020 sales of CRLX101 in renal cell carcinoma discounted back by 30%, and in platinum-resistant ovarian cancer and neoadjuvant rectal cancer by 35%.

March 19, 2015

Price
$10.66

Rating
OUTPERFORM

12-Month Price Target
$16 **(from $12)**

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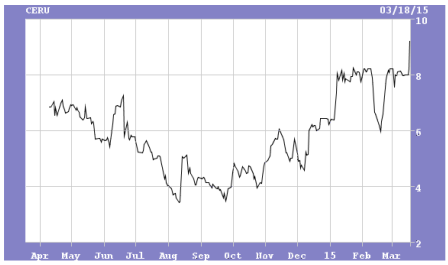
Company Information	
Shares Outst (M)	20.3
Market Cap (M)	$216.2
52-Wk Range	$3.35 - $9.70
Book Value/sh	$2.61
Cash/sh	$2.93
Enterprise Value (M)	$157.3
LT Debt/Cap %	0.0
Cash Burn (M)	$51.1

Company Description

CERU is developing tumor-targeted nanopharmaceutical drug candidates for the treatment of cancer. The company's lead product candidate is CRLX101, a nanopharmaceutical of camptothecin in Phase II trials in multiple cancer indications.

FYE Dec	2013A	2014A			2015E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	0.0A	0.0A		$0.0A	0.0E		$0.0E
Q2 Jun	0.0A	0.0A		0.0A	0.0E		0.0E
Q3 Sep	0.0A	0.0A		0.0A	0.0E		0.0E
Q4 Dec	0.0A	0.0A		0.0A	0.0E		0.0E
Year*	**0.0A**	**0.1A**		**$0.1A**	**0.0E**		**$0.0E**
Change	--	1233%			-100%		
	2013A	**2014A**			**2015E**		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.00A	($3.70)A		--	($0.46)E	($0.40)E	--
Q2 Jun	$0.00A	($0.44)A		--	($0.61)E	($0.55)E	--
Q3 Sep	($0.96)A	($0.28)A		--	($0.54)E	($0.55)E	--
Q4 Dec	($0.24)A	($0.37)A	($0.30)A	--	($0.58)E	($0.59)E	--
Year*	**($1.20)A**	**($1.60)A**	**($4.71)A**	**--**	**($2.19)E**	**($2.09)E**	**--**
P/E	--	--			--		
Change	--	-34%			-37%		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*



Source: Thomson Reuters

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- **CERU also announced interim data from two further ISTs**. In an ongoing Ph II trial of CRLX101 plus avastin in patients with relapsed ovarian cancer, one patient achieved a partial response (PR), one additional patient achieved tumor reduction in excess of 20% and 9 out of 9 patients achieved stable disease (SD) or better. Furthermore, four of the nine patients remain on study with no serious adverse events recorded to date with CRLX101 at its MTD. In an ongoing Ph Ib/2 study of CRLX101 plus chemoradiotherapy (CRT) in patients with non-metastatic rectal cancer, 2 out of 8 patients enrolled achieved a pathological complete response (CR) and 7 out of 8 achieving an AJCC/UICC tumor regression score of 0 or 1 on a scale of 0 to 3. Importantly, no dose limiting toxicities were observed and the trial will move forward to the Ph 2 stage with the MTD as 15 mg/m^2.

- **Three posters detailing investigator-sponsored preclinical work on CRX101 will be presented at the AACR Annual Meeting in Philadelphia (April 18-22).** Abstracts for these posters detail preclinical studies of CRLX101 in triple-negative breast cancer (TNBC) (Poster 1384), preclinical studies of CRLX101 in a model of metastatic breast cancer (Poster 4124), and preclinical and initial clinical results of CRLX101 in locally advanced rectal cancer (Poster 5515).

  Poster 1384: CRLX101, an investigational camptothecin-containing nanoparticle-drug conjugate, reverses the HIF-1α-mediated increase in cancer stem cells caused by bevacizumab in a preclinical model of triple-negative breast cancer
  Poster 4124: Potent anti-tumor and metastatic breast cancer efficacy of bevacizumab with CRLX101, an investigational chemotherapy nanoparticle-drug conjugate that secondarily suppresses HIF-1α
  Poster 5515: "Neoadjuvant chemoradiotherapy for rectal cancer with CRLX101, an investigational nanoparticle-drug conjugate with a camptothecin payload".

- Risks to the achievement of our price target include failure to gain approval for CRLX101 in the ovarian, renal cell carcinoma and neoadjuvant rectal cancer settings, failure to achieve sales estimates for CRLX101 and failure to achieve earnings estimates.

Milestones

May 29-June 2:	Presentation of updated data for the Phase 1b/2 IST of CRLX101 plus Avastin in relapsed RCC by Dr. Keefe at the 2015 ASCO Annual Meeting
2015:	Data from the ongoing Phase 2 IST of CRLX101 plus Avastin in relapsed ovarian cancer
2015:	Data from the ongoing Phase 1b/2 IST of CRLX101 plus CRT in non-metastatic rectal cancer
Q4:15	Phase I data for CRLX301
Q2:16:	Top-line data from Phase II study of CRLX101 plus Avastin in relapsed RCC

3/19/2015
Ticker: (CERU:Nasdaq)
Cerulean Pharma, Inc

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	2013	Q1	Q2	Q3	Q4	2014A	2015E	2016E	2017E	2018E	2019E	2020E
Revenues:												
US Product Sales	$0	$0	$0	$0	$0	$0	$0	$0	$0	$50,086	$130,122	$220,946
ex-US sales	$0	$0	$0	$0	$0	$0	$0	$0	$0	$8,864	$81,616	$148,413
Licensing and other revenue	$6	$47	$33	$0	$0	$80	$0	$0	$0	$0	$0	$0
Total Revenues	**6**	**47**	**33**	**0**	**0**	**80**	**0**	**0**	**0**	**58,950**	**211,738**	**369,359**
Cost and Expenses:												
Cost of Sales	0	0	0	0	0	0	0	0	0	5,009	13,012	22,095
R&D	9,700	1,495	2,648	2,928	4,701	11,772	40,804	53,396	57,797	62,561	67,718	73,301
SG&A	6,166	1,510	2,029	2,441	2,607	8,587	10,960	11,573	12,345	36,537	76,000	100,709
Total Operating Expenses	**15,866**	**3,005**	**4,677**	**5,369**	**7,308**	**20,359**	**51,764**	**64,968**	**70,142**	**104,107**	**156,730**	**196,104**
Operating Income (Loss)	(15,860)	(2,958)	(4,644)	(5,369)	(7,308)	(20,279)	(51,764)	(64,968)	(70,142)	(45,157)	55,008	173,255
Net Interest Income (Expense)	(1,485)	(460)	(266)	(189)	(159)	(3,567)	(509)	(1,171)	(1,009)	(1,239)	193	227
Other non-operating Income (Expense)	202	504	(2,493)	0	0	(1,989)	0	0	0	0	0	0
Income Before Income Taxes	(17,143)	(2,914)	(7,403)	(5,558)	(7,467)	(25,835)	(52,273)	(66,139)	(71,151)	(46,396)	55,201	173,481
Provision for Income Taxes	0	0	0	0	0	0	0	0	0	0	21,529	67,658
Net Income (Loss)	(17,143)	(2,914)	(7,403)	(5,558)	(7,467)	(25,835)	(52,273)	(66,139)	(71,151)	(46,396)	33,673	105,824
Non-GAAP EPS	**(1.15)**	**(3.52)**	**(0.36)**	**(0.26)**	**(0.36)**	**(1.20)**	**(1.89)**	**(1.90)**	**(2.05)**	**(1.32)**	**1.01**	**3.11**
GAAP EPS	**(1.20)**	**(3.70)**	**(0.44)**	**(0.28)**	**(0.37)**	**(1.60)**	**(2.19)**	**(2.17)**	**(2.07)**	**(1.35)**	**0.98**	**3.08**
Total Shares Outstanding	14,305	787	20,123	20,125	20,125	20,125	27,361	34,361	34,361	34,361	34,361	34,361
Cash Burn	(15,238)	(2,811)	(4,448)	(5,084)	(7,051)	(19,394)	(51,069)	(67,089)	(69,717)	(24,656)	20,085	161,457
Cash Balance	5,488	8,468	64,271	57,786	51,174	51,174	131,196	180,042	109,391	57,245	55,754	149,138

Source: Wedbush Securities

Analyst Biography

David Nierengarten, Ph.D. is an Analyst covering stocks in the Biotechnology/Biopharmaceuticals/BioDefense sector. His prior sellside research experience at Robert W. Baird & Co. covered biotechnology companies of all market capitalizations, with a focus on oncology and rare diseases.
David received his B.S. (Biochemistry) from the University of Wisconsin-Madison and Ph.D. (Molecular and Cell Biology) from the University of California-Berkeley.
David's Edge: David's early stage venture capital investing experience gives him a balanced perspective on developmental-stage biotechnology companies and their ultimate risk/reward potential. His experience on the other side of that equation in a clinical-stage, venture backed biotechnology company provides him with insights into corporate operations. The combination of experiences creates a focus on value creation in this event-driven space.

Analyst Certification
I, David M. Nierengarten, Ph.D., Dilip Joseph, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ414.pdf

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

Rating Distribution (as of December 31, 2014)	**Investment Banking Relationships (as of December 31, 2014)**
Outperform:58% Neutral: 39% Underperform: 3%	Outperform:19% Neutral: 2% Underperform: 0%

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Company	Disclosure
Cerulean Pharma	1,3,4,5

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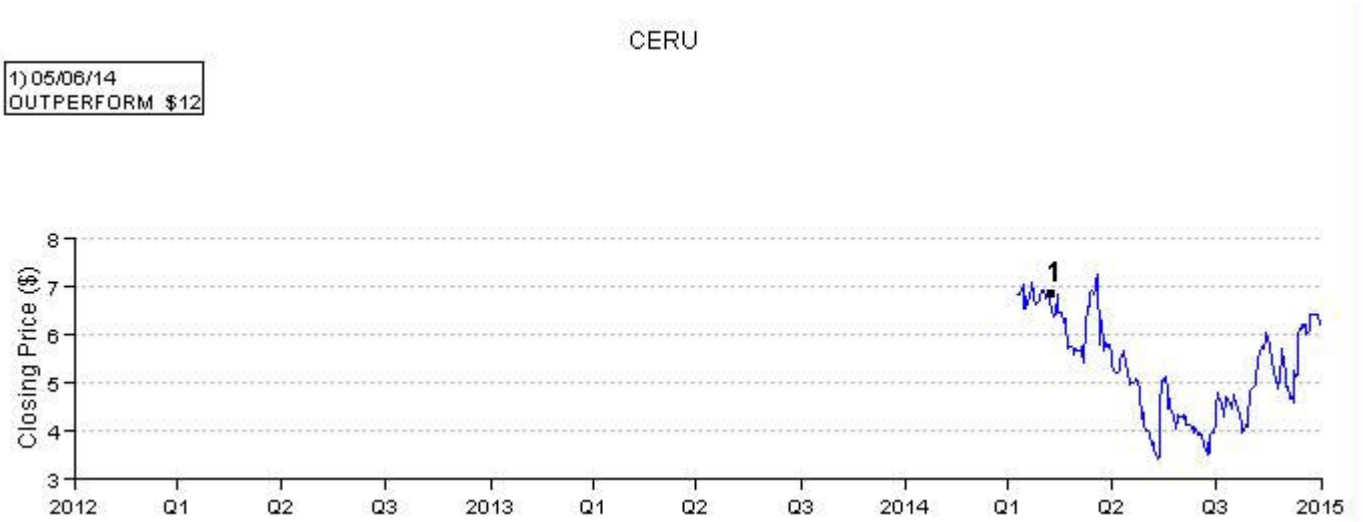

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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