

Cerulean Pharma (CERU)

Q2:14 EPS, CERU Shares Look Attractive on Risk/Reward, Reiterate OUTPERFORM

- CERU CEO Dr. Oliver Fetzter presented at our Life Sciences Management Access Conference on August 13 and provided a thorough overview of the company's dynamic tumor-targeting platform and nanoparticle-drug conjugates CRLX101 and CRLX301.
- We believe the market is overestimating the risk associated with CERU's treatment approach. On the safety front, CRLX101 is a nanoparticle formulation of camptothecin that appears to be less toxic than irinotecan and topotecan, both of which are camptothecin-analogs that are already approved. CRLX101 has also demonstrated inhibition of hypoxia inducible factor-1alpha (HIF-1alpha), which no approved agent has been able to durably inhibit. Since HIF-1alpha drives angiogenesis and resistance to chemotherapy and radiotherapy, CRLX101 is expected to be synergistic with standard of care treatments. As for CRLX301, its payload is the established agent docetaxel, which in our view, should reduce the development and regulatory time to approval. In preclinical animal models CRLX301 has demonstrated superior tumor penetration and efficacy measures compared to docetaxel alone.
- Q2 net loss was \$7.4M, and CERU ended the quarter with \$64.3M in cash. We view the funds as being sufficient to support operations through 2015, when data from multiple studies should read out.
- Catalysts on the horizon. Data from the single-arm Phase II combo studies of CRLX101 with Avastin in relapsed ovarian cancer and with chemoradiation in non-metastatic rectal cancer is expected to read out in Q1:15. A Phase II randomized study of CRLX101 in combination with Avastin in relapsed renal cell carcinoma patients is currently screening patients, with data expected in YE:15. CERU also plans to advance its CRLX301 candidate into the clinic late this year, with data available in Q4:15. We expect positive outcomes from these studies, which should drive investor interest.
- With a <\$50M EV, we believe investors have undervalued CERU and we continue to view its risk/reward ratio as attractive.
- Reiterate OUTPERFORM rating and \$12 price target. Our \$12 price target is derived from applying a 6 multiple to estimated 2020 sales of CRLX101, discounted back by 35%.

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Price
\$5.07

Rating
OUTPERFORM

12-Month Price Target
\$12

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Company Information

Shares Outst (M)	20.1
Market Cap (M)	\$102.0
52-Wk Range	\$5.00 - \$8.06
Book Value/sh	\$-1.08
Cash/sh	\$3.19
Enterprise Value (M)	\$40.0
LT Debt/Cap %	-0.2
Cash Burn (M)	\$24.5

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.



Source: Thomson Reuters

FYE Dec	2013A	2014E			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	0.0E		0.0E	0.0E		0.0E
Q4 Dec	0.0A	0.0E		0.0E	0.0E		0.0E
Year*	0.0A	0.1E	0.0E	\$0.0E	0.0E		\$0.0E
Change	--	1233%			-100%		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$0.00A	(\$3.70)A		--	(\$0.34)E	(\$0.27)E	--
Q2 Jun	\$0.00A	(\$0.44)A	(\$0.29)A	--	(\$0.49)E	(\$0.43)E	--
Q3 Sep	(\$0.96)A	(\$0.19)E	(\$0.12)E	--	(\$0.49)E	(\$0.44)E	--
Q4 Dec	(\$0.24)A	(\$0.24)E	(\$0.17)E	--	(\$0.53)E	(\$0.48)E	--
Year*	(\$1.20)A	(\$4.56)E	(\$4.29)E	--	(\$1.84)E	(\$1.62)E	--
P/E	--	--			--		
Change	--	-281%			60%		

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

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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

- YE:14 Initiation of Phase I study of CRLX301 in advanced cancers
- Q1:15 Potential data from Phase II trial of CRLX101 in combination with Avastin in relapsed ovarian cancer
- Q1:15 Potential data from Phase I/II trial of CRLX101 in combination with chemoradiation in non-metastatic rectal cancer
- Q4:15 Phase I data for CRLX301
- Q4:15 Potential data from Phase II trial of CRLX101 in combination with Avastin in relapsed RCC

Investment Thesis

Cerulean Pharma (NASDAQ:CERU) is focused on developing dynamically tumor-targeted nanopharmaceuticals for the treatment of cancer. The company's lead product candidate, CRLX101, is a nanopharmaceutical formulation of camptothecin in Phase II development for multiple cancers, including renal cell carcinoma and ovarian cancer, and in the Phase I/II stage for neoadjuvant rectal cancer. CRLX101 is being developed as an add-on therapy in these lead indications, due to the synergistic effect the dual topoisomerase I and hypoxia inducible factor inhibitor has with VEGF inhibitors and radiotherapy. The company is also developing CRLX301, a nanopharmaceutical formulation of docetaxel that is expected to enter the clinic by the end of 2014.

Financial Model

8/14/2014
Ticker: (CERU:Nasdaq)
Cerulean Pharma, Inc

Wedbush PacGrow Life Sciences
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	2011	2012	2013	Q1	Q2	Q3	Q4	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues:														
US Product Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$6,410	\$69,227	\$151,200	\$245,284
ex-US sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$32,926	\$103,235	\$176,520
Licensing and other revenue	\$305	\$625	\$6	\$47	\$33	\$0	\$0	\$80	\$0	\$0	\$0	\$0	\$0	\$0
Total Revenues	305	625	6	47	33	0	0	80	0	0	6,410	102,153	254,435	421,805
Cost and Expenses:														
Cost of Sales	0	0	0	0	0	0	0	0	0	0	641	6,923	15,120	24,528
R&D	13,848	15,807	9,700	1,495	2,648	2,701	3,701	10,545	36,804	49,191	53,246	57,635	62,386	67,529
SG&A	5,335	6,393	6,166	1,510	2,029	1,540	1,571	6,650	6,605	6,974	9,042	52,983	100,599	126,319
Total Operating Expenses	19,183	22,200	15,866	3,005	4,677	4,241	5,272	17,195	43,408	56,165	62,929	117,541	178,106	218,377
Operating Income (Loss)	(18,878)	(21,575)	(15,860)	(2,958)	(4,644)	(4,241)	(5,272)	(17,115)	(43,408)	(56,165)	(56,519)	(15,388)	76,329	203,428
Net Interest Income (Expense)	(25)	(565)	(1,485)	(460)	(2,759)	457	456	(2,306)	1,549	1,579	1,476	1,876	1,852	3,998
Other non-operating Income (Expense)	(660)	(34)	202	504	0	0	0	0	0	0	0	0	0	0
Income Before Income Taxes	(19,563)	(22,174)	(17,143)	(2,914)	(7,403)	(3,785)	(4,816)	(19,421)	(41,860)	(54,586)	(55,042)	(13,512)	78,181	207,426
Provision for Income Taxes	0	0	0	0	0	0	0	0	0	0	0	27	30,491	80,896
Net Income (Loss)	(19,563)	(22,174)	(17,143)	(2,914)	(7,403)	(3,785)	(4,816)	(19,421)	(41,860)	(54,586)	(55,042)	(13,540)	47,691	126,530
Non-GAAP EPS	(1.51)	(1.51)	(1.15)	(3.52)	(0.36)	(0.19)	(0.24)	(0.95)	(1.68)	(1.82)	(1.61)	(0.38)	1.45	3.79
GAAP EPS	(1.37)	(1.55)	(1.20)	(3.70)	(0.44)	(0.19)	(0.24)	(4.56)	(1.84)	(2.03)	(1.82)	(0.40)	1.42	3.77
Total Shares Outstanding	14,305	14,305	14,305	787	20,123	20,450	20,475	20,475	24,575	29,575	33,575	33,575	33,575	33,575
Cash Burn	(18,590)	(18,590)	(7,840)	4,002	(20,951)	(2,469)	(5,086)	(24,505)	(44,854)	(55,117)	(57,024)	(21,297)	67,738	191,164
Cash Balance	16,707	16,707	5,488	8,468	64,271	60,805	56,177	56,177	50,070	66,284	66,503	46,708	85,533	199,079

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, Liana Moussatos, Ph.D., 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.

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Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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Company	Disclosure
Cerulean Pharma	1,3,5,7

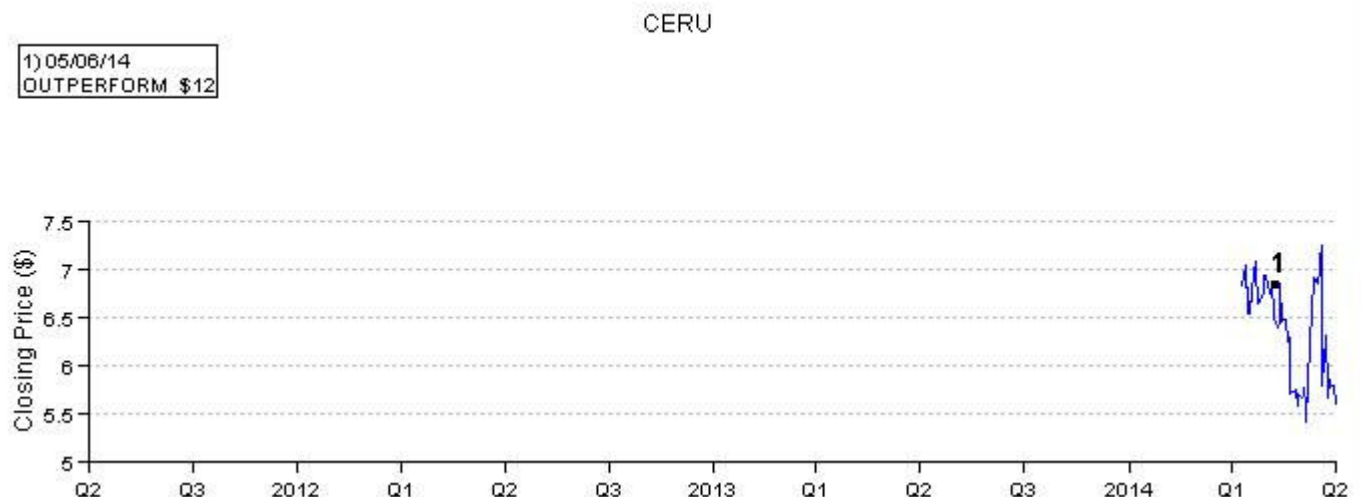
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