Cerulean Pharma Inc. (CERU)

Reports 4Q14 Results and Highlights Impressive Results in Phase Ib/II Trial in Refractory Renal Cell Carcinoma

MARKET OUTPERFORM | Price: $10.66 | Target Price: $16.00

MARKET DATA

Price	$10.66
52-Week Range:	$3.35 - $9.70
Shares Out. (M):	20.1
Market Cap ($M):	$214.3
Average Daily Vol. (000):	383.0
Cash (M):	$51
Cash/Share:	$2.54
Enterprise Value (M):	$132
Float (M):	17.4
LT Debt (M):	$1

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014A	2015E	2016E
Revenue ($M)	1Q	$0.0	$0.0	--
	2Q	$0.0	$0.0	--
	3Q	$0.0	$0.0	--
	4Q	$0.2	$0.0	--
	FY	**$0.1**	**$0.0**	**$0.0**
EPS	1Q	($3.71)	($0.42)	--
	2Q	($0.44)	($0.43)	--
	3Q	($0.28)	($0.44)	--
	4Q	($0.36)	($0.40)	--
	FY	**($1.60)**	**($1.59)**	**($2.25)**
Previous FY		($2.91)	($2.57)	($2.93)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Cerulean Pharma reported 4Q14 results, highlighting an advancing development pipeline with highly encouraging results in the early stage trial of refractory renal cell carcinoma; we reiterate our Market Outperform rating and increase our price target to $16 from $14, based on rolling forward our estimates to 2015. CERU reported a 4Q14 net loss of $7.35M vs. our estimate of $7.51M. We remind investors that the performance of CERU is dependent upon execution against clinical milestones, and not quarter-to-quarter financial metrics. Total operating expenses were in line with expectations ($7.31M vs. JMP of $7.3M). CERU finished the quarter and year with $51.2M in cash and cash equivalents, which should provide sufficient runway to continue operations into 3Q16. The company released highly encouraging top line data from a Phase Ib/II investigator sponsored trial of CRLX101, its lead candidate nanoparticle conjugated camptothecin, in the treatment of third and fourth line renal cell carcinoma (RCC) patients. We currently attribute peak 2025 sales potential of $772M in this indication. Our $16 price target is based on a synthesis of our DCF, CAGR, and comparable company valuation methodologies.

CERU's highlights of 4Q14 reflect an expanding pipeline with multiple value inflection points. As mentioned, the company announced compelling results from its 22-patient single arm trial of CRLX101 in combination with bevacizumab (Avastin, RHBBY, NC), demonstrating an objective response rate of 23% as compared to historical results of 2-4%, and a highly promising preliminary PFS of 9.9 months as compared to 3.5 month historical control. We note that seven out of the 22 patients remain on drug, and the complete results expected to be presented at ASCO 2015, can shift the PFS balance in either direction. With the caveat of small patient numbers, lending to outlier effects, we are encouraged by the results in this difficult to treat patient population, in which there are few treatment options. Management also highlighted the advancement of CRLX101 into a randomized 110-patient Phase II clinical trial in combination with bevacizumab in relapsed renal-cell carcinoma (RCC), with the study 80% powered to demonstrate a 2.3 month improvement over the currently accepted 3.5 month standard of care. This study should complete enrollment by YE15. In our opinion, this result is achievable in light of current data, with the caveat of a currently incomplete data set in hand. We look forward to the upcoming ASCO presentation for complete results and greater clarity.

Additional encouraging evidence in ovarian and rectal cancer. The company also announced interim data from clinical development of CRLX101 plus bevacizumab in relapsed ovarian cancer where one of the first eight patients enrolled has achieved a partial RECIST response, and nine of nine treated patients have stable disease with no serious adverse events, with patients dosed at the CRLX101 MTD.

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In the ongoing Phase I/IIb rectal cancer study of CRLX101, two patients have sustained a pathological complete response. Seven of eight patients achieved an AJCC/UICC tumor regression score of 0 or 1 on a scale of 0 to 3, with 0 being the best (a pCR) and 3 being the worst. As a reminder, clinical results with irinotecan, the active therapy in this nanoformulation, have shown pathological CR rates of 21-27%; however, the drug's serious adverse events include significant GI toxicity. Clinical studies have demonstrated CRLX101 to have a safe and well tolerated safety profile that is potentially superior to irinotecan in the clinic. Additionally, the company is also continuing development of CRLX301 in an ongoing Phase I clinical trial in various advanced solid tumors with results expected in 4Q15.

Changes to our model. We are making adjustments to our model to reflect anticipated increases in operational expenses and changes to outstanding shares, with Figures 3 and 4 reflecting our estimate adjustments.

In our view, Cerulean embodies much of what investors found attractive about Abraxis: a differentiated chemotherapy that maintains or increases its antitumor activity, but has a superior tolerability profile, making it more amenable to combination regimens. On balance, we believe CERU bears a favorable risk/upside potential profile, rooted in the known antitumor activity of camptothecin, as well as the regulatory and commercial paths forward for CRLX101 in its intended indications. Management guided toward multiple value inflection points for throughout 2015. Provided the data are positive, these events could be expected to bring CERU's market cap in line with comparable platform technologies (BIND (MO, $25 PT), ECYT, MACK, NKTR, SRNE) that trade at an average market cap of ~$500M, a significant premium to CERU's present valuation.

FIGURE 1. Potential CERU Catalysts

Timing	Candidate	Catalysts
1Q15	CRLX101	Potential initiation of randomized Phase II neoadjuvant rectal cancer study (100 pts)
1Q15	CRLX101	Potential initiation of pivotal ovarian Phase II trial in combination with Avastin
4Q15	CRLX301	Phase I read-outs (PK, MTD, and preliminary efficacy)
4Q15	CRLX101	Read-out from randomized RCC Phase II in combo with Avastin

Source: Company presentations

FIGURE 2. Results vs. Estimates

Cerulean Pharma(CERU) Abridged Income Statement ($ MM)	4Q14 Results			FY14 Results		
	JMP Estimate	Actual	Variance (JMP vs. Actual)	JMP Estimate	Actual	Variance (JMP vs. Actual)
Total Revenues	**-**	**0.16**	**(0.16)**	**-**	**0.08**	**(0.08)**
Operating Expenses	**7.30**	**7.31**	**(0.0)**	**27.31**	**20.36**	**7.0**
Research and development	4.10	4.70	(0.6)	16.76	11.77	5.0
General and administrative	3.20	2.61	0.6	10.56	8.59	2.0
Operating income (loss)	**(7.30)**	**(7.15)**	**(0.2)**	**(27.31)**	**(20.12)**	**(7.2)**
Other income (expense)	**(0.21)**	**(0.16)**	(0.1)	**0.00**	**(3.06)**	**#REF!**
Pretax income (loss)	**(7.51)**	(7.30)	(0.20)	**(27.31)**	(23.18)	(4.13)
Net income (loss)	**(7.51)**	(7.35)	(0.15)	**(27.31)**	(23.23)	(4.08)
EPS Calculations						
Basic EPS	**$ (0.93)**	**$ (0.36)**	**$ (0.57)**	**$ (2.57)**	**$ (1.60)**	**$ (0.97)**
Diluted EPS	**$ (0.93)**	**$ (0.36)**	**$ (0.57)**	**$ (2.57)**	**$ (1.60)**	**$ (0.97)**
Basic shares outstanding	8.099	20.400	(12.301)	10.622	14.549	(3.927)
Diluted shares outstanding	8.099	20.399	(12.300)	10.622	14.549	(3.927)

Source: JMP Securities LLC, Company filings

FIGURE 3. Changes to Our Model

Cerulean Pharma (CERU)	1Q15E		2Q15E		3Q15E		4Q15E		FY 2015E		FY 2016E	
($ MM)	Old	New	Old	New	Old	New	Old	New	Old	New		New
Collaboration Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other												
Total Revenues	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	0.0	**-**	0.0	**-**
COGS	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	-	-	-	-	-	-	-	-	-	-	-	-
Operating Expenses	**7.4**	**7.4**	**7.5**	**7.5**	**7.7**	**7.7**	**7.8**	**7.8**	**27.3**	**32.2**	**42.0**	**46.1**
Research and development	4.7	4.7	4.8	4.8	4.8	4.8	4.9	4.9	16.8	19.3	29.8	31.8
General and administrative	2.7	2.7	2.8	2.8	2.9	2.9	3.0	3.0	10.6	12.9	12.2	14.3
Operating income (loss)	(7.4)	(7.4)	(7.5)	(7.5)	(7.7)	(7.7)	(7.8)	(7.8)	(27.3)	(32.2)	(42.0)	(46.1)
Other income (expense)	(0.8)	(0.8)	(0.6)	(0.6)	(0.4)	(0.4)	(0.2)	(0.2)	-	-	-	-
Interest income	(0.8)	(0.8)	(0.6)	(0.6)	(0.4)	(0.4)	(0.2)	(0.2)	-	-	-	-
Pretax income	(8.2)	(8.2)	(8.2)	(8.2)	(8.1)	(8.1)	(8.1)	(8.1)	(27.3)	(32.2)	(42.0)	(46.1)
Provision for Income Tax	-	-	-	-	-	-	-	-	-	-	-	-
Net income	(8.2)	(8.2)	(8.2)	(8.2)	(8.1)	(8.1)	(8.1)	(8.1)	(27.3)	(32.2)	(42.0)	(46.1)
Basic EPS	**$ (0.46)**	**$ (0.46)**	**$ (0.45)**	**$ (0.45)**	**$ (0.45)**	**$ (0.45)**	**$ (0.40)**	**$ (0.40)**	**$ (2.57)**	**$ (1.59)**	**$ (3.13)**	**$ (2.25)**
Diluted EPS	**$ (0.46)**	**$ (0.46)**	**$ (0.45)**	**$ (0.45)**	**$ (0.45)**	**$ (0.45)**	**$ (0.40)**	**$ (0.40)**	**$ (2.57)**	**$ (1.59)**	**$ (3.13)**	**$ (2.25)**
Basic shares outstanding	17.94	17.94	18.03	18.03	18.11	18.11	20.19	20.19	10.62	20.19	13.43	20.51
Diluted shares outstanding	17.94	17.94	18.03	18.03	18.11	18.11	20.19	20.19	10.62	20.19	13.43	20.51

Source: JMP Securities LLC

FIGURE 4. Income Statement

Income Statement ($MM)	1Q15E	2Q15E	3Q15E	4Q14E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties:															
CRLX101															
US Sales					-	-	-	49.8	164.9	278.0	421.5	558.9	693.2	832.2	882.6
ROW Royalties					-	-	-	-	7.7	27.8	50.3	76.1	101.3	123.0	132.9
CRLX301															
US Sales					-	-	-	-	105.6	221.2	341.1	501.2	623.6	673.3	697.4
ROW Royalties					-	-	-	-	-	15.8	32.3	49.8	71.0	86.0	90.8
Total Product Sales and Royalties	-	-	-	-	-	-	-	49.8	278.2	542.7	845.2	1,186.0	1,489.2	1,714.6	1,803.6
Collaboration Revenue					-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	49.8	278.2	542.7	845.2	1,186.0	1,489.2	1,714.6	1,803.6
Cost of Goods Sold								6.0	18.1	27.8	42.1	55.9	69.3	83.2	88.3
Gross Profit	-	-	-	-	0.0	0.0	0.0	43.9	260.0	514.9	803.0	1,130.1	1,419.8	1,631.3	1,715.4
Operating Expenses:															
Research and Development	4.7	4.8	4.8	4.9	19.3	31.8	63.7	79.6	91.6	103.5	115.9	127.5	140.2	154.2	169.6
% Growth	*0.0*	*1.0%*	*1.1%*	*1.2%*	*63.9%*	*65.0%*	*100.0%*	*25.0%*	*15.0%*	*13.0%*	*12.0%*	*10.0%*	*10.0%*	*10.0%*	*10.0%*
% Total US Net Sales								*160%*	*34%*	*21%*	*15%*	*12%*	*11%*	*10%*	*11%*
General and administrative	2.7	2.8	2.9	3.0	12.9	14.3	52.5	70.8	92.1	115.1	138.1	154.7	170.2	187.2	205.9
% Growth	*0.0*	*3.0%*	*3.3%*	*3.6%*	*50.0%*	*11.0%*	*267.0%*	*35.0%*	*30.0%*	*25.0%*	*20.0%*	*12.0%*	*10.0%*	*10.0%*	*10.0%*
% Total US Net Sales								*142%*	*34%*	*23%*	*18%*	*15%*	*13%*	*12%*	*13%*
Total operating expenses	7.4	7.5	7.7	7.8	32.2	46.1	116.2	150.4	183.6	218.6	254.0	282.2	310.4	341.4	375.6
Operating income (loss)	(7.4)	(7.5)	(7.7)	(7.8)	(32.2)	(46.1)	(116.2)	(106.6)	76.4	296.3	549.0	847.9	1,109.5	1,289.9	1,339.8
Other income (expense):															
Interest income	0.0	0.0	0.0	0.0											
Interest expense	(0.2)	(0.2)	(0.2)	(0.2)											
Loss on extinguishment of debt															
Decrease in value of preferred stock warrant liability	0.0	0.0	0.0	0.0											
Total other income, net	(0.2)	(0.2)	(0.2)	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax net income (loss)	(7.6)	(7.7)	(7.9)	(8.1)	(32.2)	(46.1)	(116.2)	(106.6)	76.4	296.3	549.0	847.9	1,109.5	1,289.9	1,339.8
Income tax benefit (provision)					0.0	0.0	0.0	0.0	(11.5)	(59.3)	(137.3)	(254.4)	(388.3)	(451.5)	(468.9)
Tax Rate					*0%*	*0%*	*0%*	*0%*	*15%*	*20%*	*25%*	*30%*	*35%*	*35%*	*35%*
Comprehensive income (loss)	(7.6)	(7.7)	(7.9)	(8.1)	(32.2)	(46.1)	(116.2)	(106.6)	64.9	237.0	411.8	593.5	721.2	838.4	870.9
Accretion of redeemable convertible preferred stock															
Net income (loss) attributable to common stockholders	(7.6)	(7.7)	(7.9)	(8.1)	(32.2)	(46.1)	(116.2)	(106.6)	64.9	237.0	411.8	593.5	721.2	838.4	870.9
Basic EPS to common shareholders	$ (0.42)	$ (0.43)	$ (0.44)	$ (0.40)	$ (1.59)	$ (2.25)	$ (5.01)	$ (3.82)	$ 2.12	$ 7.55	$ 12.80	$ 18.03	$ 21.42	$ 24.36	$ 24.75
Diluted EPS to common shareholders	$ (0.42)	$ (0.43)	$ (0.44)	$ (0.40)	$ (1.59)	$ (2.25)	$ (5.01)	$ (3.82)	$ 1.74	$ 6.23	$ 10.61	$ 14.99	$ 17.86	$ 20.36	$ 20.75
Basic shares outstanding	17.9	18.0	18.1	20.2	20.2	20.5	23.2	27.9	30.7	31.4	32.2	32.9	33.7	34.4	35.2
Diluted shares outstanding	17.9	18.0	18.1	20.2	20.2	20.5	23.2	27.9	37.3	38.0	38.8	39.6	40.4	41.2	42.0

Source: JMP Securities LLC, Company filings

Company Description

Cerulean Pharma Inc. (CERU) is a Cambridge, MA-based, clinical-stage nanopharmaceutical company that is developing dynamic, tumor-targeted medicines with the aim of maximizing the uptake of drug by tumor cells while preserving healthy tissue across various solid tumor malignancies. The company's lead pipeline candidate, CRLX101, is a nanopharmaceutical formulation of camptothecin - a highly active anti-cancer agent, and highly toxic when delivered as a free compound. CRLX101 is entering randomized Phase II testing for the treatment of third/fourth-line renal cell carcinoma in combination with Avastin. CRLX101 is also being developed for the treatment of recurrent ovarian carcinoma and rectal cancer in the neoadjuvant setting.

Investment Risks

Potential risks to our price target include, but are not limited to, clinical, regulatory, commercial and competitive factors.

Clinical. Drug development is an inherently risky business. Like all clinical trials, CRLX101 clinical development carries some risk of failure. CRLX101 may fail to maintain acceptable tolerability or to demonstrate meaningful enough efficacy to warrant further development through large Phase III trials or regulatory approval.

Regulatory and commercial. The ability of Cerulean or its potential partners to market its drugs depends upon those drugs obtaining approval from the FDA and foreign regulatory agencies. Failure to achieve approval or delays in the timelines to approval could negatively impact the company's share price.

Competitive. Oncology drug development is an increasingly competitive field and Cerulean faces considerable competition from companies with development-stage drug candidates, utilizing similar delivery formulation technology, and also from companies with marketed products seeking to expand the number of indications approved for use. Some of these companies may possess greater R&D and commercial resources than Cerulean or its potential partners.

Financial. Following the IPO, we estimate that Cerulean will have adequate resources to support current trials, the launch of a randomized Phase II trial of CRLX101 plus Avastin in third/fourth-line RCC, and company operations into 2H15. In the event current dose-finding studies in ovarian and neoadjuvant rectal cancer yield positive data and Cerulean elects to further development in these indications (a likely scenario, in our view), we anticipate Cerulean will seek additional equity financing in the form of a secondary offering during 2015, thereby exposing existing shareholders to some degree of dilution risk.

JMP FACTS AND DISCLOSURES

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JMP Securities currently makes a market in the securities of Cerulean Pharma Inc. and BIND Therapeutics, Inc.

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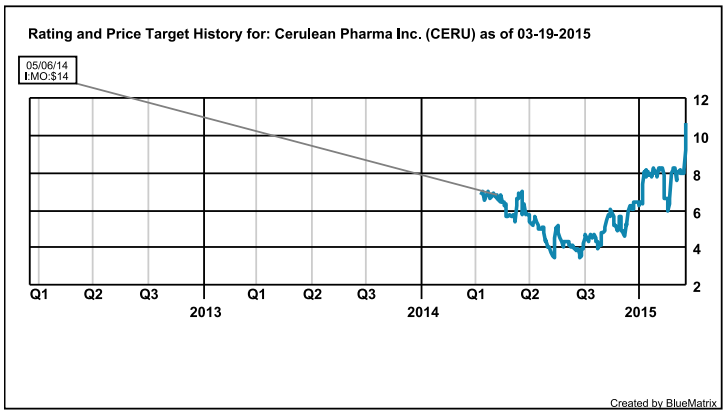
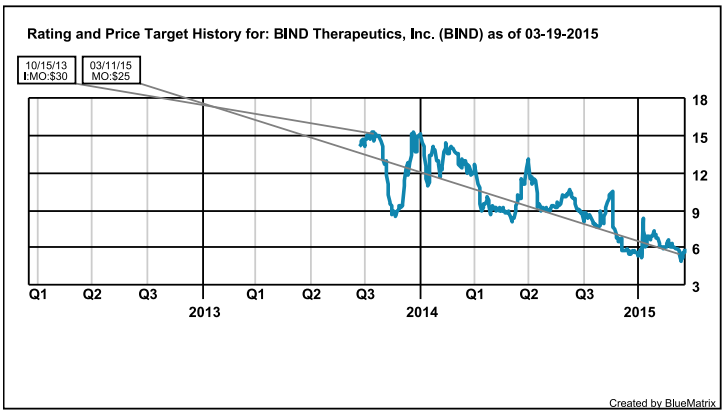
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	286	*63.84%*	Buy	286	*63.84%*	90	*31.47%*
MARKET PERFORM	Hold	152	*33.93%*	Hold	152	*33.93%*	22	*14.47%*
MARKET UNDERPERFORM	Sell	8	*1.79%*	Sell	8	*1.79%*	0	*0%*
COVERAGE IN TRANSITION		1	*0.22%*		1	*0.22%*	0	*0%*
TOTAL:		448	*100%*		448	*100%*	112	*25.00%*

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.





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