

# **Cerulean Pharma Inc.** (CERU)

Reports Second Quarter 2014 Results and Highlights Clinical Development

MARKET DATA	
Price 52-Week Range: Shares Out. (M):	\$3.46 \$3.35 - \$8.06 14.3
Market Cap (\$M):	\$49.5
Average Daily Vol. (000):	18.0
Cash (M):	\$65
Cash/Share:	\$3.19
Enterprise Value (M):	\$165
LT Debt (M):	\$2
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2013A	2014E	2015E
Revenue (\$	M) 1Q		\$0.0A	\$0.0
	2Q		\$0.0A	\$0.0
	3Q		\$0.0	\$0.0
	4Q		\$0.0	\$0.1
	FY	\$0.0	\$0.1	\$0.0
EPS	1Q		(\$3.71)A	(\$0.44)
	2Q		(\$0.44)A	(\$0.86)
	3Q		(\$0.86)	(\$0.94)
	4Q		(\$0.94)	(\$3.09)
	FY	(\$2.17)	(\$3.09)	(\$2.73)
Previ	ous FY	NC	(\$1.69)	(\$1.74)
Source: Compa	ny reports an	d JMP Securities L	LC	



MARKET OUTPERFORM | Price: \$3.46 | Target Price: \$14.00

## **INVESTMENT HIGHLIGHTS**

Cerulean Pharma reports 2Q14, highlighting strong cash position and advancing development pipeline; we reiterate our Market Outperform rating, with a year-end price target of \$14 based on a synthesis of our DCF, CAGR, and comparables valuation methodologies. We remain optimistic regarding upcoming milestones and advancement of CRLX101 into a number of oncologic indications. CERU reported 2Q14 net loss of \$7.4MM, or earnings of (\$0.44) per share, better than JMP estimates of \$7.4MM, or (\$0.82) per share, primarily due to higher than estimated shares outstanding (16.884MM versus JMP estimate of 7.94MM) and lower operating expenses (\$4.68MM versus JMP estimates of \$6MM). CERU finished the quarter with \$65.4MM cash and cash equivalents, providing sufficient runway to continue operations to the end of 2015. A summary of 2Q14 actual results versus JMP estimates is shown in Figure 2. Incremental changes to our model reflecting 2Q14 results and calculated share count are summarized in Figure 3.

CERU highlights of 2Q14 reflect an expanding pipeline with multiple value inflection points. On the call, management recapped an optimistic year that began with a successful IPO, raising \$59.9MM, the proceeds from which have supported the initiation of a randomized Phase II clinical trial of CRLX101 in combination with bevacizumab in relapsed renal-cell carcinoma (RCC). This patient population represents an unmet clinical need for which most treatment options have failed, including TKI's and mTOR inhibitors. Additionally these funds will support the clinical development of CRLX101 in relapsed ovarian cancer and a single arm Phase IB/II clinical trial in non-metastatic colorectal cancer, as well as a Phase I clinical trial in various advanced solid tumors of CRLX301. The potential of CRLX101 in colorectal cancer is particularly intriguing because of its topoisomerase inhibitory activity. Clinical results with irinotecan, a related therapy, showed pathological CR rates of 21-27%; however, the drug's serious adverse events include significant GI toxicity. Clinical studies have shown CRLX101 to have a well-tolerated safety profile that is potentially superior to irinotecan in the clinic. In line with CRLX101 potential in colorectal cancer, the company also highlighted the results of the phase IB/II study of neoadjuvant chemoradiotherapy with CRLX101 and capecitabine for locally advanced rectal cancer where maximum safety and tolerability had been seen at the 15 mg/m<sup>2</sup>. In the continued Phase II arm, dosing is completed in the 12 mg/m<sup>2</sup> cohort and patients are currently

being dosed at the 15 mg/m<sup>2</sup> level.

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In our view, Cerulean Therapeutics 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 2H14 and into 1H15, including the initiation of a Phase I trial of CRLX301 by end of year with results expected in 4Q15, proof-of-principle data supporting go/no go decisions in relapsing ovarian and non-metastatic colorectal cancer by 1Q15, and read-out of the Phase II trial for CRLX101 in relapsed RCC in 4Q15. Provided the data are positive, these events could be expected to bring CERU's market cap in line with comparable platform technologies (e.g., BIND, ECYT, MACK, NKTR, SRNE) that trade at an average market cap of ~\$500MM - a significant premium to CERU's present valuation.



FIGURE 1. Upcoming Catalysts

Ti	iming	Candidate	Catalysts
4	IQ14	CRLX101	Read-out from single Avastin combo in ovarian cancer
4	IQ14	CRLX101	Read-out from single-arm neoadjuvant rectal cancer IST (UNC)
4	IQ14	CRLX301	Initiation of Phase I trial in advances solid tumors
1	Q15	CRLX101	Potential initiation of randomized Phase II neoadjuvant rectal cancer study (100 pts)
1	Q15	CRLX101	Potential initiation of pivotal ovarian Phase II trial in combination with Avastin
4	IQ15	CRLX301	Phase I read-outs (PK, MTD, and preliminary efficacy)
4	IQ15	CRLX101	Read-out from randomized RCC Phase II in combo with Avastin

Source: Company presentations

FIGURE 2. 2Q14 CERU Results vs. JMP Estimates

Cerulean Pharma(CERU)	2Q14 Results							
Abridged Income Statement (\$ MM)	JMP Estimate	Actual	Variance (JMP vs. Actual)					
Total Revenues	-	0.03	(0.03)					
Operating Expenses Research and development General and administrative	<b>6.00</b> 3.50 2.50	<b>4.68</b> 2.65 2.03	<b>1.3</b> 0.9 0.5					
Operating income (loss)	(6.00)	(4.64)						
Other income (expense) Pretax income (loss)	0.50 (6.50)	<b>(2.76)</b> (7.40)						
Net income (loss)	(6.50)	(7.40)	0.90					
EPS Calculations								
Basic EPS	\$ (0.82)	1	·					
Diluted EPS	\$ (0.82)	\$ (0.44)	\$ (0.38)					
Basic shares outstanding Diluted shares outstanding	7.940 7.940	16.884 16.884	(8.944) (8.944)					

Source: JMP Securities LLC, Company filings



FIGURE 3. Changes to Our Model

Cerulean Pharma (CERU)	3 <b>Q</b> 1	I4E	4Q <sup>2</sup>	14E	FY 2	014E	FY 2015E		FY 20	)16E
(\$ MM)	Old	New	Old	New	Old	New	Old	New		New
Collorboration Revenue Other	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
Total Revenues	-	-	-	-	-	0.1	-	-	-	-
COGS	-	-	-	-	-	-	1	•	-	-
Gross Profit	-	-		-	0.05	0.08	-	-	-	-
Operating Expenses Research and development	<b>6.6</b> 3.8	<b>6.6</b> 3.8	<b>7.3</b> 4.1	<b>7.3</b> 4.1	<b>22.9</b> 12.9	<b>21.6</b> 12.0	<b>30.9</b> 19.3	<b>29.0</b> 18.1	<b>44.7</b> 31.9	<b>42.0</b> 29.8
General and administrative  Operating income (loss)	2.8 (6.6)	2.8 (6.6)	(7.3)	3.2 (7.3)	10.0 (22.9)	9.5 (21.5)	11.5 (30.9)	11.0 (29.0)	12.8 (44.7)	12.2 (42.0)
Other income (expense) Interest income	(0.6) (0.6)	(0.3)	(0.6) (0.6)	(0.3)	(2.1) (2.1)	(1.3) (1.3)	-			-
Pretax income	(7.2)	(6.9)	(7.9)	(7.6)	(25.0)	(22.8)	(30.9)	(29.0)	(44.7)	(42.0)
Provision for Income Tax	-	- (5.5)	-	- (= -)	-	-	-	- (== -)	-	-
Net income	(7.2)	(6.9)	(7.9)	(7.6)	(25.0)	(22.8)	(30.9)	(29.0)	(44.7)	(42.0)
Basic EPS Diluted EPS	\$ (0.89) \$ (0.89)	\$ (0.86) \$ (0.86)		\$ (0.94) \$ (0.94)						\$ (3.13) \$ (3.13)
Basic shares outstanding Diluted shares outstanding	8.02 8.02	8.02 8.02	8.10 8.10	8.10 8.10	8.05 8.05	8.05 8.05	10.62 10.62	10.62 10.62	13.43 13.43	13.43 13.43

Source: JMP Securities LLC

# FIGURE 4. Income Statement

Cerulean Pharma (CERU)	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Income Statement (\$MM)	2012A	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Product Sales and Royalties:			•												
CRLX101															
US Sales								-	-	-	49.8	164.9	278.0	421.5	558.9
ROW Royalties								-	-	-	-	7.7	27.8	50.3	76.1
CRLX301															
US Sales								-	-	-	-	105.6	221.2	341.1	501.2
ROW Royalties								-	-	-	-	-	15.8	32.3	49.8
Total Product Sales and Royalties	0.0	0.0	0.00	-	-	-	-	-	-	-	49.8	278.2	542.7	845.2	1,186.0
Collaboration Revenue	0.6	0.0					_	-	-	-	-	-	-	-	-
Total Revenue	0.6	0.0	0.05	0.0	-	-	0.1	-	-	-	49.8	278.2	542.7	845.2	1,186.0
Cost of Goods Sold											6.0	18.1	27.8	42.1	55.9
Gross Profit	0.6	0.0	0.05	0.0	0.0	0.0	0.1	0.0	0.0	0.0	43.9	260.0	514.9	803.0	1,130.1
Operating Expenses:															
Research and Development	15.8	9.7	1.50	2.6	3.8	4.1	12.043	18.1	29.8	59.6	74.5	85.7	96.8	108.5	119.3
General and administrative	6.4	6.2	1.51	2.0	2.8	3.2	9.539	11.0	12.2	44.7	60.3	78.4	98.0	117.6	131.8
Total operating expenses	22.2	15.9	3.01	4.7	6.6	7.3	21.582	29.0	42.0	104.3	134.8	164.1	194.9	226.1	251.1
Operating income (loss)	(21.6)	(15.9)	(3.0)	(4.6)	(6.6)	(7.3)	(21.502)	(29.0)	(42.0)	(104.3)	(91.0)	95.9	320.0	576.9	879.0
Other income (expense):															
Interest income	0.0	0.0	0.00	0.0	0.0	0.0	0.0								
Interest expense	(0.6)	(1.5)	(0.46)	(0.3)	(0.3)	(0.3)	(1.3)								
Loss on extinguishment of debt				(2.5)											
Decrease in value of preferred stock warrant liability	0.0	0.2	0.50		0.0	0.0	0.5								
Total other income, net	(0.5)	(1.3)	0.04	(2.8)	(0.3)	(0.3)	(1.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax net income (loss)	(22.1)	(17.143)	(2.92)	(7.4)	(6.9)	(7.6)	(24.834)	(29.0)	(42.0)	(104.3)	(91.0)	95.9	320.0	576.9	879.0
Income tax benefit (provision)  Tax Rate							0.0 <i>0%</i>	0.0 <i>0</i> %	0.0 <i>0</i> %	0.0 <i>0</i> %	0.0 <i>0</i> %	(14.4) 15%	(64.0) 20%	(144.2) 25%	(263.7) 30%
Comprehensive income (loss)	(22.1)	(17.1)	(2.92)	(7.4)	(6.9)	(7.6)	(24.834)	(29.0)	(42.0)	(104.3)	(91.0)	81.5	256.0	432.7	615.3
Accretion of redeemable convertible preferred stock	(0.1)	0.0	0.00												
Net income (loss) attributable to common stockholders	(22.2)	(17.143)	(2.92)	(7.4)	(6.9)	(7.6)	(24.8)	(29.0)	(42.0)	(104.3)	(91.0)	81.5	256.0	432.7	615.3
net income (1033) attributable to common stockholders	(22.2)	(17.143)	(2.92)	(7.4)	(0.9)	(7.0)	(24.0)	(29.0)	(42.0)	(104.3)	(91.0)	01.3	230.0	432.7	013.3
Basic EPS to common shareholders	\$ (36.39)	\$ (2.17)	(3.71) \$	(0.44)	\$ (0.86) \$	(0.94)	\$ (3.09)	\$ (2.73)	\$ (3.13)	\$ (6.47)	\$ (4.36)	\$ 3.46	\$ 10.52	\$ 17.25	\$ 23.82
Diluted EPS to common shareholders	\$ (36.39)	\$ (2.17)	(3.71) \$	(0.44)	\$ (0.86)	(0.94)	\$ (3.09)	\$ (2.73)	\$ (3.13)	\$ (6.47)	\$ (4.36)	\$ 2.70	\$ 8.27	\$ 13.64	\$ 18.92
Basic shares outstanding	0.6	7.9	0.79	16.9	8.0	8.1	8.0	10.6	13.4	16.1	20.9	23.6	24.3	25.1	25.8
Diluted shares outstanding	0.6	7.9	0.79	16.9	8.0	8.1	8.0	10.6	13.4	16.1	20.9	30.2	31.0	31.7	32.5

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 anticancer agent, and highly toxic when delivered as a free compound. CRLX101 is entering randomized Phase II testing for the treatment of 3rd/4th 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**

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, as well as 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 complete 1Q14 with approximately \$56MM in cash and cash equivalents—adequate resources to support current trials, the launch of a randomized Phase II trial of CRLX101 plus Avastin in 3rd/4th-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 that 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.



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JMP Securities currently makes a market in the security of Cerulean Pharma Inc.

JMP Securities was manager or co-manager of a public offering of securities for Cerulean Pharma Inc. (CERU) in the past 12 months, and received compensation for doing so.

## **JMP Securities Investment Opinion Definitions:**

Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

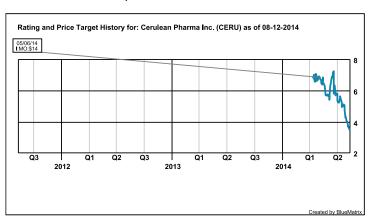
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of August 13, 2014)

							# Co's	
							Receiving	
							IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	267	60.00%	Buy	267	60.00%	97	36.33%
MARKET PERFORM	Hold	138	31.01%	Hold	138	31.01%	18	13.04%
MARKET UNDERPERFORM	Sell	4	0.90%	Sell	4	0.90%	0	0%
COVERAGE IN TRANSITION		36	8.09%		36	8.09%	0	0%
TOTAL:		445	100%		445	100%	115	25.84%
IOIAL.		773	100/0		773	10076	113	20.07/0

#### **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 guarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



# Cerulean Pharma Inc. (CERU)



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