

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

Early Signs of Clinical Activity for CRLX101 Presented at ASCO GI

MARKET DATA	
Price	\$7.68
52-Week Range:	\$3.35 - \$8.25
Shares Out. (M):	20.1
Market Cap (\$M):	\$154.4
Average Daily Vol. (000):	10.0
Cash (M):	\$64
Cash/Share:	\$3.19
Enterprise Value (M):	\$166
LT Debt (M):	\$2
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2014E	2015E	2016E				
Revenue (\$M)	1Q	\$0.0A	\$0.0					
	2Q	\$0.0A	\$0.0					
	3Q	\$0.0A	\$0.0					
	4Q	\$0.0	\$0.1					
	FY	\$0.1	\$0.0	\$0.0				
EPS	1Q	(\$3.71)A	(\$0.44)					
	2Q	(\$0.44)A	(\$0.28)					
	3Q	(\$0.28)A	(\$0.93)					
	4Q	(\$0.93)	(\$2.91)					
	FY	(\$2.91)	(\$2.57)	(\$2.93)				
Source: Company reports and JMP Securities LLC								



MARKET OUTPERFORM | Price: \$7.68 | Target Price: \$14.00

## **INVESTMENT HIGHLIGHTS**

Cerulean presented early clinical data at ASCO GI from continuing studies of CRLX101 for the treatment of non-metastatic rectal cancer; we reiterate our Market Outperform rating, with a year-end price target of \$14 based on a synthesis of our DCF, CAGR, and comparable company valuation methodologies. At the ASCO 2015 Gastrointestinal Cancers Symposium this weekend, the company reported interim results from a Phase Ib/II trial of CRLX101 in combination with chemoradiotherapy in non-metastatic rectal cancer patients. One out of three patients from the stage 1 portion of the trial demonstrated a pCR. The trial is a two-stage, openlabel, single-arm study initiated in December 2013. With the encouraging current interim data, we look forward to further results expected by late 2015 or early 2016.

**Expectations for CRLX101.** According to the study's protocol, based on a Simon's two-stage design, a total of 53 patients will be accrued in this Phase Ib/II trial. We expect 31 patients will be accrued in stage 1, and based on a Type I error rate of 5%, power of 80% with a *p0* historical pCR of 15-25%, and an expected pCR *p1* of 35%, we would expect the trial to continue with seven patients (7/31, 22.5%) demonstrating pCR. Encouragingly, one pCR out of three enrolled patients has been observed. Additionally, according to the trial design, we believe that 15 pCRs of the targeted 53 patient enrollment (28%) will be required for a positive report. The trial began enrollment in December 2013 and complete results for the primary outcome are expected in December 2021. We expect Phase Ib results to support advancement into Stage 2 in late 2015 or early 2016.

Preclinical results encourage continued study. Additionally, preclinical studies of CRLX101 were reported that support its use in the treatment of colorectal tumors. CRLX101 was explored in treatment of colorectal xenograft models, including HT29 and SW840. In the HT29 xenograft model, CRLX101+5FU+XRT delayed tumor growth significantly more than the other treatment regimens evaluated. In the SW480 xenograft model, CRLX101+5FU+XRT and CRLX101+XRT delayed tumor growth more than other regimens, but there was no statistical advantage to the addition of 5FU to CRLX101+XRT. The addition of CRLX101 to 5FU+XRT did not increase hematologic or skin toxicities.

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, and the regulatory and commercial paths forward for CRLX101 in its intended indications. Management guided toward multiple value inflection points

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including results of a Phase I trial of CRLX301 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 (MO, \$30 PT), ECYT, MACK, NKTR, SRNE) that trade at an average market cap of ~\$500MM, a significant premium to CERU's present valuation.

FIGURE 1. U	<b>Jpcoming</b>	CERU Cataly	sts
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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. Income Statement

Income Statement (\$MM)	1Q14A	2Q14A	3Q14A	4Q14E	2014E	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	0.00	-	-	-	-	-	-	-	49.8	278.2	542.7	845.2	1,186.0	1,489.2	1,714.6	1,803.6
Collaboration Revenue					-	_	-	-	-	_	-	-	_	-	-	_
Total Revenue	0.05	0.0	-		0.1	-	-	-	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	0.05	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	1,419.8	1,631.3	1,715.4
Operating Expenses:																
Research and Development	1.50	2.6	2.9	4.1	11.2	16.8	27.6	55.3	69.1	79.5	89.8	100.6	110.7	121.7	133.9	147.3
General and administrative	1.51	2.0	2.4	3.2	9.2	10.6	11.7	43.0	58.1	75.5	94.3	113.2	126.8	139.5	153.4	168.8
Total operating expenses	3.01	4.7	5.4	7.3	20.4	27.3	39.4	98.3	127.2	155.0	184.2	213.8	237.5	261.2	287.3	316.1
Operating income (loss)	(3.0)	(4.6)	(5.4)	(7.3)	(20.3)	(27.3)	(39.4)	(98.3)	(83.3)	105.1	330.7	589.2	892.6	1,158.6	1,344.0	1,399.3
Other income (expense):																
Interest income	0.00	0.0	0.0	0.0	0.0											
Interest expense	(0.46)	(0.3)	(0.2)	(0.2)	(1.1)											
Loss on extinguishment of debt		(2.5)														
Decrease in value of preferred stock warrant liability	0.50			0.0	0.5											
Total other income, net	0.04	(2.8)	(0.2)	(0.2)	(1.1)	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)	(2.92)	(7.4)	(5.6)	(7.5)	(23.4)	(27.3)	(39.4)	(98.3)	(83.3)	105.1	330.7	589.2	892.6	1,158.6	1,344.0	1,399.3
Income tax benefit (provision)					0.0	0.0	0.0	0.0	0.0	(15.8)	(66.1)	(147.3)	(267.8)	(405.5)	(470.4)	(489.8)
Tax Rate					0%	0%	0%	0%	0%	15%	20%	25%	30%	35%	35%	35%
Comprehensive income (loss)	(2.92)	(7.4)	(5.6)	(7.5)	(23.4)	(27.3)	(39.4)	(98.3)	(83.3)	89.3	264.6	441.9	624.8	753.1	873.6	909.5
Accretion of redeemable convertible preferred stock	0.00															
Net income (loss) attributable to common stockholders	(2.92)	(7.4)	(5.6)	(7.5)	(23.4)	(27.3)	(39.4)	(98.3)	(83.3)	89.3	264.6	441.9	624.8	753.1	873.6	909.5
Basic EPS to common shareholders	(3.71) \$	6 (0.44) \$		,		. ,				\$ 3.79	•		\$ 24.19	\$ 28.33	\$ 31.95	\$ 32.36
Diluted EPS to common shareholders	(3.71) \$	(0.44) \$	(0.28)	\$ (0.93)	\$ (2.91)	\$ (2.57)	\$ (2.93)	\$ (6.10)	\$ (4.00)	\$ 2.96	\$ 8.55	\$ 13.93	\$ 19.22	\$ 22.61	\$ 25.62	\$ 26.07
Basic shares outstanding	0.79	16.9	20.1	8.1	8.0	10.6	13.4	16.1	20.9	23.6	24.3	25.1	25.8	26.6	27.3	28.1
Diluted shares outstanding	0.79	16.9	20.1	8.1	8.0	10.6	13.4	16.1	20.9	30.2	31.0	31.7	32.5	33.3	34.1	34.9

Source: JMP Securities LLC and 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 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**

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.



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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 expects to receive OR intends to seek compensation for investment banking services from Cerulean Pharma Inc. and BIND Therapeutics, Inc. in the next 3 months.

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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.

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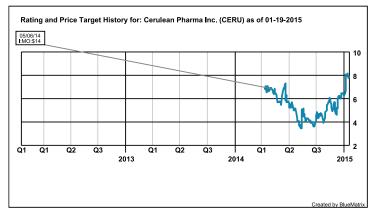
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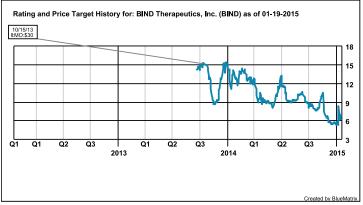
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JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
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MARKET OUTPERFORM	Buy	292	64.75%	Buy	292	64.75%	100	34.25%
MARKET PERFORM	Hold	151	33.48%	Hold	151	33.48%	18	11.92%
MARKET UNDERPERFORM	Sell	5	1.11%	Sell	5	1.11%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL:		451	100%		451	100%	120	26.61%

### **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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